CCR I-Review Reports

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Version 3.0

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Introduction

Integrated Review or I-Review is client/server data review tool fully integrated with NCI's Cancer Centralized Clinical Database (C^3D). I-Review makes it easy to access, review, report and graph clinical data residing in C^3D. This powerful, user-friendly Windows application supports data review with interactive and integrated patient listings, detailed reports, summary reports, formatted reports, and graphical reports. I-Review has a companion web-based product call JReview that provides similar functionality via a standard web browser. For further information on the core products refer to the following websites:

Integrated Review Version 8 – Guide to Exploring Clinical Data
http://ncicbsupport.nci.nih.gov/sw/content/C3D/I-Review8.pdf

Computer Based Training for Integrated Review (CBT)
http://octrials-train.nci.nih.gov/StartCBT.html

Integrated Clinical System Website
http://www.i-review.com/

This document is intended to provide NCI Center for Cancer Research (CCR) specific guidelines for using common I-Review functionalities and descriptions of CCR specific generic I-Review reports (canned reports) that are available for use across all studies. The next section provides general instructions and the subsequent sections describe domain specific canned reports that are available for use.

General Instructions

Help for I-Review

If you experience difficulties using I-Review, report the problem to the NCICB Application Support. If you would like help developing a complex I-Review report, contact NCICB Application Support. The request will be forwarded to appropriate individuals who will contact you for further information. NCICB Application Support can be contacted via the following methods:

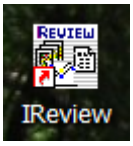
Phone: 301-451-4384

Email: ncicb@pop.nci.nih.gov

Installing I-Review

I-Review is a client-server application and is deployed on your Personal Computer via NIH's Application Launcher (NAL). Completion of the required modules of the CBT for I-Review is necessary for availing this application on your desktop. Requests should be made to NCICB Application Support by either the Nurse Educator or C^3D Trainer upon verification of the CBT certificates.

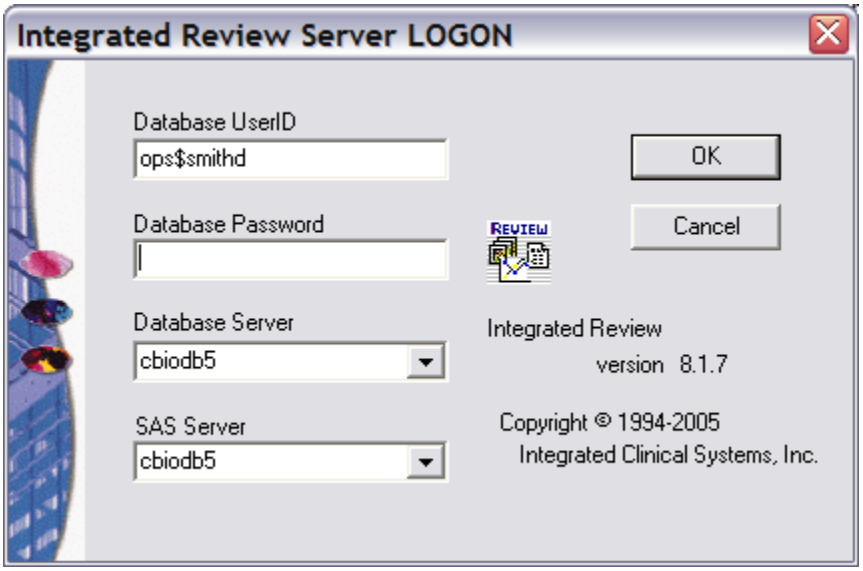
Once installed, restart the computer first. Then log back into the NIH Network. The following I-Review icon is presented on the desktop.



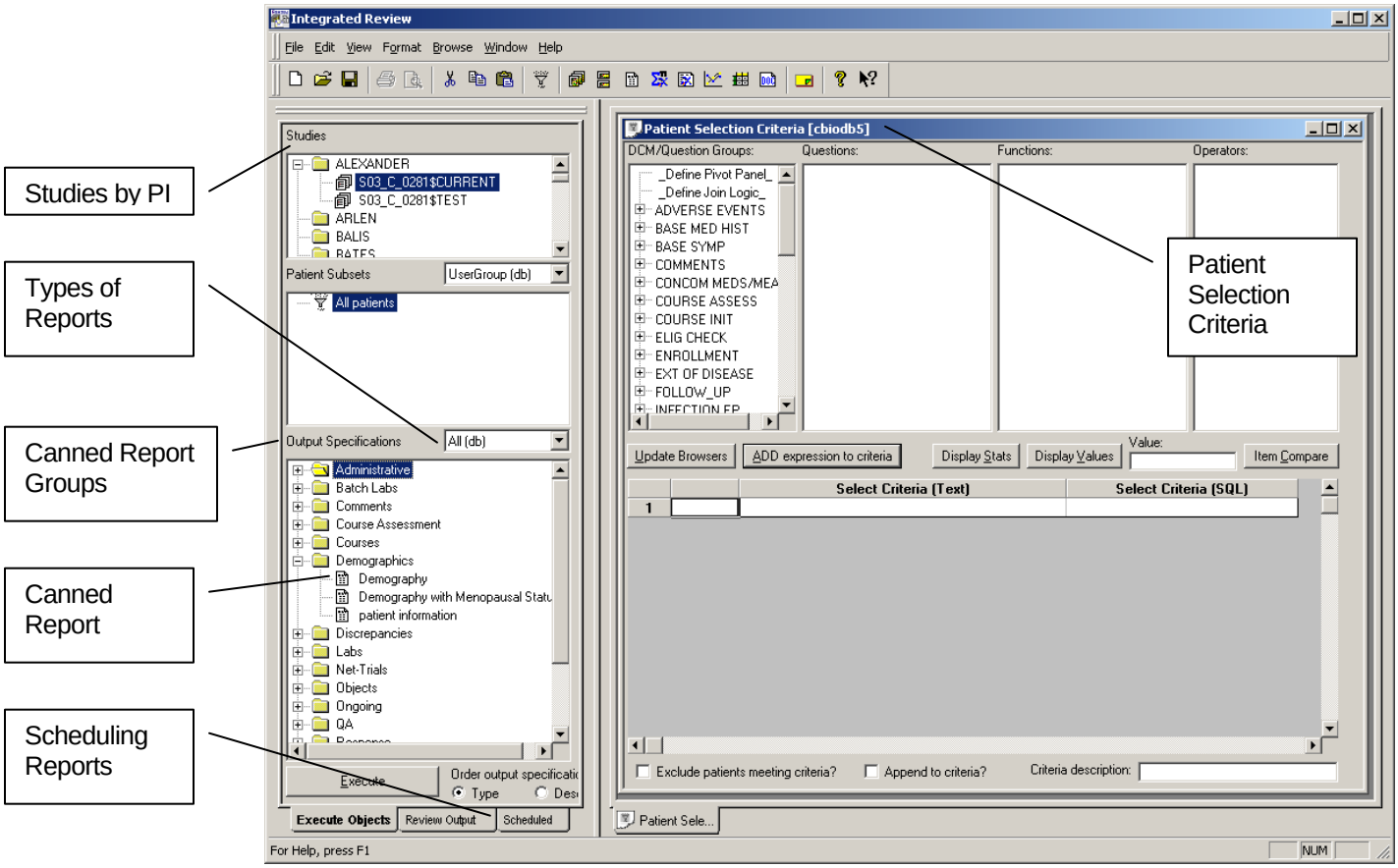
Logging into I-Review

The user and study level security for I-Review is completely integrated with C^{3}D. You should use your C^{3}D User ID and Passwords to access data via I-Review. You will be able to review data for only those studies that you have been granted access to in C^{3}D. Moreover, the functionality of I-Review available for your use is limited by your user role type (PI, RN, QA, etc.).

The login screen for I-Review appears as below. The database *cbiodb5* should be used to access study data. While using I-Review against the training database used *cbiodb2:octrn* as the database server name (The server name might change). Currently, a SAS server is not being used and thereby can be left blank.



User Interface



Once logged into the database, I-Review presents the above User Interface to begin with. The noteworthy features of I-Review User Interface are as below.

Studies are organized by PI. Only studies that you have access to are presented in the top left window. Current Data for a given study can be accessed by choosing the STUDY$CURRENT selection.

The Output Specification filter can be used to limit the canned reports to Private, Usergroup, Public or All reports. These terms are explained later.

Canned Reports are organized by logical groups such as Administrative, Discrepancy, Demographics, etc.

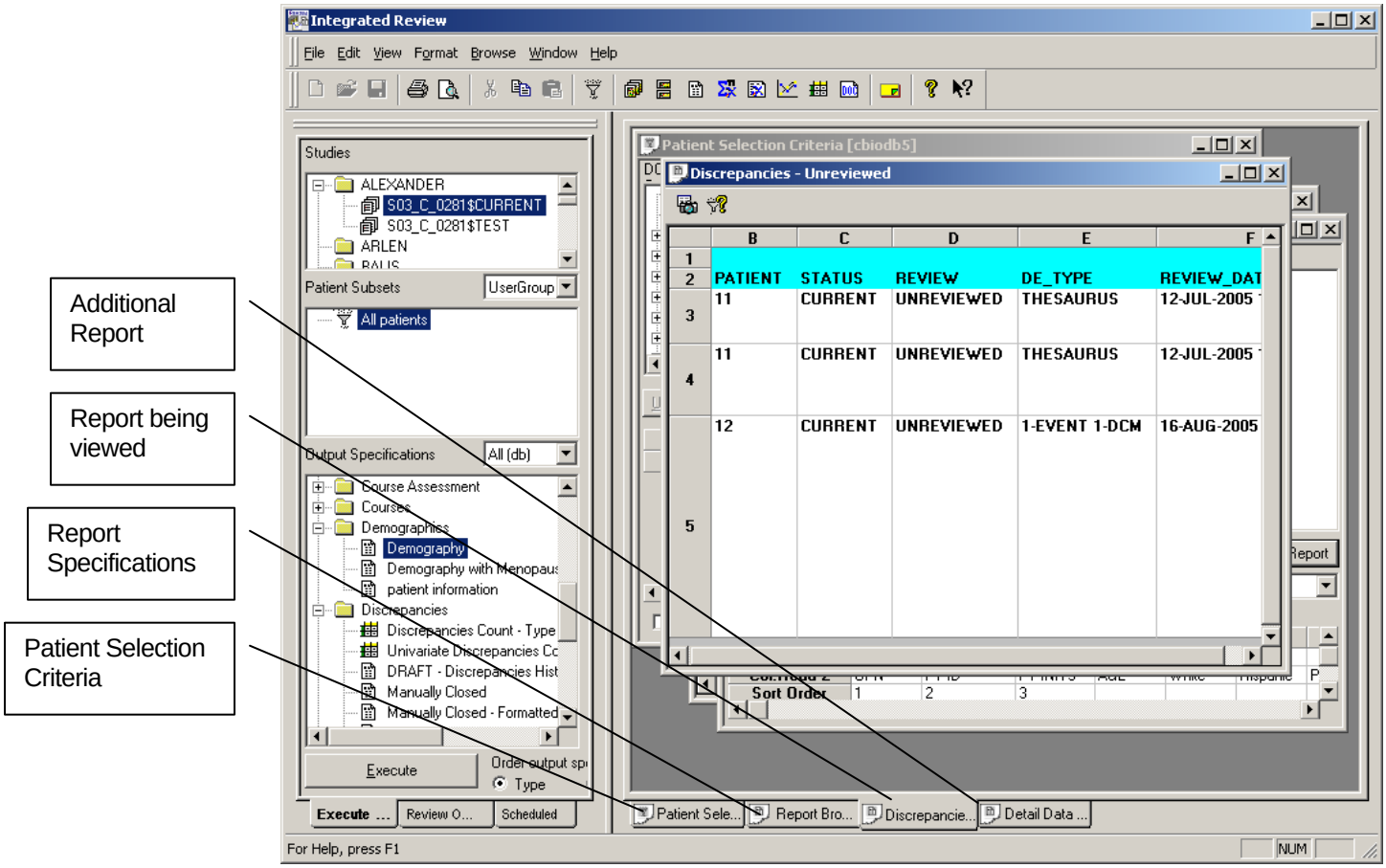
Canned Reports are presented within the folders. Double clicking the reports runs the report within the context of the chosen study. You may run multiple reports simultaneously by double clicking on them. Each output is presented in a separate window.

Reports could be setup to run on a predetermined schedule.

All Reports can be simultaneously limited to certain Patients by setting up a Patient Selection Criteria.

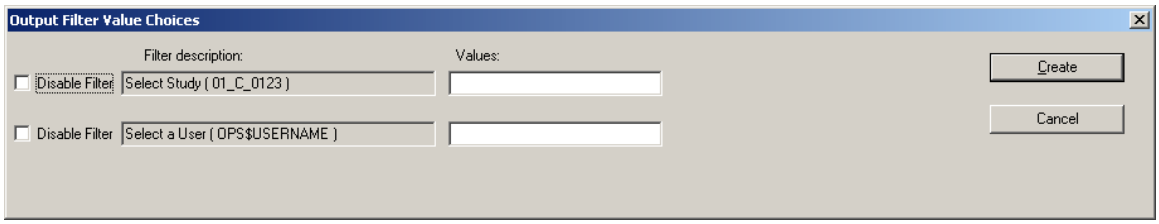
Running Canned Reports

Canned Reports can be run by double clicking on the interested report while in the context of a study. The output of the report will be presented in a separate window. Note that you may run multiple reports within a study by just double clicking on the interested report one at a time. Each of the outputs will be presented in a separate window. The Report Browser will display the specifications of report that was run last. The Patient Selection Criteria is always available to further subset the report. See below for an illustration.



Parameterized Canned Reports

Certain Canned Reports allow for parameters that can be specified by the users. The parameter window is presented when the report is double clicked. An illustration of the window is below.

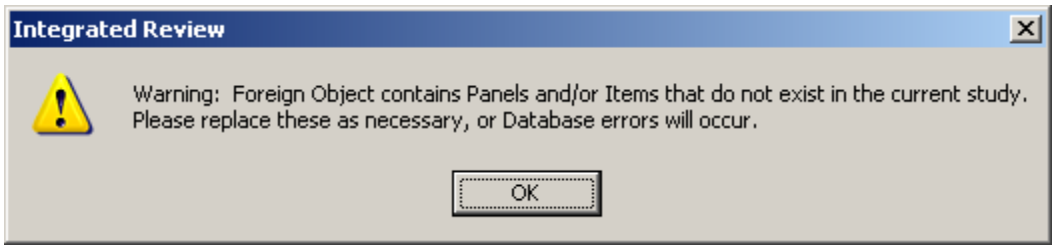


You have an option to specify values for the parameter or disable the filter.

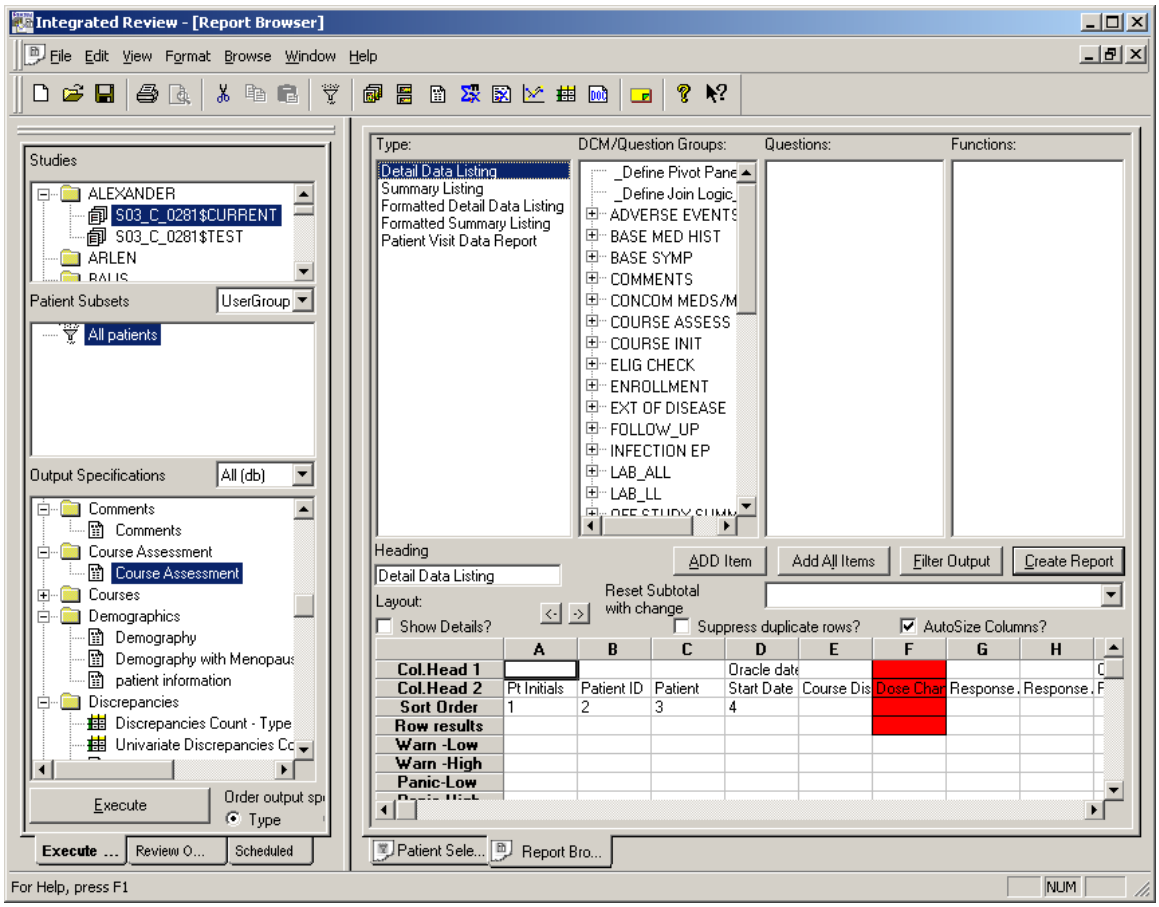
Failure of Canned Reports

Though every effort is made to make the canned reports generic, occasionally the canned reports would fail for a particular study due to a missing column in the particular study.

The error message for this failure is as below.



Click on OK for the error message and browse to the Report Browser. The missing columns are indicated in red as shown below. Delete the missing column by selecting and cutting it. You can now run the report by clicking on the Create Report button. You may optionally save this version of the report as explained later.



User and Study Access Level

Apart from organizing the canned reports in logical folders, an effort is made to limit the reports that you see to those that have relevance for your role in C^3D and for the type of the study. This is achieved by saving the reports at various combinations of Study Group and User Group access levels.

I-Review users are classified into various User Groups based on their role: Clinical (PI/RN), DM, QA, Builders, etc. Each study in C^3D can also be classified into various groups based on whether it is a CTMS Study, CDUS Study, Version of Standard CRFs it is built on, etc. All possible combinations of these two parameters are summarized in the table below.

Study Group --> **User Group**	**Study**	**Project**	**Study Group**	**Global**
Private	Reports specific to a study that only you can access.	Reports relevant to all studies for a PI that only you can access.	Reports relevant to a group of Studies, e.g. CTMS, that only you can access.	Reports relevant to all studies that only you can access.
User Group	Reports specific to a study shared across a User Group, such as QA, DM, etc.	Reports relevant to all studies for a PI and shared across a User Group, such as QA, DM, etc.	Report relevant to a group of studies, such as CTMS, and shared across a User Group, such as QA, DM, etc.	Reports relevant to all studies and shared across a User Group, such as DM, QA, etc.
Public	Reports specific to a study shared with everyone.	Reports relevant to all studies for a PI and shared with everyone.	Reports relevant to a group of studies, such as CTMS, and with everyone.	Reports relevant to all studies that anyone can run.

Capability to save reports with Global access is limited to advanced users to limit proliferation of incorrect reports.

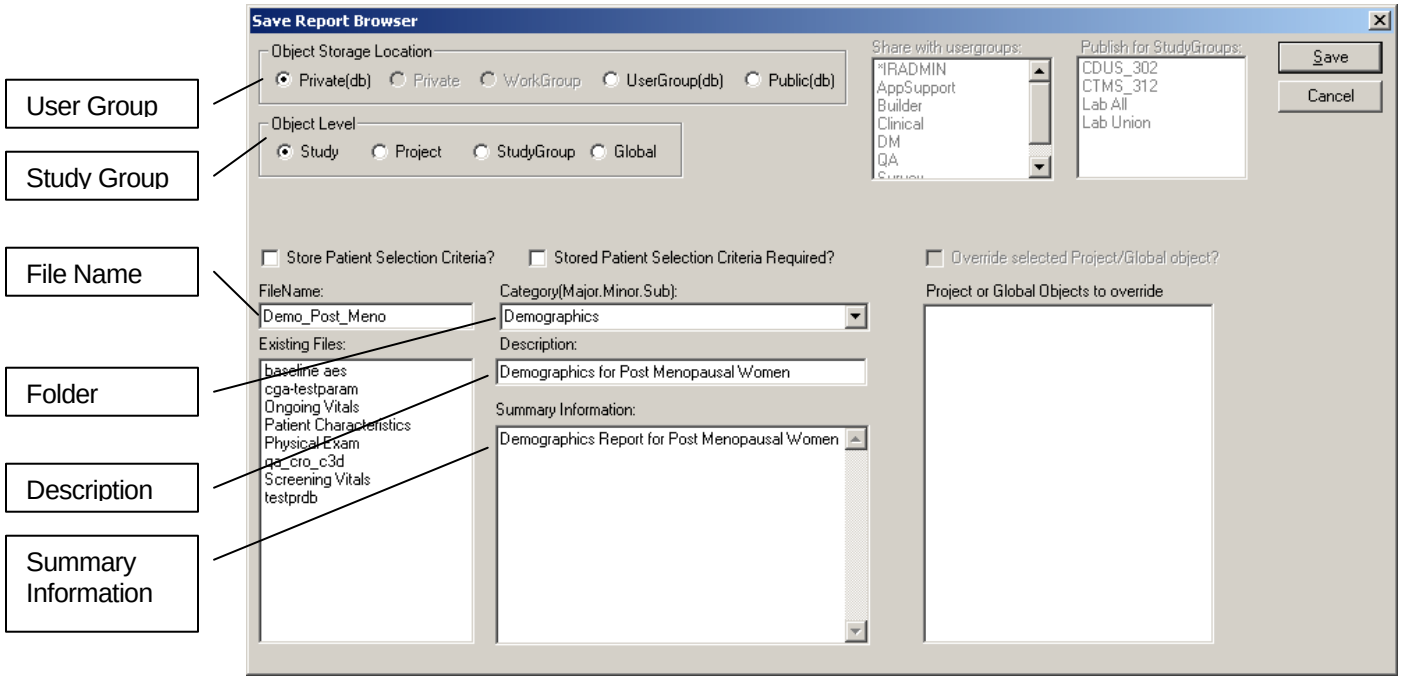
Modifying Canned Reports & Resaving

Canned Reports can be modified and resaved using the following steps:

Open a canned report of interest by right clicking on it and choosing Open.

Make appropriate modifications to the design of the report such as add/remove columns, rename column headings, change sort order, etc.

Click on Save.



Specify a file name (up to 20 characters), the Category (Folder) you want the report to appear in, a Short Description, and Summary Information for the report.

Click Save.

Extracting Data to MS Excel

Data from I-Review reports can be extracted to Microsoft Excel Reports using the following steps:

Run the canned or developed IReveiw report.

Choose File → Export

Specify the Folders and give the Extracted file a name retaining the .xls extension.

Browse to the Folder and find the report.

The Excel files are generated with write protection so as to prevent accidental changes to data in Excel. In order to unprotect the sheet choose Tools → Protection → Unprotect Sheet in Excel. Once unlocked, the report can be sorted and filtered. I-Review puts a two row header on Excel files. In order to use Excel optimally delete the top row before sorting and filtering.

Types of Reports

I-Review reports are broadly classified into the following categories:

Detail Data Listing: These are detailed listing of the data being queried, e.g. listing of all AEs in a study. These reports are ideal for exporting data to MS Excel.

Formatted Detail Data Listing: These are detailed listing of the data being queried in a production quality pdf format. The report could include various font sizes, types, header, footer, etc. These are ideal for reports that are used on an ongoing basis to review data and need to be quickly printed out or emailed in a pre-formatted manner. For example, a formatted listing of open AEs in a study could be used by a team to resolve AEs post clinics.

Summary Listing: These are summary reports that provide cross-tabulation of the data, e.g. a table summarizing the number AEs experienced by a patient by Type and Grade. These reports are ideal for exporting data to MS Excel. Summary Analyses for research abstracts and reports could be generated using these reports.

Formatted Summary Listing: These are summary reports formatted in a pdf format with options to control font sizes, font types, header, footer, etc.

Patient Visit Data Report: These reports list clinical data in chronological order. This report replaces the SYLK report available in legacy systems such as the PDMS. Information from various sources such as Labs, Vitals, Drugs, could be consolidated in a chronological date order using these reports.

Course Stop Date

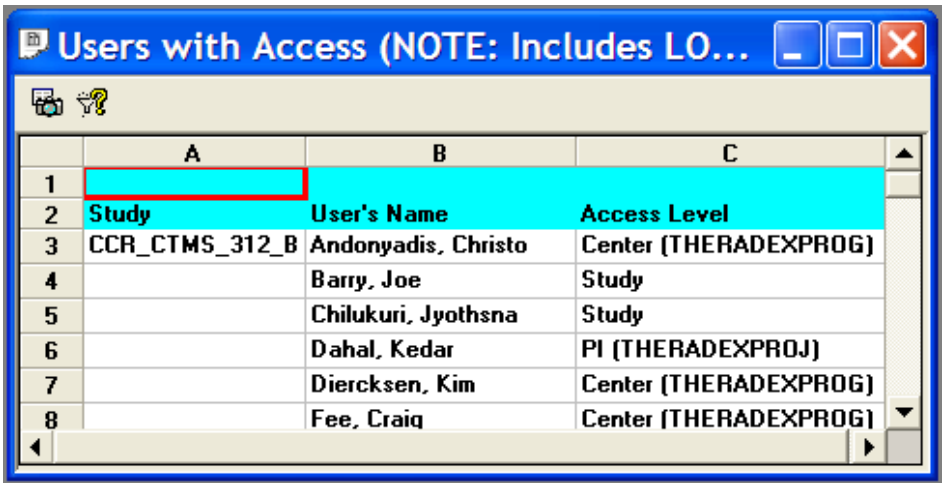
The Course Initiation and Course Assessment CRFs have a Stop Date of 3501-AUG-01 (35010801 or 08-01-3501) for ongoing courses. Disregard this date since it is used internally for derivation and submission purposes.

Administrative Reports

Access: Study Access

Description

This report lists all users who have access to a study. It provides a quick method for ensuring that appropriate users have access to the study. Note the list includes LOCKED account.



	A	B	C
1			
2	Study	User's Name	Access Level
3	CCR_CTMS_312_B	Andonyadis, Christo	Center (THERADEXPROG)
4		Barry, Joe	Study
5		Chilukuri, Jyothsna	Study
6		Dahal, Kedar	PI (THERADEXPROJ)
7		Diercksen, Kim	Center (THERADEXPROG)
8		Fee, Craig	Center (THERADEXPROG)

Access

User Level: IRADMIN, Builder, QA

Study Level: Global

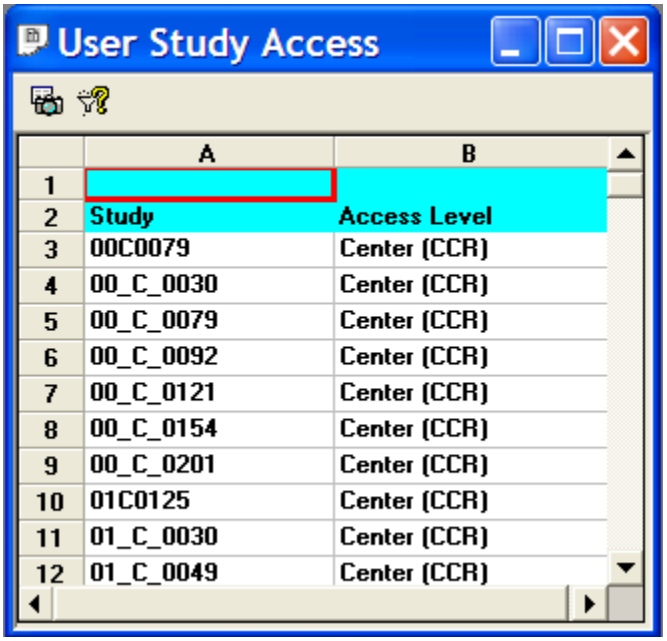
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
User's Name	Name of the User
Access Level	Center (Project name): This user has access to all studies under this Project PI (PI name): This user has access to all studies belonging to this PI. Study: This user has access to the specified study.

Access: User Study Access

Description

This report lists all studies that the logged user has access to. It provides a quick method of ensuring that you have access to a particular study.



Access

User Level: Public

Study Level: Global

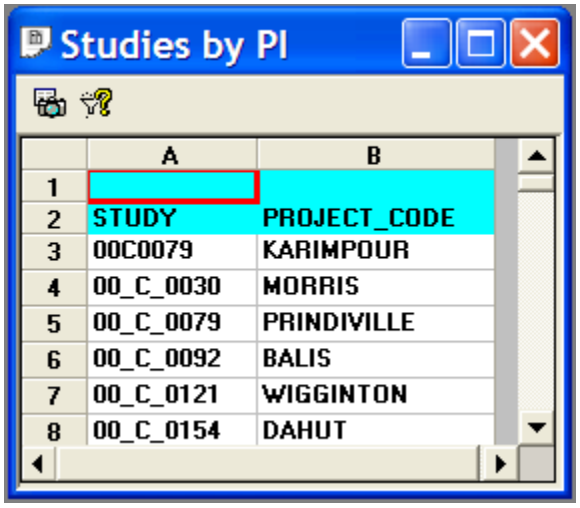
Columns

Field	*Description*
Study	Protocol Number that the User has Access to
Access Level	Center (CCR): This user has access to all CCR studies. PI (PI name): This user has access to all studies belonging to this PI. Study: This user has access to the specified study.

Studies: Study by PI

Description

This report lists all studies and the corresponding PI. It provides a quick method of finding the PI corresponding to a Study.



Access

User Level: Public

Study Level: Global

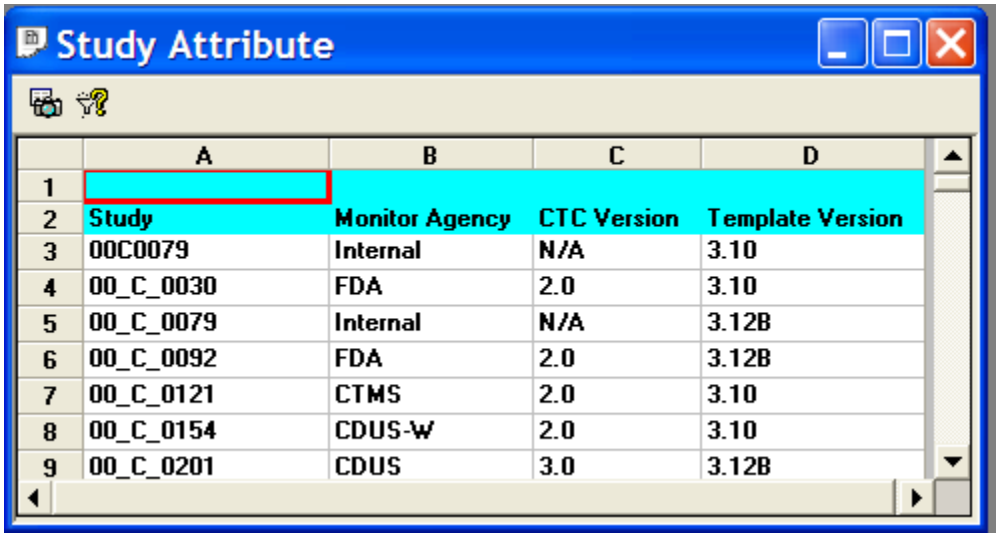
Columns

Field	*Description*
Study	Protocol Number
Project_Code	Project Code

Studies: Study Attribute

Description

This report lists study objective: monitoring agency, CTC version used in study, study template the study is built upon. It helps the user to find the appropriate report.



Access

User Level: Public

Study Level: CCR_Program

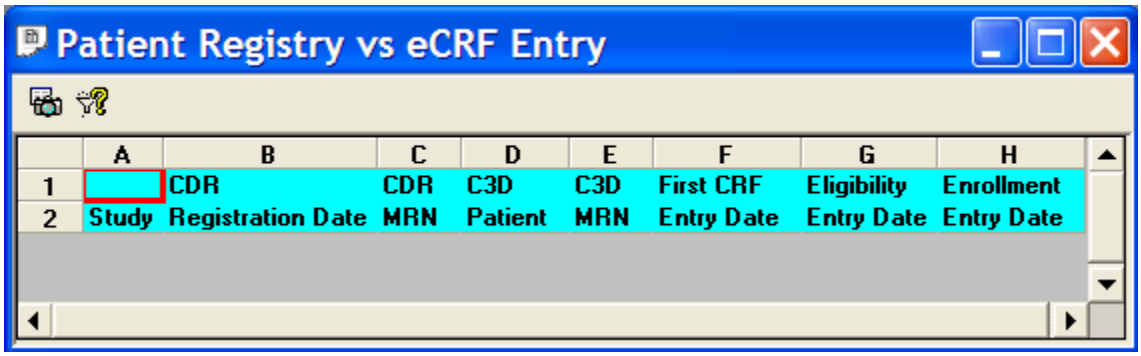
Columns

Field	*Description*
Study	Protocol Number
Monitor Agency	Monitor Agency
CTC Version	Adverse Event CTC Version Used in the Study
Template Version	The Study Template Which Is Used to Build the Study

Tracking: Patient Registry vs eCRF Entry

Description

This report lists CDR (Clinical Data Registry) registration records and C3D data entry. It provides a method of tracking the process of C3D CRFs after the patient is registered to the study. Note that if the C3D is missing an Enrollment Patient ID or has the wrong Patient ID, the corresponding C3D columns will be empty.



Access

User Level: Builder, QA

Study Level: CCR_Program

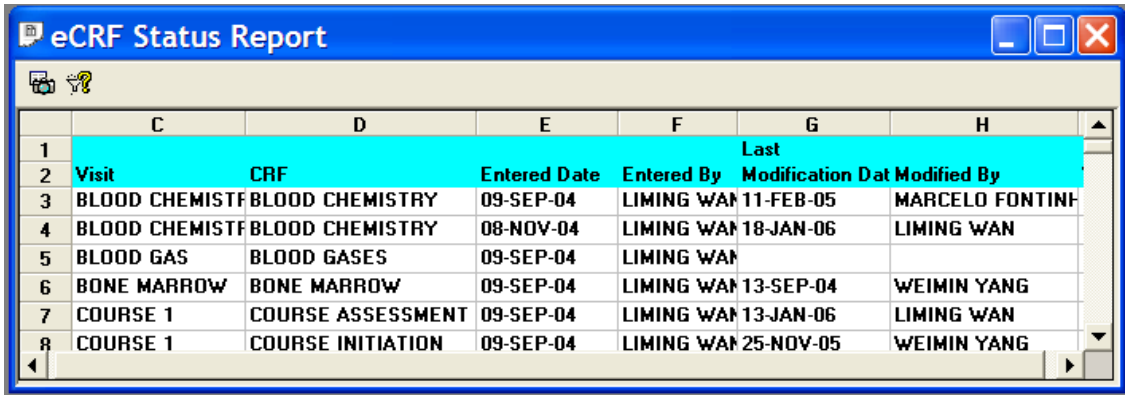
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
CDR Registration Date	Patient Registration Date to the study on CDR
CDR MRN	Patient ID on CDR
C3D Patient	C3D Patient ID, generally it is number like 1, 2
C3D MRN	Patient's Local Identifier Used by the Treating Institution
First CRF Entry Date	The Entry Date of the First CRF created on C3D
Eligibility Entry Date	The Entry Date of the Eligibility Form
Enrollment Entry Date	The Entry Date of the Enrollment Form

Tracking: eCRF Status Report

Description

This report lists CRF Status and its related timestamp. The modification, verification and approval are the latest action of its type. Note that the loaded labs are excluded.



	C	D	E	F	G	H
1					Last	
2	Visit	CRF	Entered Date	Entered By	Modification Dat	Modified By
3	BLOOD CHEMISTF	BLOOD CHEMISTRY	09-SEP-04	LIMING WAN	11-FEB-05	MARCELO FONTINH
4	BLOOD CHEMISTF	BLOOD CHEMISTRY	08-NOV-04	LIMING WAN	18-JAN-06	LIMING WAN
5	BLOOD GAS	BLOOD GASES	09-SEP-04	LIMING WAN		
6	BONE MARROW	BONE MARROW	09-SEP-04	LIMING WAN	13-SEP-04	WEIMIN YANG
7	COURSE 1	COURSE ASSESSMENT	09-SEP-04	LIMING WAN	13-JAN-06	LIMING WAN
8	COURSE 1	COURSE INITIATION	09-SEP-04	LIMING WAN	25-NOV-05	WEIMIN YANG

Access

User Level: Builder, QA

Study Level: CCR_Program

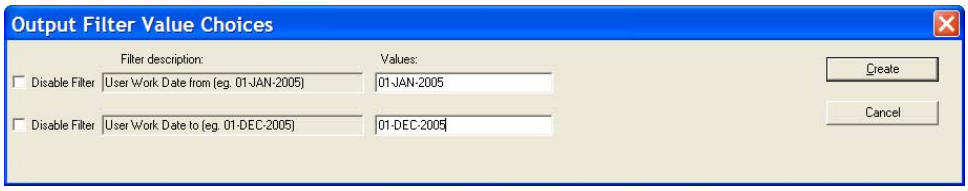
Columns

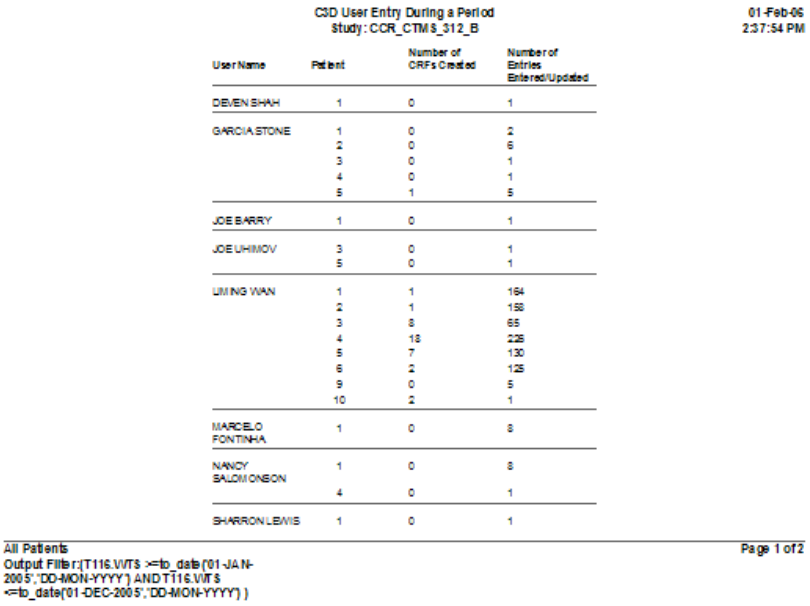
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	Patient ID
Visit	Clinical Event
CRF	CRF Form
Entered Date	CRF Entry Date
Entered By	The Person Who Creates the CRF
Last Modification Date	The Latest CRF Modification Date
Modified By	The Person Who Made the Latest Modification
Last Verified Date	The Latest CRF Verification Date
Verified By	The Person Who Made the Latest Verification
Approved Date	The Latest CRF Approval Date
Approved By	The Person Who Made the Latest Approval
Blank Flag	Whether CRF is Blank

Tracking: C3D User Entry During a Period

Description

This report lists the user's data entry effort for the study during a date range. It includes the number of CRFs created, the number of enterable fields entered/updated. Note that in some cases the system might use a time system that differs from the 'current' time system. Please do not just open an empty form without any other action.





C3D User Entry During a Period
Study: CCR_CTM$_312_B

01-Feb-06
2:37:54 PM

User Name	Patient	Number of CRFs Created	Number of Entries Entered/Updated
DEVEN SHAH	1	0	1
GARCIA STONE	1	0	2
	2	0	6
	3	0	1
	4	0	1
	5	1	5
JOE BARRY	1	0	1
JOE UHIMOV	3	0	1
	5	0	1
LIMING WAN	1	1	164
	2	1	158
	3	8	65
	4	18	226
	5	7	130
	6	2	125
	9	0	5
	10	2	1
MARCELO FONTINHA	1	0	8
NANCY SALOMONSON	1	0	8
	4	0	1
SHARRON LEWIS	1	0	1

All Patients
Output Filter:(T116.V/T$ >=to_date('01-JAN-2005','DD-MON-YYYY') AND T116.V/T$ <=to_date('01-DEC-2005','DD-MON-YYYY'))

Page 1 of 2

Access

User Level: Builder

Study Level: CCR_Program

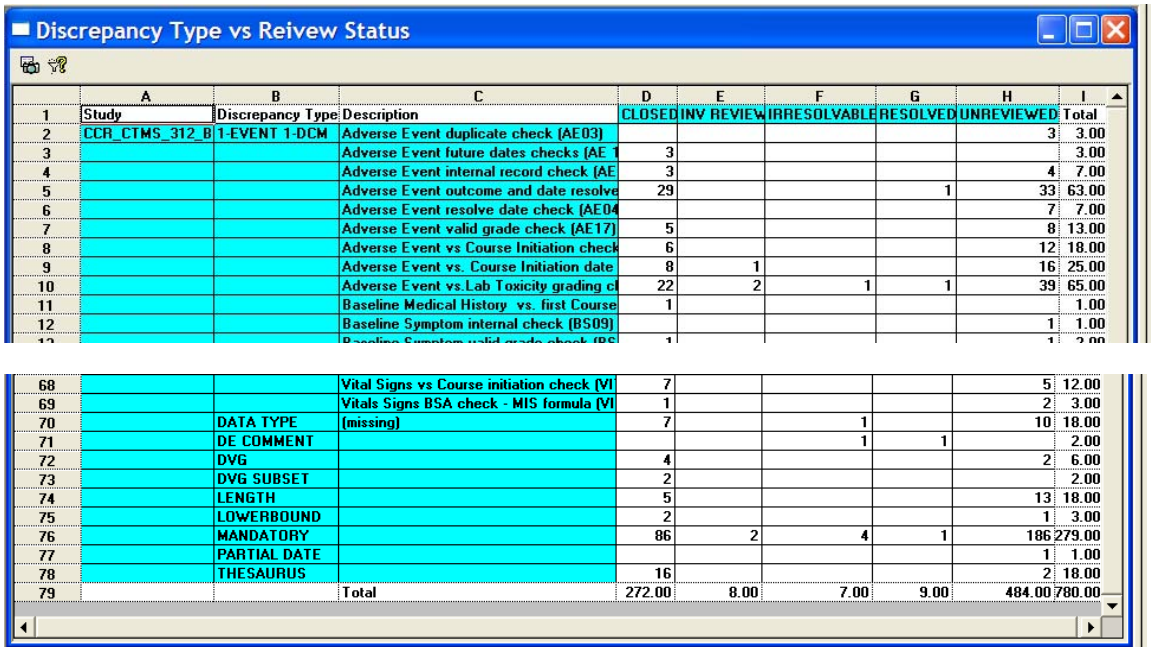
Columns

Field	*Description*
Study (Header)	Protocol Number for which Access is being Queried
User Name	User's Full Name
Patient	C3D Patient ID
Number of CRFs Created	Number of CRFs Created During the Specified Period
Number of Responses Entered/Updated	Number of Data Entries During the Specified Period

Discrepancy: Discrepancy Type vs. Review Status

Description

This report lists the count of discrepancies categorized by type and review status. The columns displayed depend on the type of discrepancy review status in the selected study.



Discrepancy Type vs Reivew Status

	A	B	C	D	E	F	G	H	I
1	Study	Discrepancy Type	Description	CLOSED	INV REVIEW	IRRESOLVABLE	RESOLVED	UNREVIEWED	Total
2	CCR_CTMS_312_B	1-EVENT 1-DCM	Adverse Event duplicate check (AE03)					3	3.00
3			Adverse Event future dates checks (AE 1	3					3.00
4			Adverse Event internal record check (AE	3				4	7.00
5			Adverse Event outcome and date resolve	29			1	33	63.00
6			Adverse Event resolve date check (AE04					7	7.00
7			Adverse Event valid grade check (AE17)	5				8	13.00
8			Adverse Event vs Course Initiation check	6				12	18.00
9			Adverse Event vs. Course Initiation date	8	1			16	25.00
10			Adverse Event vs.Lab Toxicity grading cl	22	2	1	1	39	65.00
11			Baseline Medical History vs. first Course	1					1.00
12			Baseline Symptom internal check (BS09)					1	1.00
68			Vital Signs vs Course initiation check (VI	7				5	12.00
69			Vitals Signs BSA check - MIS formula (VI	1				2	3.00
70		DATA TYPE	(missing)	7		1		10	18.00
71		DE COMMENT				1	1		2.00
72		DVG		4				2	6.00
73		DVG SUBSET		2					2.00
74		LENGTH		5				13	18.00
75		LOWERBOUND		2				1	3.00
76		MANDATORY		86	2	4	1	186	279.00
77		PARTIAL DATE						1	1.00
78		THESAURUS		16				2	18.00
79			Total	272.00	8.00	7.00	9.00	484.00	780.00

Access

User Level: Public

Study Level: Global

Columns

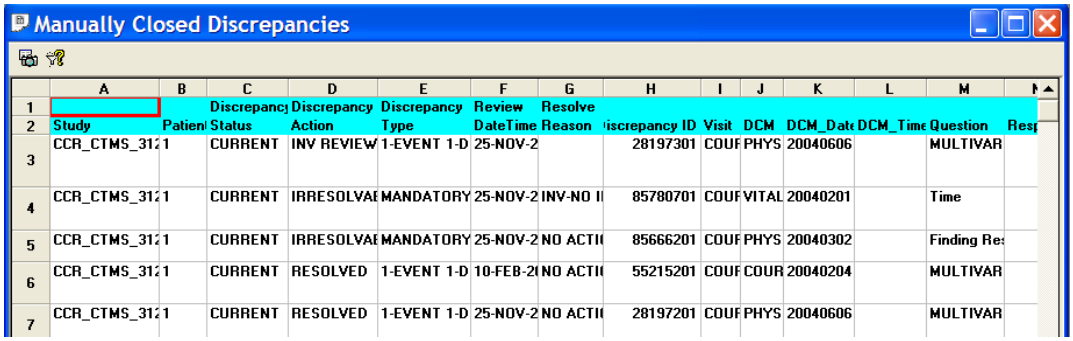
Field	*Description*	
Study	Protocol Number for which Access is being Queried	
Discrepancy Type	1-Event 1-DCM:	Multivariate discrepancy. Marked as red on RDC.
	DATA TYPE:	Univariate discrepancy. Response value type is not appropriate.
	LENGTH:	Univariate discrepancy. Response value length exceeds the maximum question length.
	DE COMMENT:	Manual discrepancy.
	DVG/ DVG SUBSET:	Univariate discrepancy. Response value is not on pick list.
	LOWER BOUND:	Univariate discrepancy. Response value is lower than the lower limit.

	UPPER BOUND:	Univariate discrepancy. Response value is higher than the upper limit.
	MANDATORY:	Univariate discrepancy. Response value is not put.
	PARTIAL DATE:	Univariate discrepancy. The response value type is not a complete date or time.
	THESAURUS:	Univariate discrepancy. Response value is not on standard Thesaurus pick list.
	PRECISION:	Univariate discrepancy. Response value exceeds decimal value.
	INDICATOR:	Indicator discrepancy. The required filed is missing.
Description	The Edit Checks.	
CLOSED	Number of Closed Discrepancies.	
RESOLVED	Number of Resolved Discrepancies.	
UNREVIEWED	Number of Unreivewed Discrepancies.	
IRRESOVABLE	Number of Irresovable Discrepancies	
INV REVIEW	Number of Discrepancies Sent to Site	
DM REVIEW	Number of Discrepancies Sent from CRA to Data Manager	
Total	Total Number of Discrepancies on the Row	

Discrepancy: Manually Closed Discrepancies

Description

This report lists the manually closed discrepancies. It also provides details of the discrepancies and their related data.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1			Discrepanc	Discrepancy	Discrepancy	Review	Resolve							
2	Study	Patien	Status	Action	Type	DateTime	Reason	iscrepancy ID	Visit	DCM	DCM_Dat	DCM_Time	Question	Resp
3	CCR_CTMS_312	1	CURRENT	INV REVIEW	1-EVENT 1-D	25-NOV-2		28197301	COUF	PHYS	20040606		MULTIVAR	
4	CCR_CTMS_312	1	CURRENT	IRRESOLVAE	MANDATORY	25-NOV-2	INV-NO I	85780701	COUF	VITAL	20040201		Time	
5	CCR_CTMS_312	1	CURRENT	IRRESOLVAE	MANDATORY	25-NOV-2	NO ACTI	85666201	COUF	PHYS	20040302		Finding Re	
6	CCR_CTMS_312	1	CURRENT	RESOLVED	1-EVENT 1-D	10-FEB-2(	NO ACTI	55215201	COUF	COUR	20040204		MULTIVAR	
7	CCR_CTMS_312	1	CURRENT	RESOLVED	1-EVENT 1-D	25-NOV-2	NO ACTI	28197201	COUF	PHYS	20040606		MULTIVAR	

Access

User Level: Public

Study Level: Global

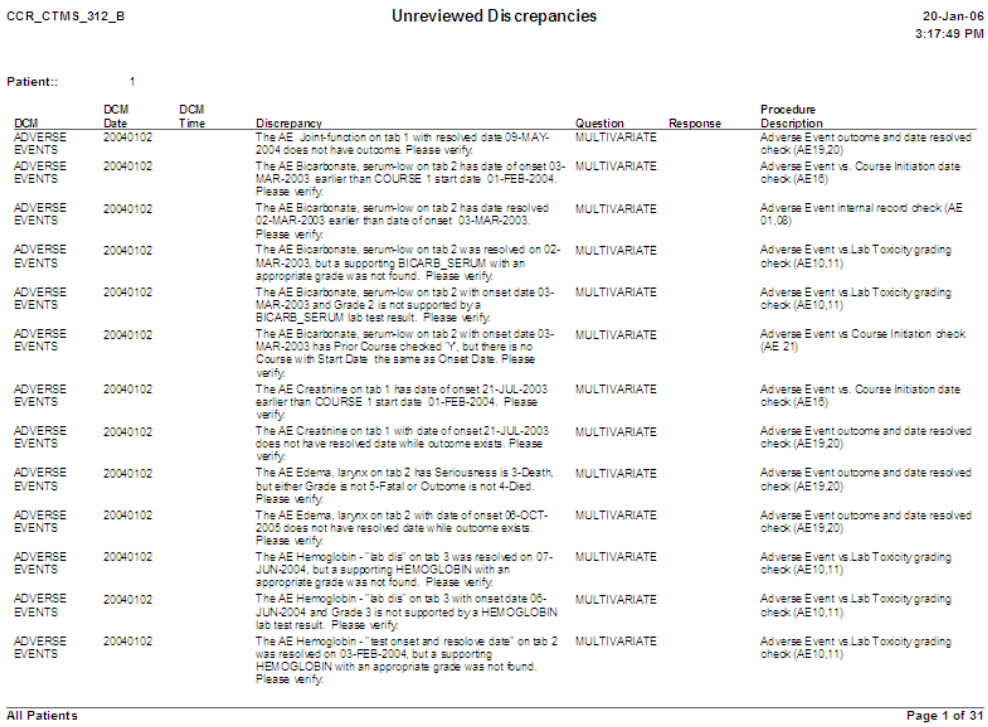
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID
Discrepancy Status	Status of the Discrepancy. Manually Closed Discrepancy Has Status of ‘Current’.
Discrepancy Action	Discrepancy Action of DM
Discrepancy Type	Type of the Discrepancy
Review DateTime	Review Date and Time
Resolve Reason	Reason to Resolve the Discrepancy
Discrepancy ID	Discrepancy ID
Visit	Clinical Event
DCM	Form Name
DCM_Date	DCM Date
DCM_Time	DCM Time
Question	Applies to Univariate Discrepancy. The question which Triggers Discrepancy
Response	Question Value
Procedure	Applies to Multivarite Discrepancy. The Procedure Name
Procedure Description	The Edit Check
Discrepancy	Discrepancy Message
Reviewed By	The Person Who Review the Discrepancy
Resolution Comment	The Comment Entered when Close the Discrepancy

Discrepancy: Unreviewed Discrepancies (Formatted)

Description

This report lists the unreviewed discrepancies. The layout is formatted.



CCR_CTMS_312_B — Unreviewed Discrepancies — 20-Jan-06 3:17:49 PM

Patient:: 1

DCM	DCM Date	DCM Time	Discrepancy	Question	Response	Procedure Description
ADVERSE EVENTS	20040102		The AE Joint-function on tab 1 with resolved date 09-MAY-2004 does not have outcome. Please verify.	MULTIVARIATE		Adverse Event outcome and date resolved check (AE19,20)
ADVERSE EVENTS	20040102		The AE Bicarbonate, serum-low on tab 2 has date of onset 03-MAR-2003 earlier than COURSE 1 start date 01-FEB-2004. Please verify.	MULTIVARIATE		Adverse Event vs. Course Initiation date check (AE16)
ADVERSE EVENTS	20040102		The AE Bicarbonate, serum-low on tab 2 has date resolved 02-MAR-2003 earlier than date of onset 03-MAR-2003. Please verify.	MULTIVARIATE		Adverse Event internal record check (AE 01,08)
ADVERSE EVENTS	20040102		The AE Bicarbonate, serum-low on tab 2 was resolved on 02-MAR-2003, but a supporting BICARB_SERUM with an appropriate grade was not found. Please verify.	MULTIVARIATE		Adverse Event vs Lab Toxicity grading check (AE10,11)
ADVERSE EVENTS	20040102		The AE Bicarbonate, serum-low on tab 2 with onset date 03-MAR-2003 and Grade 2 is not supported by a BICARB_SERUM lab test result. Please verify.	MULTIVARIATE		Adverse Event vs Lab Toxicity grading check (AE10,11)
ADVERSE EVENTS	20040102		The AE Bicarbonate, serum-low on tab 2 with onset date 03-MAR-2003 has Prior Course checked 'Y', but there is no Course with Start Date the same as Onset Date. Please verify.	MULTIVARIATE		Adverse Event vs Course Initation check (AE 21)
ADVERSE EVENTS	20040102		The AE Creatinine on tab 1 has date of onset 21-JUL-2003 earlier than COURSE 1 start date 01-FEB-2004. Please verify.	MULTIVARIATE		Adverse Event vs. Course Initiation date check (AE16)
ADVERSE EVENTS	20040102		The AE Creatinine on tab 1 with date of onset 21-JUL-2003 does not have resolved date while outcome exists. Please verify.	MULTIVARIATE		Adverse Event outcome and date resolved check (AE19,20)
ADVERSE EVENTS	20040102		The AE Edema, larynx on tab 2 has Seriousness is 3-Death, but either Grade is not 5-Fatal or Outcome is not 4-Died. Please verify.	MULTIVARIATE		Adverse Event outcome and date resolved check (AE19,20)
ADVERSE EVENTS	20040102		The AE Edema, larynx on tab 2 with date of onset 06-OCT-2005 does not have resolved date while outcome exists. Please verify.	MULTIVARIATE		Adverse Event outcome and date resolved check (AE19,20)
ADVERSE EVENTS	20040102		The AE Hemoglobin - "lab dis" on tab 3 was resolved on 07-JUN-2004, but a supporting HEMOGLOBIN with an appropriate grade was not found. Please verify.	MULTIVARIATE		Adverse Event vs Lab Toxicity grading check (AE10,11)
ADVERSE EVENTS	20040102		The AE Hemoglobin - "lab dis" on tab 3 with onset date 06-JUN-2004 and Grade 3 is not supported by a HEMOGLOBIN lab test result. Please verify.	MULTIVARIATE		Adverse Event vs Lab Toxicity grading check (AE10,11)
ADVERSE EVENTS	20040102		The AE Hemoglobin - "test onset and resolove date" on tab 2 was resolved on 03-FEB-2004, but a supporting HEMOGLOBIN with an appropriate grade was not found. Please verify.	MULTIVARIATE		Adverse Event vs Lab Toxicity grading check (AE10,11)

All Patients — Page 1 of 31

Access

User Level: Public

Study Level: Global

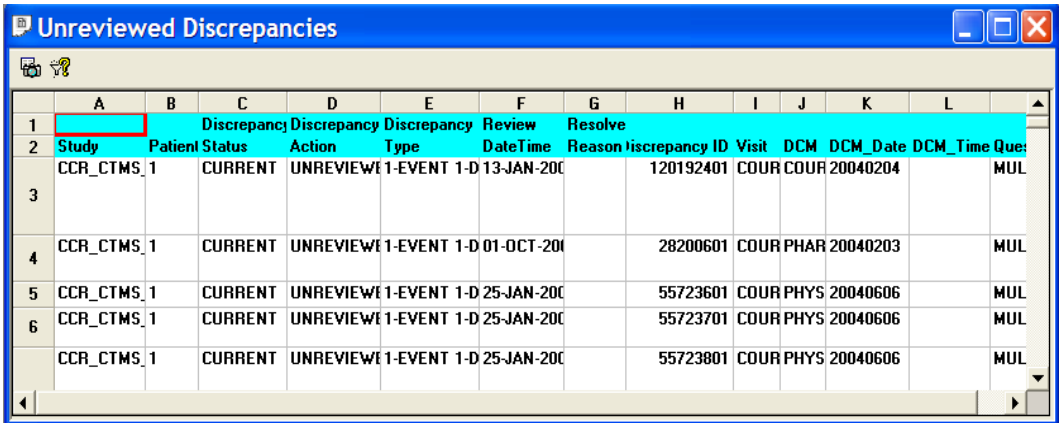
Columns

Field	*Description*
Study (Header)	Protocol Number that the User has Access to
Patient (Group Header)	C3D Patient ID
DCM	Form Name
DCM_Date	DCM Date
DCM_Time	DCM Time
Discrepancy	Discrepancy Message
Question	Applies to Univariate Discrepancy. The Question Which Triggers Discrepancy
Response	Question Value
Procedure Description	The Edit Check

Discrepancy: Unreviewed Discrepancies

Description

This report lists the Unreviewed discrepancies.



	A	B	C	D	E	F	G	H	I	J	K	L	
1			Discrepancy	Discrepancy	Discrepancy	Review	Resolve						
2	Study	Patient	Status	Action	Type	DateTime	Reason	Discrepancy ID	Visit	DCM	DCM_Date	DCM_Time	Ques
3	CCR_CTMS_	1	CURRENT	UNREVIEWE	1-EVENT 1-D	13-JAN-200		120192401	COUR	COUR	20040204		MUL
4	CCR_CTMS_	1	CURRENT	UNREVIEWE	1-EVENT 1-D	01-OCT-200		28200601	COUR	PHAR	20040203		MUL
5	CCR_CTMS_	1	CURRENT	UNREVIEWE	1-EVENT 1-D	25-JAN-200		55723601	COUR	PHYS	20040606		MUL
6	CCR_CTMS_	1	CURRENT	UNREVIEWE	1-EVENT 1-D	25-JAN-200		55723701	COUR	PHYS	20040606		MUL
	CCR_CTMS_	1	CURRENT	UNREVIEWE	1-EVENT 1-D	25-JAN-200		55723801	COUR	PHYS	20040606		MUL

Access

User Level: Public

Study Level: Global

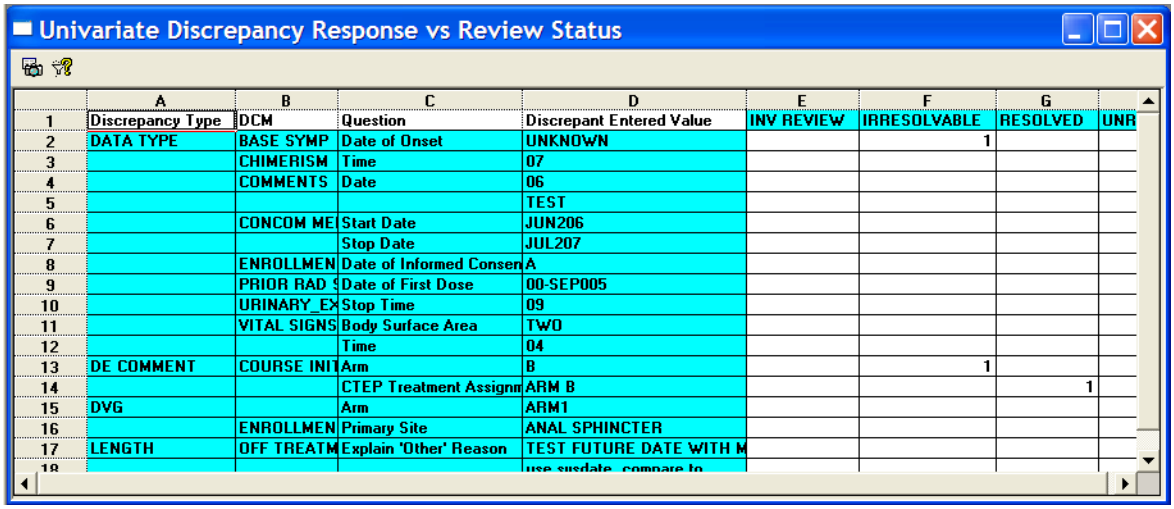
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID
Discrepancy Status	Status of the Discrepancy. Manually Closed Discrepancy has Status of ‘Current’.
Discrepancy Action	Discrepancy Action of DM
Discrepancy Type	Type of the Discrepancy
Review DateTime	Review Date and Time
Resolve Reason	Reason to Resolve the Discrepancy
Discrepancy ID	Discrepancy ID
Visit	Clinical Event
DCM	Form Name
DCM_Date	DCM Date
DCM_Time	DCM Time
Question	Applies to Univariate Discrepancy. The question which Triggers Discrepancy
Response	Question Value
Procedure	Applies to Multivarite Discrepancy. The Procedure Name
Description	The Edit Check
Discrepancy	Discrepancy Message
Reviewed By	The Person who Review the Discrepancy

Discrepancies: Univariate Discrepancy Response vs Review Status

Description

This report lists the count of univariate discrepancies categorized by discrepancy type, DCM, question, value verse review status. The columns displayed depend on the type of discrepancy review status in the selected study.



	A	B	C	D	E	F	G	
1	Discrepancy Type	DCM	Question	Discrepant Entered Value	INV REVIEW	IRRESOLVABLE	RESOLVED	UNR
2	DATA TYPE	BASE SYMP	Date of Onset	UNKNOWN		1		
3		CHIMERISM	Time	07				
4		COMMENTS	Date	06				
5				TEST				
6		CONCOM ME	Start Date	JUN206				
7			Stop Date	JUL207				
8		ENROLLMEN	Date of Informed Consen	A				
9		PRIOR RAD S	Date of First Dose	00-SEP005				
10		URINARY_EX	Stop Time	09				
11		VITAL SIGNS	Body Surface Area	TWO				
12			Time	04				
13	DE COMMENT	COURSE INIT	Arm	B		1		
14			CTEP Treatment Assignm	ARM B			1	
15	DVG		Arm	ARM1				
16		ENROLLMEN	Primary Site	ANAL SPHINCTER				
17	LENGTH	OFF TREATM	Explain 'Other' Reason	TEST FUTURE DATE WITH M				
18				use susdate, compare to				

Access

User Level: Public

Study Level: Global

Columns

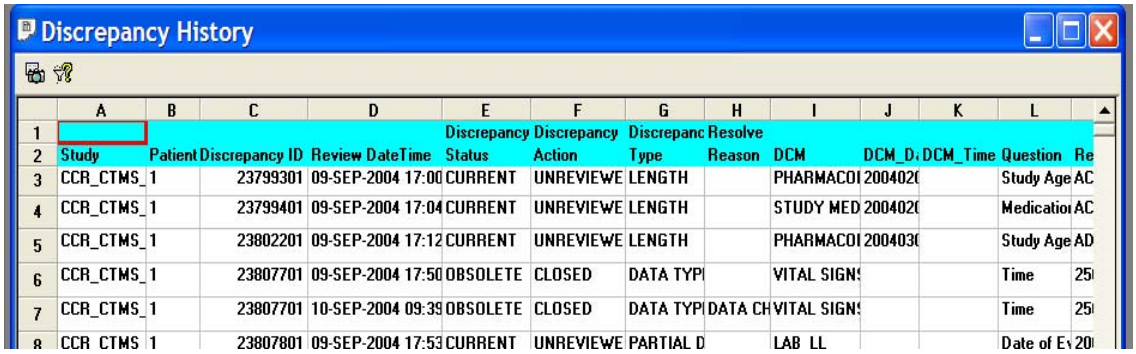
Field	*Description*
Study	Protocol Number for which Access is being Queried
Discrepancy Type	DATA TYPE: Univariate discrepancy. Response value type is not appropriate. DE COMMENT: Manual discrepancy. DVG/ DVG SUBSET: Univariate discrepancy. Response value is not on the pick list. LENGTH: Univariate discrepancy. Response value length exceeds the maximum question length. LOWER BOUND: Univariate discrepancy. Response value is lower than the lower limit. UPPER BOUND: Univariate discrepancy. Response value is higher than the upper limit. MANDATORY: Univariate discrepancy. Response value is not put. PARTIAL DATE: Univariate discrepancy. The response value type is not a complete date or time. THESAURUS: Univariate discrepancy. Response value is not on standard Thesaurus pick list. PRECISION: Univariate discrepancy. Response value exceeds decimal value. INDICATOR: Indicator discrepancy. The required filed is missing.
DCM	Form Name
Question	The Question which Triggers Discrepancy

Discrepant Entered Value	Field value
CLOSED	Number of Closed Discrepancies.
RESOLVED	Number of Resolved Discrepancies.
UNREVIEWED	Number of Unreivewed Discrepancies.
IRRESOVABLE	Number of Irresovable Discrepancies
INV REVIEW	Number of Discrepancies Sent to Site
DM REVIEW	Number of Discrepancies Sent from CRA to Data Manager
Total	Total Number of Discrepancies on the Row

Discrepancies: Discrepancies History

Description

This report lists all discrepancy history in the study.



	A	B	C	D	E	F	G	H	I	J	K	L	
1					Discrepancy	Discrepancy	Discrepanc	Resolve					
2	Study	Patient	Discrepancy ID	Review DateTime	Status	Action	Type	Reason	DCM	DCM_D	DCM_Time	Question	Re
3	CCR_CTMS_	1	23799301	09-SEP-2004 17:00	CURRENT	UNREVIEWE	LENGTH		PHARMACOI	200402(		Study Age	AC
4	CCR_CTMS_	1	23799401	09-SEP-2004 17:04	CURRENT	UNREVIEWE	LENGTH		STUDY MED	200402(		Medicatior	AC
5	CCR_CTMS_	1	23802201	09-SEP-2004 17:12	CURRENT	UNREVIEWE	LENGTH		PHARMACOI	200403(		Study Age	AD
6	CCR_CTMS_	1	23807701	09-SEP-2004 17:50	OBSOLETE	CLOSED	DATA TYPI		VITAL SIGN			Time	25
7	CCR_CTMS_	1	23807701	10-SEP-2004 09:39	OBSOLETE	CLOSED	DATA TYPI	DATA CH	VITAL SIGN			Time	25
8	CCR_CTMS	1	23807801	09-SEP-2004 17:53	CURRENT	UNREVIEWE	PARTIAL D		LAB_LL			Date of Ev	20

Access

User Level: Public

Study Level: Global

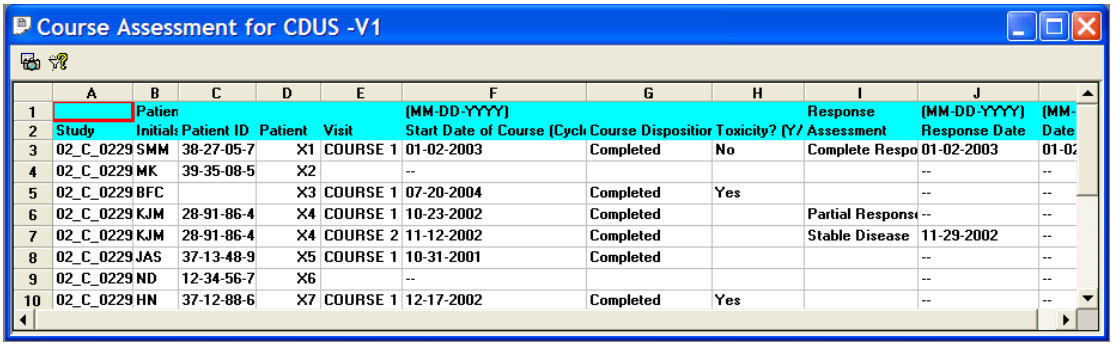
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID
Discrepancy ID	Discrepancy ID
Review Date Time	Review Date and Time
Discrepancy Status	Status of the Discrepancy. Manually Closed Discrepancy Has Status of ‘Current’.
Discrepancy Action	Discrepancy Action of DM
Discrepancy Type	Type of the Discrepancy
Resolve Reason	Reason to Resolve the Discrepancy
DCM	Form Name
DCM_Date	DCM Date
DCM_Time	DCM Time
Question	Applies to Univariate Discrepancy. The question which Triggers Discrepancy
Response	Question Value
Procedure	Applies to Multivariate Discrepancy. The Procedure Name
Description	The Edit Check
Discrepancy	Discrepancy Message
Resolution Comment	The Comment Entered when Close the Discrepancy
Reviewed By	The Person who Review the Discrepancy

CDUS: Course Assessment for CDUS –V1

Description

This report lists the course assessment for CDUS QA. It is sorted by patient and course start date. Used for CDUS_302 study. It works on studies based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	G	H	I	J	
1		Patien				(MM-DD-YYYY)			Response	(MM-DD-YYYY)	(MM-
2	Study	Initials	Patient ID	Patient	Visit	Start Date of Course (Cycl	Course Disposition	Toxicity? (Y/	Assessment	Response Date	Date
3	02_C_0229	SMM	38-27-05-7	X1	COURSE 1	01-02-2003	Completed	No	Complete Respo	01-02-2003	01-0
4	02_C_0229	MK	39-35-08-5	X2		--				--	--
5	02_C_0229	BFC		X3	COURSE 1	07-20-2004	Completed	Yes		--	--
6	02_C_0229	KJM	28-91-86-4	X4	COURSE 1	10-23-2002	Completed		Partial Respons	--	--
7	02_C_0229	KJM	28-91-86-4	X4	COURSE 2	11-12-2002	Completed		Stable Disease	11-29-2002	--
8	02_C_0229	JAS	37-13-48-9	X5	COURSE 1	10-31-2001	Completed			--	--
9	02_C_0229	ND	12-34-56-7	X6		--				--	--
10	02_C_0229	HN	37-12-88-6	X7	COURSE 1	12-17-2002	Completed	Yes		--	--

Access

User Level: Public

Study Level: CDUS_302

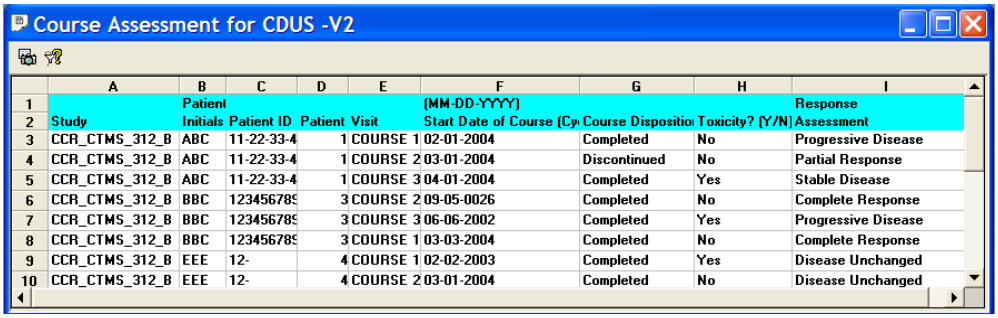
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Start Date of the Course (Cycle)	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Course Disposition	Whether the Course Has Been Conducted
Toxicity? (Y/N)	Whether Adverse Event Has Occurred During the Course
Response Assessment	Patient's Best Disease State as Assessed During the Course
Response Date	Date of the Earliest Evaluation Justifies Assessment
Date Onset of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease
Response Notes	The Reason for the Assessment
Dose Change from TAC?	Whether the Patient's Treatment was Different form that Specified by the Treatment Assignment Code for This Course
Start Date of the Course (Cycle)	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Response Date	Date of the Earliest Evaluation Justifies Assessment. The Original Value Used by System (Form YYYYMMDD)
Date Onset of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease. The Original Value Used by System (Form YYYYMMDD)

CDUS: Course Assessment for CDUS –V2

Description

This report lists the course assessment for CDUS QA. It is sorted by patient and course start date. Used for CDUS_302 studies. It works on studies based on 3.12 and 2007R1 templates.



	A	B	C	D	E	F	G	H	I
1		Patient				(MM-DD-YYYY)			Response
2	Study	Initials	Patient ID	Patient	Visit	Start Date of Course (Cy	Course Disposition	Toxicity? (Y/N)	Assessment
3	CCR_CTMS_312_B	ABC	11-22-33-4	1	COURSE 1	02-01-2004	Completed	No	Progressive Disease
4	CCR_CTMS_312_B	ABC	11-22-33-4	1	COURSE 2	03-01-2004	Discontinued	No	Partial Response
5	CCR_CTMS_312_B	ABC	11-22-33-4	1	COURSE 3	04-01-2004	Completed	Yes	Stable Disease
6	CCR_CTMS_312_B	BBC	123456789	3	COURSE 2	09-05-0026	Completed	No	Complete Response
7	CCR_CTMS_312_B	BBC	123456789	3	COURSE 3	06-06-2002	Completed	Yes	Progressive Disease
8	CCR_CTMS_312_B	BBC	123456789	3	COURSE 1	03-03-2004	Completed	No	Complete Response
9	CCR_CTMS_312_B	EEE	12-	4	COURSE 1	02-02-2003	Completed	Yes	Disease Unchanged
10	CCR_CTMS_312_B	EEE	12-	4	COURSE 2	03-01-2004	Completed	No	Disease Unchanged

Access

User Level: Public

Study Level: CCR 2007R1 STD, CDUS 302

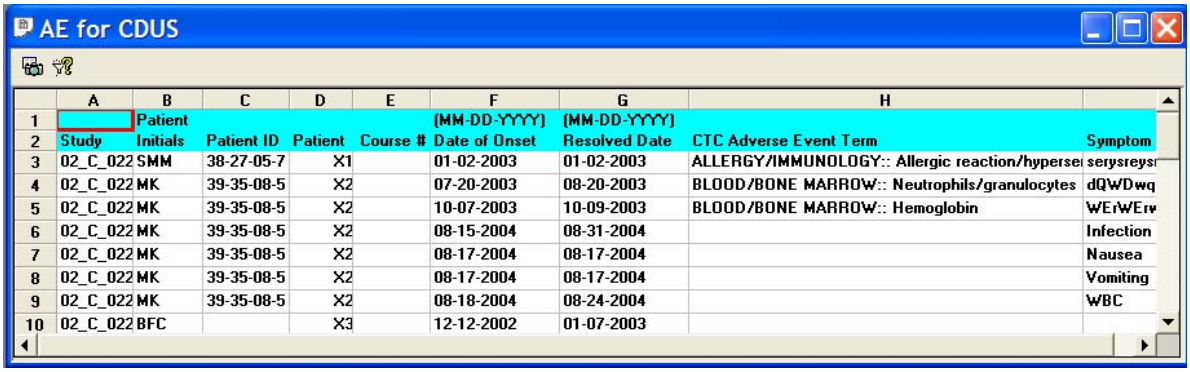
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Start Date of the Course (Cycle)	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Course Disposition	Whether the Course Has Been Conducted
Toxicity? (Y/N)	Whether Adverse Event Has Occurred During the Course
Response Assessment	Patient's Best Disease State as Assessed During the Course
Response Date	Date of the Earliest Evaluation Justifies Assessment
Date of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease
Response Notes	The Reason for the Assessment
Dose Change from TAC?	Whether the Patient's Treatment was Different form that Specified by the Treatment Assignment Code for This Course
Start Date of the Course (Cycle)	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Response Date	Date of the Earliest Evaluation Justifies Assessment. The Original Value Used by System (Form YYYYMMDD).
Date of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease. The Original Value Used by System (Form YYYYMMDD).

CDUS: AE for CDUS – V1

Description

This report lists the course assessment for CDUS QA. It is sorted by patient and adverse event onset date. Used for CDUS_302 studies.



	A	B	C	D	E	F	G	H	
1		Patient				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Initials	Patient ID	Patient	Course #	Date of Onset	Resolved Date	CTC Adverse Event Term	Symptom
3	02_C_022	SMM	38-27-05-7	X1		01-02-2003	01-02-2003	ALLERGY/IMMUNOLOGY:: Allergic reaction/hypersei	serysreysr
4	02_C_022	MK	39-35-08-5	X2		07-20-2003	08-20-2003	BLOOD/BONE MARROW:: Neutrophils/granulocytes	dQWDwq
5	02_C_022	MK	39-35-08-5	X2		10-07-2003	10-09-2003	BLOOD/BONE MARROW:: Hemoglobin	WErWErv
6	02_C_022	MK	39-35-08-5	X2		08-15-2004	08-31-2004		Infection
7	02_C_022	MK	39-35-08-5	X2		08-17-2004	08-17-2004		Nausea
8	02_C_022	MK	39-35-08-5	X2		08-17-2004	08-17-2004		Vomiting
9	02_C_022	MK	39-35-08-5	X2		08-18-2004	08-24-2004		WBC
10	02_C_022	BFC		X3		12-12-2002	01-07-2003		

Access

User Level: Public

Study Level: CDUS_302

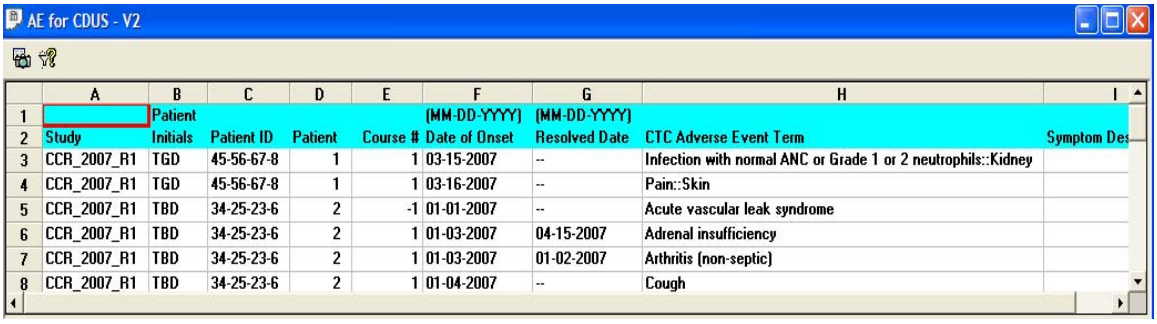
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This AE Started
Date of Onset	Date of The Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
CTC Adverse Event Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Symptom Description	The Succinct Clinical Description of This AE
AER Filed? (Y/N)	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
AE Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
AE Action	Whether Any Changes Made to the Study Regimen In Response to This AE
AE Therapy	Whether Additional Therapy Is Required to Treat This AE
AE Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Date of Onset	Date of The Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY). The Original Value Used by System (Form YYYYMMDD)

CDUS: AE for CDUS – V2

Description

This report lists the course assessment for CDUS QA. It is sorted by patient and adverse event onset date. Work for studies based on 2007R1 templates.



	A	B	C	D	E	F	G	H	I
1		Patient				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Initials	Patient ID	Patient	Course #	Date of Onset	Resolved Date	CTC Adverse Event Term	Symptom Des
3	CCR_2007_R1	TGD	45-56-67-8	1	1	03-15-2007	--	Infection with normal ANC or Grade 1 or 2 neutrophils::Kidney	
4	CCR_2007_R1	TGD	45-56-67-8	1	1	03-16-2007	--	Pain::Skin	
5	CCR_2007_R1	TBD	34-25-23-6	2	-1	01-01-2007	--	Acute vascular leak syndrome	
6	CCR_2007_R1	TBD	34-25-23-6	2	1	01-03-2007	04-15-2007	Adrenal insufficiency	
7	CCR_2007_R1	TBD	34-25-23-6	2	1	01-03-2007	01-02-2007	Arthritis (non-septic)	
8	CCR_2007_R1	TBD	34-25-23-6	2	1	01-04-2007	--	Cough	

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

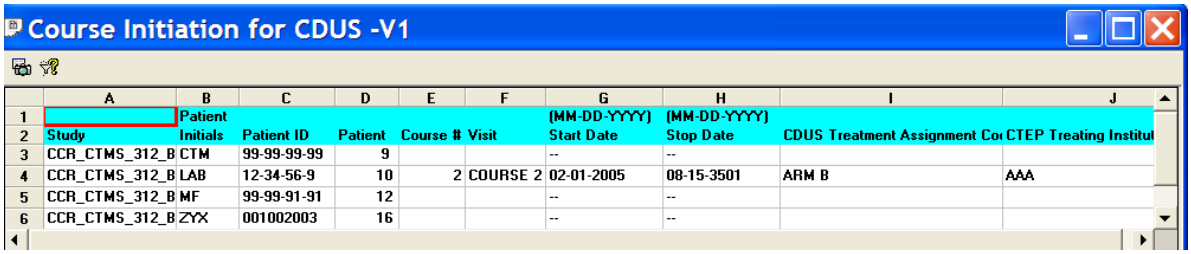
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This AE Started
Date of Onset	Date of The Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
CTC Adverse Event Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Symptom Description	The Succinct Clinical Description of This AE
AER Filed? (Y/N)	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
AE Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
AE Action	Whether Any Changes Made to the Study Regimen In Response to This AE

AE Therapy	Whether Additional Therapy Is Required to Treat This AE
AE Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Date of Onset	Date of The Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY). The Original Value Used by System (Form YYYYMMDD)

CDUS: Course Initiation for CDUS – V1

Description

This report lists the course initiation for CDUS QA. It is sorted by patient and course start date. Used for CDUS_302 studies. It works on studies based on 3.10 and 3.12 templates.



	A	B	C	D	E	F	G	H	I	J
1		Patient					(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Initials	Patient ID	Patient	Course #	Visit	Start Date	Stop Date	CDUS Treatment Assignment Co	CTEP Treating Institut
3	CCR_CTMS_312_B	CTM	99-99-99-99	9			--	--		
4	CCR_CTMS_312_B	LAB	12-34-56-9	10	2	COURSE 2	02-01-2005	08-15-3501	ARM B	AAA
5	CCR_CTMS_312_B	MF	99-99-91-91	12			--	--		
6	CCR_CTMS_312_B	ZYX	001002003	16			--	--		

Access

User Level: Public

Study Level: CDUS_302

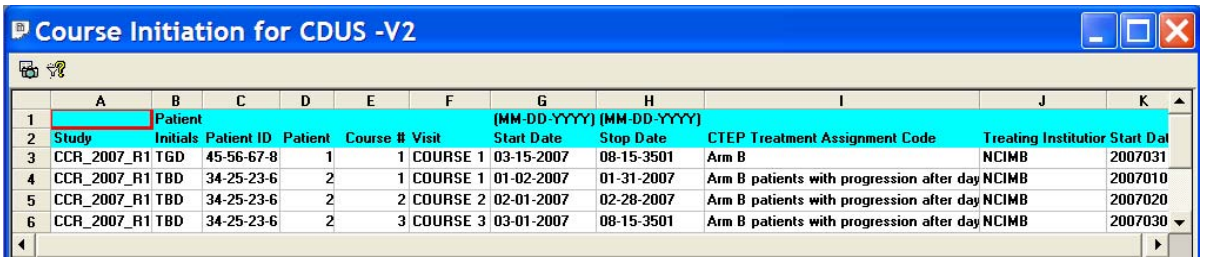
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number
Visit	Clinical Event
Start Date	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Stop Date	Date the Course (Cycle) End (Format MM-DD-YYYY)
CDUS Treatment Assignment Code	The Appropriate Treatment Assignment Code (TAC) for the Regimen and Dose Level of This Course
CTEP Treating Institution Code	The Unique CTEP Institution Code Where the Patient Actually Receives This Course of Treatment
Start Date	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Date the Course (Cycle) End. The Original Value Used by System (Form YYYYMMDD)

CDUS: Course Initiation for CDUS – V2

Description

This report lists the course initiation for CDUS QA. It is sorted by patient and course start date. Used for CDUS_302 studies. It works on studies based on 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K
1		Patient					(MM-DD-YYYY)	(MM-DD-YYYY)			
2	Study	Initials	Patient ID	Patient	Course #	Visit	Start Date	Stop Date	CTEP Treatment Assignment Code	Treating Institution	Start Dat
3	CCR_2007_R1	TGD	45-56-67-8	1	1	COURSE 1	03-15-2007	08-15-3501	Arm B	NCIMB	2007031
4	CCR_2007_R1	TBD	34-25-23-6	2	1	COURSE 1	01-02-2007	01-31-2007	Arm B patients with progression after day	NCIMB	2007010
5	CCR_2007_R1	TBD	34-25-23-6	2	2	COURSE 2	02-01-2007	02-28-2007	Arm B patients with progression after day	NCIMB	2007020
6	CCR_2007_R1	TBD	34-25-23-6	2	3	COURSE 3	03-01-2007	08-15-3501	Arm B patients with progression after day	NCIMB	2007030

Access

User Level: Public

Study Level: CCR 2007R1 STD

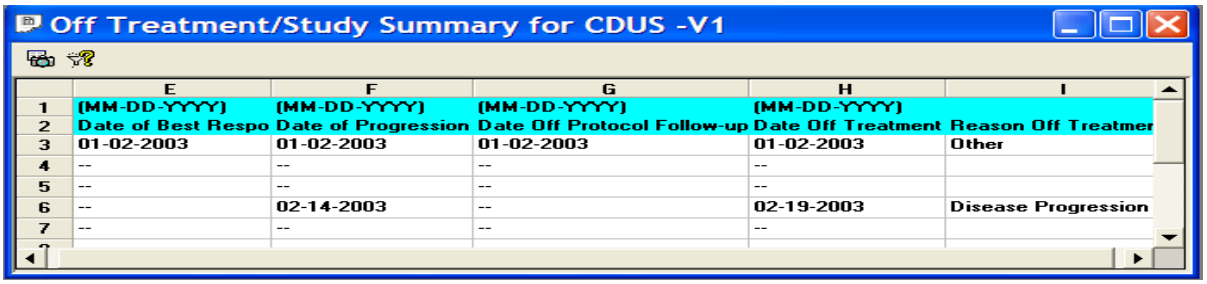
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number
Visit	Clinical Event
Start Date	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Stop Date	Date the Course (Cycle) End (Format MM-DD-YYYY)
CTEP Treatment Assignment Code	The Appropriate Treatment Assignment Code (TAC) for the Regimen and Dose Level of This Course
Treating Institution Code	The Unique CTEP Institution Code Where the Patient Actually Receives This Course of Treatment
Start Date	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Date the Course (Cycle) End. The Original Value Used by System (Form YYYYMMDD)

CDUS: Off Treatment/Study Summary for CDUS –V1

Description

This report lists the off study summary for CDUS QA. Used for CDUS_302 study. It works on studies that are based on the 3.02 and 3.10 templates.



	E	F	G	H	I
1	(MM-DD-YYYY)	(MM-DD-YYYY)	(MM-DD-YYYY)	(MM-DD-YYYY)	
2	Date of Best Respo	Date of Progression	Date Off Protocol Follow-up	Date Off Treatment	Reason Off Treatmer
3	01-02-2003	01-02-2003	01-02-2003	01-02-2003	Other
4	--	--	--	--	
5	--	--	--	--	
6	--	02-14-2003	--	02-19-2003	Disease Progression
7	--	--	--	--	

Access

User Level: Public

Study Level: CDUS_302

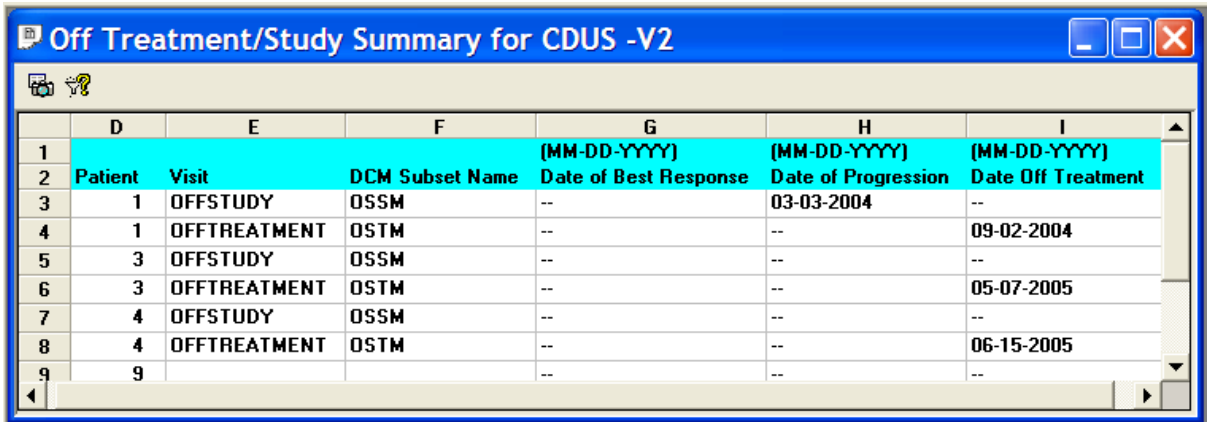
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Date of Best Response	Date of Treatment Response Was First Observed or Began (Format MM-DD-YYYY)
Date of Progression	Date of The Progression (or Relapse) Was First Observed (Format MM-DD-YYYY)
Date Off Protocol Follow-up	Date the Patient Completes or Is Removed from the Protocol-Specific Follow-up Phase (Format MM-DD-YYYY)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Went Off Treatment
Reason for Off Treatment, Other	The Explanation of 'Other' for Reason Off Treatment
Response Assessment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began. The Original Value Used by System (Form YYYYMMDD)
Date of Progression	Date of The Progression (or Relapse) Was First Observed. The Original Value Used by System (Form YYYYMMDD)
Date Off Protocol Follow-up	Date the Patient Completes or Is Removed from the Protocol-Specific Follow-up Phase. The Original Value Used by System (Form YYYYMMDD)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)

CDUS: Off Treatment/Study Summary for CDUS –V2

Description

This report lists the off treatment/study summary for CDUS QA. It is used for CDUS_302 studies. It works on studies that are based on the 3.12 template.



	D	E	F	G	H	I
1				(MM-DD-YYYY)	(MM-DD-YYYY)	(MM-DD-YYYY)
2	Patient	Visit	DCM Subset Name	Date of Best Response	Date of Progression	Date Off Treatment
3	1	OFFSTUDY	OSSM	--	03-03-2004	--
4	1	OFFTREATMENT	OSTM	--	--	09-02-2004
5	3	OFFSTUDY	OSSM	--	--	--
6	3	OFFTREATMENT	OSTM	--	--	05-07-2005
7	4	OFFSTUDY	OSSM	--	--	--
8	4	OFFTREATMENT	OSTM	--	--	06-15-2005
9	9			--	--	--

Access

User Level: Public

Study Level: CDUS_302

Columns

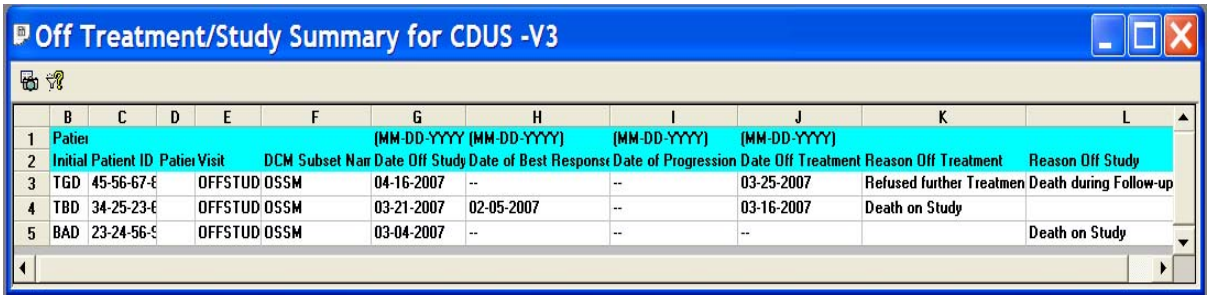
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Date of Best Response	Date of Treatment Response Was First Observed or Began (Format MM-DD-YYYY)
Date of Progression	Date of The Progression (or Relapse) Was First Observed (Format MM-DD-YYYY)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Was Off Protocol Treatment
Date Off Study	Date the Patient Went Off Study (Format MM-DD-YYYY)
Reason Off Study	Reason the Patient Went Off Study
Reason for Off Study, Other	The Explanation of 'Other' for Reason Off Study
Response Assessment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began. The Original Value Used by System (Form YYYYMMDD)

Date of Progression	Date of The Progression (or Relapse) Was First Observed. The Original Value Used by System (Form YYYYMMDD)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)
Date of Best Response	Date of Treatment Response Was First Observed or Began. The Original Value Used by System (Form YYYYMMDD)

CDUS: Off Treatment/Study Summary for CDUS –V3

Description

This report lists the off treatment/study summary for CDUS QA. It is used for CDUS_302 studies. It works on studies that are based on the 2007R1 template.



	B	C	D	E	F	G	H	I	J	K	L
1	Patier					(MM-DD-YYYY	(MM-DD-YYYY)	(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Initial	Patient ID	Patier	Visit	DCM Subset Nan	Date Off Study	Date of Best Response	Date of Progression	Date Off Treatment	Reason Off Treatment	Reason Off Study
3	TGD	45-56-67-8		OFFSTUD	OSSM	04-16-2007	--	--	03-25-2007	Refused further Treatmen	Death during Follow-up
4	TBD	34-25-23-6		OFFSTUD	OSSM	03-21-2007	02-05-2007	--	03-16-2007	Death on Study	
5	BAD	23-24-56-9		OFFSTUD	OSSM	03-04-2007	--	--	--		Death on Study

Access

User Level: Public

Study Level: CCR 2007R1 STD

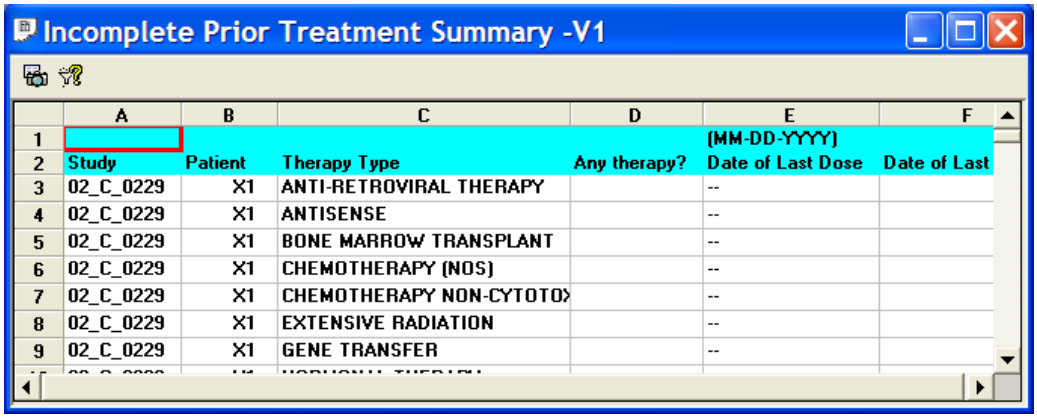
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient Initials	C3D Patient Initials
Patient ID	Patient ID User by System
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Date of Best Response	Date of Treatment Response Was First Observed or Began (Format MM-DD-YYYY)
Date of Progression	Date of The Progression (or Relapse) Was First Observed (Format MM-DD-YYYY)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Was Off Protocol Treatment
Date Off Study	Date the Patient Went Off Study (Format MM-DD-YYYY)
Reason Off Study	Reason the Patient Went Off Study
Reason for Off Study, Other	The Explanation of 'Other' for Reason Off Study
Response Assessment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began. The Original Value Used by System (Form YYYYMMDD)
Date of Progression	Date of The Progression (or Relapse) Was First Observed. The Original Value Used by System (Form YYYYMMDD)
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)
Date of Best Response	Date of Treatment Response Was First Observed or Began. The Original Value Used by System (Form YYYYMMDD)

Incomplete: Prior Treatment Summary –V1

Description

This report lists the incomplete information on prior treatment summary. It works on studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F
1					(MM-DD-YYYY)	
2	Study	Patient	Therapy Type	Any therapy?	Date of Last Dose	Date of Last
3	02_C_0229	X1	ANTI-RETROVIRAL THERAPY		--	
4	02_C_0229	X1	ANTISENSE		--	
5	02_C_0229	X1	BONE MARROW TRANSPLANT		--	
6	02_C_0229	X1	CHEMOTHERAPY (NOS)		--	
7	02_C_0229	X1	CHEMOTHERAPY NON-CYTOTOX		--	
8	02_C_0229	X1	EXTENSIVE RADIATION		--	
9	02_C_0229	X1	GENE TRANSFER		--	

Access

User Level: Public

Study Level: CCR_Program

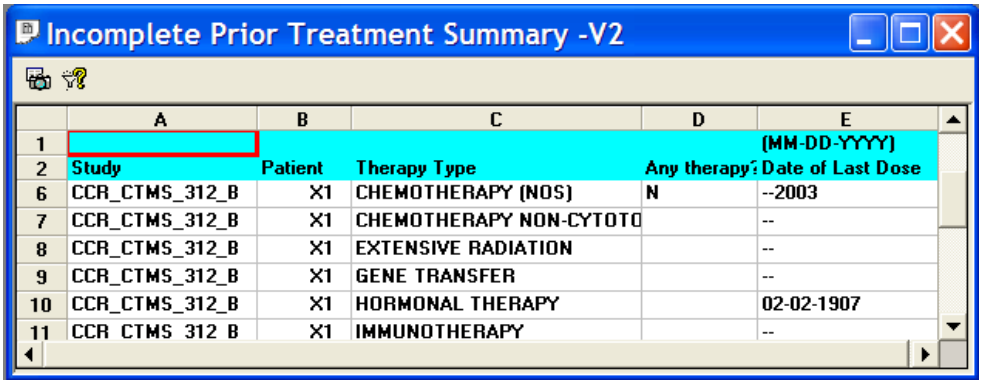
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Therapy Type	Type of Therapy
Any therapy?	Whether the Patient Has Received Any Prior Treatment for the Type of Therapy Listed
Date of Last Dose	Completion Date of the Last Dose of the Most Recent Prior Treatment Regimen for Each Therapy Type Study (Format MM-DD-YYYY)
Date of Last Dose	Completion Date of the Last Dose of the Most Recent Prior Treatment Regimen for Each Therapy Type Study. The Original Value Used by System (Form YYYYMMDD)

Incomplete: Prior Treatment Summary –V2

Description

This report lists the incomplete information on prior treatment summary. It works on studies that are based on the 3.12 and 2007R1 templates.



	A	B	C	D	E
1					(MM-DD-YYYY)
2	Study	Patient	Therapy Type	Any therapy?	Date of Last Dose
6	CCR_CTMS_312_B	X1	CHEMOTHERAPY (NOS)	N	--2003
7	CCR_CTMS_312_B	X1	CHEMOTHERAPY NON-CYTOTO		--
8	CCR_CTMS_312_B	X1	EXTENSIVE RADIATION		--
9	CCR_CTMS_312_B	X1	GENE TRANSFER		--
10	CCR_CTMS_312_B	X1	HORMONAL THERAPY		02-02-1907
11	CCR_CTMS_312_B	X1	IMMUNOTHERAPY		--

Access

User Level: Public

Study Level: CCR_Program

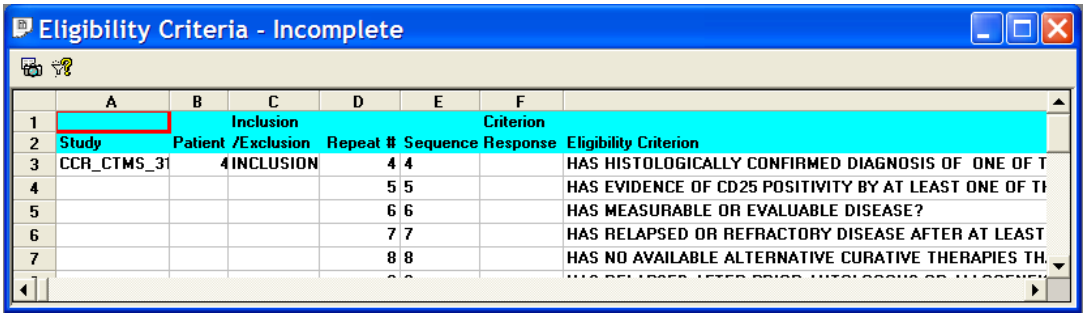
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Therapy Type	Type of Therapy
Any therapy?	Whether the Patient Has Received Any Prior Treatment for the Type of Therapy Listed
Date of Last Dose	Completion Date of the Last Dose of the Most Recent Prior Treatment Regimen for Each Therapy Type Study (Format MM-DD-YYYY)
Date of Last Dose	Completion Date of the Last Dose of the Most Recent Prior Treatment Regimen for Each Therapy Type Study. The Original Value Used by System (Form YYYYMMDD)

Incomplete: Eligibility Criteria

Description

This report lists the incomplete eligibility criteria. The response is either invalid or is missing.



	A	B	C	D	E	F	
1		Inclusion				Criterion	
2	Study	Patient	/Exclusion	Repeat #	Sequence	Response	Eligibility Criterion
3	CCR_CTMS_31	4	INCLUSION	4	4		HAS HISTOLOGICALLY CONFIRMED DIAGNOSIS OF ONE OF T
4				5	5		HAS EVIDENCE OF CD25 POSITIVITY BY AT LEAST ONE OF TI
5				6	6		HAS MEASURABLE OR EVALUABLE DISEASE?
6				7	7		HAS RELAPSED OR REFRACTORY DISEASE AFTER AT LEAST
7				8	8		HAS NO AVAILABLE ALTERNATIVE CURATIVE THERAPIES TH

Access

User Level: Public

Study Level: CCR_Program

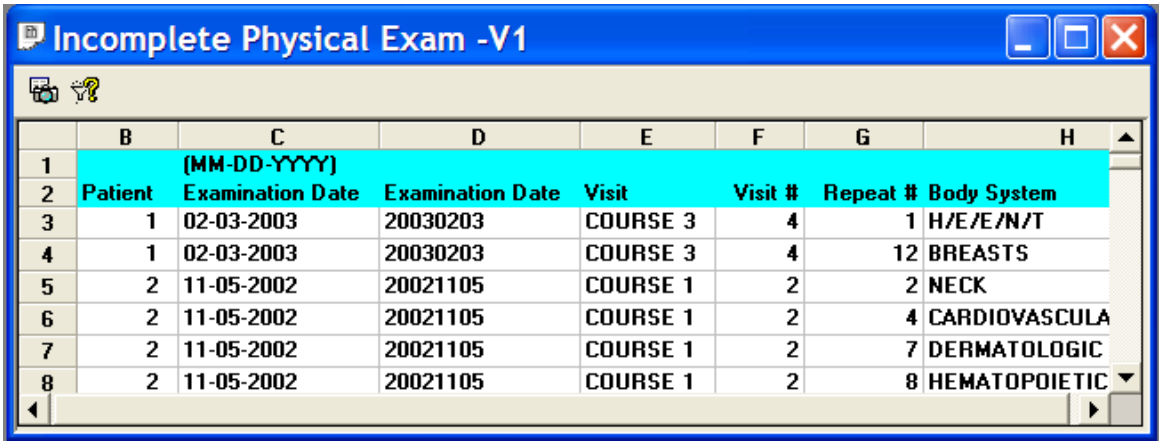
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Inclusion/Exclusion	Inclusion or Exclusion
Repeat #	The Repeat Sequence Number
Sequence	Eligibility Criteria Sequence Number
Criterion Response	Patient's Status Relative to the Eligibility Criteria
Eligibility Criteria	Eligibility Criteria Content

Incomplete: Physical Exam –V1

Description

This report lists the incomplete physical exams. The examination date is missing or the related response(s) in the repeating section is/are missing. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H
1		(MM-DD-YYYY)					
2	Patient	Examination Date	Examination Date	Visit	Visit #	Repeat #	Body System
3	1	02-03-2003	20030203	COURSE 3	4	1	H/E/E/N/T
4	1	02-03-2003	20030203	COURSE 3	4	12	BREASTS
5	2	11-05-2002	20021105	COURSE 1	2	2	NECK
6	2	11-05-2002	20021105	COURSE 1	2	4	CARDIOVASCULA
7	2	11-05-2002	20021105	COURSE 1	2	7	DERMATOLOGIC
8	2	11-05-2002	20021105	COURSE 1	2	8	HEMATOPOIETIC

Access

User Level: Public

Study Level: CCR_Program

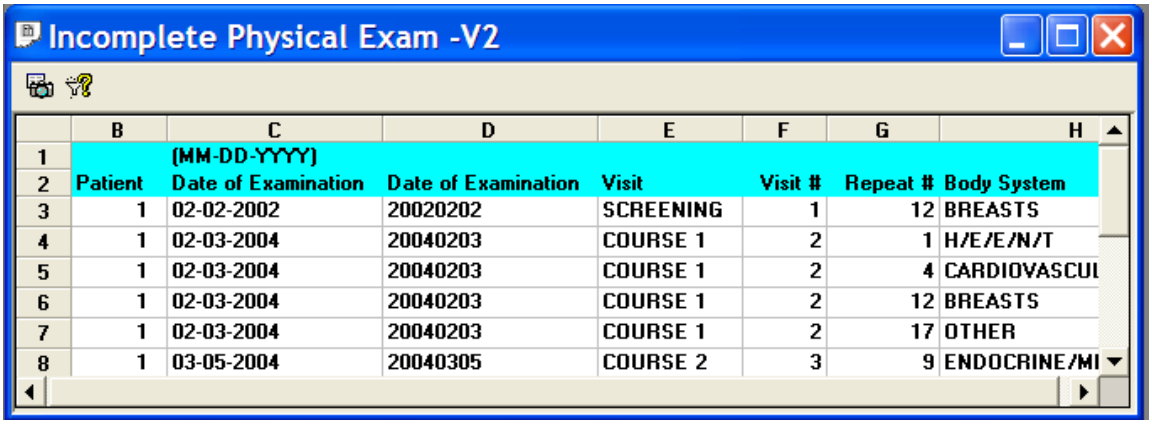
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Examination Date	Examination Date of the Physical Exam (Format MM-DD-YYYY)
Examination Date	Examination Date of the Physical Exam. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Visit	Clinical Event
Visit #	Clinical Event Number
Repeat #	The Repeat Sequence Number
Body System	Defaulted Body System
Status	The Finding Result of the Particular Body System
History If Abnormal	The Brief Description of the Status of the Body System or the Change

Incomplete: Physical Exam –V2

Description

This report lists the incomplete physical exams. The examination date is missing or the related response(s) in the repeating section is/are missing. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G	H
1		(MM-DD-YYYY)					
2	Patient	Date of Examination	Date of Examination	Visit	Visit #	Repeat #	Body System
3	1	02-02-2002	20020202	SCREENING	1	12	BREASTS
4	1	02-03-2004	20040203	COURSE 1	2	1	H/E/E/N/T
5	1	02-03-2004	20040203	COURSE 1	2	4	CARDIOVASCUL
6	1	02-03-2004	20040203	COURSE 1	2	12	BREASTS
7	1	02-03-2004	20040203	COURSE 1	2	17	OTHER
8	1	03-05-2004	20040305	COURSE 2	3	9	ENDOCRINE/MI

Access

User Level: Public

Study Level: CCR_Program

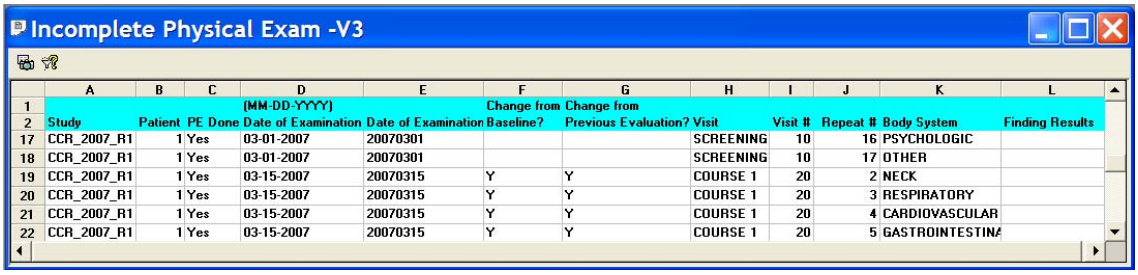
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Examination	Examination Date of the Physical Exam (Format MM-DD-YYYY)
Date of Examination	Examination Date of the Physical Exam. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Visit	Clinical Event
Visit #	Clinical Event Number
Repeat #	The Repeat Sequence Number
Body System	Defaulted Body System
Finding Results	The Finding Result of the Particular Body System
Comment	The Brief Description of the Status of the Body System or the Change
Examination Date	Examination Date of the Physical Exam. The Original Value Used by System (Form YYYYMMDD)

Incomplete: Physical Exam –V3

Description

This report lists the incomplete physical exams. The examination date is missing or the related response(s) in the repeating section is/are missing. It works on studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K	L
1				(MM-DD-YYYY)		Change from	Change from					
2	Study	Patient	PE Done	Date of Examination	Date of Examination	Baseline?	Previous Evaluation?	Visit	Visit #	Repeat #	Body System	Finding Results
17	CCR_2007_R1	1	Yes	03-01-2007	20070301			SCREENING	10	16	PSYCHOLOGIC	
18	CCR_2007_R1	1	Yes	03-01-2007	20070301			SCREENING	10	17	OTHER	
19	CCR_2007_R1	1	Yes	03-15-2007	20070315	Y	Y	COURSE 1	20	2	NECK	
20	CCR_2007_R1	1	Yes	03-15-2007	20070315	Y	Y	COURSE 1	20	3	RESPIRATORY	
21	CCR_2007_R1	1	Yes	03-15-2007	20070315	Y	Y	COURSE 1	20	4	CARDIOVASCULAR	
22	CCR_2007_R1	1	Yes	03-15-2007	20070315	Y	Y	COURSE 1	20	5	GASTROINTESTINA	

Access

User Level: Public

Study Level: CCR 2007R1 STD

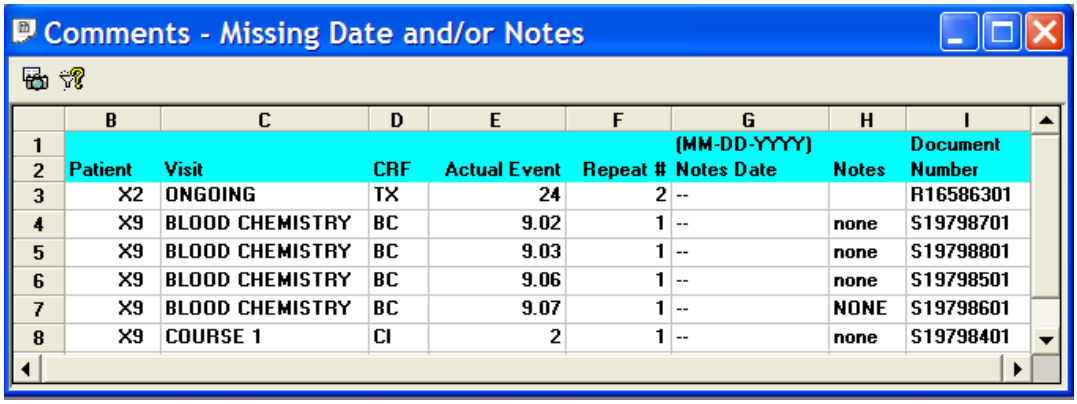
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
PE Done?	Whether the Physical Exam was Performed
Date of Examination	Examination Date of the Physical Exam (Format MM-DD-YYYY)
Date of Examination	Examination Date of the Physical Exam. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Change from Baseline?	Whether the Finding Results were Changed Compared with that of Baseline
Change from Previous Evaluation?	Whether the Finding Results were Changed Compared with the Previous Evaluation
Visit	Clinical Event
Visit #	Clinical Event Number
Repeat #	The Repeat Sequence Number
Body System	Defaulted Body System
Finding Results	The Finding Result of the Particular Body System
Comment	The Brief Description of the Status of the Body System or the Change
Examination Date	Examination Date of the Physical Exam. The Original Value Used by System (Form YYYYMMDD)

Incomplete: Comments with Missing Date and/or Notes

Description

This report lists Comments with missing dates and/or notes. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G	H	I
1						(MM-DD-YYYY)		Document
2	Patient	Visit	CRF	Actual Event	Repeat #	Notes Date	Notes	Number
3	X2	ONGOING	TX	24	2	--		R16586301
4	X9	BLOOD CHEMISTRY	BC	9.02	1	--	none	S19798701
5	X9	BLOOD CHEMISTRY	BC	9.03	1	--	none	S19798801
6	X9	BLOOD CHEMISTRY	BC	9.06	1	--	none	S19798501
7	X9	BLOOD CHEMISTRY	BC	9.07	1	--	NONE	S19798601
8	X9	COURSE 1	CI	2	1	--	none	S19798401

Access

User Level: Public

Study Level: CCR_Program

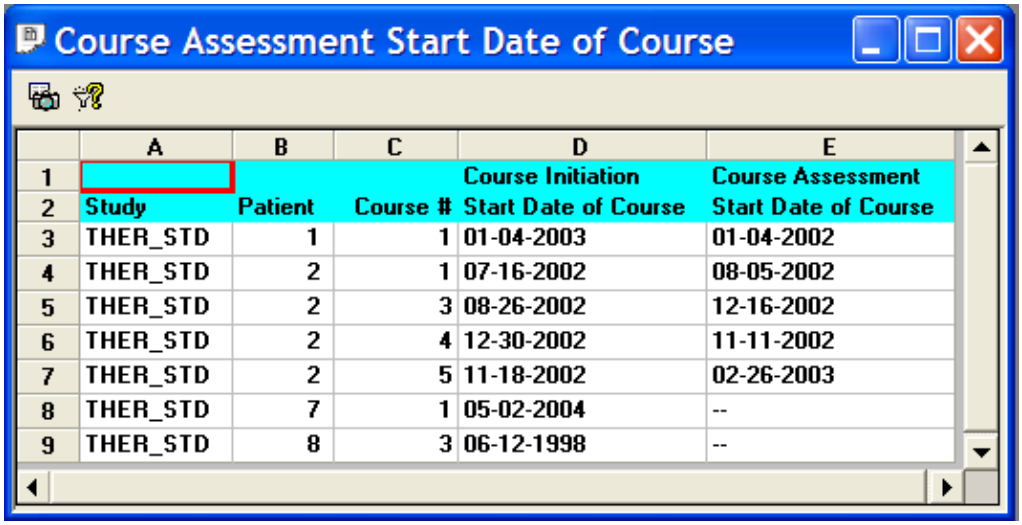
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
CRF	Initial of the CRF
Actual Event	Actual Event Number
Repeat #	The Repeat Sequence Number
Notes Date	Date of the Notes Is Given (Format MM-DD-YYYY)
Notes	Notes and/or Remarks
Document Number	System Generated Document Number
Notes Date	Date of the Notes Is Given. The Original Value Used by System (Form YYYYMMDD)

Invalid: Course Assessment Start Date

Description

This report lists the invalid course assessment start date. The course assessment start date is either different from the course initiation start date or is empty.



	A	B	C	D	E
1				Course Initiation	Course Assessment
2	Study	Patient	Course #	Start Date of Course	Start Date of Course
3	THER_STD	1	1	01-04-2003	01-04-2002
4	THER_STD	2	1	07-16-2002	08-05-2002
5	THER_STD	2	3	08-26-2002	12-16-2002
6	THER_STD	2	4	12-30-2002	11-11-2002
7	THER_STD	2	5	11-18-2002	02-26-2003
8	THER_STD	7	1	05-02-2004	--
9	THER_STD	8	3	06-12-1998	--

Access

User Level: Public

Study Level: CCR_Program

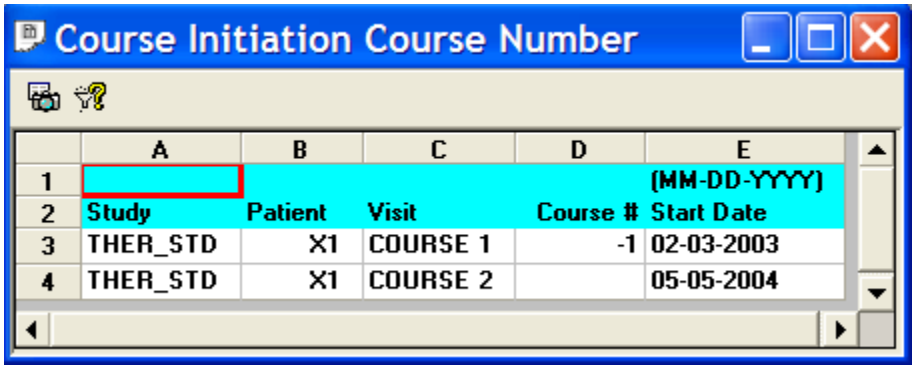
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	Course Number
Course Initiation Start Date of Course	Start Date of the Course Initiation (Format MM-DD-YYYY)
Course Assessment Start Date of Course	Start Date of the Course Assessment (Format MM-DD-YYYY)

Invalid: Course Initiation Course Number

Description

This report lists invalid course initiation course number. The course number is either less than 1 or is empty.



User Level: Public

Study Level: CCR_Program

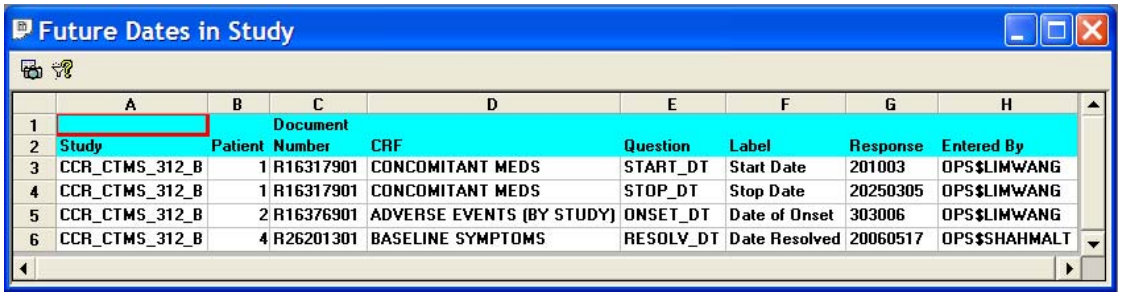
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Course #	Course Number
Start Date	Start Date of the Course Initiation (Format MM-DD-YYYY)

Invalid: Future Dates in Study

Description

This report lists all the entered dates that are greater than the current system date. Since the system date changes, the result might differ from day to day. Lab dates are not included.



	A	B	C	D	E	F	G	H
1			Document					
2	Study	Patient	Number	CRF	Question	Label	Response	Entered By
3	CCR_CTMS_312_B	1	R16317901	CONCOMITANT MEDS	START_DT	Start Date	201003	OPS$LIMWANG
4	CCR_CTMS_312_B	1	R16317901	CONCOMITANT MEDS	STOP_DT	Stop Date	20250305	OPS$LIMWANG
5	CCR_CTMS_312_B	2	R16376901	ADVERSE EVENTS (BY STUDY)	ONSET_DT	Date of Onset	303006	OPS$LIMWANG
6	CCR_CTMS_312_B	4	R26201301	BASELINE SYMPTOMS	RESOLV_DT	Date Resolved	20060517	OPS$SHAHMALT

User Level: Public

Study Level: CCR_Program

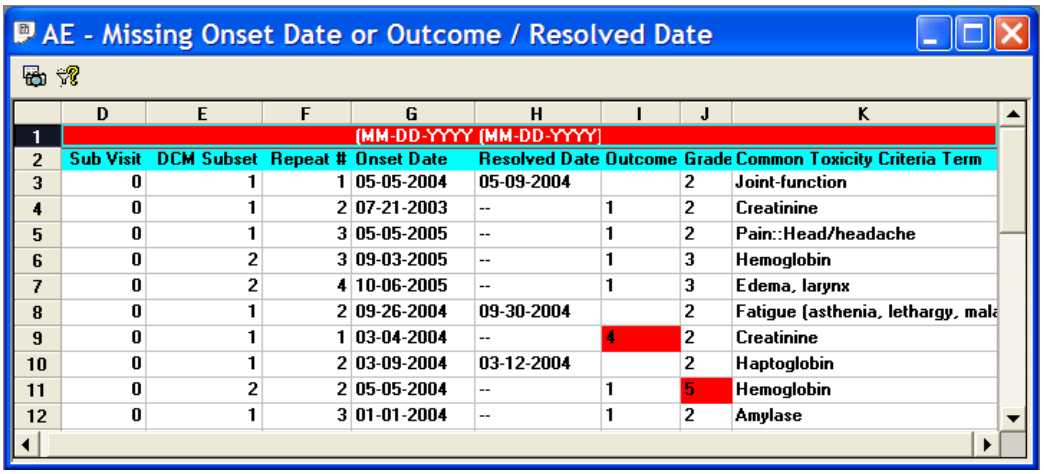
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Document Number	System Generated Document Number
CRF	CRF Form
Question	The Question Behind the Data Field
Label	Label of the Data Field
Response	Question Value Entered. The Original Value Used by System (Form YYYYMMDD)
Entered By	The Person Who Entered the Value

AE: Missing Onset Date or Outcome-Resolved Date

Description

This report lists AEs with missing Onset Date and/or without resolved date but with an outcome and/or without an outcome but with a resolved date. Outcome of 4-Died and Grade of 5-Fatal are highlighted in red. It provides a quick method for locating the related AE.



	D	E	F	G	H	I	J	K
1				(MM-DD-YYYY	(MM-DD-YYYY)			
2	Sub Visit	DCM Subset	Repeat #	Onset Date	Resolved Date	Outcome	Grade	Common Toxicity Criteria Term
3	0	1	1	05-05-2004	05-09-2004		2	Joint-function
4	0	1	2	07-21-2003	--	1	2	Creatinine
5	0	1	3	05-05-2005	--	1	2	Pain::Head/headache
6	0	2	3	09-03-2005	--	1	3	Hemoglobin
7	0	2	4	10-06-2005	--	1	3	Edema, larynx
8	0	1	2	09-26-2004	09-30-2004		2	Fatigue (asthenia, lethargy, mala
9	0	1	1	03-04-2004	--	4	2	Creatinine
10	0	1	2	03-09-2004	03-12-2004		2	Haptoglobin
11	0	2	2	05-05-2004	--	1	5	Hemoglobin
12	0	1	3	01-01-2004	--	1	2	Amylase

Access

User Level: Public

Study Level: CCR_Program

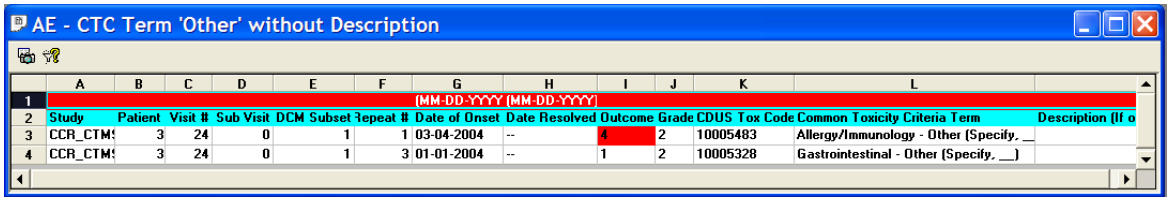
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Onset Date	Date of The Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Onset Date	Date of The Observation of This AE. The Original Value Used by System (Form YYYYMMDD)
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: CTC Term Other without Description –V1

Description

This report lists AEs with CTC Term with 'other' without description. It provides a quick method for locating the related AE.



Access

User Level: Public

Study Level: CCR_Program

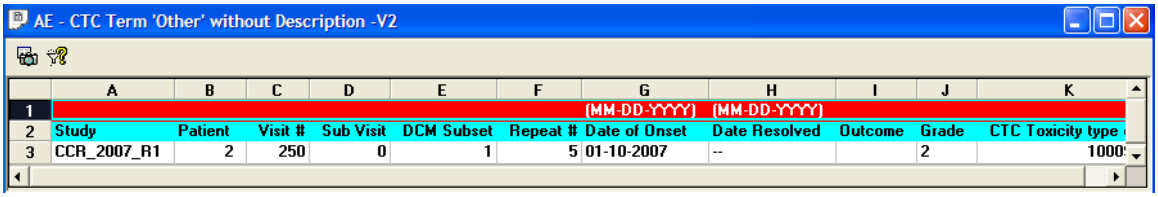
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of The Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description (If other please specify)	The Succinct Clinical Description of This AE
Date of Onset	Date of The Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: CTC Term Other without Description -V2

Description

This report lists AEs with CTC Term with 'other' without description. It provides a quick method for locating the related AE. Work for studies based on 2007R1 template.



Access

User Level: Public

Study Level: 2007R1 STD

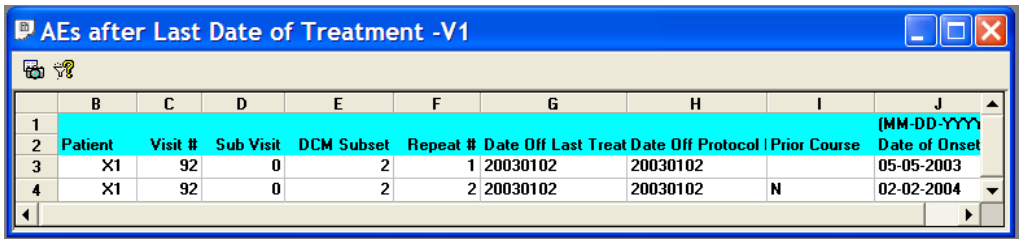
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of The Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
CTC toxicity Type Code	The Common Toxicity Criteria (CTC) Code
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description (If other please specify)	The Succinct Clinical Description of This AE
Date of Onset	Date of The Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE After Last Treatment Date –V1

Description

This report lists AEs with onset date later than the date of last treatment. It works for studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	I	J
1									(MM-DD-YYY
2	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Date Off Last Treat	Date Off Protocol	Prior Course	Date of Onset
3	X1	92	0	2	1	20030102	20030102		05-05-2003
4	X1	92	0	2	2	20030102	20030102	N	02-02-2004

Access

User Level: Public

Study Level: CCR_Program

Columns

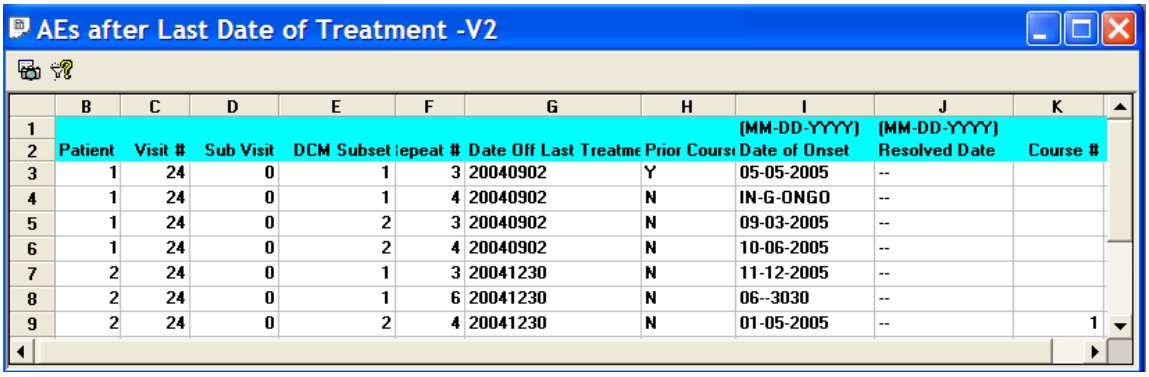
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date Off Last Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)
Date Off Protocol Follow-up	Date the Patient Completes or Is Removed from the Protocol-Specific Follow-up Phase. The Original Value Used by System (Form YYYYMMDD)
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Course #	The Course Number that This AE Started
Course Day	The Day in Course that This AE Started
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
Outcome	The Final Status of The Patient When This AE Is Considered ‘resolved’
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
AER Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Dose Limiting Toxicity	Whether This AE is Considered a ‘Dose Limiting Toxicity’

Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Therapy	Whether Additional Therapy Is Required to Treat This AE
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE After Last Treatment Date –V2

Description

This report lists AEs with onset date later than the date of last treatment. It works for studies that are based on the 3.12 template.



	B	C	D	E	F	G	H	I	J	K
1								(MM-DD-YYYY)	(MM-DD-YYYY)	
2	Patient	Visit #	Sub Visit	DCM Subset	epeat #	Date Off Last Treatme	Prior Course	Date of Onset	Resolved Date	Course #
3	1	24	0	1	3	20040902	Y	05-05-2005	--	
4	1	24	0	1	4	20040902	N	IN-G-ONGO	--	
5	1	24	0	2	3	20040902	N	09-03-2005	--	
6	1	24	0	2	4	20040902	N	10-06-2005	--	
7	2	24	0	1	3	20041230	N	11-12-2005	--	
8	2	24	0	1	6	20041230	N	06--3030	--	
9	2	24	0	2	4	20041230	N	01-05-2005	--	1

Access

User Level: Public

Study Level: CCR_Program

Columns

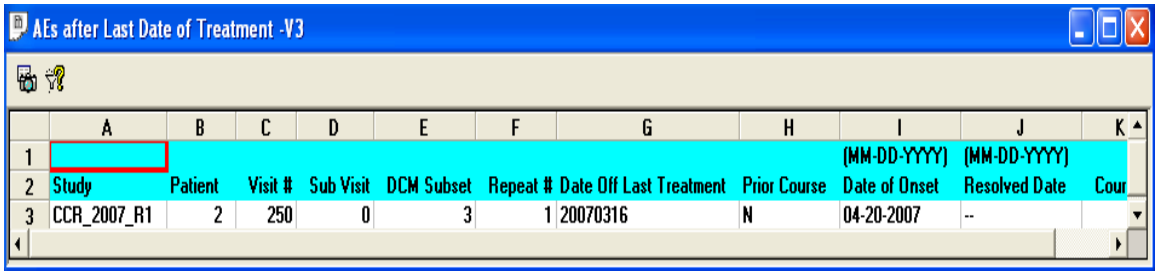
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date Off Last Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Course #	The Course Number that This AE Started
Course Day	The Day in Course that This AE Started
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
AER Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'

Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Therapy	Whether Additional Therapy Is Required to Treat This AE
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE After Last Treatment Date –V3

Description

This report lists AEs with onset date later than the date of last treatment. It works for studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K
1									(MM-DD-YYYY)	(MM-DD-YYYY)	
2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Date Off Last Treatment	Prior Course	Date of Onset	Resolved Date	Cour
3	CCR_2007_R1	2	250	0	3	1	20070316	N	04-20-2007	--	

Access

User Level: Public

Study Level: CCR 2007R STD

Columns

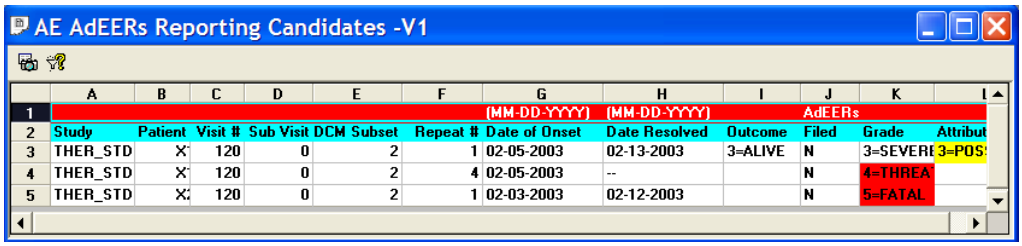
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date Off Last Treatment	Date the Patient Completes All Courses or Is Discontinued. The Original Value Used by System (Form YYYYMMDD)
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Course #	The Course Number that This AE Started
Course Day	The Day in Course that This AE Started
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
Outcome	The Final Status of The Patient When This AE Is Considered ‘resolved’
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
AER Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Dose Limiting Toxicity	Whether This AE is Considered a ‘Dose Limiting Toxicity’
Attribution to Research	Evaluate the adverse event’s relationship to the subject’s participation in the study.
Attribution to IND	Evaluate the adverse event’s relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event’s relationship to the investigational device exemption..

Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
Serious	Whether This AE Is a 'Serious' Event
Therapy	Whether Additional Therapy Is Required to Treat This AE
CTC Toxicity Type Code	The Common Toxicity Criteria (CTC) Code
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AdEERs Candidate –V1

Description

This report lists AEs most likely to require expedited reporting. Since C3D does not have information regarding whether an AE is 'expected/unexpected'. Some AEs with grade 2 and 3 might not need to be reported. All AEs with grade 4 or 5 should to be reported. It works for studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	G	H	I	J	K	L
1							(MM-DD-YYYY)	(MM-DD-YYYY)		AdEERs		
2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Date of Onset	Date Resolved	Outcome	Filed	Grade	Attribut
3	THER_STD	X	120	0	2	1	02-05-2003	02-13-2003	3=ALIVE	N	3=SEVERE	3=POS
4	THER_STD	X	120	0	2	4	02-05-2003	--		N	4=THREA	
5	THER_STD	X	120	0	2	1	02-03-2003	02-12-2003		N	5=FATAL	

Access

User Level: Public

Study Level: CCR_Program

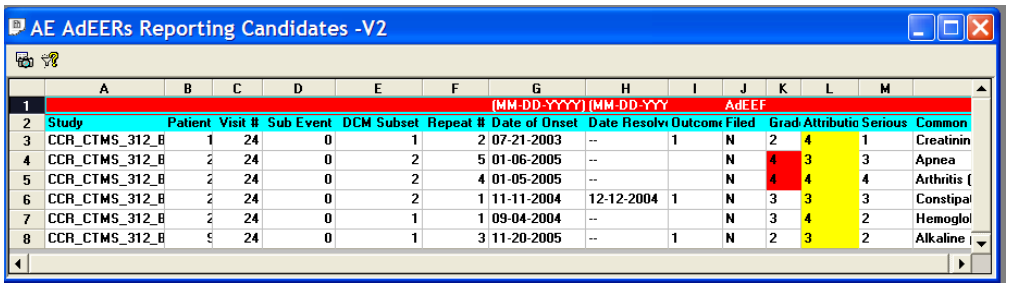
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered ‘resolved’
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a ‘Serious’ Event
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AdEERs Candidate –V2

Description

This report lists AEs most likely to require expedited reporting. Since C3D does not have information regarding 'expected/unexpected' AE some AEs with grade 2 and 3 might not need to be reported. All AEs with grade 4 or 5 should be reported. It works for studies that are based on the 3.12 template.



	A	B	C	D	E	F	G	H	I	J	K	L	M	
1							(MM-DD-YYYY)	(MM-DD-YYY		AdEEF				
2	Study	Patient	Visit #	Sub Event	DCM Subset	Repeat #	Date of Onset	Date Resolv	Outcom	Filed	Grad	Attributio	Serious	Common
3	CCR_CTMS_312_B	1	24	0	1	2	07-21-2003	--	1	N	2	4	1	Creatinin
4	CCR_CTMS_312_B	2	24	0	2	5	01-06-2005	--		N	4	3	3	Apnea
5	CCR_CTMS_312_B	2	24	0	2	4	01-05-2005	--		N	4	4	4	Arthritis [
6	CCR_CTMS_312_B	2	24	0	2	1	11-11-2004	12-12-2004	1	N	3	3	3	Constipat
7	CCR_CTMS_312_B	2	24	0	1	1	09-04-2004	--		N	3	4	2	Hemoglol
8	CCR_CTMS_312_B	9	24	0	1	3	11-20-2005	--	1	N	2	3	2	Alkaline

Access

User Level: Public

Study Level: CCR_Program

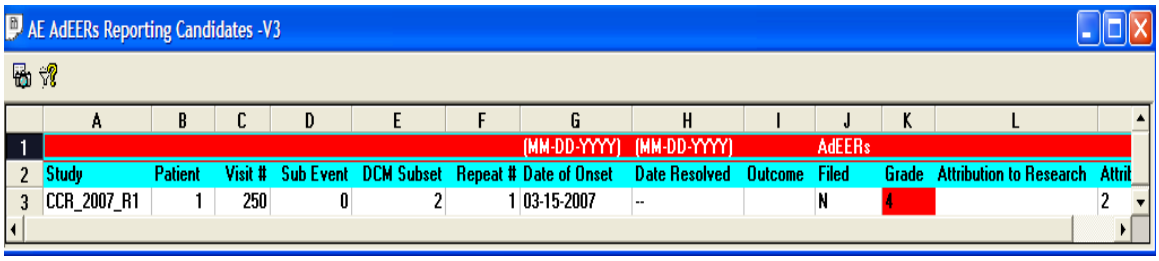
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Event	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AdEERs Candidate –V3

Description

This report lists AEs most likely to require expedited reporting. Since C3D does not have information regarding 'expected/unexpected' AE some AEs with grade 2 and 3 might not need to be reported. All AEs with grade 4 or 5 should be reported. It works for studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K	L
1							(MM-DD-YYYY)	(MM-DD-YYYY)		AdEERs		
2	Study	Patient	Visit #	Sub Event	DCM Subset	Repeat #	Date of Onset	Date Resolved	Outcome	Filed	Grade	Attribution to Research
3	CCR_2007_R1	1	250	0	2	1	03-15-2007	--		N	4	

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

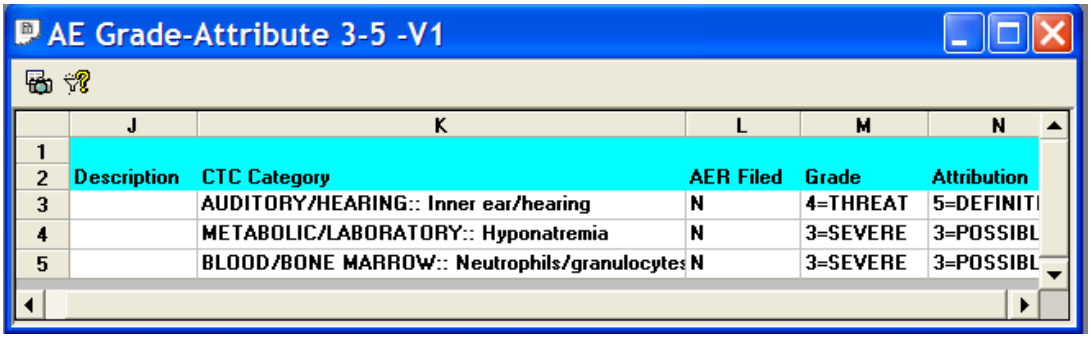
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Event	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.

Serious	Whether This AE Is a 'Serious' Event
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE Grade and Attribute 3-5 V1

Description

This report lists attributions for AEs with Grades 3, 4 and 5. It works for studies that are based on the 3.02 and 3.10 templates.



	J	K	L	M	N
1					
2	Description	CTC Category	AER Filed	Grade	Attribution
3		AUDITORY/HEARING:: Inner ear/hearing	N	4=THREAT	5=DEFINITI
4		METABOLIC/LABORATORY:: Hyponatremia	N	3=SEVERE	3=POSSIBL
5		BLOOD/BONE MARROW:: Neutrophils/granulocytes	N	3=SEVERE	3=POSSIBL

Access

User Level: Public

Study Level: CCR_Program

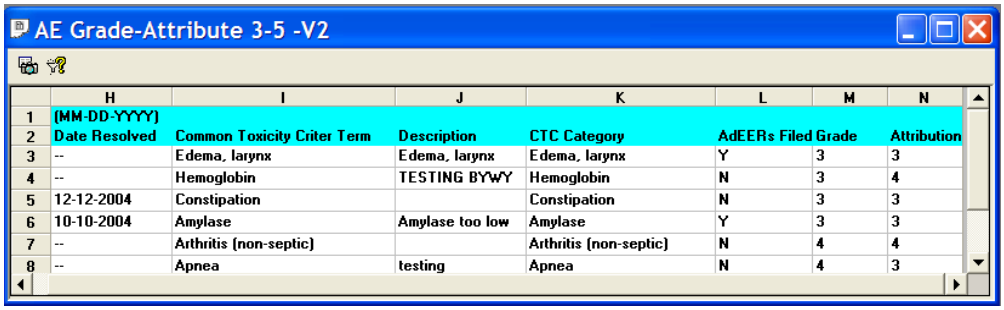
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Category	Broad Classification of AE
AER Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE Grade and Attribute 3-5 V2

Description

This report lists attributes for AEs with Grades 3, 4 and 5. It works for studies that are based on the 3.12 template.



	H	I	J	K	L	M	N
1	(MM-DD-YYYY)						
2	Date Resolved	Common Toxicity Criter Term	Description	CTC Category	AdEERs Filed	Grade	Attribution
3	--	Edema, larynx	Edema, larynx	Edema, larynx	Y	3	3
4	--	Hemoglobin	TESTING BYWY	Hemoglobin	N	3	4
5	12-12-2004	Constipation		Constipation	N	3	3
6	10-10-2004	Amylase	Amylase too low	Amylase	Y	3	3
7	--	Arthritis (non-septic)		Arthritis (non-septic)	N	4	4
8	--	Apnea	testing	Apnea	N	4	3

Access

User Level: Public

Study Level: CCR_Program

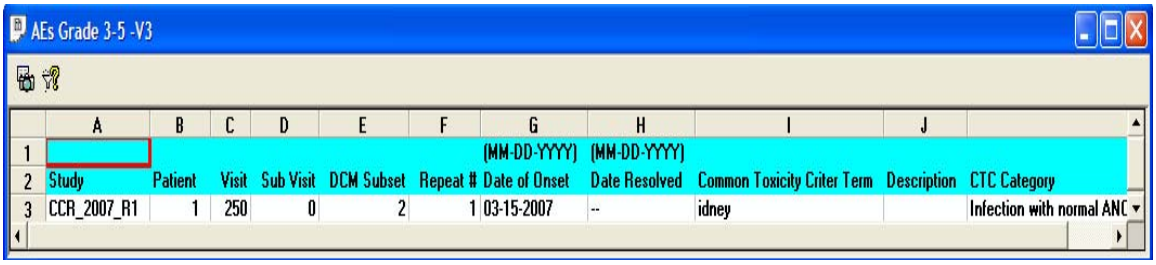
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Category	Broad Classification of AE
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE Grade and Attribute 3-5 V3

Description

This report lists attributes for AEs with Grades 3, 4 and 5. It works for studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	
1							(MM-DD-YYYY)	(MM-DD-YYYY)			
2	Study	Patient	Visit	Sub Visit	DCM Subset	Repeat #	Date of Onset	Date Resolved	Common Toxicity Criter Term	Description	CTC Category
3	CCR_2007_R1	1	250	0	2	1	03-15-2007	--	idney		Infection with normal ANC

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

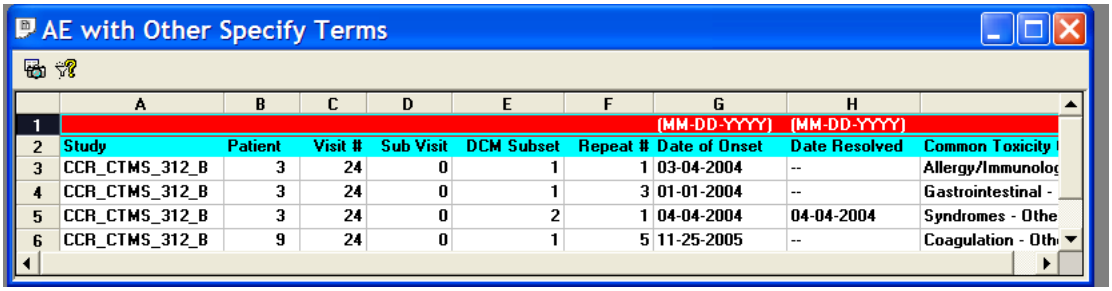
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Category	Broad Classification of AE
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.

Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
Serious	Whether This AE Is a 'Serious' Event
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE with Other Specify Terms

Description

This report lists AEs with CTC Term of 'other'. It provides a quick method to locate the related AE. It is used for CDUS_302, CTMS_302, CTMS_310 and CTMS_312 studies.



	A	B	C	D	E	F	G	H	
1							(MM-DD-YYYY)	(MM-DD-YYYY)	
2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Date of Onset	Date Resolved	Common Toxicity
3	CCR_CTMS_312_B	3	24	0	1	1	03-04-2004	--	Allergy/Immunolog
4	CCR_CTMS_312_B	3	24	0	1	3	01-01-2004	--	Gastrointestinal -
5	CCR_CTMS_312_B	3	24	0	2	1	04-04-2004	04-04-2004	Syndromes - Othe
6	CCR_CTMS_312_B	9	24	0	1	5	11-25-2005	--	Coagulation - Oth

Access

User Level: Public

Study Level: CDUS_302, CTMS_302, CTMS_310, CTMS_312

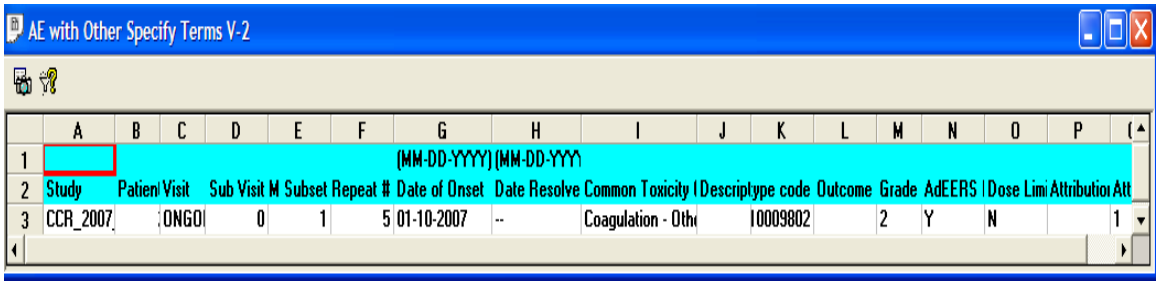
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD)
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: AE with Other Specify Terms –V2

Description

This report lists AEs with CTC Term of 'other'. It provides a quick method to locate the related AE. Work for studies based on 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

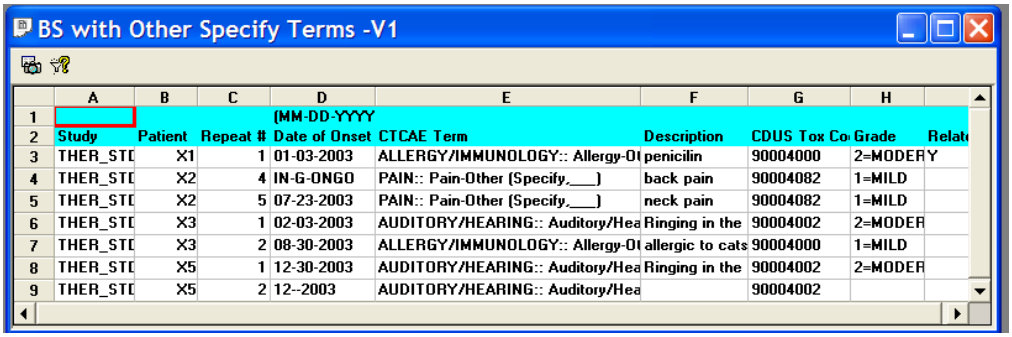
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Toxicity Type Code	The Common Toxicity Criteria (CTC) Code
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.

Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD)
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD)

AE: BS with Other Specify Terms –V1

Description

This report lists baseline symptoms with CTC Term of 'other'. It provides a quick method to locate the related records. It is used for CDUS_302, CTMS_302 and CTMS_310 studies. It works for studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	G	H
1				(MM-DD-YYYY				
2	Study	Patient	Repeat #	Date of Onset	CTCAE Term	Description	CDUS Tox Co	Grade
3	THER_STD	X1	1	01-03-2003	ALLERGY/IMMUNOLOGY:: Allergy-Ot	penicilin	90004000	2=MODER
4	THER_STD	X2	4	IN-G-ONGO	PAIN:: Pain-Other (Specify.___)	back pain	90004082	1=MILD
5	THER_STD	X2	5	07-23-2003	PAIN:: Pain-Other (Specify.___)	neck pain	90004082	1=MILD
6	THER_STD	X3	1	02-03-2003	AUDITORY/HEARING:: Auditory/Hea	Ringing in the	90004002	2=MODER
7	THER_STD	X3	2	08-30-2003	ALLERGY/IMMUNOLOGY:: Allergy-Ot	allergic to cats	90004000	1=MILD
8	THER_STD	X5	1	12-30-2003	AUDITORY/HEARING:: Auditory/Hea	Ringing in the	90004002	2=MODER
9	THER_STD	X5	2	12--2003	AUDITORY/HEARING:: Auditory/Hea		90004002	

Access

User Level: Public

Study Level: CDUS_302, CTMS_302, CTMS_310

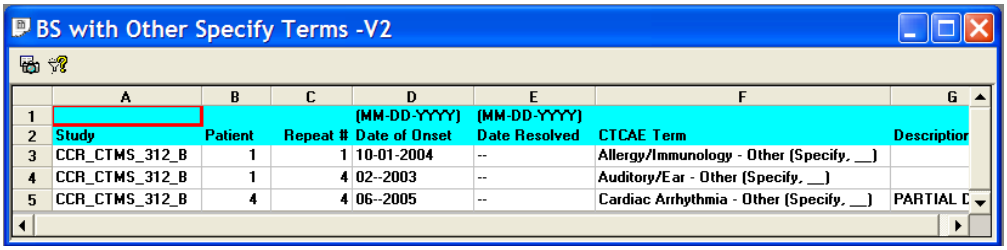
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

AE: BS with Other Specify Terms –V2

Description

This report lists baseline symptoms with CTC Term of 'other'. It provides a quick method to locate the related records. It is used for CDUS_302 and CTM_312 studies. It works for studies that are based on the 3.12 template.



	A	B	C	D	E	F	G
1				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Patient	Repeat #	Date of Onset	Date Resolved	CTCAE Term	Description
3	CCR_CTMS_312_B	1	1	10-01-2004	--	Allergy/Immunology - Other (Specify, __)	
4	CCR_CTMS_312_B	1	4	02--2003	--	Auditory/Ear - Other (Specify, __)	
5	CCR_CTMS_312_B	4	4	06--2005	--	Cardiac Arrhythmia - Other (Specify, __)	PARTIAL D

Access

User Level: Public

Study Level: CDUS_302, CTMS_312

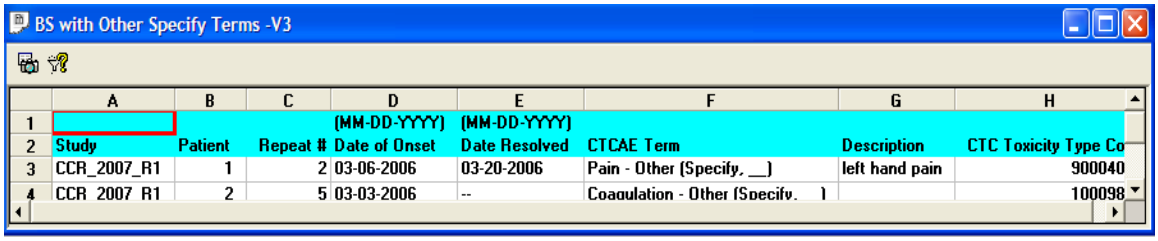
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This Symptom (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This Symptom. The Original Value Used by System (Form YYYYMMDD)

AE: BS with Other Specify Terms –V3

Description

This report lists baseline symptoms with CTC Term of 'other'. It provides a quick method to locate the related records. It works for studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H
1				(MM-DD-YYYY)	(MM-DD-YYYY)			
2	Study	Patient	Repeat #	Date of Onset	Date Resolved	CTCAE Term	Description	CTC Toxicity Type Co
3	CCR_2007_R1	1	2	03-06-2006	03-20-2006	Pain - Other (Specify, __)	left hand pain	900040
4	CCR_2007_R1	2	5	03-03-2006	--	Coagulation - Other (Specify,)		100098

Access

User Level: Public

Study Level: CCR 2007R1 STD

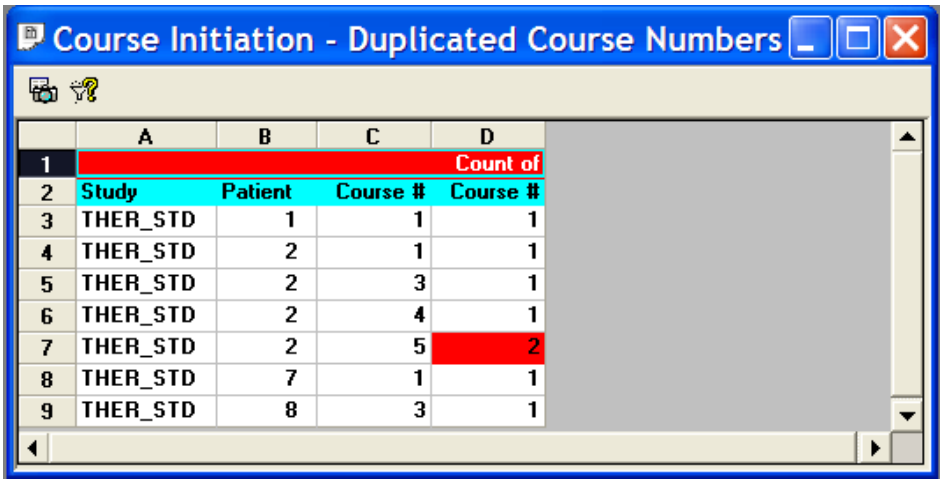
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This Symptom (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CTC Toxicity Type Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This Symptom. The Original Value Used by System (Form YYYYMMDD)

Duplication: Course Initiation Duplicated Course Number

Description

This report lists the duplication of course number on course initiation form. Count of Course # in red indicates that the same course number was entered more than once on the Course Initiation Forms.



	A	B	C	D
1				Count of
2	Study	Patient	Course #	Course #
3	THER_STD	1	1	1
4	THER_STD	2	1	1
5	THER_STD	2	3	1
6	THER_STD	2	4	1
7	THER_STD	2	5	2
8	THER_STD	7	1	1
9	THER_STD	8	3	1

Access

User Level: Public

Study Level: CCR_Program

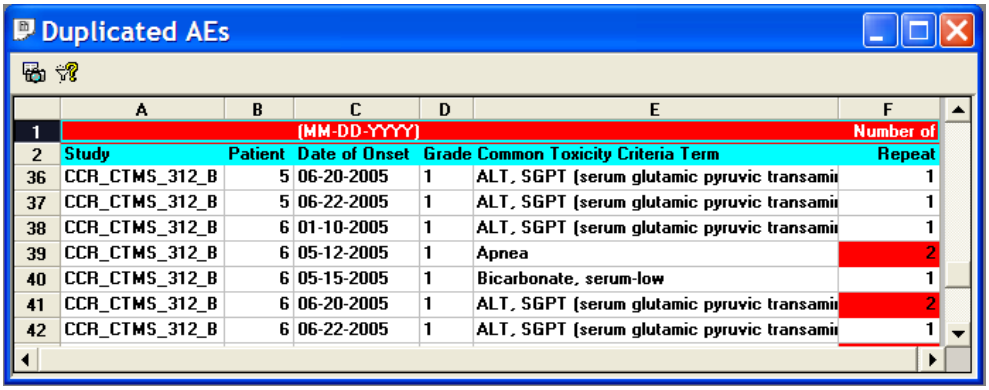
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number
Count of Course #	Number of Times the Course Number was Entered

Duplication: Duplicated AEs

Description

This report lists duplicate AE records (same term, onset date, and grade). A duplicated AE has a number of repeat greater than 1 and appears in red.



	A	B	C	D	E	F
1	(MM-DD-YYYY)					Number of
2	Study	Patient	Date of Onset	Grade	Common Toxicity Criteria Term	Repeat
36	CCR_CTMS_312_B	5	06-20-2005	1	ALT, SGPT (serum glutamic pyruvic transamin	1
37	CCR_CTMS_312_B	5	06-22-2005	1	ALT, SGPT (serum glutamic pyruvic transamin	1
38	CCR_CTMS_312_B	6	01-10-2005	1	ALT, SGPT (serum glutamic pyruvic transamin	1
39	CCR_CTMS_312_B	6	05-12-2005	1	Apnea	2
40	CCR_CTMS_312_B	6	05-15-2005	1	Bicarbonate, serum-low	1
41	CCR_CTMS_312_B	6	06-20-2005	1	ALT, SGPT (serum glutamic pyruvic transamin	2
42	CCR_CTMS_312_B	6	06-22-2005	1	ALT, SGPT (serum glutamic pyruvic transamin	1

Access

User Level: Public

Study Level: CCR_Program

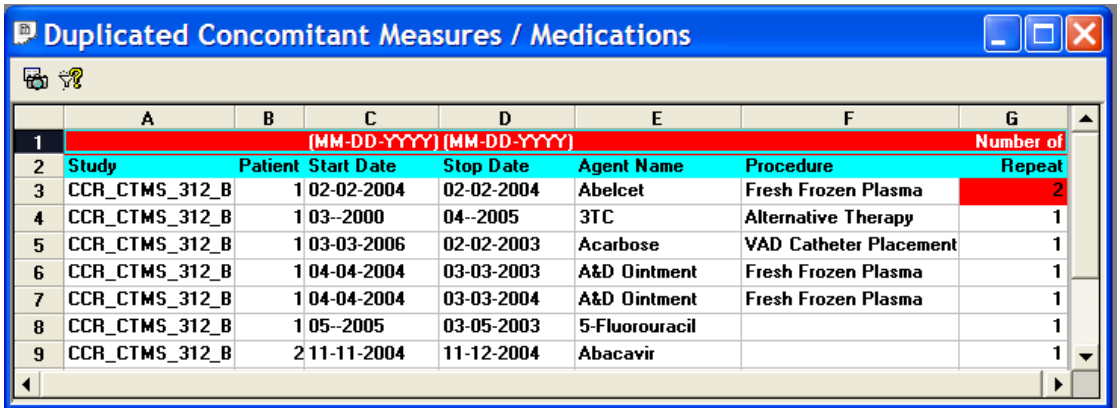
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Number of Repeat	Number of Duplication

Duplication: Duplicated Conmeds

Description

This report lists duplicate Conmeds records. A duplicate Conmed has a number of repeat greater than 1 and appears in red.



	A	B	C	D	E	F	G
1			(MM-DD-YYYY)	(MM-DD-YYYY)			Number of
2	Study	Patient	Start Date	Stop Date	Agent Name	Procedure	Repeat
3	CCR_CTMS_312_B	1	02-02-2004	02-02-2004	Abelcet	Fresh Frozen Plasma	2
4	CCR_CTMS_312_B	1	03--2000	04--2005	3TC	Alternative Therapy	1
5	CCR_CTMS_312_B	1	03-03-2006	02-02-2003	Acarbose	VAD Catheter Placement	1
6	CCR_CTMS_312_B	1	04-04-2004	03-03-2003	A&D Ointment	Fresh Frozen Plasma	1
7	CCR_CTMS_312_B	1	04-04-2004	03-03-2004	A&D Ointment	Fresh Frozen Plasma	1
8	CCR_CTMS_312_B	1	05--2005	03-05-2003	5-Fluorouracil		1
9	CCR_CTMS_312_B	2	11-11-2004	11-12-2004	Abacavir		1

Access

User Level: Public

Study Level: CCR_Program

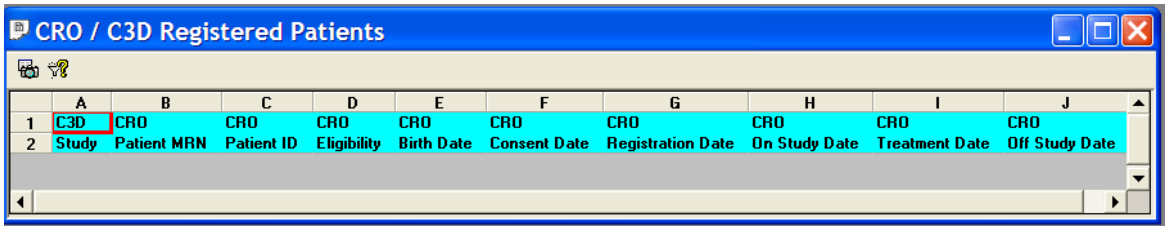
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Start Date	Start Date of the Measure or Medication (Format MM-DD-YYYY)
Stop Date	Stop Date of the Measure or Medication (Format MM-DD-YYYY)
Agent Name	The Generic Name of the Drug
Procedure	The Procedure/Measure
Number of Repeat	Number of Duplication

Registration: CRO / C3D Registered Patients

Description

This report lists registration records from the CRO and related information from C3D. Note that if C3D has a missing or invalid patient ID, the C3D columns will be blank.



Access

User Level: Public

Study Level: CCR_Program (version 1), CCR_2008V1_STD (version 2)

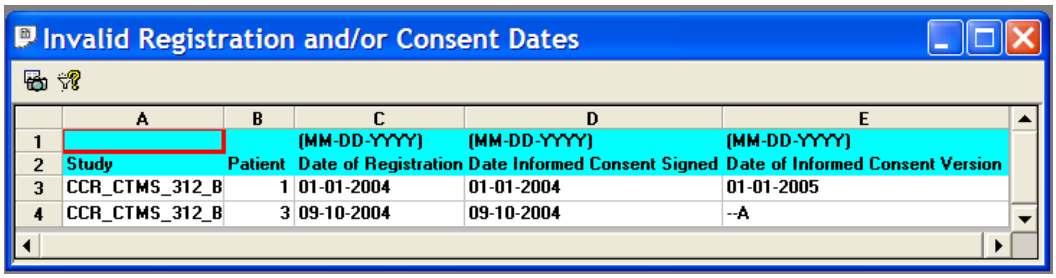
Columns

Field	*Description*
C3D Study	C3D Protocol Number for which Access is being Queried
CRO Patient MRN	CRO Patient's Identification Displayed with the format of C3D
CRO Patient ID	CRO Patient's ID
CRO Eligibility	CRO Record: Weather Patient is Eligible
CRO Birth Date	CRO Record: Patient's Birth Date
CRO Consent Date	CRO Records: Date Patient Signed the Informed Consent for A Protocol
CRO Registration Date	CRO Records: Date the Eligibility Checklist Is Received in the CRO.
CRO On Study Date	CRO Records: Date Protocol Intervention Is Initiated
CRO Treatment Date	CRO Records: For A Two Phase Study Design (Screening/Treatment), Treatment Start Date for Eligible Patient
CRO Off Study Date	CRO Records: Date the Patient Either Completes or Is Removed From the Protocol
CRO Off Study Reason	CRO Records: Reason the Patient's Treatment Was Stopped/Discontinued
C3D Patient	C3D Patient ID Displayed on RDC
C3D Patient ID	Patient' Local Identifier Used by the Treating Institution
C3D Birth Date	C3D Records: Patient's Birth Date (Format MM-DD-YYYY)
C3D Date of Registration	C3D Records: Patient's Registration Date (Format MM-DD-YYYY). Not available in V2.
C3D Date Informed Consent Signed	C3D Records: Patient's Consent Date (Format MM-DD-YYYY)

Registration: Invalid Registration and/or Consent Dates

Description

This report lists enrollment records with missing registration date, consent date or consent version date. It also list records where the registration date is before the consent date or the consent date is before the consent version date. Version 2 does not deal with registration date.



	A	B	C	D	E
1			(MM-DD-YYYY)	(MM-DD-YYYY)	(MM-DD-YYYY)
2	Study	Patient	Date of Registration	Date Informed Consent Signed	Date of Informed Consent Version
3	CCR_CTMS_312_B	1	01-01-2004	01-01-2004	01-01-2005
4	CCR_CTMS_312_B	3	09-10-2004	09-10-2004	--A

Access

User Level: Public

Study Level: CCR_Program (version 1), CCR_2008V1_STD (version 2)

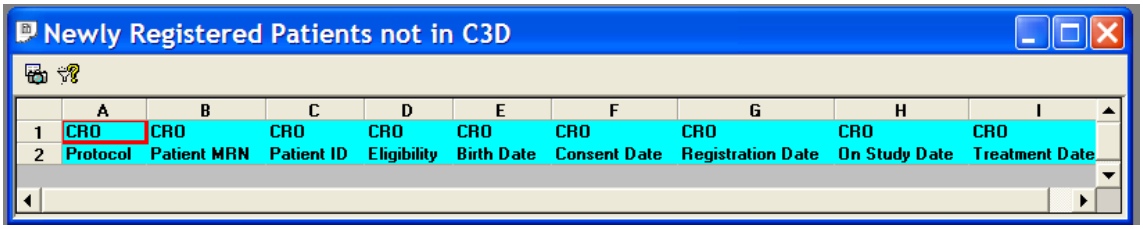
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Registration	Date the Patient Was Registered to the Study (Format MM-DD-YYYY). Not available in V2.
Date Informed Consent Signed	Date the Patient Signed the Informed Consent From (Format MM-DD-YYYY)
Date of Informed Consent Version	Date of the Informed Consent Version of the IRB Approved Informed Consent Form (Format MM-DD-YYYY)

Registration: Newly Registered Patients not in C3D

Description

This report lists the eligible patients in the CRO database that are not yet in C3D. The MRN on the enrollment CRF is used in the check. Due to the nature of the CRO IDs, the report may not work correctly for Navy and outside patients.



Access

User Level: Public

Study Level: CCR_Program (version 1), CCR_2008V1_STD (version 2)

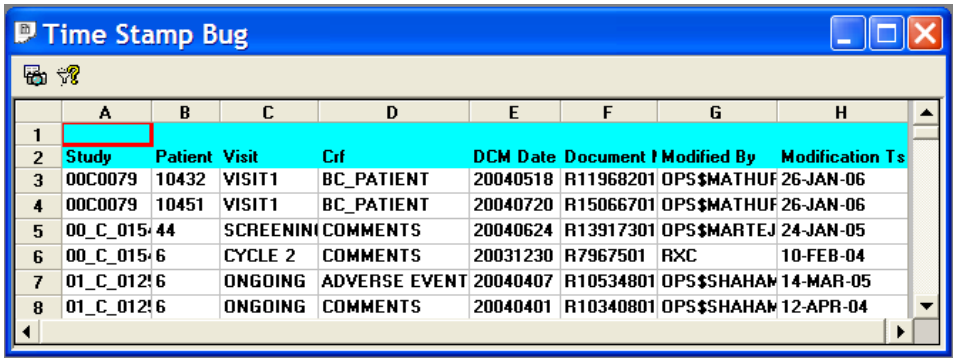
Columns

Field	*Description*
CRO Protocol	The Clinical Center Protocol Number on Which the Patient Was or Is Enrolled
CRO Patient MRN	CRO Patient's Identification Displayed with the format of C3D
CRO Patient ID	CRO Patient's ID
CRO Eligibility	CRO Record: Weather Patient is Eligible
CRO Birth Date	CRO Record: Patient's Birth Date
CRO Consent Date	CRO Records: Date Patient Signed the Informed Consent for A Protocol
CRO Registration Date	CRO Records: Date the Eligibility Checklist Is Received in the CRO
CRO On Study Date	CRO Records: Date Protocol Intervention Is Initiated
CRO Treatment Date	CRO Records: For A Two Phase Study Design (Screening/Treatment), Treatment Start Date for Eligible Patient
CRO Off Study Date	CRO Records: Date the Patient Either Completes or Is Removed From the Protocol
CRO Off Study Reason	CRO Records: Reason the Patient's Treatment Was Stopped/Discontinued
C3D Patient	C3D Patient ID Displayed on RDC
C3D Patient ID	Patient' Local Identifier Used by the Treating Institution
C3D Birth Date	C3D Records: Patient's Birth Date (Format MM-DD-YYYY)
C3D Date of Registration	C3D Records: Patient's Registration Date (Format MM-DD-YYYY). Not available in V2.
C3D Date Informed Consent Signed	C3D Records: Patient's Consent Date (Format MM-DD-YYYY)

Bug Related: Time Stamp Bug

Description

This report lists all the study forms that will be affected by the timestamp bug. CTMS submission will be affected.



	A	B	C	D	E	F	G	H
1								
2	Study	Patient	Visit	Crf	DCM Date	Document N	Modified By	Modification Ts
3	00C0079	10432	VISIT1	BC_PATIENT	20040518	R11968201	OPS$MATHUF	26-JAN-06
4	00C0079	10451	VISIT1	BC_PATIENT	20040720	R15066701	OPS$MATHUF	26-JAN-06
5	00_C_015	44	SCREENIN	COMMENTS	20040624	R13917301	OPS$MARTEJ	24-JAN-05
6	00_C_015	6	CYCLE 2	COMMENTS	20031230	R7967501	RXC	10-FEB-04
7	01_C_012	6	ONGOING	ADVERSE EVENT	20040407	R10534801	OPS$SHAHAN	14-MAR-05
8	01_C_012	6	ONGOING	COMMENTS	20040401	R10340801	OPS$SHAHAN	12-APR-04

Access

User Level: Public

Study Level: Lab All

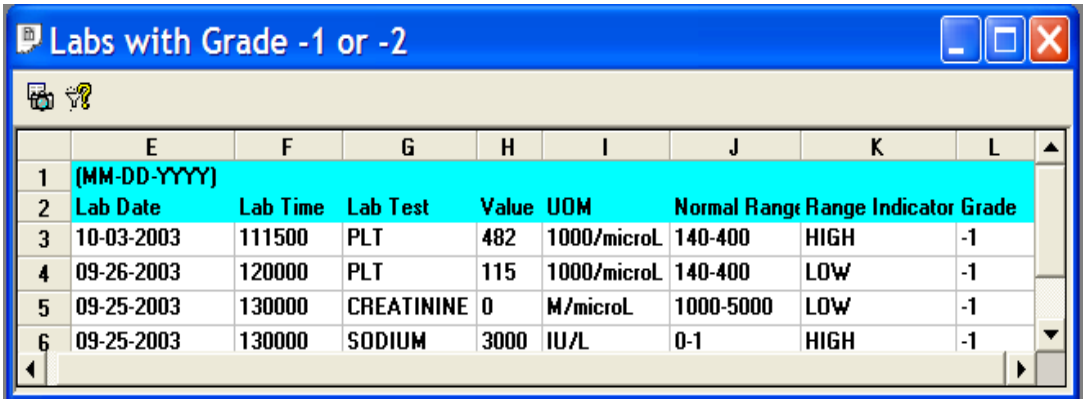
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
CRF	CRF Name
DCM Date	DCM Date
Document_Number	Document Number of the CRF
Modified By	The User Who Made the Latest Modification of the CRF
Modification Ts	The Latest Modification Timestamp

Lab: Labs with Grade -1 or -2

Description

This report lists labs with Grades -1 or -2. It is used for Lab Union study or All Lab studies.



	E	F	G	H	I	J	K	L
1	(MM-DD-YYYY)							
2	Lab Date	Lab Time	Lab Test	Value	UOM	Normal Range	Range Indicator	Grade
3	10-03-2003	111500	PLT	482	1000/microL	140-400	HIGH	-1
4	09-26-2003	120000	PLT	115	1000/microL	140-400	LOW	-1
5	09-25-2003	130000	CREATININE	0	M/microL	1000-5000	LOW	-1
6	09-25-2003	130000	SODIUM	3000	IU/L	0-1	HIGH	-1

Access

User Level: Public

Study Level: Lab Union or Lab All

Columns

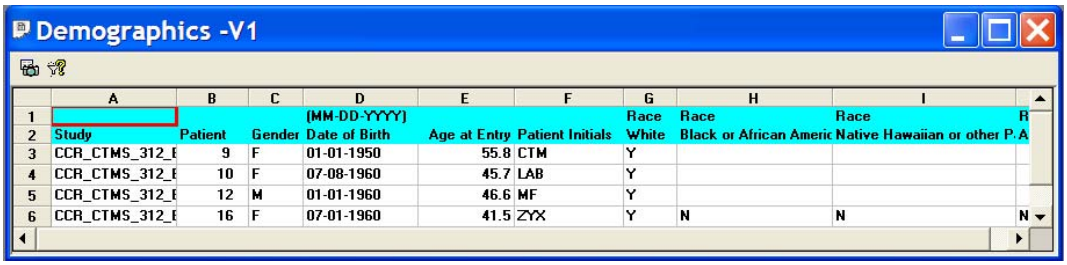
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0

Demography Reports

Demographics –V1

Description

This report lists patient demographic information. It works on studies based on 3.02, 310 and 3.12 templates.



	A	B	C	D	E	F	G	H	I
1				(MM-DD-YYYY)			Race	Race	Race
2	Study	Patient	Gender	Date of Birth	Age at Entry	Patient Initials	White	Black or African Americ	Native Hawaiian or other P
3	CCR_CTMS_312_E	9	F	01-01-1950	55.8	CTM	Y		
4	CCR_CTMS_312_E	10	F	07-08-1960	45.7	LAB	Y		
5	CCR_CTMS_312_E	12	M	01-01-1960	46.6	MF	Y		
6	CCR_CTMS_312_E	16	F	07-01-1960	41.5	ZYX	Y	N	N

Access

User Level: Public

Study Level: CCR_Program

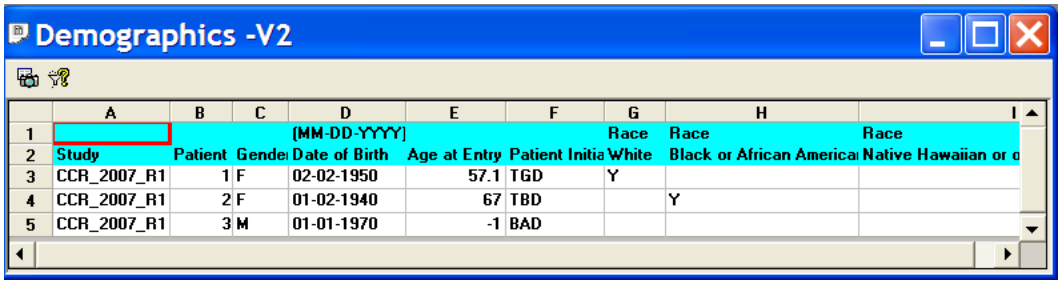
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Gender	Patient's Gender
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Age at Entry	Patient's Age at the Enrollment
Patient Initials	C3D Patient Initials
Race White	Whether A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
Race Black or African American	Whether A person having origins in any of the black racial groups of Africa.
Race Native Hawaiian or other Pacific Island	Whether A person having origins in any of the original peoples of Hawaii, or other Pacific Islands.
Race Asian	Whether A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (including the Philippine Islands).
Race American Indian or Alaska Native	Whether A person having origins in any of the original peoples of North, South, and Central America and who maintains tribal affiliation or community attachment.
Race Not Reported	Whether Refused or data not available
Race Unknown	Whether Race unknown
Ethnicity	Patient's Ethnicity
Patient ID	Patient' Local Identifier Used by the Treating Institution

Demographics –V2

Description

This report lists patient demographic information. It works on studies based on 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

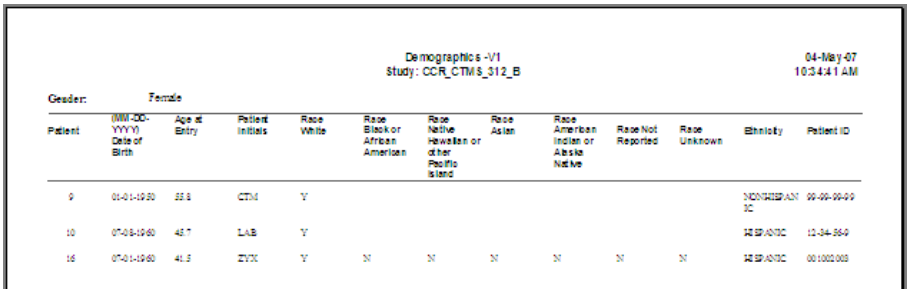
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Gender	Patient's Gender
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Age at Entry	Patient's Age at the Enrollment
Patient Initials	C3D Patient Initials
Race White	Whether A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
Race Black or African American	Whether A person having origins in any of the black racial groups of Africa.
Race Native Hawaiian or other Pacific Island	Whether A person having origins in any of the original peoples of Hawaii, or other Pacific Islands.
Race Asian	Whether A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (including the Philippine Islands).
Race American Indian or Alaska Native	Whether A person having origins in any of the original peoples of North, South, and Central America and who maintains tribal affiliation or community attachment.
Race Not Reported	Whether Refused or data not available
Race Unknown	Whether Race unknown
Ethnicity	Patient's Ethnicity
Patient ID	Patient' Local Identifier Used by the Treating Institution

Demographics (Formatted) – V1

Description

This report lists formatted patient demographic information grouped by gender. It works on studies based on 3.02, 310 and 3.12 templates.



Demographics -V1
Study: CCR_CTMS_312_B

04-May-07
10:34:41 AM

Gender: Female

Patient	(MM-DD-YYYY) Date of Birth	Age at Entry	Patient Initials	Race White	Race Black or African American	Race Native Hawaiian or other Pacific Island	Race Asian	Race American Indian or Alaska Native	Race Not Reported	Race Unknown	Ethnicity	Patient ID
9	01-01-1930	55.8	CTM	Y							NONHISPANIC	99-99-99-99
10	07-08-1960	46.7	LAB	Y							HISPANIC	12-34-56-9
16	07-01-1960	46.8	ZYX	Y	N	N	N	N	N	N	HISPANIC	001002003

Access

User Level: Public

Study Level: CCR_Program

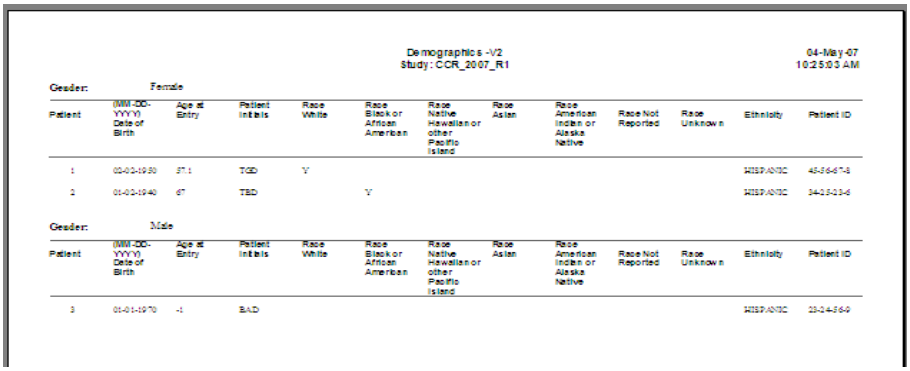
Columns

Field	*Description*
Study (Header)	Protocol Number for which Access is being Queried
Gender	Patient's Gender
Patient	C3D Patient ID Displayed on RDC
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Age at Entry	Patient's Age at the Enrollment
Patient Initials	C3D Patient Initials
Race White	Whether A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
Race Black or African American	Whether A person having origins in any of the black racial groups of Africa.
Race Native Hawaiian or other Pacific Island	Whether A person having origins in any of the original peoples of Hawaii, or other Pacific Islands.
Race Asian	Whether A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (including the Philippine Islands).
Race American Indian or Alaska Native	Whether A person having origins in any of the original peoples of North, South, and Central America and who maintains tribal affiliation or community attachment.
Race Not Reported	Whether Refused or data not available
Race Unknown	Whether Race unknown
Ethnicity	Patient's Ethnicity
Patient ID	Patient' Local Identifier Used by the Treating Institution

Demographics (Formatted) – V2

Description

This report lists formatted patient demographic information grouped by gender. It works on studies based on 2007R1 template.



Demographics -V2
Study : CCR_2007_R1

04-May-07
10:25:03 AM

Gender: Female

Patient	(MM-DD-YYYY) Date of Birth	Age at Entry	Patient Initials	Race White	Race Black or African American	Race Native Hawaiian or other Pacific Island	Race Asian	Race American Indian or Alaska Native	Race Not Reported	Race Unknown	Ethnicity	Patient ID
1	02-02-1930	57.1	TGD	Y							HISPANIC	45-56-67-8
2	01-02-1940	67	TBD		Y						HISPANIC	34-23-23-6

Gender: Male

Patient	(MM-DD-YYYY) Date of Birth	Age at Entry	Patient Initials	Race White	Race Black or African American	Race Native Hawaiian or other Pacific Island	Race Asian	Race American Indian or Alaska Native	Race Not Reported	Race Unknown	Ethnicity	Patient ID
3	01-01-1970	-1	BAD								HISPANIC	23-24-56-9

Access

User Level: Public

Study Level: CCR 2007R1 STD

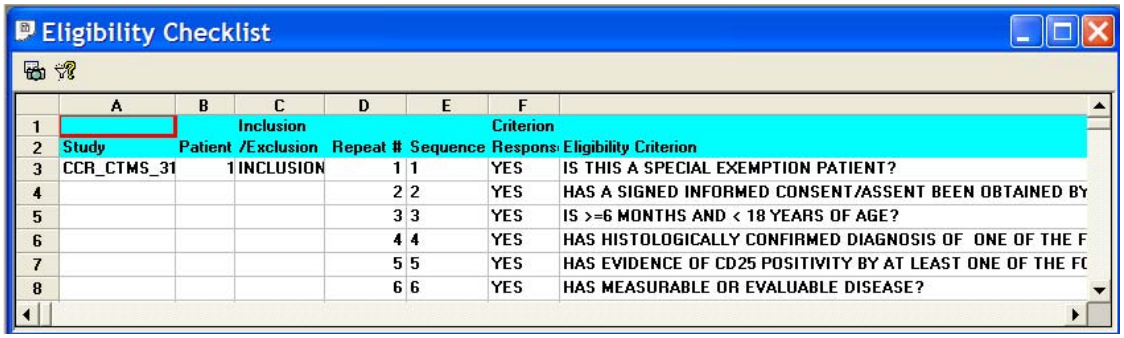
Columns

Field	*Description*
Study (Header)	Protocol Number for which Access is being Queried
Gender	Patient's Gender
Patient	C3D Patient ID Displayed on RDC
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Age at Entry	Patient's Age at the Enrollment
Patient Initials	C3D Patient Initials
Race White	Whether A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
Race Black or African American	Whether A person having origins in any of the black racial groups of Africa.
Race Native Hawaiian or other Pacific Island	Whether A person having origins in any of the original peoples of Hawaii, or other Pacific Islands.
Race Asian	Whether A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (including the Philippine Islands).
Race American Indian or Alaska Native	Whether A person having origins in any of the original peoples of North, South, and Central America and who maintains tribal affiliation or community attachment.
Race Not Reported	Whether Refused or data not available
Race Unknown	Whether Race unknown
Ethnicity	Patient's Ethnicity
Patient ID	Patient' Local Identifier Used by the Treating Institution

Eligibility Checklist

Description

This report lists the eligibility criteria.



	A	B	C	D	E	F	
1			Inclusion			Criterion	
2	Study	Patient	/Exclusion	Repeat #	Sequence	Respons	Eligibility Criterion
3	CCR_CTMS_31	1	INCLUSION	1	1	YES	IS THIS A SPECIAL EXEMPTION PATIENT?
4				2	2	YES	HAS A SIGNED INFORMED CONSENT/ASSENT BEEN OBTAINED BY
5				3	3	YES	IS >=6 MONTHS AND < 18 YEARS OF AGE?
6				4	4	YES	HAS HISTOLOGICALLY CONFIRMED DIAGNOSIS OF ONE OF THE F
7				5	5	YES	HAS EVIDENCE OF CD25 POSITIVITY BY AT LEAST ONE OF THE FC
8				6	6	YES	HAS MEASURABLE OR EVALUABLE DISEASE?

Access

User Level: Public

Study Level: CCR_Program

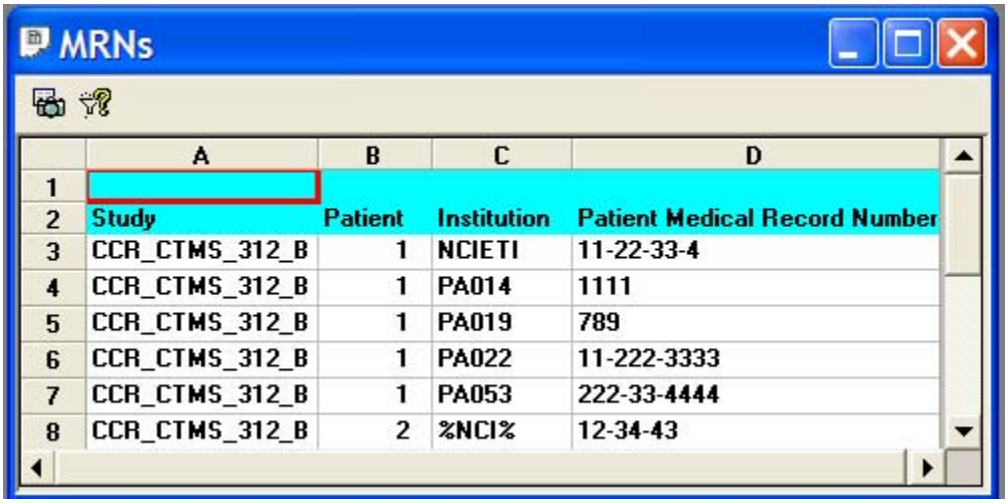
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Inclusion/Exclusion	Inclusion or Exclusion
Repeat #	The Repeat Sequence Number
Sequence	Eligibility Criteria Sequence Number
Criterion Response	Patient's Status Relative to the Eligibility Criteria
Eligibility Criteria	Eligibility Criteria Content

MRNs

Description

This report lists patient identification information.



	A	B	C	D
1				
2	Study	Patient	Institution	Patient Medical Record Number
3	CCR_CTMS_312_B	1	NCIETI	11-22-33-4
4	CCR_CTMS_312_B	1	PA014	1111
5	CCR_CTMS_312_B	1	PA019	789
6	CCR_CTMS_312_B	1	PA022	11-222-3333
7	CCR_CTMS_312_B	1	PA053	222-33-4444
8	CCR_CTMS_312_B	2	%NCI%	12-34-43

Access

User Level: Public

Study Level: CCR_Program

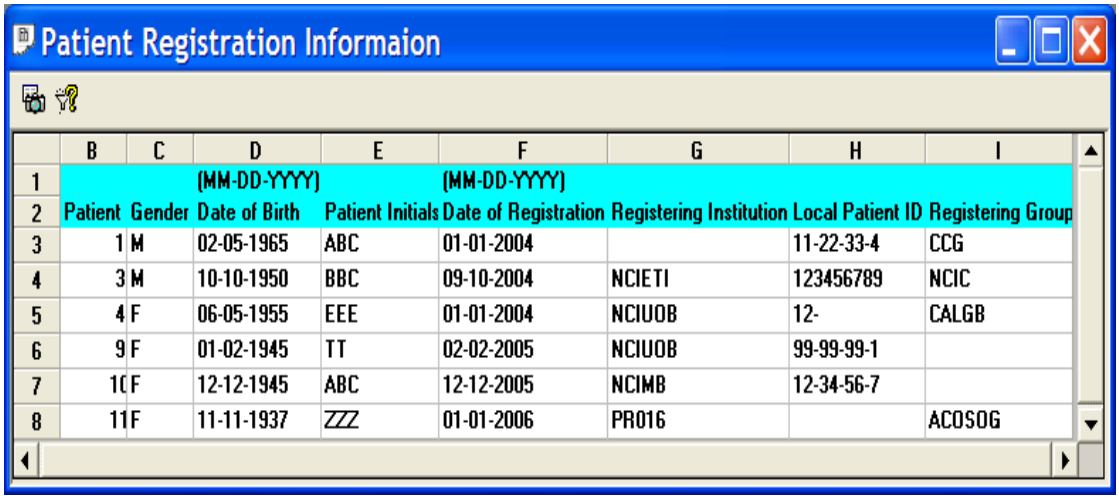
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Institution	Patient's Registering Institution
Patient Medical Record Number	Patient's Medical Record Number for the Registering Institution

Patient Registration Information

Description

This report lists patient registration information from the enrollment CRF.



	B	C	D	E	F	G	H	I
1			(MM-DD-YYYY)		(MM-DD-YYYY)			
2	Patient	Gender	Date of Birth	Patient Initials	Date of Registration	Registering Institution	Local Patient ID	Registering Group
3	1	M	02-05-1965	ABC	01-01-2004		11-22-33-4	CCG
4	3	M	10-10-1950	BBC	09-10-2004	NCIETI	123456789	NCIC
5	4	F	06-05-1955	EEE	01-01-2004	NCIUOB	12-	CALGB
6	9	F	01-02-1945	TT	02-02-2005	NCIUOB	99-99-99-1	
7	10	F	12-12-1945	ABC	12-12-2005	NCIMB	12-34-56-7	
8	11	F	11-11-1937	ZZZ	01-01-2006	PR016		ACOSOG

Access

User Level: Public

Study Level: CCR_Program

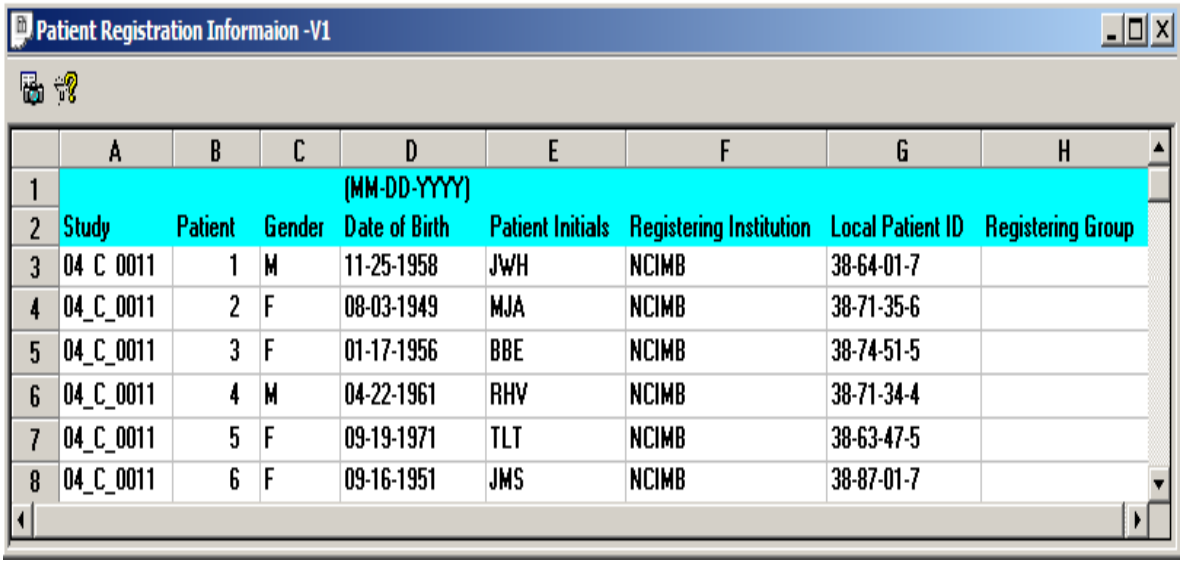
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Gender	Patient's Gender
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Patient Initials	C3D Patient Initials
Date of Registration	Date the Patient Was Registered to the Study (Format MM-DD-YYYY)
Registering Institution	Patient's Registering Institution
Local Patient ID	Patient' Local Identifier Used by the Treating Institution
Registering Group	The CTEP Group Code From Which the Patient Was Originally Registered on Study

Patient Registration Info –V1

Description

This report lists patient registration information from the enrollment CRF.



	A	B	C	D	E	F	G	H
1				(MM-DD-YYYY)				
2	Study	Patient	Gender	Date of Birth	Patient Initials	Registering Institution	Local Patient ID	Registering Group
3	04 C 0011	1	M	11-25-1958	JWH	NCIMB	38-64-01-7	
4	04_C_0011	2	F	08-03-1949	MJA	NCIMB	38-71-35-6	
5	04_C_0011	3	F	01-17-1956	BBE	NCIMB	38-74-51-5	
6	04_C_0011	4	M	04-22-1961	RHV	NCIMB	38-71-34-4	
7	04_C_0011	5	F	09-19-1971	TLT	NCIMB	38-63-47-5	
8	04_C_0011	6	F	09-16-1951	JMS	NCIMB	38-87-01-7	

Access

User Level: Public

Study Level: CCR_Program

Columns

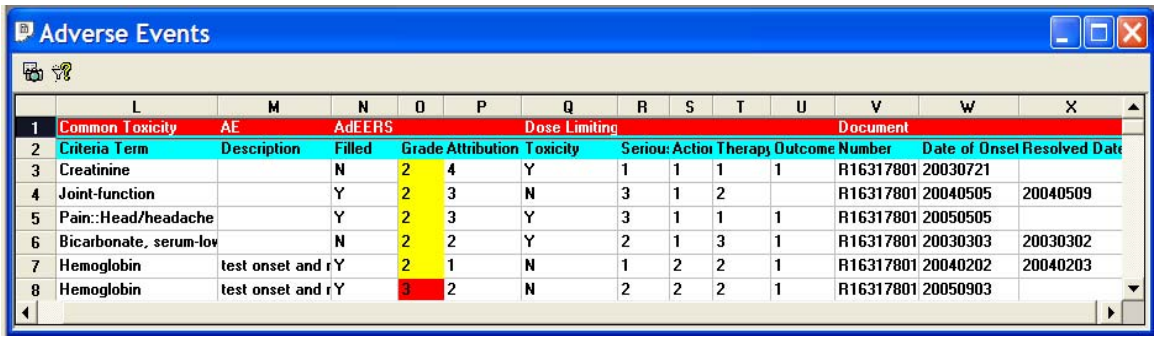
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Gender	Patient's Gender
Date of Birth	Patient's Date of Birth (Format MM-DD-YYYY)
Patient Initials	C3D Patient Initials
Registering Institution	Patient's Registering Institution
Local Patient ID	Patient' Local Identifier Used by the Treating Institution
Registering Group	The CTEP Group Code From Which the Patient Was Originally Registered on Study

Adverse Event Reports

All AEs –V1

Description

This report lists all adverse events in the specified study. Grades of 2 are highlighted in yellow and higher grades are highlighted in red.



	L	M	N	O	P	Q	R	S	T	U	V	W	X
1	Common Toxicity	AE	AdEERS			Dose Limiting					Document		
2	Criteria Term	Description	Filled	Grade	Attribution	Toxicity	Seriou	Actio	Therap	Outcome	Number	Date of Onset	Resolved Dat
3	Creatinine		N	2	4	Y	1	1	1	1	R16317801	20030721	
4	Joint-function		Y	2	3	N	3	1	2		R16317801	20040505	20040509
5	Pain::Head/headache		Y	2	3	Y	3	1	1	1	R16317801	20050505	
6	Bicarbonate, serum-lov		N	2	2	Y	2	1	3	1	R16317801	20030303	20030302
7	Hemoglobin	test onset and r	Y	2	1	N	1	2	2	1	R16317801	20040202	20040203
8	Hemoglobin	test onset and r	Y	3	2	N	2	2	2	1	R16317801	20050903	

Access

User Level: Public

Study Level: CCR_Program

Columns

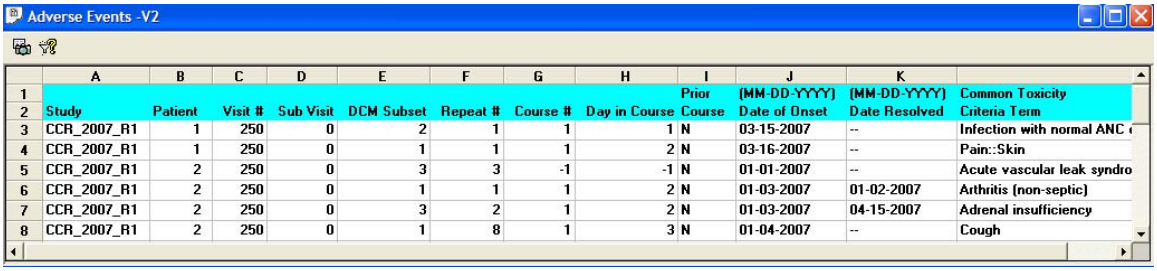
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
AE Description	The Succinct Clinical Description of This AE
AdEERS Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'

Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Document Number	Document Number of the CRF
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

All AEs –V2

Description

This report lists all adverse events in the specified study. Grades of 2 are highlighted in yellow and higher grades are highlighted in red. Work for studies based on 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K	
1									Prior	(MM-DD-YYYY)	(MM-DD-YYYY)	Common Toxicity
2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course #	Day in Course	Course	Date of Onset	Date Resolved	Criteria Term
3	CCR_2007_R1	1	250	0	2	1	1	1	N	03-15-2007	--	Infection with normal ANC
4	CCR_2007_R1	1	250	0	1	1	1	2	N	03-16-2007	--	Pain::Skin
5	CCR_2007_R1	2	250	0	3	3	-1	-1	N	01-01-2007	--	Acute vascular leak syndro
6	CCR_2007_R1	2	250	0	1	1	1	2	N	01-03-2007	01-02-2007	Arthritis (non-septic)
7	CCR_2007_R1	2	250	0	3	2	1	2	N	01-03-2007	04-15-2007	Adrenal insufficiency
8	CCR_2007_R1	2	250	0	1	8	1	3	N	01-04-2007	--	Cough

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

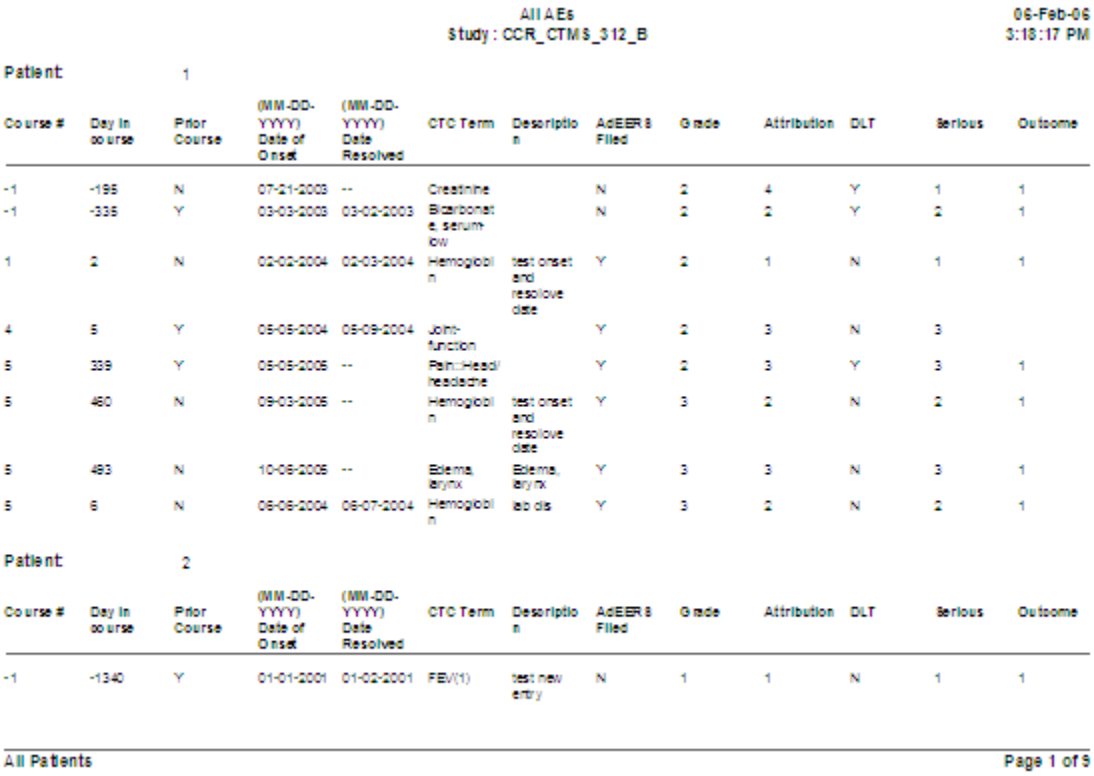
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
AE Description	The Succinct Clinical Description of This AE
AdEERS Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.

Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Document Number	Document Number of the CRF
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

All AEs (Formatted) –V1

Description

This report lists all adverse events in the specified study.



All AEs
Study : CCR_CTMS_312_B

06-Feb-06
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Patient: 1

Course #	Day in course	Prior Course	(MM-DD-YYYY) Date of Onset	(MM-DD-YYYY) Date Resolved	CTC Term	Description	AdEER8 Filed	Grade	Attribution	DLT	Serious	Outcome
-1	-195	N	07-21-2003	--	Creatinine		N	2	4	Y	1	1
-1	-335	Y	03-03-2003	03-02-2003	Bicarbonate, serum-low		N	2	2	Y	2	1
1	2	N	02-02-2004	02-03-2004	Hemoglobin	test onset and resolove date	Y	2	1	N	1	1
4	5	Y	05-05-2004	05-09-2004	Joint-function		Y	2	3	N	3	
5	339	Y	05-05-2005	--	Pain-Head/headache		Y	2	3	Y	3	1
5	460	N	09-03-2005	--	Hemoglobin	test onset and resolove date	Y	3	2	N	2	1
5	483	N	10-06-2005	--	Edema, laryn	Edema, laryn	Y	3	3	N	3	1
5	6	N	06-06-2004	06-07-2004	Hemoglobin	lab dis	Y	3	2	N	2	1

Patient: 2

Course #	Day in course	Prior Course	(MM-DD-YYYY) Date of Onset	(MM-DD-YYYY) Date Resolved	CTC Term	Description	AdEER8 Filed	Grade	Attribution	DLT	Serious	Outcome
-1	-1340	Y	01-01-2001	01-02-2001	FEV(1)	test new entry	N	1	1	N	1	1

All Patients

Page 1 of 9

Access

User Level: Public

Study Level: CCR_Program

Columns

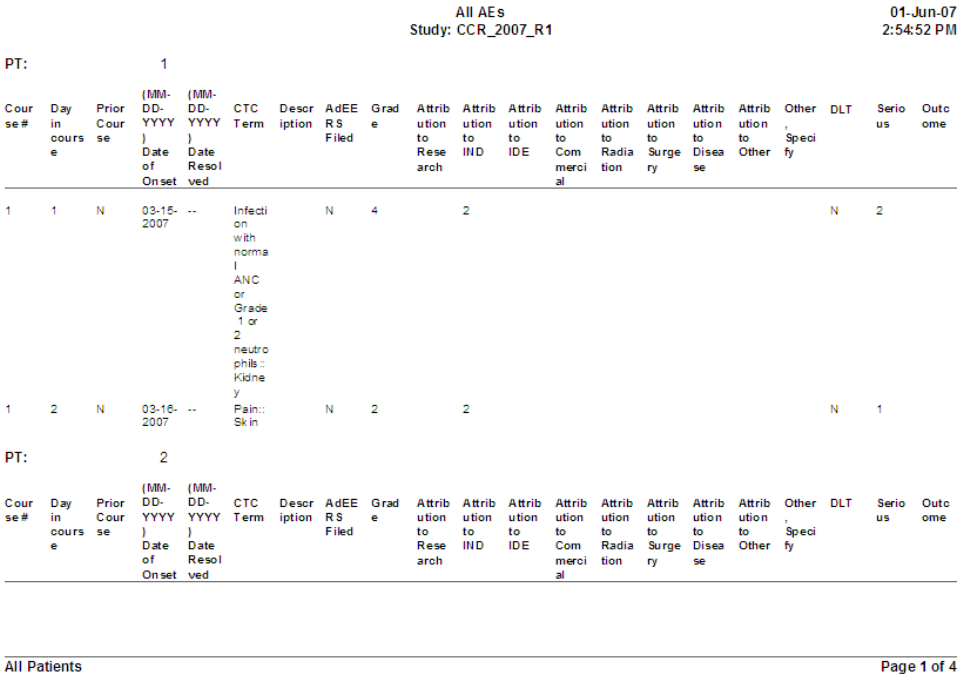
Field	*Description*
Study (Header)	Protocol Number for which Access is being Queried
Patient (Header)	C3D Patient ID Displayed on RDC
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started
Prior Course	Whether this AE Is Related to The Prior Course

Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
CTC Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
AdEERS Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
DLT	Whether This AE is Considered a 'Dose Limiting Toxicity'
Serious	Whether This AE Is a 'Serious' Event
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'

All AEs (Formatted) –V2

Description

This report lists all adverse events in the specified study. Works for studies based on 2007R1 template.



All AEs
Study: CCR_2007_R1

01-Jun-07
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PT: 1

Course #	Day in course	Prior Course	(MM-DD-YYYY) Date of Onset	(MM-DD-YYYY) Date Resolved	CTC Term	Description	AdEERS Filed	Grade	Attribution to Research	Attribution to IND	Attribution to IDE	Attribution to Commercial	Attribution to Radiation	Attribution to Surgery	Attribution to Disease	Attribution to Other	Other, Specify	DLT	Serious	Outcome
1	1	N	03-15-2007	--	Infection with normal ANC or Grade 1 or 2 neutrophils:: Kidney		N	4		2								N	2	
1	2	N	03-16-2007	--	Pain:: Skin		N	2		2								N	1	

PT: 2

Course #	Day in course	Prior Course	(MM-DD-YYYY) Date of Onset	(MM-DD-YYYY) Date Resolved	CTC Term	Description	AdEERS Filed	Grade	Attribution to Research	Attribution to IND	Attribution to IDE	Attribution to Commercial	Attribution to Radiation	Attribution to Surgery	Attribution to Disease	Attribution to Other	Other, Specify	DLT	Serious	Outcome

All Patients

Page 1 of 4

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

Field	*Description*
Study (Header)	Protocol Number for which Access is being Queried
Patient (Header)	C3D Patient ID Displayed on RDC
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started

Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
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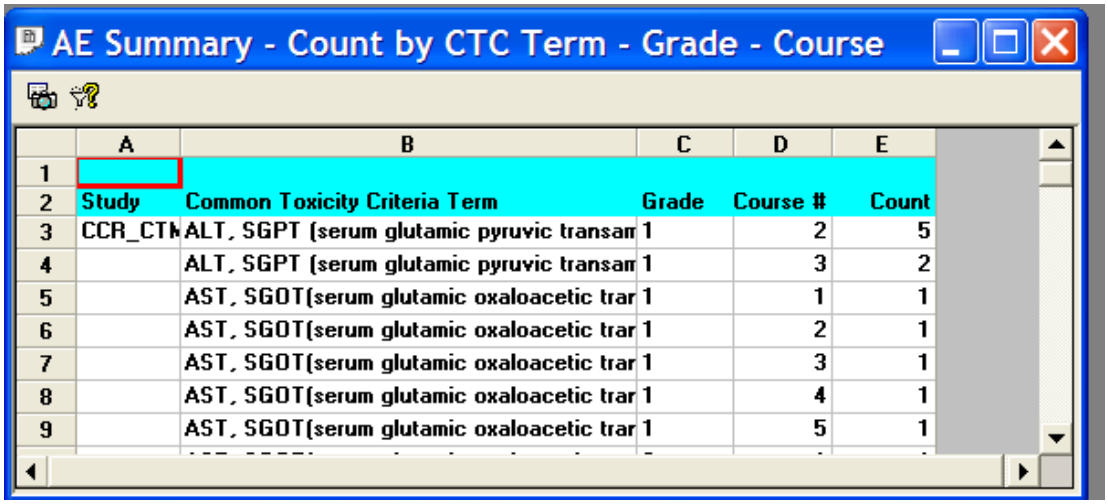
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..
Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
DLT	Whether This AE is Considered a 'Dose Limiting Toxicity'
Serious	Whether This AE Is a 'Serious' Event
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'

AE Summary - Counts by CTC Term-Grade-Course

Description

This report provides a count of the CTCAE term, and provides grade and course number.



	A	B	C	D	E
1					
2	Study	Common Toxicity Criteria Term	Grade	Course #	Count
3	CCR_CTN	ALT, SGPT (serum glutamic pyruvic transam	1	2	5
4		ALT, SGPT (serum glutamic pyruvic transam	1	3	2
5		AST, SGOT(serum glutamic oxaloacetic trar	1	1	1
6		AST, SGOT(serum glutamic oxaloacetic trar	1	2	1
7		AST, SGOT(serum glutamic oxaloacetic trar	1	3	1
8		AST, SGOT(serum glutamic oxaloacetic trar	1	4	1
9		AST, SGOT(serum glutamic oxaloacetic trar	1	5	1

Access

User Level: Public

Study Level: CCR_Program

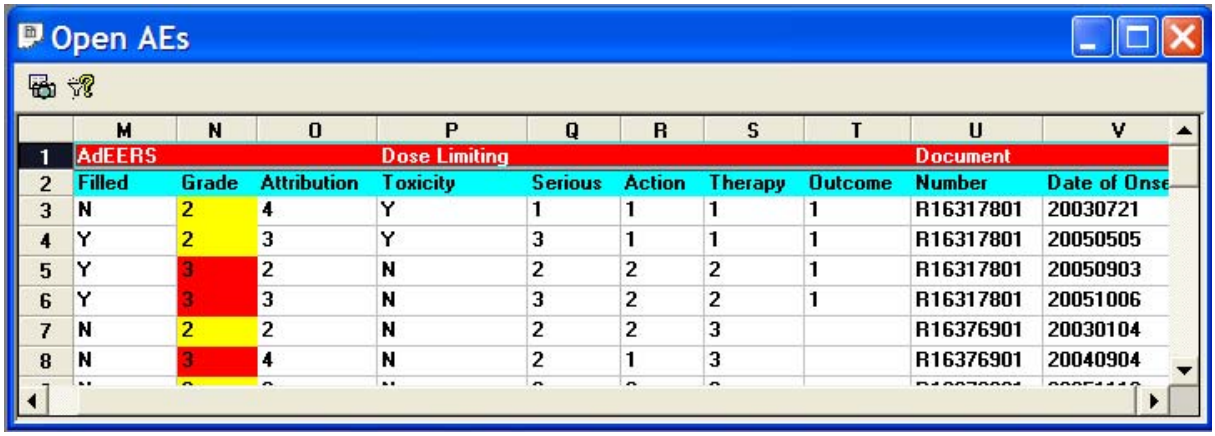
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Course	The Course Number that This AE Started
Count	Number of Times for AEs With the Same CTC Term, Grade and Course Number

Open AEs –V1

Description

This report lists all open adverse events in the specified study. Grades of 2 are highlighted in yellow and higher grades are highlighted in red.



	M	N	O	P	Q	R	S	T	U	V
1	AdEERS			Dose Limiting					Document	
2	Filled	Grade	Attribution	Toxicity	Serious	Action	Therapy	Outcome	Number	Date of Onse
3	N	2	4	Y	1	1	1	1	R16317801	20030721
4	Y	2	3	Y	3	1	1	1	R16317801	20050505
5	Y	3	2	N	2	2	2	1	R16317801	20050903
6	Y	3	3	N	3	2	2	1	R16317801	20051006
7	N	2	2	N	2	2	3		R16376901	20030104
8	N	3	4	N	2	1	3		R16376901	20040904

Access

User Level: Public

Study Level: CCR_Program

Columns

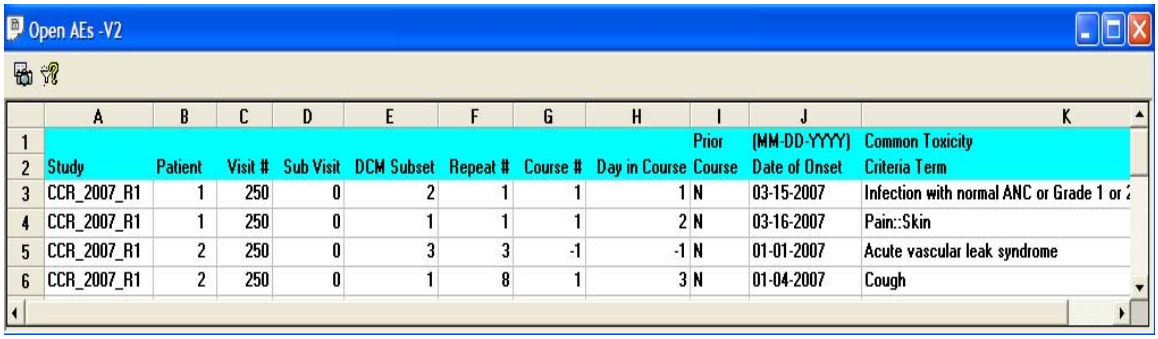
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
AE Description	The Succinct Clinical Description of This AE
AdEERS Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'

Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Document Number	Document Number of the CRF
Date of Onset	Date of the Observation of This AE. The (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Open AEs -V2

Description

This report lists all open adverse events in the specified study. Grades of 2 are highlighted in yellow and higher grades are highlighted in red. Work for studies based on 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	K
1									Prior	(MM-DD-YYYY)	Common Toxicity
2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course #	Day in Course	Course	Date of Onset	Criteria Term
3	CCR_2007_R1	1	250	0	2	1	1	1	N	03-15-2007	Infection with normal ANC or Grade 1 or 2
4	CCR_2007_R1	1	250	0	1	1	1	2	N	03-16-2007	Pain::Skin
5	CCR_2007_R1	2	250	0	3	3	-1	-1	N	01-01-2007	Acute vascular leak syndrome
6	CCR_2007_R1	2	250	0	1	8	1	3	N	01-04-2007	Cough

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

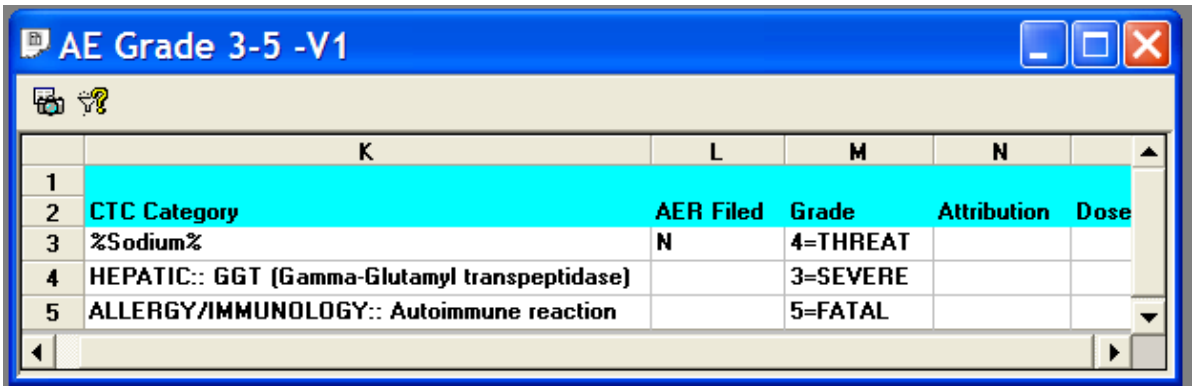
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This AE Started
Day in Course	The Day in Course that This AE Started
Prior Course	Whether this AE Is Related to The Prior Course
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Resolved Date	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
AE Description	The Succinct Clinical Description of This AE
AdEERS Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
Attribution to IDE	Evaluate the adverse event's relationship to the investigational device exemption..

Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Document Number	Document Number of the CRF
Date of Onset	Date of the Observation of This AE. The (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Resolved Date	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

AEs Grade 3-5 V1

Description

This report lists AEs with grades 3, 4 or 5. It works for studies that are based on the 3.12 template.



	K	L	M	N	
1					
2	CTC Category	AER Filed	Grade	Attribution	Dose
3	%Sodium%	N	4=THREAT		
4	HEPATIC:: GGT (Gamma-Glutamyl transpeptidase)		3=SEVERE		
5	ALLERGY/IMMUNOLOGY:: Autoimmune reaction		5=FATAL		

Access

User Level: Public

Study Level: CCR_Program

Columns

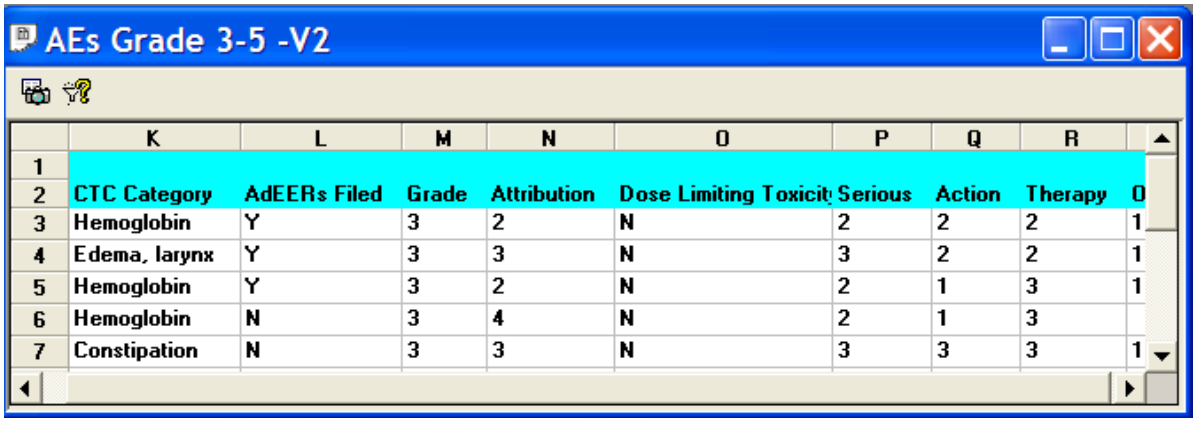
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Category	Broad Classification of AE
AER Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE

Therapy	Whether Additional Therapy Is Required to Treat This AE
Outcome	The Final Status of The Patient When This AE Is Considered 'resolved'
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

AEs Grade 3-5 V2

Description

This report lists AEs with grades 3, 4 or 5. It works for studies that are based on the 3.12 template.



	K	L	M	N	O	P	Q	R
1								
2	CTC Category	AdEERs Filed	Grade	Attribution	Dose Limiting Toxicit	Serious	Action	Therapy
3	Hemoglobin	Y	3	2	N	2	2	2
4	Edema, larynx	Y	3	3	N	3	2	2
5	Hemoglobin	Y	3	2	N	2	1	3
6	Hemoglobin	N	3	4	N	2	1	3
7	Constipation	N	3	3	N	3	3	3

Access

User Level: Public

Study Level: CCR_Program

Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
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AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution	Evaluation for Relationship Between AE and the Study Therapy
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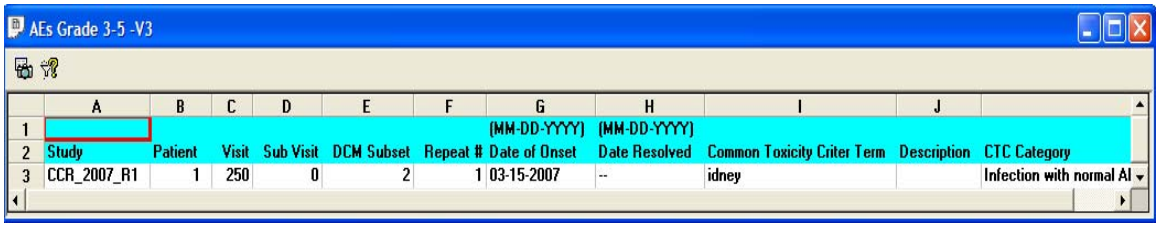
Serious	Whether This AE Is a 'Serious' Event
Action	Whether Any Changes Made to the Study Regimen In Response to This AE
Therapy	Whether Additional Therapy Is Required to Treat This AE

Outcome	The Final Status of The Patient When This AE Is Considered ‘resolved’
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

AEs Grade 3-5 V3

Description

This report lists AEs with grades 3, 4 or 5. Work for studies based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I	J	
1							(MM-DD-YYYY)	(MM-DD-YYYY)			
2	Study	Patient	Visit	Sub Visit	DCM Subset	Repeat #	Date of Onset	Date Resolved	Common Toxicity Criter Term	Description	CTC Category
3	CCR_2007_R1	1	250	0	2	1	03-15-2007	--	idney		Infection with normal AI

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
DCM Subset	DCM Subset Number
Repeat #	The Repeat Sequence Number
Date of Onset	Date of the Observation of This AE (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This AE (Format MM-DD-YYYY)
Common Toxicity Criteria Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This AE
CTC Category	Broad Classification of AE
AdEERs Filed	Whether an Adverse Event Report (AER) was Filed to IRB/Sponsor
Grade	Grade of This AE Using CTC Version 2.0 or 3.0
Attribution to Research	Evaluate the adverse event's relationship to the subject's participation in the study.
Attribution to IND	Evaluate the adverse event's relationship to the investigational agent.
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Attribution to Commercial	Evaluate the adverse event's relationship to the commercial agent.
Attribution to Radiation	Evaluate the adverse event's relationship to the Radiation therapy.
Attribution to Surgery	Evaluate the adverse event's relationship to the surgery.
Attribution to Disease	Evaluate the adverse event's relationship to the disease.
Attribution to other	Evaluate the adverse event's relationship to the other causes not listed above.
Others Specify	An explanation when 'Attribute to other' is selected.

Dose Limiting Toxicity	Whether This AE is Considered a 'Dose Limiting Toxicity'
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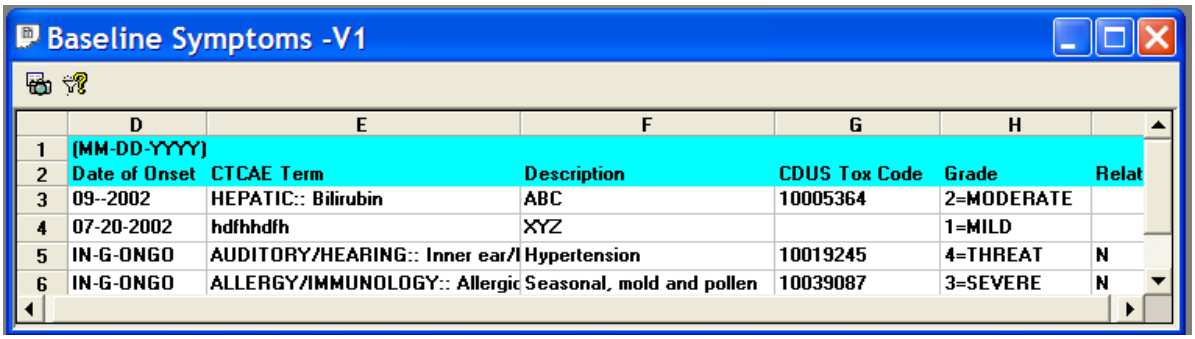
Date of Onset	Date of the Observation of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This AE. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Baseline Symptoms -V1

Description

This report lists baseline symptoms. It works for studies that are based on the 3.02 and 3.10 templates.



	D	E	F	G	H	
1	(MM-DD-YYYY)					
2	Date of Onset	CTCAE Term	Description	CDUS Tox Code	Grade	Relat
3	09--2002	HEPATIC:: Bilirubin	ABC	10005364	2=MODERATE	
4	07-20-2002	hdfhhdfh	XYZ		1=MILD	
5	IN-G-ONGO	AUDITORY/HEARING:: Inner ear/I	Hypertension	10019245	4=THREAT	N
6	IN-G-ONGO	ALLERGY/IMMUNOLOGY:: Allergic	Seasonal, mold and pollen	10039087	3=SEVERE	N

Access

User Level: Public

Study Level: CCR_Program

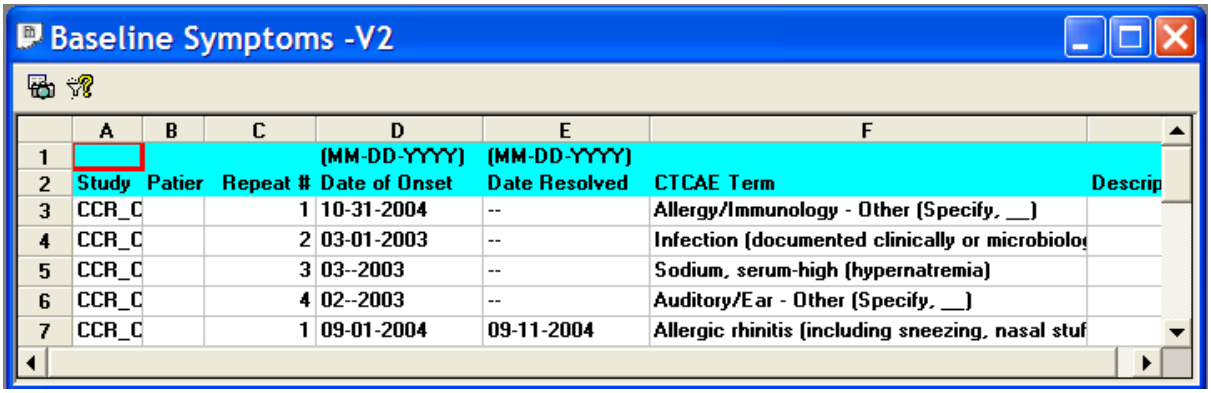
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Baseline Symptoms –V2

Description

This report lists baseline symptoms. It works for studies that are based on the 3.12 template.



	A	B	C	D	E	F	
1				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Patier	Repeat #	Date of Onset	Date Resolved	CTCAE Term	Descrip
3	CCR_C		1	10-31-2004	--	Allergy/Immunology - Other (Specify, __)	
4	CCR_C		2	03-01-2003	--	Infection (documented clinically or microbiolo	
5	CCR_C		3	03--2003	--	Sodium, serum-high (hypernatremia)	
6	CCR_C		4	02--2003	--	Auditory/Ear - Other (Specify, __)	
7	CCR_C		1	09-01-2004	09-11-2004	Allergic rhinitis (including sneezing, nasal stuf	

Access

User Level: Public

Study Level: CCR_Program

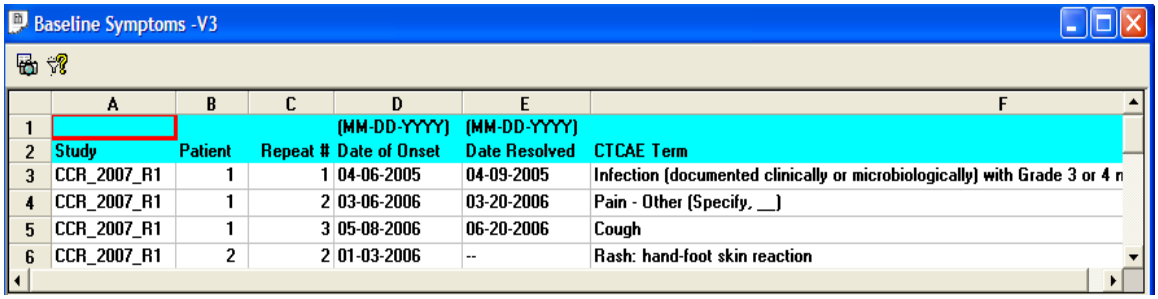
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This Symptom (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CDUS Tox Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This Symptom. The Original Value Used by System (Form YYYYMMDD)

Baseline Symptoms –V3

Description

This report lists baseline symptoms. It works for studies that are based on the 2007R1 template.



	A	B	C	D	E	F
1				(MM-DD-YYYY)	(MM-DD-YYYY)	
2	Study	Patient	Repeat #	Date of Onset	Date Resolved	CTCAE Term
3	CCR_2007_R1	1	1	04-06-2005	04-09-2005	Infection (documented clinically or microbiologically) with Grade 3 or 4 n
4	CCR_2007_R1	1	2	03-06-2006	03-20-2006	Pain - Other (Specify, __)
5	CCR_2007_R1	1	3	05-08-2006	06-20-2006	Cough
6	CCR_2007_R1	2	2	01-03-2006	--	Rash: hand-foot skin reaction

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

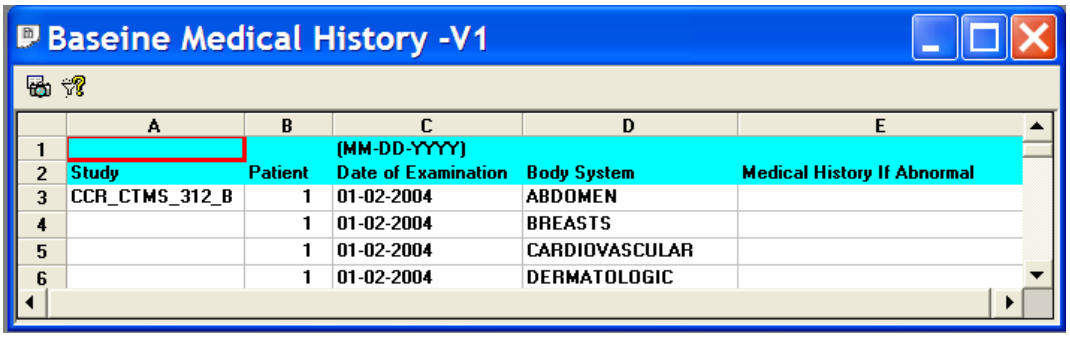
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Onset	Date the Symptom was first Observed/Experienced (Format MM-DD-YYYY)
Date Resolved	Date of Resolution of This Symptom (Format MM-DD-YYYY)
CTCAE Term	The Common Toxicity Criteria (CTC) Term. Can Be Version 2.0 or 3.0
Description	The Succinct Clinical Description of This Symptom
CTC Toxicity type Code	The Common Toxicity Criteria (CTC) Code
Grade	Severity of the Symptom Using CTC Version 2.0 or 3.0
Related To Disease?	Whether the Symptom Is Related to the Study Disease
Date of Onset	Date the Symptom was first Observed/Experienced. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date of Resolution of This Symptom. The Original Value Used by System (Form YYYYMMDD)

Patient History Reports

Baseline Medical History –V1

Description

This report lists baseline medical history. It works on studies based on 3.02, 310 and 3.12 templates.



Access

User Level: Public

Study Level: CCR_Program

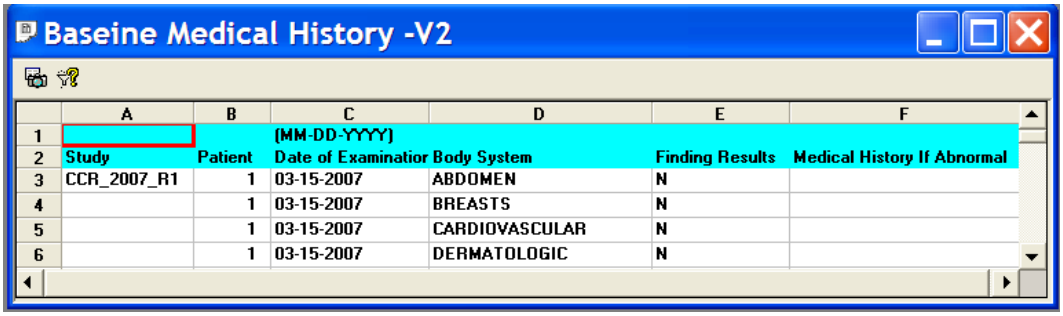
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Examination	Date that the Patient Was Examined And the Medical History Was Documented (Format MM-DD-YYYY)
Body System	Defaulted Body System
Medical History If Abnormal	The Brief Description of Major Medical And Surgical Events During the Patient's Lifetime

Baseline Medical History –V2

Description

This report lists baseline medical history. It works on studies based on 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

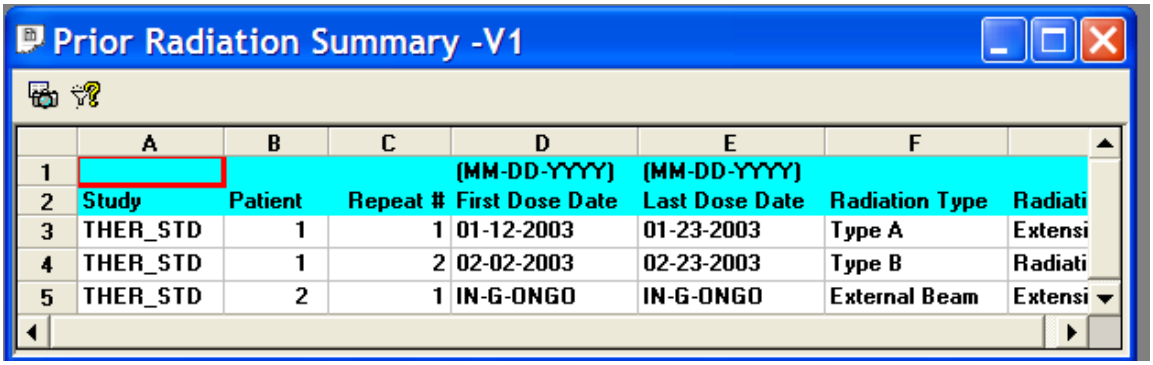
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Examination	Date that the Patient Was Examined And the Medical History Was Documented (Format MM-DD-YYYY)
Body System	Defaulted Body System
Finding Results	The Finding Results for the Particular Body System.
Medical History If Abnormal	The Brief Description of Major Medical And Surgical Events During the Patient's Lifetime

Prior Radiation Summary –V1

Description

This report lists prior radiation summary. It works on studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	
1				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Patient	Repeat #	First Dose Date	Last Dose Date	Radiation Type	Radiati
3	THER_STD	1	1	01-12-2003	01-23-2003	Type A	Extensi
4	THER_STD	1	2	02-02-2003	02-23-2003	Type B	Radiati
5	THER_STD	2	1	IN-G-ONGO	IN-G-ONGO	External Beam	Extensi

Access

User Level: Public

Study Level: CCR_Program

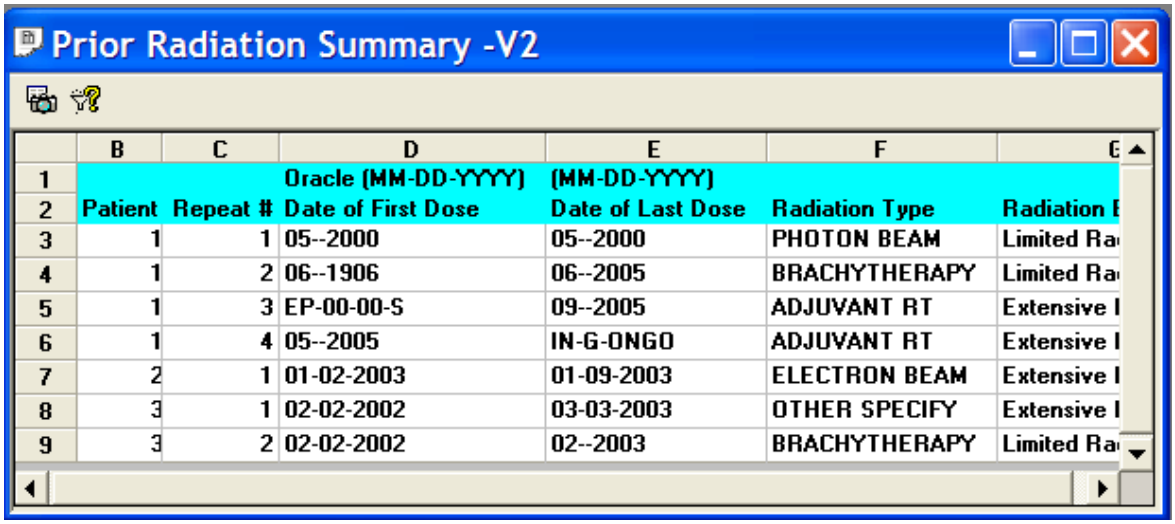
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
First Dose Date	Date of The First Dose of The Radiation Therapy (Format MM-DD-YYYY)
Last Dose Date	Date of The Last Dose of The Radiation Therapy (Format MM-DD-YYYY)
Radiation Type	Type of The Radiation Therapy
Radiation Extent	Extent of The Radiation Therapy
Site	Site of The Radiation Therapy
Schedule	Schedule of The Radiation Therapy
Dose UOM	Total Radiation Dose The Patient Received During The Treatment Period
Best Response	The Best Response Encounted
First Dose Date	Date of The First Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Last Dose Date	Date of The Last Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD).

Prior Radiation Summary –V2

Description

This report lists prior radiation summary. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G
1			Oracle (MM-DD-YYYY)	(MM-DD-YYYY)		
2	Patient	Repeat #	Date of First Dose	Date of Last Dose	Radiation Type	Radiation E
3	1	1	05--2000	05--2000	PHOTON BEAM	Limited Ra
4	1	2	06--1906	06--2005	BRACHYTHERAPY	Limited Ra
5	1	3	EP-00-00-S	09--2005	ADJUVANT RT	Extensive I
6	1	4	05--2005	IN-G-ONGO	ADJUVANT RT	Extensive I
7	2	1	01-02-2003	01-09-2003	ELECTRON BEAM	Extensive I
8	3	1	02-02-2002	03-03-2003	OTHER SPECIFY	Extensive I
9	3	2	02-02-2002	02--2003	BRACHYTHERAPY	Limited Ra

Access

User Level: Public

Study Level: CCR_Program

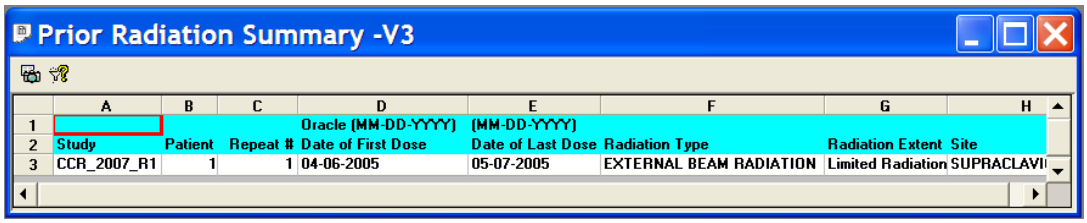
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of First Dose	Date of The First Dose of The Radiation Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Radiation Therapy (Format MM-DD-YYYY)
Radiation Type	Type of The Radiation Therapy
Radiation Extent	Extent of The Radiation Therapy
Site	Site of The Radiation Therapy
Schedule	Schedule of The Radiation Therapy
Dose UOM	Total Radiation Dose The Patient Received During The Treatment Period
Best Response	The Best Response Encounted
Date of First Dose	Date of The First Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date of Last Dose	Date of The Last Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD).

Prior Radiation Summary –V3

Description

This report lists prior radiation summary. It works on studies that are based on the 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

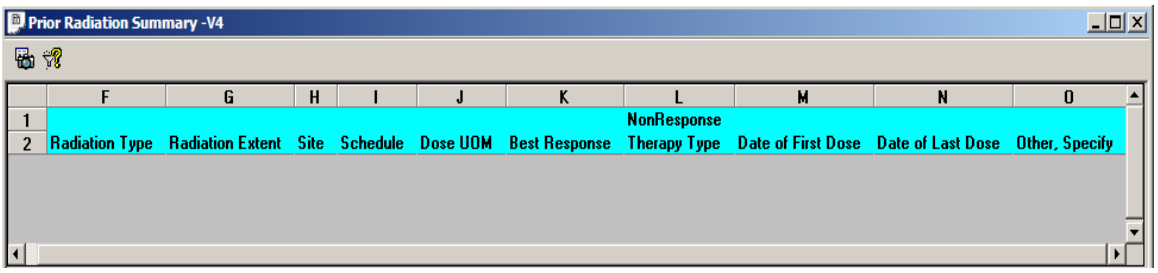
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of First Dose	Date of The First Dose of The Radiation Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Radiation Therapy (Format MM-DD-YYYY)
Radiation Type	Type of The Radiation Therapy
Radiation Extent	Extent of The Radiation Therapy
Site	Site of The Radiation Therapy
Schedule	Schedule of The Radiation Therapy
Dose UOM	Total Radiation Dose The Patient Received During The Treatment Period
Best Response	The Best Response Encounted
NonResponse Therapy Type	The Non-Response Therapy Type Entered
Date of First Dose	Date of The First Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date of Last Dose	Date of The Last Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD).

Prior Radiation Summary –V4

Description

This report lists prior radiation summary. It works on studies that are based on the 2008V1 template.



Access

User Level: Public

Study Level: CCR 2008V1 STD

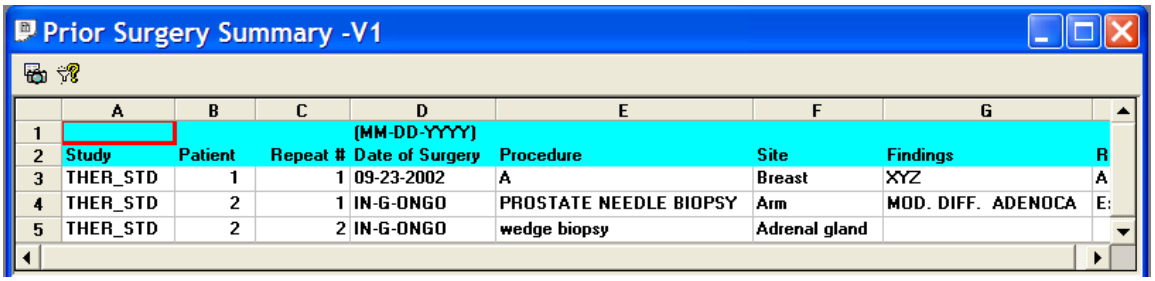
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of First Dose	Date of The First Dose of The Radiation Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Radiation Therapy (Format MM-DD-YYYY)
Radiation Type	Type of The Radiation Therapy
Radiation Extent	Extent of The Radiation Therapy
Site	Site of The Radiation Therapy
Schedule	Schedule of The Radiation Therapy
Dose UOM	Total Radiation Dose The Patient Received During The Treatment Period
Best Response	The Best Response Encounted
NonResponse Therapy Type	The Non-Response Therapy Type Entered
Date of First Dose	Date of The First Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date of Last Dose	Date of The Last Dose of The Radiation Therapy. The Original Value Used by System (Form YYYYMMDD).
Other Specify	Description of 'Other'

Prior Surgery Summary –V1

Description

This report lists prior surgery summary. It works on studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	G	
1				(MM-DD-YYYY)				
2	Study	Patient	Repeat #	Date of Surgery	Procedure	Site	Findings	R
3	THER_STD	1	1	09-23-2002	A	Breast	XYZ	A
4	THER_STD	2	1	IN-G-ONGO	PROSTATE NEEDLE BIOPSY	Arm	MOD. DIFF. ADENOCA	E:
5	THER_STD	2	2	IN-G-ONGO	wedge biopsy	Adrenal gland		

Access

User Level: Public

Study Level: CCR_Program

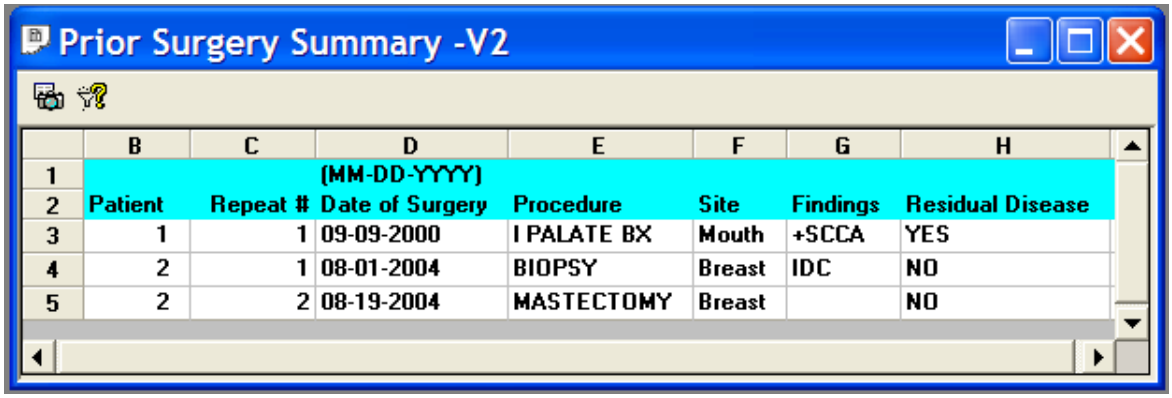
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Surgery	Date of The Surgical Procedure (Format MM-DD-YYYY)
Procedure	Type of Procedure Performed to Diagnose/Treat the Patient's Disease
Site	The Anatomical Site of The Procedure
Findings	Brief Description of The Findings of The Procedure
Residual Disease	Brief Description of The Extent of The Residual Disease
Therapeutic Indicator	Whether The Surgical Procedure Was Performed With Curative Intent
Date of Surgery	Date of The Surgical Procedure. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Prior Surgery Summary –V2

Description

This report lists prior surgery summary. It works on studies that are based on the 3.12 and 2007R1 templates.



	B	C	D	E	F	G	H
1			(MM-DD-YYYY)				
2	Patient	Repeat #	Date of Surgery	Procedure	Site	Findings	Residual Disease
3	1	1	09-09-2000	I PALATE BX	Mouth	+SCCA	YES
4	2	1	08-01-2004	BIOPSY	Breast	IDC	NO
5	2	2	08-19-2004	MASTECTOMY	Breast		NO

Access

User Level: Public

Study Level: CCR_Program I

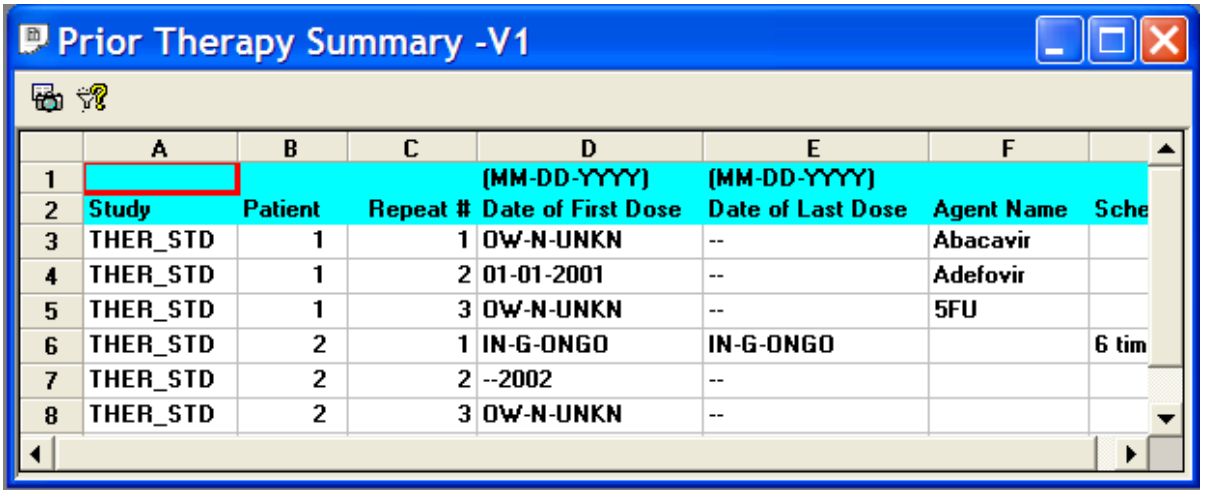
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Surgery	Date of The Surgical Procedure (Format MM-DD-YYYY)
Procedure	Type of Procedure Performed to Diagnose/Treat the Patient's Disease
Site	The Anatomical Site of The Procedure
Findings	Brief Description of The Findings of The Procedure
Residual Disease	Brief Description of The Extent of The Residual Disease
Therapeutic Indicator	Whether The Surgical Procedure Was Performed With Curative Intent
Date of Surgery	Date of The Surgical Procedure. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Prior Therapy Summary –V1

Description

This report lists prior therapy summary. It works on studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F	
1				(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Study	Patient	Repeat #	Date of First Dose	Date of Last Dose	Agent Name	Sche
3	THER_STD	1	1	OW-N-UNKN	--	Abacavir	
4	THER_STD	1	2	01-01-2001	--	Adefovir	
5	THER_STD	1	3	OW-N-UNKN	--	5FU	
6	THER_STD	2	1	IN-G-ONGO	IN-G-ONGO		6 tim
7	THER_STD	2	2	--2002	--		
8	THER_STD	2	3	OW-N-UNKN	--		

Access

User Level: Public

Study Level: CCR_Program

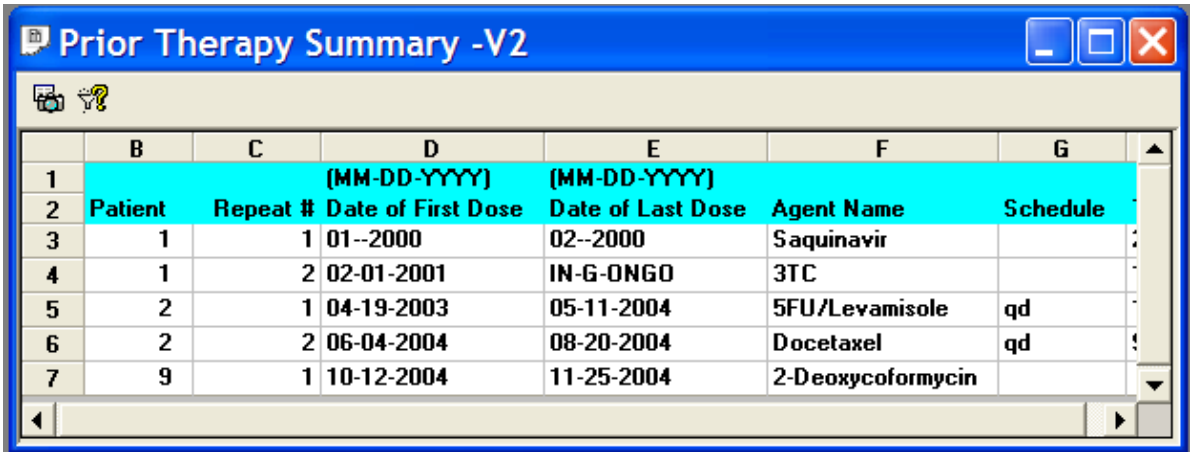
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of First Dose	Date of The First Dose of The Prior Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Prior Therapy (Format MM-DD-YYYY)
Agent Name	The Generic Name of The Agent That Was User
Schedule	The Schedule on Which The Agent (Or Combination) Was Given
Total Dose	The Total Dose of The Agent
Dose UOM	The Total Dose Unit of Measement
Best Response	Best Response Encounted
Therapy Type	Prior Therapy Type
Date of First Dose	Date of The First Dose of The Prior Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date of Last Dose	Date of The Last Dose of The Prior Therapy. The Original Value Used by System (Form YYYYMMDD)

Prior Therapy Summary –V2

Description

This report lists prior therapy summary. It works on studies that are based on the 3.12 and 2007R1 templates.



	B	C	D	E	F	G
1			(MM-DD-YYYY)	(MM-DD-YYYY)		
2	Patient	Repeat #	Date of First Dose	Date of Last Dose	Agent Name	Schedule
3	1	1	01--2000	02--2000	Saquinavir	
4	1	2	02-01-2001	IN-G-ONGO	3TC	
5	2	1	04-19-2003	05-11-2004	5FU/Levamisole	qd
6	2	2	06-04-2004	08-20-2004	Docetaxel	qd
7	9	1	10-12-2004	11-25-2004	2-Deoxycoformycin	

Access

User Level: Public

Study Level: CCR_Program

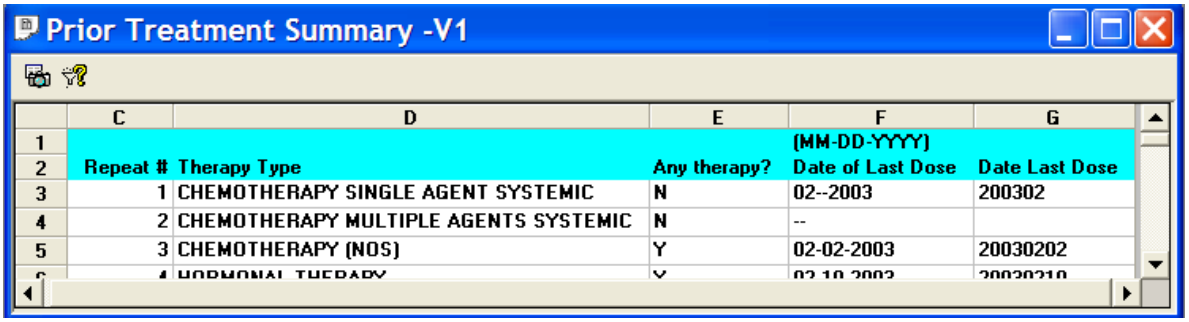
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of First Dose	Date of The First Dose of The Prior Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Prior Therapy (Format MM-DD-YYYY)
Agent Name	The Generic Name of The Agent That Was User
Schedule	The Schedule on Which The Agent (Or Combination) Was Given
Total Dose	The Total Dose of The Agent
Dose UOM	The Total Dose Unit of Measement
Best Response	Best Response Encounted
NonResponse Therapy Type	The Non Response Therapy Type
Therapy Type	Prior Therapy Type
Date of First Dose	Date of The First Dose of The Prior Therapy. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date of Last Dose	Date of The Last Dose of The Prior Therapy. The Original Value Used by System (Form YYYYMMDD)

Prior Treatment Summary –V1

Description

This report lists prior treatment summary. It works on studies that are based on the 3.02 and 3.10 templates.



	C	D	E	F	G
1				(MM-DD-YYYY)	
2	Repeat #	Therapy Type	Any therapy?	Date of Last Dose	Date Last Dose
3	1	CHEMOTHERAPY SINGLE AGENT SYSTEMIC	N	02--2003	200302
4	2	CHEMOTHERAPY MULTIPLE AGENTS SYSTEMIC	N	--	
5	3	CHEMOTHERAPY (NOS)	Y	02-02-2003	20030202
6	4	HORMONAL THERAPY	Y	02-10-2003	20030210

Access

User Level: Public

Study Level: CCR_Program

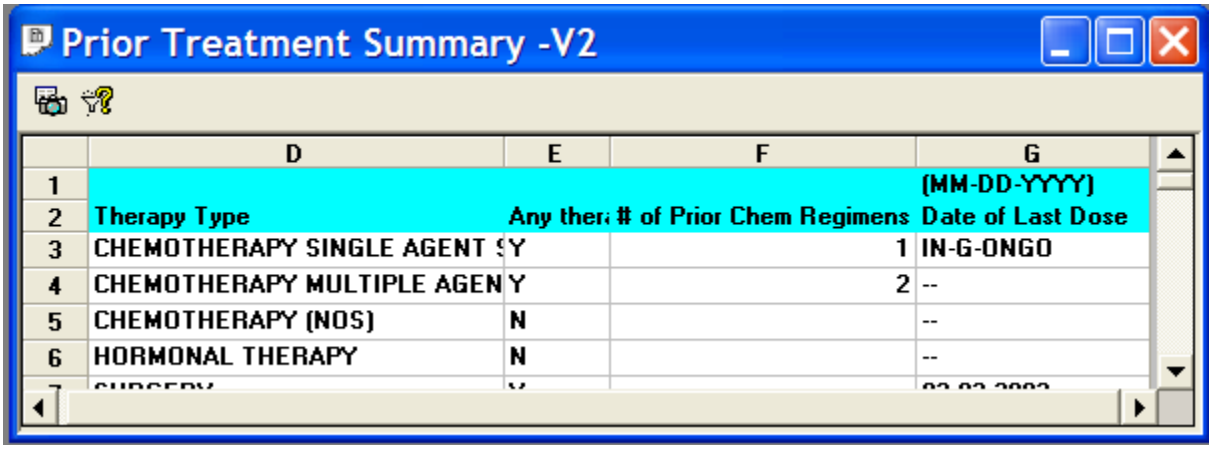
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Therapy Type	Type of Therapy
Any therapy?	Whether The Patient Has Received Any Prior Treatment for The Corresponding Type of Therapy
Date of Last Dose	Date of The Last Dose of The Most Recent Prior Treatment Regimen for The Corresponding Type of Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Most Recent Prior Treatment Regimen for The Corresponding Type of Therapy. The Original Value Used by System (Form YYYYMMDD)

Prior Treatment Summary –V2

Description

This report lists prior treatment summary. It works on studies that are based on the 3.12 and 2007R1 templates.



	D	E	F	G
1				(MM-DD-YYYY)
2	Therapy Type	Any ther	# of Prior Chem Regimens	Date of Last Dose
3	CHEMOTHERAPY SINGLE AGENT	Y	1	IN-G-ONGO
4	CHEMOTHERAPY MULTIPLE AGEN	Y	2	--
5	CHEMOTHERAPY (NOS)	N		--
6	HORMONAL THERAPY	N		--

Access

User Level: Public

Study Level: CCR_Program

Columns

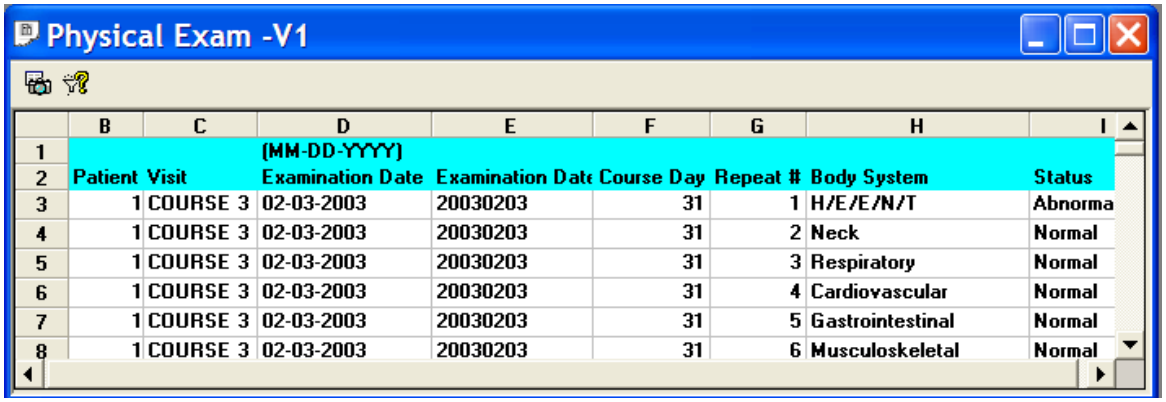
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Therapy Type	Type of Therapy
Any therapy?	Whether The Patient Has Received Any Prior Treatment for The Corresponding Type of Therapy
# of Prior Chem Regimens	The Number of Prior Regimens Received for The Corresponding Type of Therapy
Date of Last Dose	Date of The Last Dose of The Most Recent Prior Treatment Regimen for The Corresponding Type of Therapy (Format MM-DD-YYYY)
Date of Last Dose	Date of The Last Dose of The Most Recent Prior Treatment Regimen for The Corresponding Type of Therapy. The Original Value Used by System (Form YYYYMMDD)

Physical Exam Reports

Physical Exam -V1

Description

This report lists physical exam. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	I
1			(MM-DD-YYYY)					
2	Patient	Visit	Examination Date	Examination Date	Course Day	Repeat #	Body System	Status
3	1	COURSE 3	02-03-2003	20030203	31	1	H/E/E/N/T	Abnorma
4	1	COURSE 3	02-03-2003	20030203	31	2	Neck	Normal
5	1	COURSE 3	02-03-2003	20030203	31	3	Respiratory	Normal
6	1	COURSE 3	02-03-2003	20030203	31	4	Cardiovascular	Normal
7	1	COURSE 3	02-03-2003	20030203	31	5	Gastrointestinal	Normal
8	1	COURSE 3	02-03-2003	20030203	31	6	Musculoskeletal	Normal

Access

User Level: Public

Study Level: CCR_Program

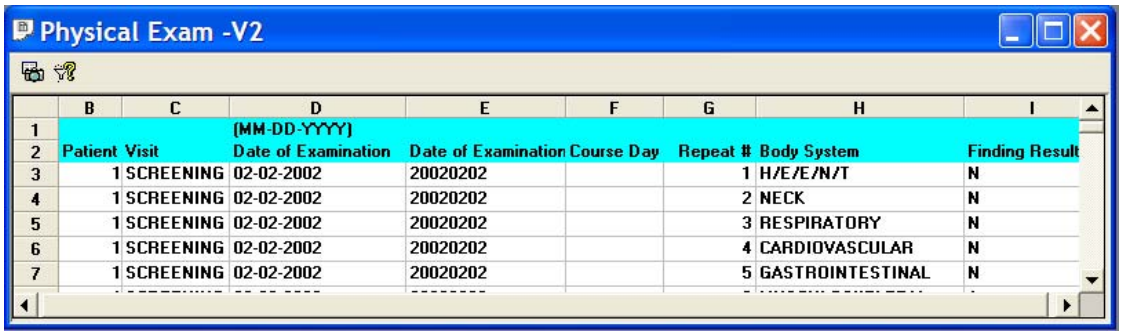
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Examination Date	Date The Physical Examination Took Place (Format MM-DD-YYYY)
Examination Date	Date The Physical Examination Took Place. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Course Day	Number of Days Since The Beginning of The Course
Repeat #	The Repeat Sequence Number
Body System	Body System
Status	Status of The Finding Result for The Corresponding Body System
Comments	Brief Description of The Change

Physical Exam –V2

Description

This report lists physical exam. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G	H	I
1			(MM-DD-YYYY)					
2	Patient	Visit	Date of Examination	Date of Examination	Course Day	Repeat #	Body System	Finding Result
3	1	SCREENING	02-02-2002	20020202		1	H/E/E/N/T	N
4	1	SCREENING	02-02-2002	20020202		2	NECK	N
5	1	SCREENING	02-02-2002	20020202		3	RESPIRATORY	N
6	1	SCREENING	02-02-2002	20020202		4	CARDIOVASCULAR	N
7	1	SCREENING	02-02-2002	20020202		5	GASTROINTESTINAL	N

Access

User Level: Public

Study Level: CCR_Program

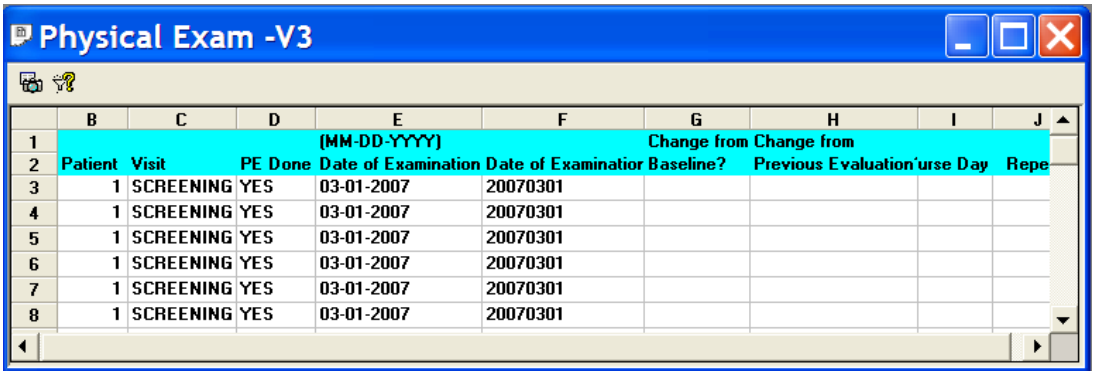
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Date of Examination	Date The Physical Examination Took Place (Format MM-DD-YYYY)
Date of Examination	Date The Physical Examination Took Place. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Course Day	Number of Days Since The Beginning of The Course
Repeat #	The Repeat Sequence Number
Body System	Body System
Finding Results	Status of The Finding Result for The Corresponding Body System
Comments	Brief Description of The Change

Physical Exam –V3

Description

This report lists physical exam. It works on studies that are based on the 2007R1 template.



	B	C	D	E	F	G	H	I	J
1				(MM-DD-YYYY)		Change from	Change from		
2	Patient	Visit	PE Done	Date of Examination	Date of Examinatior	Baseline?	Previous Evaluation	urse Day	Repe
3	1	SCREENING	YES	03-01-2007	20070301				
4	1	SCREENING	YES	03-01-2007	20070301				
5	1	SCREENING	YES	03-01-2007	20070301				
6	1	SCREENING	YES	03-01-2007	20070301				
7	1	SCREENING	YES	03-01-2007	20070301				
8	1	SCREENING	YES	03-01-2007	20070301				

Access

User Level: Public

Study Level: CCR 2007R1 STD

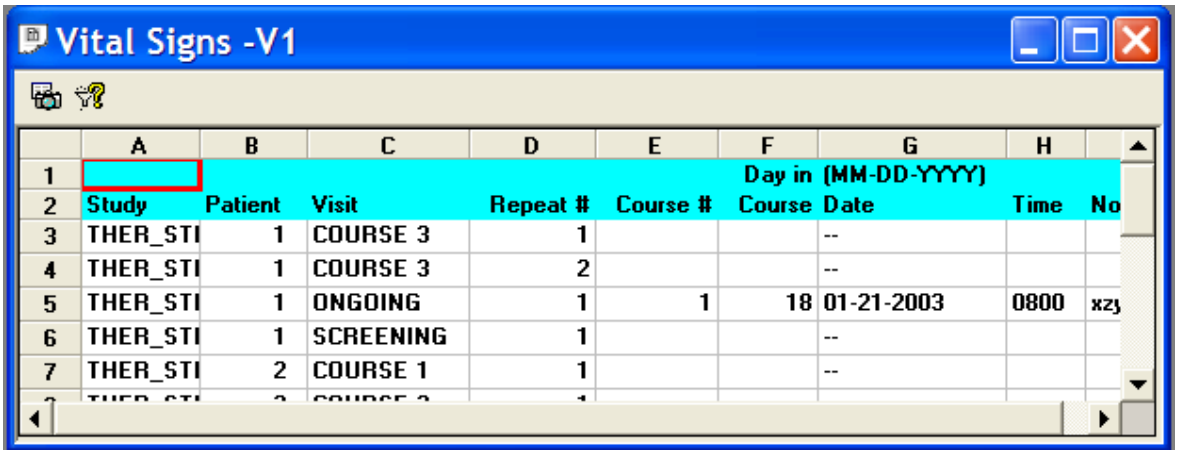
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
PE Done?	Whether the Physical Exam was Performed
Date of Examination	Date The Physical Examination Took Place (Format MM-DD-YYYY)
Date of Examination	Date The Physical Examination Took Place. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Change from Baseline?	Whether the Finding Results were Changed Compared with that of Baseline
Change from Previous Evaluation?	Whether the Finding Results were Changed Compared with the Previous Evaluation
Course Day	Number of Days Since The Beginning of The Course
Repeat #	The Repeat Sequence Number
Body System	Body System
Finding Results	Status of The Finding Result for The Corresponding Body System
Comments	Brief Description of The Change

Vital Signs –V1

Description

This report lists vital signs. It works on studies that are based on the 3.02 and 3.10 templates.



Access

User Level: Public

Study Level: CCR_Program

Columns

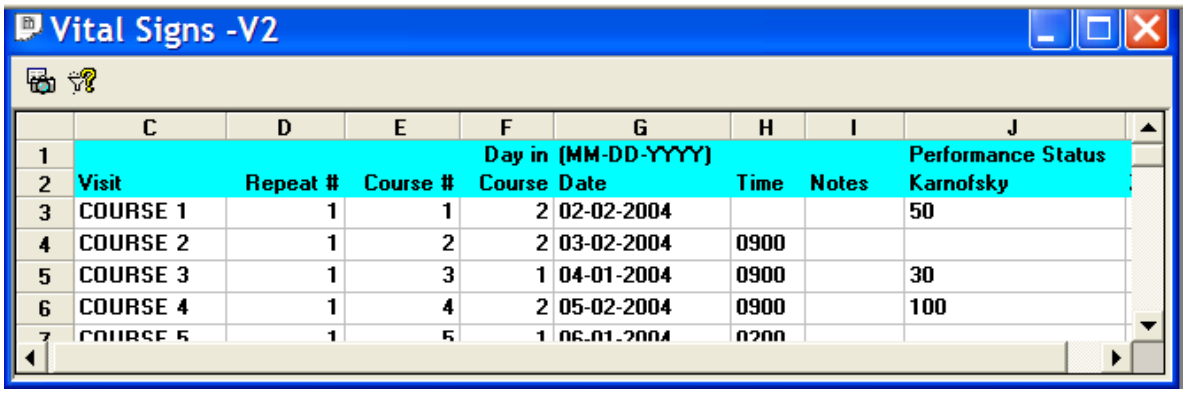
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Repeat #	The Repeat Sequence Number
Course #	The Course Which The Vital Sign Is Related To
Day in Course	Number of Days Since The Beginning of The Course The Vital Sign Is Related To
Date	Date The Vital Sign Were Taken (Format MM-DD-YYYY)
Time	Time The Vital Sign Were Taken
Notes	Brief Notes for The The Vital Sign
Karnofsky	Karnofsky Performance
Zubrod/ECOG	Zubrod/ECOG Performance
Height (cm)	Height in Centimeter
Weight (kg)	Weight in Kilogram
BSA	Body Surface Area
Temperature (celsius)	Temperature in Celsius
Pulse	Pulse Rate
Respiration Rate	Respiration Rate
Systolic BP	Systolic Blood Pressure

Diastolic BP	Diastolic Blood Pressure
Date	Date The Vital Sign Were Taken. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Vital Signs –V2

Description

This report lists vital signs. It works on studies that are based on the 3.12 template. It works on studies that are based on the 3.12 and 2007R1 templates.



	C	D	E	F	G	H	I	J
1				Day in	(MM-DD-YYYY)			Performance Status
2	Visit	Repeat #	Course #	Course	Date	Time	Notes	Karnofsky
3	COURSE 1	1	1	2	02-02-2004			50
4	COURSE 2	1	2	2	03-02-2004	0900		
5	COURSE 3	1	3	1	04-01-2004	0900		30
6	COURSE 4	1	4	2	05-02-2004	0900		100
7	COURSE 5	1	5	1	06-01-2004	0200		

Access

User Level: Public

Study Level: CCR_Program

Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Repeat #	The Repeat Sequence Number
Course #	The Course Which The Vital Sign Is Related To
Day in Course	Number of Days Since The Beginning of The Course The Vital Sign Is Related To
Date	Date The Vital Sign Were Taken (Format MM-DD-YYYY)
Time	Time The Vital Sign Were Taken
Notes	Brief Notes for The The Vital Sign
Karnofsky	Karnofsky Performance
Zubrod/ECOG	Zubrod/ECOG Performance
Lansky	Lansky Performance
Height (cm)	Height in Centimeter
Height (feet)	Height in Feet
Height (inches)	Height in Inch
Weight (kg)	Weight in Kilogram
Weight (pound)	Weight in Pound
BSA	Body Surface Area
Temperature (celsius)	Temperature in Celsius

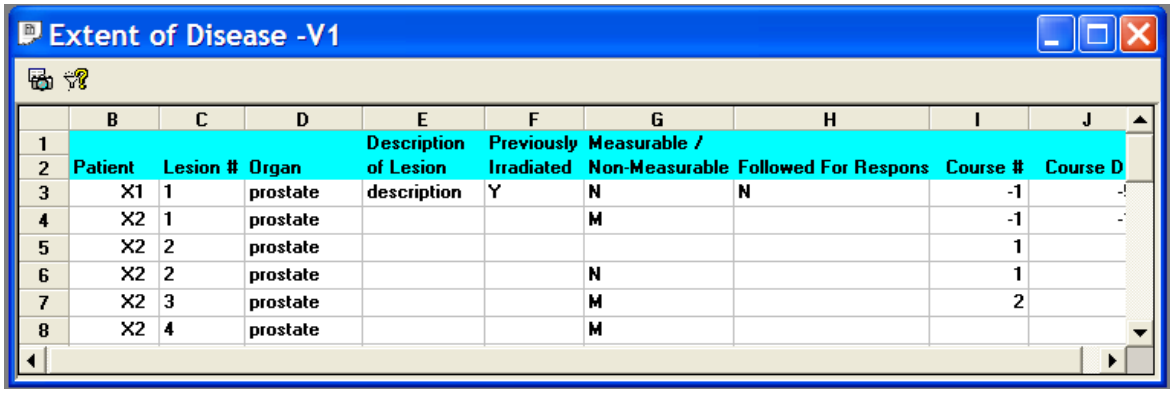
Temperature (fahrenheit)	Temperature in Fahrenheit
Pulse	Pulse Rate
Respiration Rate	Respiration Rate
Systolic BP	Systolic Blood Pressure
Diastolic BP	Diastolic Blood Pressure
Pulse Ox	Pulse Oximetry
Date	Date The Vital Sign Were Taken. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Extent of Disease Reports

Extent of Disease –V1

Description

This report lists extent of disease. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	I	J
1				Description	Previously	Measurable /			
2	Patient	Lesion #	Organ	of Lesion	Irradiated	Non-Measurable	Followed For Respons	Course #	Course D
3	X1	1	prostate	description	Y	N	N	-1	
4	X2	1	prostate			M		-1	
5	X2	2	prostate					1	
6	X2	2	prostate			N		1	
7	X2	3	prostate			M		2	
8	X2	4	prostate			M			

Access

User Level: Public

Study Level: CCR_Program

Columns

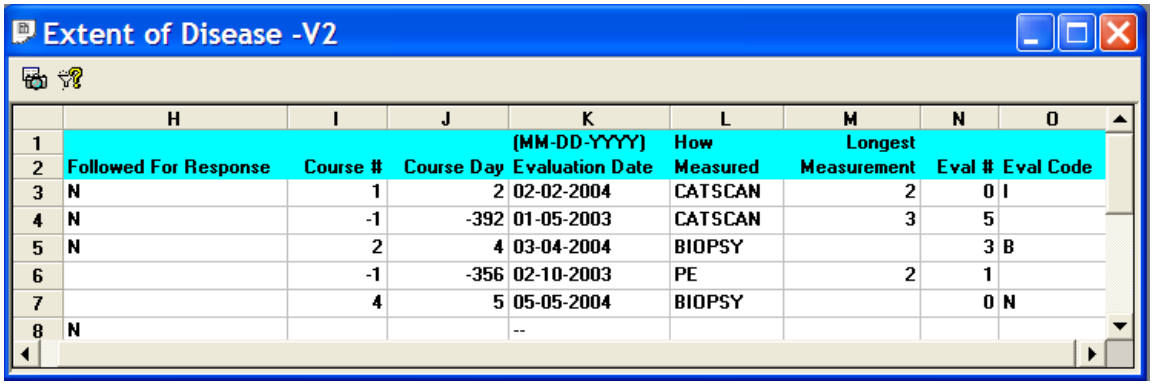
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Lesion #	The Unique Number for Each Lesion
Organ	The Organ System Where the Lesion Is Located
Description of Lesion	The Brief Description of the Anatomical Site of Each Lesion
Previously Irradiated	Whether the Site or Lesion Has Been Previously Irradiated
Measurable / Non-Measurable	The Lesion Is Measurable or Non- Measurable
Followed For Response	Whether the Lesion Will Be Assessed for Response
Course #	The Course Number That the Lesion Evaluation Was done
Course Day	The Day Since the Beginning of Course That the Lesion Evaluation Was done
Evaluation Date	Date of the Evaluation (Format MM-DD-YYYY)
How Measured	How the Lesion Measurement Was Determined
Longest	The Longest Lesion Measurement in Centimeters

Measurement	
Second Measurement	The Second Longest Lesion Measurement in Centimeters
Eval #	The Sequential Number of Each Lesion
Eval Code	Status of the Lesion at the Time of Each Evaluation
Evaluation Date	Date of the Evaluation. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Extent of Disease –V2

Description

This report lists extent of disease. It works on studies that are based on the 3.12 template.



	H	I	J	K	L	M	N	O
1				(MM-DD-YYYY)	How	Longest		
2	Followed For Response	Course #	Course Day	Evaluation Date	Measured	Measurement	Eval #	Eval Code
3	N	1	2	02-02-2004	CATSCAN	2	0	I
4	N	-1	-392	01-05-2003	CATSCAN	3	5	
5	N	2	4	03-04-2004	BIOPSY		3	B
6		-1	-356	02-10-2003	PE	2	1	
7		4	5	05-05-2004	BIOPSY		0	N
8	N			--				

Access

User Level: Public

Study Level: CCR_Program

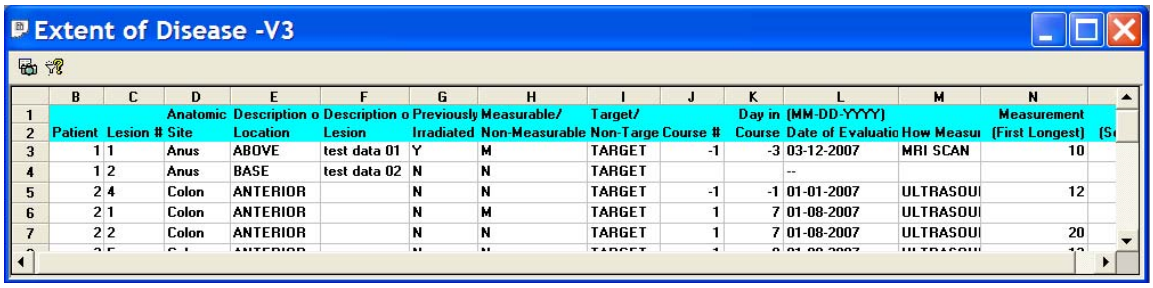
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Lesion #	The Unique Number for Each Lesion
Organ	The Organ System Where the Lesion Is Located
Description of Lesion	The Brief Description of the Anatomical Site of Each Lesion
Previously Irradiated	Whether the Site or Lesion Has Been Previously Irradiated
Measurable / Non-Measurable	The Lesion Is Measurable or Non- Measurable
Followed For Response	Whether the Lesion Will Be Assessed for Response
Course #	The Course Number That the Lesion Evaluation Was done
Course Day	The Day Since the Beginning of Course That the Lesion Evaluation Was done
Evaluation Date	Date of the Evaluation (Format MM-DD-YYYY)
How Measured	How the Lesion Measurement Was Determined
Longest Measurement	The Longest Lesion Measurement in Centimeters
Eval #	The Sequential Number of Each Lesion
Eval Code	Status of the Lesion at the Time of Each Evaluation
Evaluation Date	Date of the Evaluation. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Extent of Disease –V3

Description

This report lists extent of disease. It works on studies that are based on the 2007R1 template.



	B	C	D	E	F	G	H	I	J	K	L	M	N
1			Anatomic	Description o	Description o	Previously	Measurable/	Target/		Day in	(MM-DD-YYYY)		Measurement
2	Patient	Lesion #	Site	Location	Lesion	Irradiated	Non-Measurable	Non-Targe	Course #	Course	Date of Evaluatio	How Measu	(First Longest)
3	1	1	Anus	ABOVE	test data 01	Y	M	TARGET	-1	-3	03-12-2007	MRI SCAN	10
4	1	2	Anus	BASE	test data 02	N	N	TARGET			--		
5	2	4	Colon	ANTERIOR		N	N	TARGET	-1	-1	01-01-2007	ULTRASOU	12
6	2	1	Colon	ANTERIOR		N	M	TARGET	1	7	01-08-2007	ULTRASOU	
7	2	2	Colon	ANTERIOR		N	N	TARGET	1	7	01-08-2007	ULTRASOU	20

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Lesion #	The Unique Number for Each Lesion
Anatomic Site	The Anatomic Position of the Lesion
Description of Location	The Brief Description of Lesion Location
Description of Lesion	The Brief Description of Each Lesion
Previously Irradiated	Whether the Site or Lesion Has Been Previously Irradiated
Measurable / Non-Measurable	The Lesion Is Measurable or Non- Measurable
Targer/Non-Target	Whether the Lesion Will Be Assessed for Response
Course #	The Course Number That the Lesion Evaluation Was done
Course Day	The Day Since the Beginning of Course That the Lesion Evaluation Was done
Evaluation Date	Date of the Evaluation (Format MM-DD-YYYY)
How Measured	How the Lesion Measurement Was Determined
Longest Measurement	The Longest Lesion Measurement in Centimeters
Second Longest Measurement	The Second Longest Lesion Measurement in Centimeters
Third Longest Measurement	The Longest Lesion Measurement in Centimeters
Product	The Tumor Product
Total Tumor Volume	The Total Tumor Volume
Eval #	The Sequential Number of Each Lesion

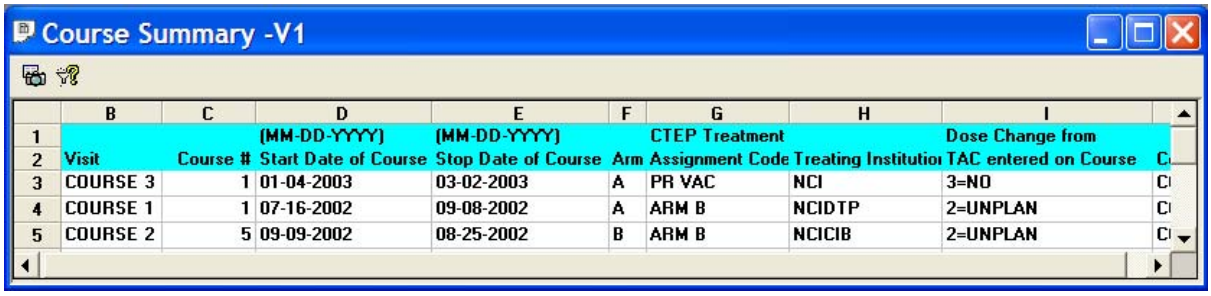
Eval Code	Status of the Lesion at the Time of Each Evaluation
Evaluation Date	Date of the Evaluation. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Course Assessment Reports

Course Summary –V1

Description

This report lists course initiation and course assessment. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	I
1			(MM-DD-YYYY)	(MM-DD-YYYY)		CTEP Treatment		Dose Change from
2	Visit	Course #	Start Date of Course	Stop Date of Course	Arm	Assignment Code	Treating Institutio	TAC entered on Course
3	COURSE 3	1	01-04-2003	03-02-2003	A	PR VAC	NCI	3=NO
4	COURSE 1	1	07-16-2002	09-08-2002	A	ARM B	NCIDTP	2=UNPLAN
5	COURSE 2	5	09-09-2002	08-25-2002	B	ARM B	NCICIB	2=UNPLAN

Access

User Level: Public

Study Level: CCR_Program

Columns

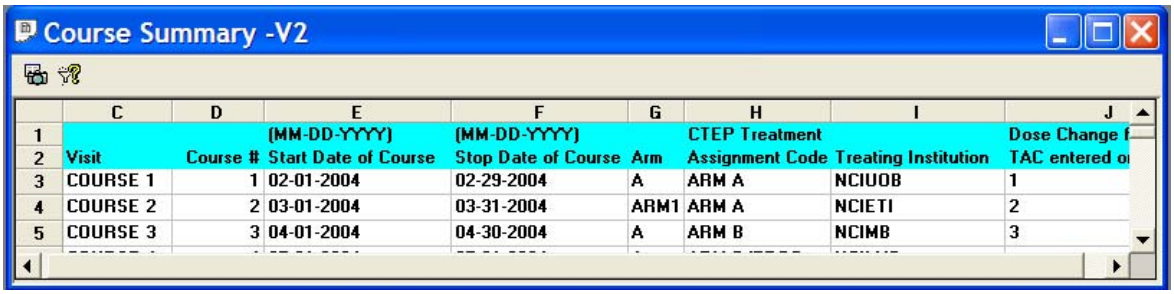
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Course #	The Course Number
Start Date of Course	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Stop Date of Course	Date the Course (Cycle) End (Format MM-DD-YYYY)
Arm	The 'Arm' of the Protocol-Specific Treatment Regimen the Patient Is to Receive
CTEP Treatment Assignment Code	The Appropriate Treatment Assignment Code (TAC) for the Regimen and Dose Level of This Course
Treating Institution	The Unique CTEP Institution Code Where the Patient Actually Receives This Course of Treatment
Dose Change from TAC entered on Course	Whether the Patient's Treatment was Different form that Specified by the Treatment Assignment Code for This Course
Course Disposition	Whether the Course Has Been Conducted
Response Assessment	Patient's Best Disease State as Assessed During the Course
Response Notes	The Reason for the Assessment
Response Onset	Date of the Earliest Evaluation Justifies Assessment (Format MM-DD-YYYY)
Progression Onset	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease (Format MM-DD-YYYY)
Any AEs in this Course?	Whether Adverse Event Has Occurred During the Course

Start Date of Course	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date of Course	Date the Course (Cycle) End. The Original Value Used by System (Form YYYYMMDD)

Course Summary –V2

Description

This report lists course initiation and course assessment. It works on studies that are based on the 3.12 template.



	C	D	E	F	G	H	I	J
1			(MM-DD-YYYY)	(MM-DD-YYYY)		CTEP Treatment		Dose Change f
2	Visit	Course #	Start Date of Course	Stop Date of Course	Arm	Assignment Code	Treating Institution	TAC entered o
3	COURSE 1	1	02-01-2004	02-29-2004	A	ARM A	NCIUOB	1
4	COURSE 2	2	03-01-2004	03-31-2004	ARM1	ARM A	NCIETI	2
5	COURSE 3	3	04-01-2004	04-30-2004	A	ARM B	NCIMB	3

Access

User Level: Public

Study Level: CCR_Program

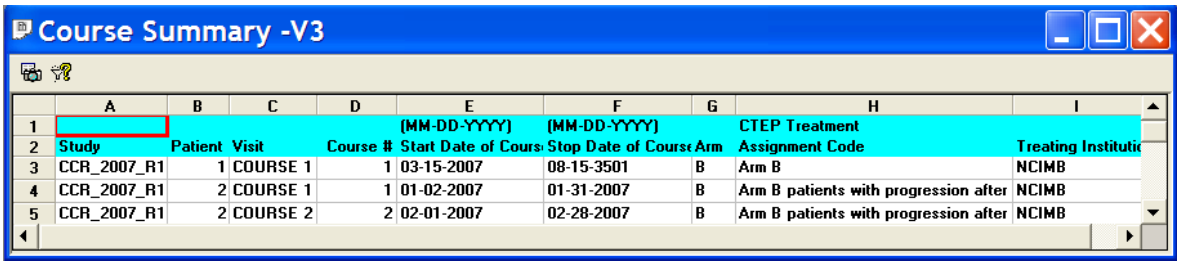
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Course #	The Course Number
Start Date of Course	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Stop Date of Course	Date the Course (Cycle) End (Format MM-DD-YYYY)
Arm	The 'Arm' of the Protocol-Specific Treatment Regimen the Patient Is to Receive
CTEP Treatment Assignment Code	The Appropriate Treatment Assignment Code (TAC) for the Regimen and Dose Level of This Course
Treating Institution	The Unique CTEP Institution Code Where the Patient Actually Receives This Course of Treatment
Dose Change from TAC entered on Course	Whether the Patient's Treatment was Different form that Specified by the Treatment Assignment Code for This Course
Course Disposition	Whether the Course Has Been Conducted
Response Assessment	Patient's Best Disease State as Assessed During the Course
Response Notes	The Reason for the Assessment
Date of Response	Date of the Earliest Evaluation Justifies Assessment (Format MM-DD-YYYY)
Date of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease (Format MM-DD-YYYY)
Any AEs in this Course?	Whether Adverse Event Has Occurred During the Course
Start Date of Course	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date of Course	Date the Course (Cycle) End. The Original Value Used by System (Form YYYYMMDD)

Course Summary –V3

Description

This report lists course initiation and course assessment. It works on studies that are based on the 2007R1 template.



	A	B	C	D	E	F	G	H	I
1					(MM-DD-YYYY)	(MM-DD-YYYY)		CTEP Treatment	
2	Study	Patient	Visit	Course #	Start Date of Cours	Stop Date of Course	Arm	Assignment Code	Treating Institutio
3	CCR_2007_R1	1	COURSE 1	1	03-15-2007	08-15-3501	B	Arm B	NCIMB
4	CCR_2007_R1	2	COURSE 1	1	01-02-2007	01-31-2007	B	Arm B patients with progression after	NCIMB
5	CCR_2007_R1	2	COURSE 2	2	02-01-2007	02-28-2007	B	Arm B patients with progression after	NCIMB

Access

User Level: Public

Study Level: CCR 2007R1 STD

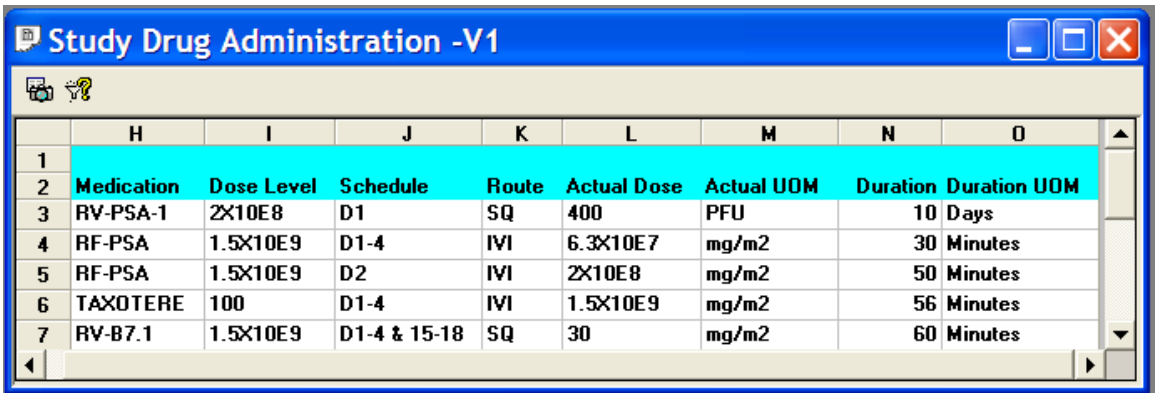
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
Course #	The Course Number
Start Date of Course	Date the Course (Cycle) Began (Format MM-DD-YYYY)
Stop Date of Course	Date the Course (Cycle) End (Format MM-DD-YYYY)
Arm	The 'Arm' of the Protocol-Specific Treatment Regimen the Patient Is to Receive
CTEP Treatment Assignment Code	The Appropriate Treatment Assignment Code (TAC) for the Regimen and Dose Level of This Course
Treating Institution	The Unique CTEP Institution Code Where the Patient Actually Receives This Course of Treatment
Dose Change from TAC entered on Course	Whether the Patient's Treatment was Different form that Specified by the Treatment Assignment Code for This Course
Course Disposition	Whether the Course Has Been Conducted
Response Assessment	Patient's Best Disease State as Assessed During the Course
Response Notes	The Reason for the Assessment
Date of Response	Date of the Earliest Evaluation Justifies Assessment (Format MM-DD-YYYY)
Date of Progression	Date of the Evaluation to Determine the Patient's Disease Status of Progressive Disease (Format MM-DD-YYYY)
Any AEs in this Course?	Whether Adverse Event Has Occurred During the Course
Start Date of Course	Date the Course (Cycle) Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date of Course	Date the Course (Cycle) End. The Original Value Used by System (Form YYYYMMDD)

Study Drug Administration –V1

Description

This report lists study drug administration information. It works on studies that are based on the 3.02 and 3.10 templates.



	H	I	J	K	L	M	N	O
1								
2	Medication	Dose Level	Schedule	Route	Actual Dose	Actual UOM	Duration	Duration UOM
3	RV-PSA-1	2X10E8	D1	SQ	400	PFU	10	Days
4	RF-PSA	1.5X10E9	D1-4	IVI	6.3X10E7	mg/m2	30	Minutes
5	RF-PSA	1.5X10E9	D2	IVI	2X10E8	mg/m2	50	Minutes
6	TAXOTERE	100	D1-4	IVI	1.5X10E9	mg/m2	56	Minutes
7	RV-B7.1	1.5X10E9	D1-4 & 15-18	SQ	30	mg/m2	60	Minutes

Access

User Level: Public

Study Level: CCR_Program

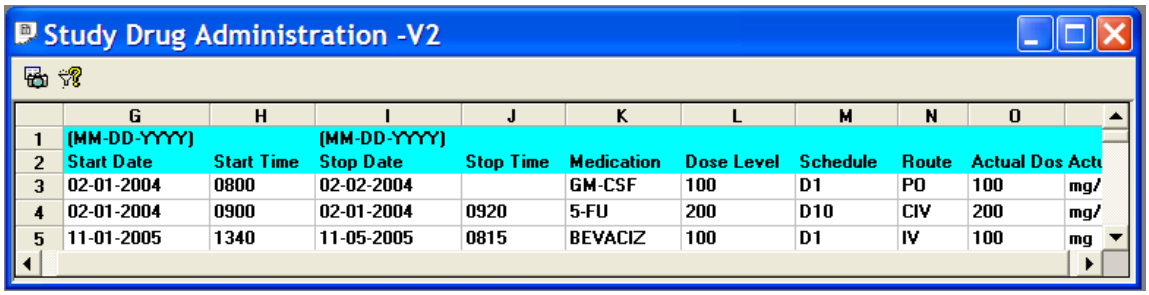
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
MRN	Patient' Local Identifier Used by the Treating Institution
Initials	Patient Initials
Visit	Clinical Event
Course Day	Number of Days Since The Beginning of The Course The Drug Given Is Related To
Start Date	Date the Medication Was Administrated (Format MM-DD-YYYY)
Medication	Name of the Drug
Dose Level	The Planned Amount of Medication
Schedule	Medication Schedule Indicated In the Protocol
Route	Route the Medication Given
Actual Dose	The Total Actual Dose Given for the Medication by the Time Period Indicated
Actual UOM	The Actual Dose Level Unit of Measurement
Duration	Time Period the Medication Given
Duration UOM	Unit of Measurement for The Time Period Duration
Start Date	Date the Medication Was Administrated. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Study Drug Administration –V2

Description

This report lists study drug administration information. It works on studies that are based on the 3.12 template.



	G	H	I	J	K	L	M	N	O	
1	(MM-DD-YYYY)		(MM-DD-YYYY)							
2	Start Date	Start Time	Stop Date	Stop Time	Medication	Dose Level	Schedule	Route	Actual Dos	Actu
3	02-01-2004	0800	02-02-2004		GM-CSF	100	D1	PO	100	mg/
4	02-01-2004	0900	02-01-2004	0920	5-FU	200	D10	CIV	200	mg/
5	11-01-2005	1340	11-05-2005	0815	BEVACIZ	100	D1	IV	100	mg

Access

User Level: Public

Study Level: CCR_Program

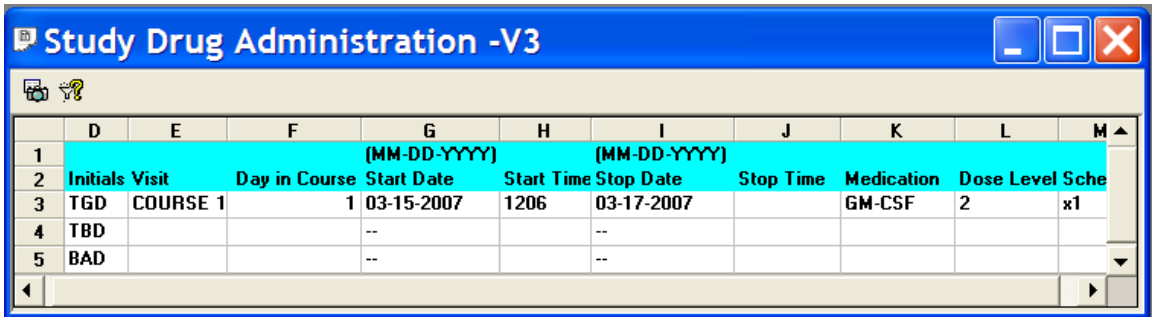
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
MRN	Patient' Local Identifier Used by the Treating Institution
Initials	Patient Initials
Visit	Clinical Event
Day in Course	Number of Days Since The Beginning of The Course The Drug Given Is Related To
Start Date	Date the Medication Was Administrated (Format MM-DD-YYYY)
Start Time	Time the Medication Was Administrated
Stop Date	Date the Medication Was Discontinued (Format MM-DD-YYYY)
Stop Time	Time the Medication Was Discontinued
Medication	Name of the Drug
Dose Level	The Planned Amount of Medication
Schedule	Medication Schedule Indicated In the Protocol
Route	Route the Medication Given
Actual Dose	The Total Actual Dose Given for the Medication by the Time Period Indicated
Actual UOM	The Actual Dose Level Unit of Measurement
Duration	Time Period the Medication Given
Duration UOM	Unit of Measurement for The Time Period Duration
Start Date	Date the Medication Was Administrated. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Study Drug Administration –V3

Description

This report lists study drug administration information. It works on studies that are based on the 2007R1 template.



	D	E	F	G	H	I	J	K	L	M
1				(MM-DD-YYYY)		(MM-DD-YYYY)				
2	Initials	Visit	Day in Course	Start Date	Start Time	Stop Date	Stop Time	Medication	Dose Level	Sche
3	TGD	COURSE 1	1	03-15-2007	1206	03-17-2007		GM-CSF	2	x1
4	TBD			--		--				
5	BAD			--		--				

Access

User Level: Public

Study Level: CCR 2007R1 STD

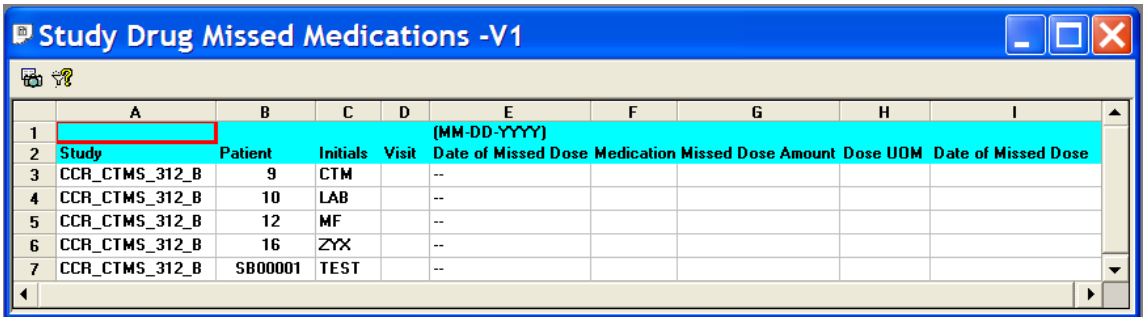
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
MRN	Patient' Local Identifier Used by the Treating Institution
Initials	Patient Initials
Visit	Clinical Event
Day in Course	Number of Days Since The Beginning of The Course The Drug Given Is Related To
Start Date	Date the Medication Was Administrated (Format MM-DD-YYYY)
Start Time	Time the Medication Was Administrated
Stop Date	Date the Medication Was Discontinued (Format MM-DD-YYYY)
Stop Time	Time the Medication Was Discontinued
Medication	Name of the Drug
Dose Level	The Planned Amount of Medication
Schedule	Medication Schedule Indicated In the Protocol
Route	Route the Medication Given
Actual Dose	The Total Actual Dose Given for the Medication by the Time Period Indicated
Actual UOM	The Actual Dose Level Unit of Measurement
Duration	Time Period the Medication Given
Duration UOM	Unit of Measurement for The Time Period Duration
Start Date	Date the Medication Was Administrated. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Missed Medication –V1

Description

This report lists missed medications. It works on studies that are based on the 3.12 template.



	A	B	C	D	E	F	G	H	I
1					(MM-DD-YYYY)				
2	Study	Patient	Initials	Visit	Date of Missed Dose	Medication	Missed Dose Amount	Dose UOM	Date of Missed Dose
3	CCR_CTMS_312_B	9	CTM		--				
4	CCR_CTMS_312_B	10	LAB		--				
5	CCR_CTMS_312_B	12	MF		--				
6	CCR_CTMS_312_B	16	ZYX		--				
7	CCR_CTMS_312_B	SB00001	TEST		--				

Access

User Level: Public

Study Level: CCR_Program

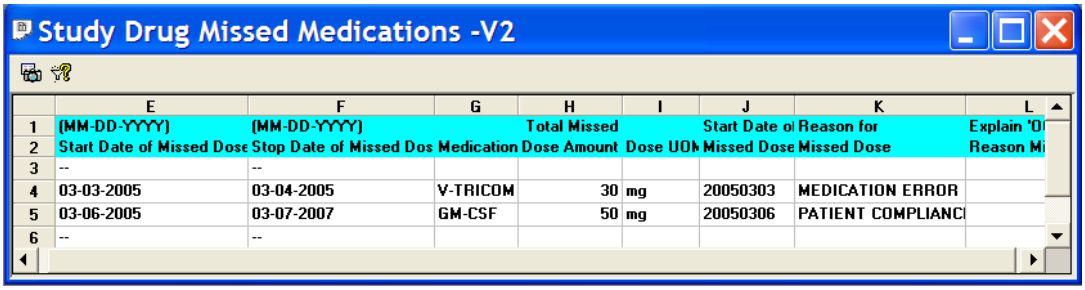
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Initials	Patient Initials
Visit	Clinical Event
Date of Missed Dose	Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Medication	Name of the Missed Drug
Missed Dose Amount	The Actual Amount of Medication Missed
Dose UOM	Missed Dose Amount Unit of Measurement
Date of Missed Dose	Date the Medication Was Not Administrated. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Missed Medication –V2

Description

This report lists missed medications. It works on studies that are based on the 2007R1 template.



	E	F	G	H	I	J	K	L
1	(MM-DD-YYYY)	(MM-DD-YYYY)		Total Missed		Start Date o	Reason for	Explain 'O
2	Start Date of Missed Dose	Stop Date of Missed Dos	Medication	Dose Amount	Dose UOM	Missed Dose	Missed Dose	Reason Mi
3	--	--						
4	03-03-2005	03-04-2005	V-TRICOM	30	mg	20050303	MEDICATION ERROR	
5	03-06-2005	03-07-2007	GM-CSF	50	mg	20050306	PATIENT COMPLIANCI	
6	--	--						

Access

User Level: Public

Study Level: CCR 2007R1 STD

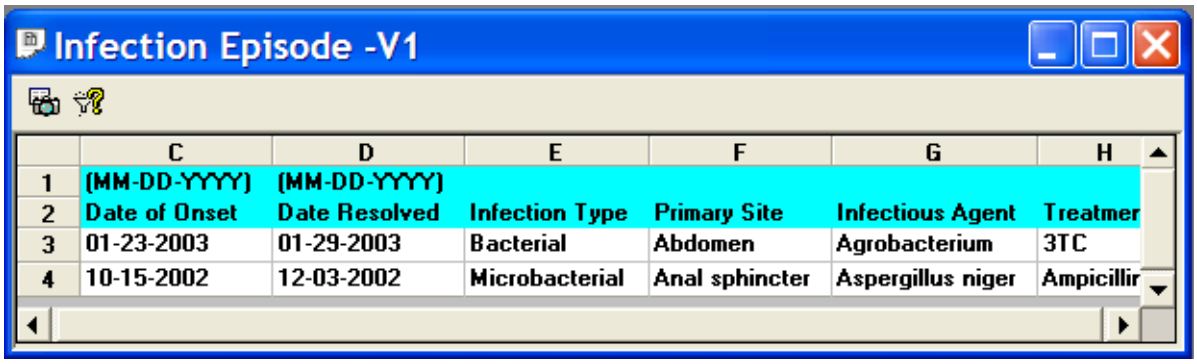
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Initials	Patient Initials
Visit	Clinical Event
Start Date of Missed Dose	Start Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Stop Date of Missed Dose	Stop Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Medication	Name of the Missed Drug
Total Missed Dose Amount	The Actual Amount of Medication Missed
Dose UOM	Missed Dose Amount Unit of Measurement
Start Date of Missed Dose	Start Date the Medication Was Not Administrated. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Reason for Missed Dose	Reason for Missed Dose Entered
Explain 'Other' Reason Missed	The Explanation for 'Other' Reason for Missed Dose

Infection Episode –V1

Description

This report lists infection episodes. It works on studies that are based on the 3.02 and 3.10 templates.



Access

User Level: Public

Study Level: CCR_Program

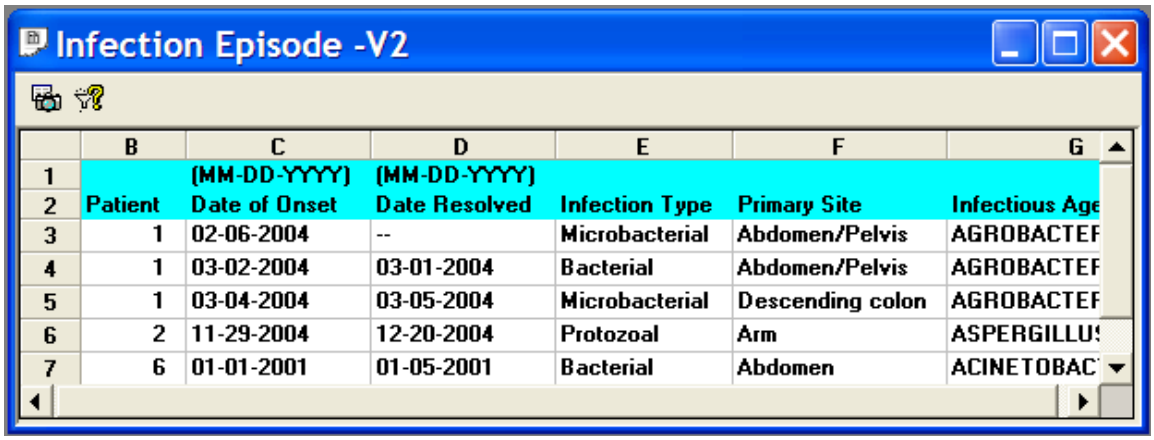
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Onset	Date the Infection Episode Began (Format MM-DD-YYYY)
Date Resolved	Date the Infection Episode Resolved (Format MM-DD-YYYY)
Infection Type	Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Primary Site	Primary Site of the Infection
Infectious Agent	The Actual Infectious Agent
Treatment	The Treatment (or Lack of) Given for the Infection
Outcome	Outcome of the Infection
Date of Onset	Date the Infection Episode Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date the Infection Episode Resolved . The Original Value Used by System (Form YYYYMMDD)

Infection Episode -V2

Description

This report lists infection episodes. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G
1		(MM-DD-YYYY)	(MM-DD-YYYY)			
2	Patient	Date of Onset	Date Resolved	Infection Type	Primary Site	Infectious Age
3	1	02-06-2004	--	Microbacterial	Abdomen/Pelvis	AGROBACTEF
4	1	03-02-2004	03-01-2004	Bacterial	Abdomen/Pelvis	AGROBACTEF
5	1	03-04-2004	03-05-2004	Microbacterial	Descending colon	AGROBACTEF
6	2	11-29-2004	12-20-2004	Protozoal	Arm	ASPERGILLU
7	6	01-01-2001	01-05-2001	Bacterial	Abdomen	ACINETOBAC

Access

User Level: Public

Study Level: CCR_Program

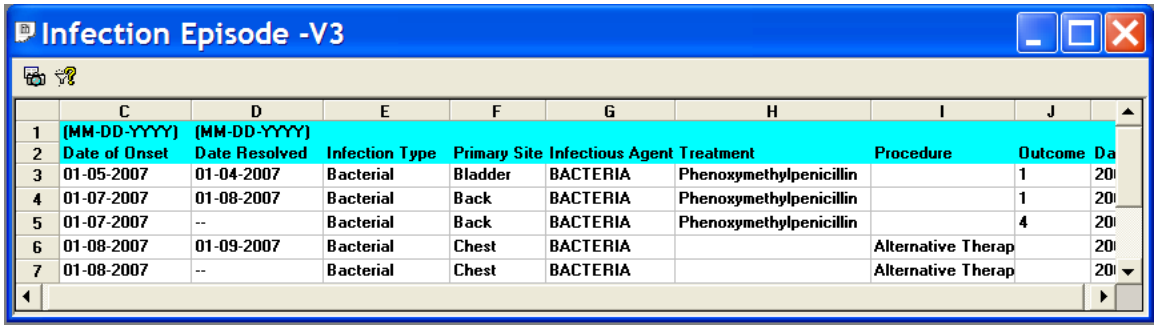
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Onset	Date the Infection Episode Began (Format MM-DD-YYYY)
Date Resolved	Date the Infection Episode Resolved (Format MM-DD-YYYY)
Infection Type	Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Primary Site	Primary Site of the Infection
Infectious Agent	The Actual Infectious Agent
Treatment	The Treatment (or Lack of) Given for the Infection
Procedure	The Procedure Done for the Infection
Outcome	Outcome of the Infection
Date of Onset	Date the Infection Episode Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date the Infection Episode Resolved. The Original Value Used by System (Form YYYYMMDD)

Infection Episode –V3

Description

This report lists infection episodes. It works for studies based on the 2007R1 template.



	C	D	E	F	G	H	I	J	
1	(MM-DD-YYYY)	(MM-DD-YYYY)							
2	Date of Onset	Date Resolved	Infection Type	Primary Site	Infectious Agent	Treatment	Procedure	Outcome	Da
3	01-05-2007	01-04-2007	Bacterial	Bladder	BACTERIA	Phenoxymethylpenicillin		1	20
4	01-07-2007	01-08-2007	Bacterial	Back	BACTERIA	Phenoxymethylpenicillin		1	20
5	01-07-2007	--	Bacterial	Back	BACTERIA	Phenoxymethylpenicillin		4	20
6	01-08-2007	01-09-2007	Bacterial	Chest	BACTERIA		Alternative Therap		20
7	01-08-2007	--	Bacterial	Chest	BACTERIA		Alternative Therap		20

Access

User Level: Public

Study Level: CCR 2007R1 STD

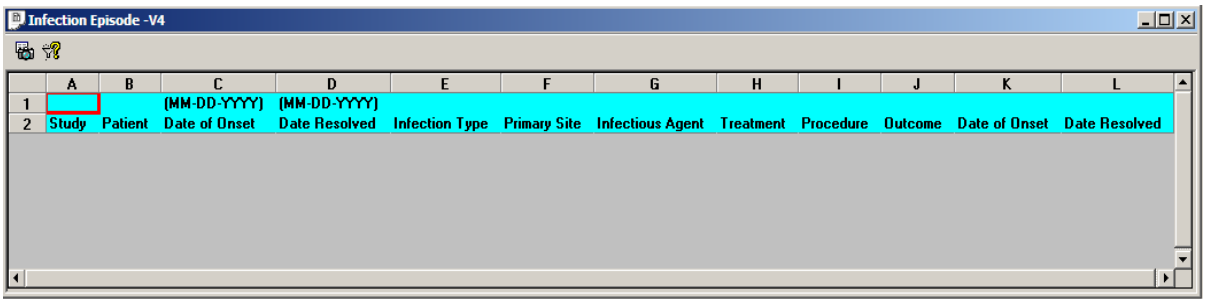
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Onset	Date the Infection Episode Began (Format MM-DD-YYYY)
Date Resolved	Date the Infection Episode Resolved (Format MM-DD-YYYY)
Infection Type	Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Primary Site	Primary Site of the Infection
Infectious Agent	The Actual Infectious Agent
Treatment	The Treatment (or Lack of) Given for the Infection
Procedure	The Procedure Done for the Infection
Outcome	Outcome of the Infection
Date of Onset	Date the Infection Episode Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date the Infection Episode Resolved. The Original Value Used by System (Form YYYYMMDD)

Infection Episode –V4

Description

This report lists infection episodes. It works for studies based on the 2008V1 template.



Access

User Level: Public

Study Level: CCR 2008V1 STD

Columns

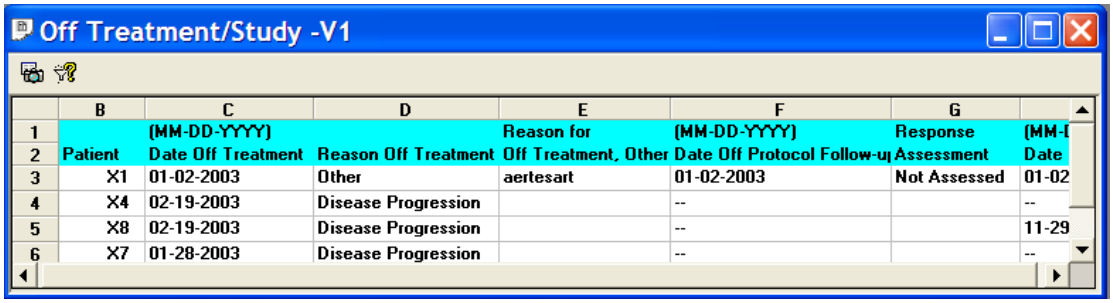
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Onset	Date the Infection Episode Began (Format MM-DD-YYYY)
Date Resolved	Date the Infection Episode Resolved (Format MM-DD-YYYY)
Infection Type	Date the Medication Was Not Administrated (Format MM-DD-YYYY)
Primary Site	Primary Site of the Infection
Infectious Agent	The Actual Infectious Agent
Treatment	The Treatment (or Lack of) Given for the Infection
Procedure	The Procedure Done for the Infection
Outcome	Outcome of the Infection
Date of Onset	Date the Infection Episode Began. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Date Resolved	Date the Infection Episode Resolved. The Original Value Used by System (Form YYYYMMDD)

Off Treatment Off Study Reports

Off Treatment/Off Study -V1

Description

This report lists the off treatment/study summary. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	
1		(MM-DD-YYYY)		Reason for	(MM-DD-YYYY)	Response	(MM-D
2	Patient	Date Off Treatment	Reason Off Treatment	Off Treatment, Other	Date Off Protocol Follow-up	Assessment	Date
3	X1	01-02-2003	Other	aertesart	01-02-2003	Not Assessed	01-02
4	X4	02-19-2003	Disease Progression		--		--
5	X8	02-19-2003	Disease Progression		--		11-29
6	X7	01-28-2003	Disease Progression		--		--

Access

User Level: Public

Study Level: CCR_Program

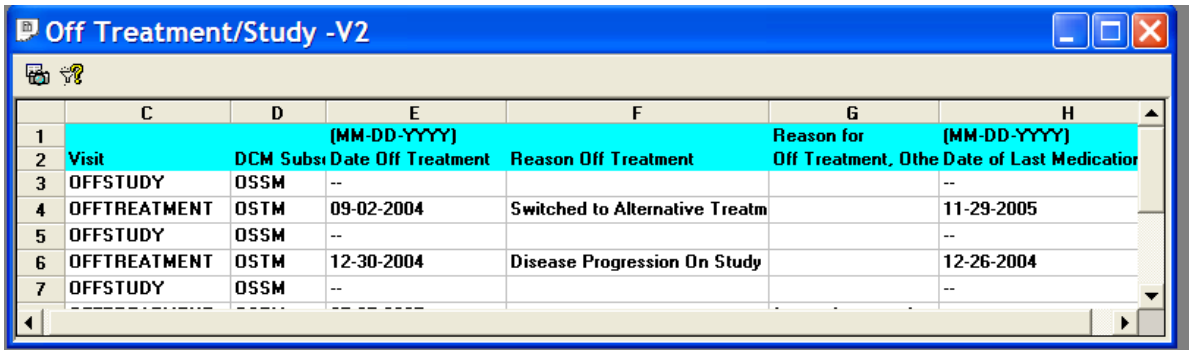
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Went Off Treatment
Reason for Off Treatment, Other	The Explanation of 'Other' for Reason Off Treatment
Date Off Protocol Follow-up	Date the Patient Completes or Is Removed from the Protocol-Specific Follow-up Phase (Format MM-DD-YYYY)
Response Assessment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began
Date of Progression	Date of The Progression (or Relapse) Was First Observed

Off Treatment/Off Study –V2

Description

This report lists the off treatment/study summary. It works on studies that are based on the 3.12 template.



	C	D	E	F	G	H
1			(MM-DD-YYYY)		Reason for	(MM-DD-YYYY)
2	Visit	DCM Subs	Date Off Treatment	Reason Off Treatment	Off Treatment, Othe	Date of Last Medicatior
3	OFFSTUDY	OSSM	--			--
4	OFFTREATMENT	OSTM	09-02-2004	Switched to Alternative Treatm		11-29-2005
5	OFFSTUDY	OSSM	--			--
6	OFFTREATMENT	OSTM	12-30-2004	Disease Progression On Study		12-26-2004
7	OFFSTUDY	OSSM	--			--

Access

User Level: Public

Study Level: CCR_Program

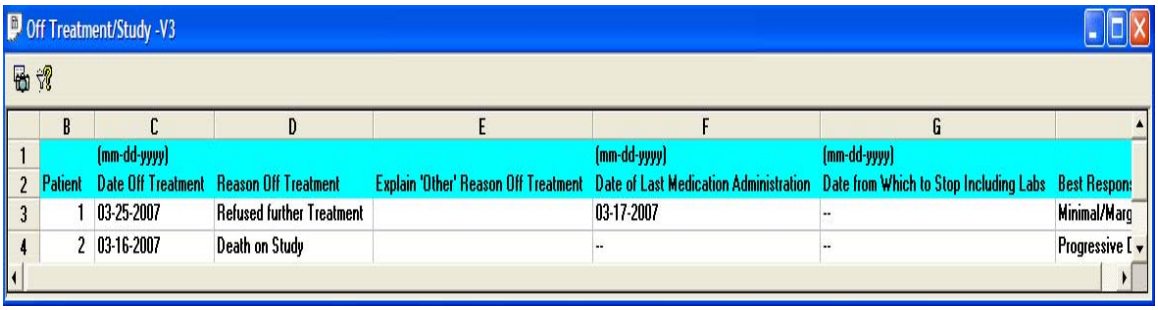
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Went Off Treatment
Reason for Off Treatment, Other	The Explanation of 'Other' for Reason Off Treatment
Date of Last Medication Adm	Date the Last Medication Was Administrated (Format MM-DD-YYYY)
Date from Which to Stop Including Labs	Date the Lab Data Stops Being Loaded
Response Assessment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began
Date of Disease Progression	Date of The Progression (or Relapse) Was First Observed
Date Off Study	Date the Patient Went Off Study (Format MM-DD-YYYY)
Reason Off Study	Reason the Patient Went Off Study
Reason for Off Study, Other	The Explanation of 'Other' for Reason Off Study

Off Treatment/Off Study –V3

Description

This report lists the off treatment/study summary. It works on studies that are based on the 2007R1 template.



	B	C	D	E	F	G	
1		(mm-dd-yyyy)			(mm-dd-yyyy)	(mm-dd-yyyy)	
2	Patient	Date Off Treatment	Reason Off Treatment	Explain 'Other' Reason Off Treatment	Date of Last Medication Administration	Date from Which to Stop Including Labs	Best Respons
3	1	03-25-2007	Refused further Treatment		03-17-2007	--	Minimal/Marg
4	2	03-16-2007	Death on Study		--	--	Progressive D

Access

User Level: Public

Study Level: CCR 2007R1 STD

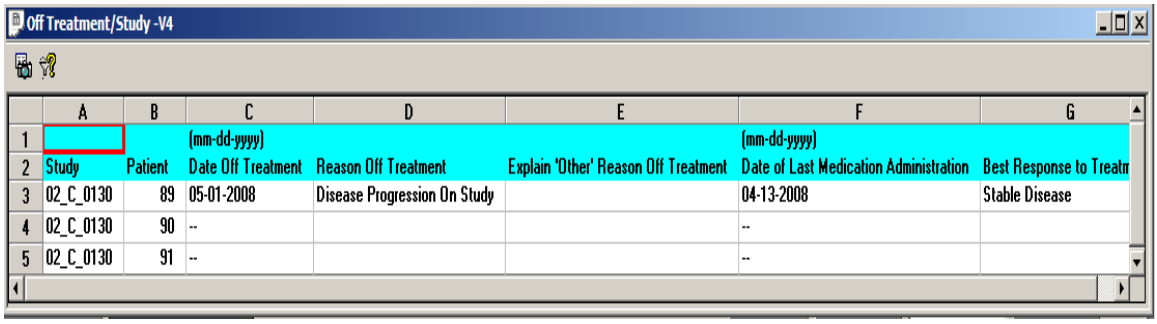
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Went Off Treatment
Explain 'Other' Reason for Off Treatment, Other	The Explanation of 'Other' for Reason Off Treatment
Date of Last Medication Administration	Date the Last Medication Was Administrated (Format MM-DD-YYYY)
Date from Which to Stop Including Labs	Date the Lab Data Stops Being Loaded
Best Response to Treatment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began (Format MM-DD-YYYY)
Date of Disease Progression	Date of The Progression (or Relapse) Was First Observed (Format MM-DD-YYYY)
Date Off Study	Date the Patient Went Off Study (Format MM-DD-YYYY)
Reason Off Study	Reason the Patient Went Off Study
Explain 'Other' Reason	The Explanation of 'Other' for Reason Off Study
Off Study Date of Disease Progression	

Off Treatment/Off Study –V4

Description

This report lists the off treatment/study summary. It works on studies that are based on the 2008V1 template.



	A	B	C	D	E	F	G
1			(mm-dd-yyyy)			(mm-dd-yyyy)	
2	Study	Patient	Date Off Treatment	Reason Off Treatment	Explain 'Other' Reason Off Treatment	Date of Last Medication Administration	Best Response to Treatm
3	02_C_0130	89	05-01-2008	Disease Progression On Study		04-13-2008	Stable Disease
4	02_C_0130	90	--			--	
5	02_C_0130	91	--			--	

Access

User Level: Public

Study Level: CCR 2008V1 STD

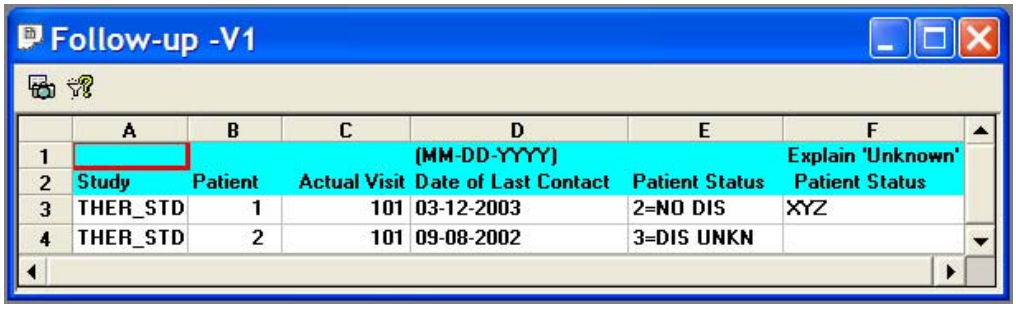
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Date Off Treatment	Date the Patient Completes All Courses or Is Discontinued (Format MM-DD-YYYY)
Reason Off Treatment	Reason the Patient Went Off Treatment
Explain 'Other' Reason for Off Treatment, Other	The Explanation of 'Other' for Reason Off Treatment
Date of Last Medication Administration	Date the Last Medication Was Administrated (Format MM-DD-YYYY)
Best Response to Treatment	The Best Overall Response to Treatment While on Protocol
Date of Best Response	Date of Treatment Response Was First Observed or Began (Format MM-DD-YYYY)
Date of Disease Progression	Date of The Progression (or Relapse) Was First Observed (Format MM-DD-YYYY)
Date Off Study	Date the Patient Went Off Study (Format MM-DD-YYYY)
Reason Off Study	Reason the Patient Went Off Study
Explain 'Other' Reason	The Explanation of 'Other' for Reason Off Study
Off Study Date of Disease Progression	

Follow-up –V1

Description

This report lists the off treatment/study summary. It works on studies that are based on the 3.02 and 3.10 templates.



	A	B	C	D	E	F
1				(MM-DD-YYYY)		Explain 'Unknown'
2	Study	Patient	Actual Visit	Date of Last Contact	Patient Status	Patient Status
3	THER_STD	1	101	03-12-2003	2=NO DIS	XYZ
4	THER_STD	2	101	09-08-2002	3=DIS UNKN	

Access

User Level: Public

Study Level: CCR_Program

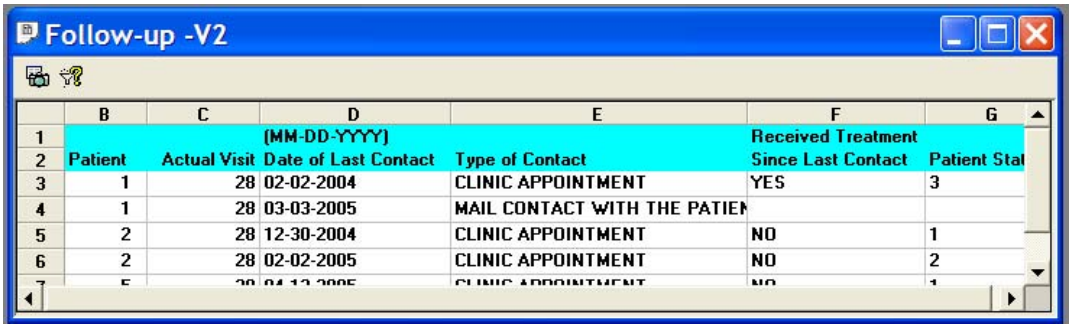
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Actual Visit	Actual Clinical Event Number
Date of Last Contact	Date the Patient Was Last Contacted (Format MM-DD-YYYY)
Patient Status	Patient's Last Known Status
Explain 'Unknown' Patient Status	The Explanation of 'Unknown' for Patient Status
Date of Last Contact	Date the Patient Was Last Contacted. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Follow-up -V2

Description

This report lists the off treatment/study summary. It works on studies that are based on the 3.12 and 2007R1 template.



	B	C	D	E	F	G
1			(MM-DD-YYYY)		Received Treatment	
2	Patient	Actual Visit	Date of Last Contact	Type of Contact	Since Last Contact	Patient Stat
3	1	28	02-02-2004	CLINIC APPOINTMENT	YES	3
4	1	28	03-03-2005	MAIL CONTACT WITH THE PATIEN		
5	2	28	12-30-2004	CLINIC APPOINTMENT	NO	1
6	2	28	02-02-2005	CLINIC APPOINTMENT	NO	2

Access

User Level: Public

Study Level: CCR_Program

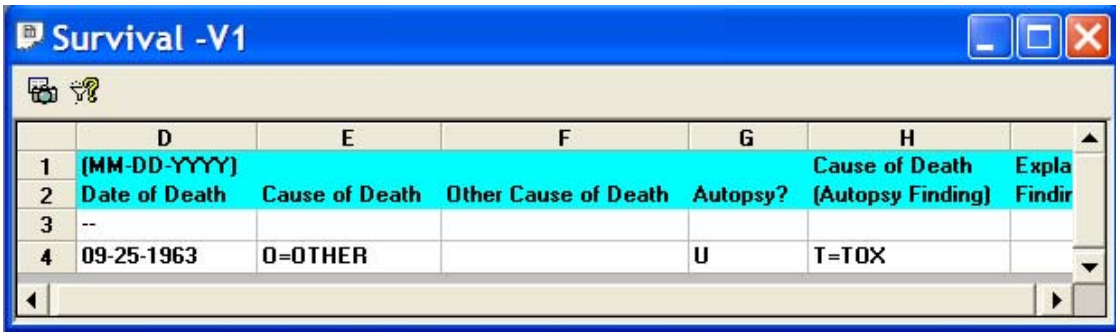
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Actual Visit	Actual Clinical Event Number
Date of Last Contact	Date the Patient Was Last Contacted (Format MM-DD-YYYY)
Type of Contact	How the Information Was Obtained
Received Treatment Since Last Contact	Whether the Patient Has Received Further Treatment Since the Last Contact
Patient Status	Patient's Last Known Status
Explain 'Unknown' Patient Status	The Explanation of 'Unknown' for Patient Status
Date of Last Contact	Date the Patient Was Last Contacted. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Survival –V1

Description

This report lists the death and autopsy information. It works on studies that are based on the 3.02 and 3.10 templates.



Access

User Level: Public

Study Level: CCR_Program

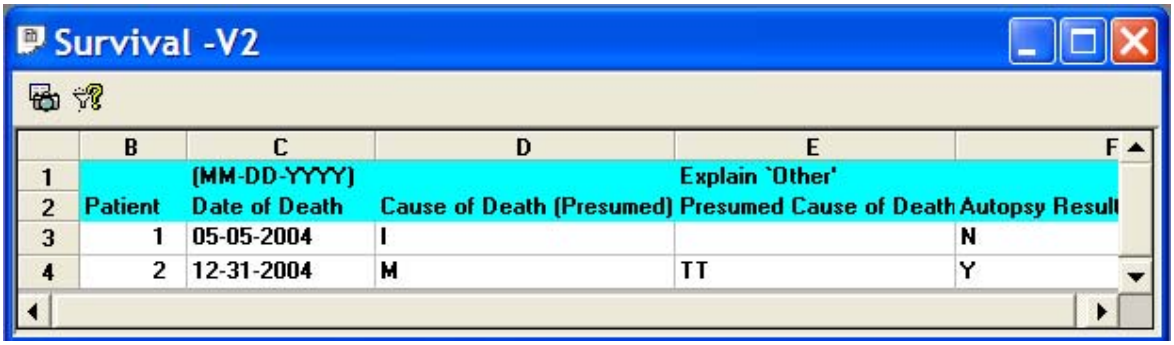
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Death	Date the Patient Died (Format MM-DD-YYYY)
Cause of Death	Caused of Death When Patient Died without Intervening Therapy Specific to the Disease for Which the Patient Was Put on Study
Other Cause of Death	Succinct Description of 'Other' Cause of Death
Autopsy?	Whether the Result of An Autopsy Are Available
Cause of Death (Autopsy Finding)	Cause of Death Determined by Autopsy
Explain `Other' Autopsy Finding Cause of Death	Succinct Description of 'Other' Cause of Death by Autopsy Finding

Survival –V2

Description

This report lists the death and autopsy information. It works on studies that are based on the 3.12 template.



Access

User Level: Public

Study Level: CCR_Program

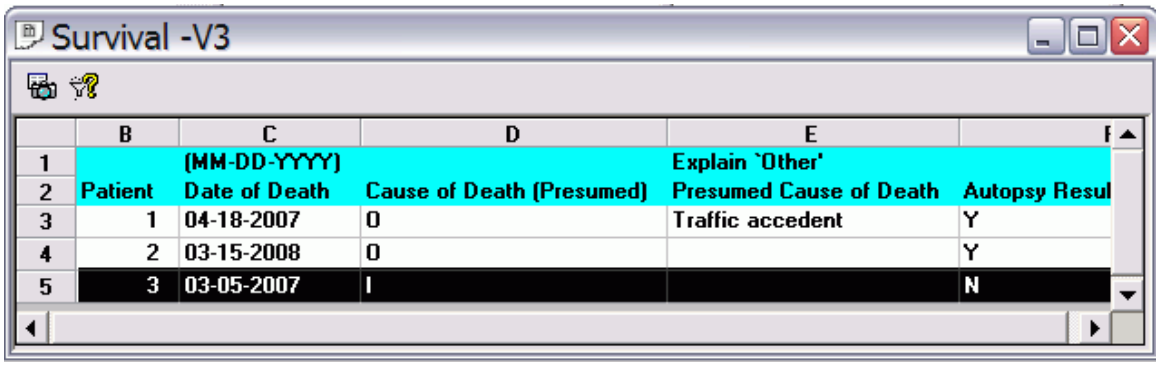
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Death	Date the Patient Died (Format MM-DD-YYYY)
Cause of Death (Presumed)	Caused of Death When Patient Died without Intervening Therapy Specific to the Disease for Which the Patient Was Put on Study
Explain `Other' Presumed Cause of Death	Succinct Description of 'Other' Cause of Death
Autopsy Results Available?	Whether the Result of An Autopsy Are Available
Cause of Death (Autopsy Finding)	Cause of Death Determined by Autopsy
Explain `Other' Autopsy Finding Cause of Death	Succinct Description of 'Other' Cause of Death by Autopsy Finding

Survival –V3

Description

This report lists the death and autopsy information. It works on studies that are based on the 2007 R1 template.



	B	C	D	E	F
1		(MM-DD-YYYY)		Explain `Other'	
2	Patient	Date of Death	Cause of Death (Presumed)	Presumed Cause of Death	Autopsy Resul
3	1	04-18-2007	O	Traffic accedent	Y
4	2	03-15-2008	O		Y
5	3	03-05-2007	I		N

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

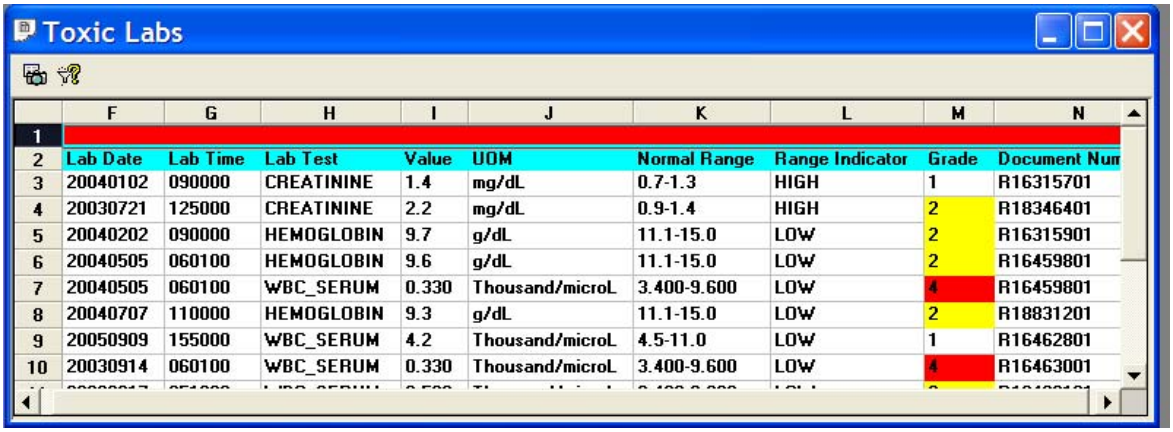
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Death	Date the Patient Died (Format MM-DD-YYYY)
Cause of Death (Presumed)	Caused of Death When Patient Died without Intervening Therapy Specific to the Disease for Which the Patient Was Put on Study
Explain `Other' Presumed Cause of Death	Succinct Description of 'Other' Cause of Death
Autopsy Results Available?	Whether the Result of An Autopsy Are Available
Cause of Death (Autopsy Finding)	Cause of Death Determined by Autopsy
Explain `Other' Autopsy Finding Cause of Death	Succinct Description of 'Other' Cause of Death by Autopsy Finding

Labs Reports

Toxic Labs

Description

This report lists all labs with abnormal grade.



	F	G	H	I	J	K	L	M	N
1									
2	Lab Date	Lab Time	Lab Test	Value	UOM	Normal Range	Range Indicator	Grade	Document Num
3	20040102	090000	CREATININE	1.4	mg/dL	0.7-1.3	HIGH	1	R16315701
4	20030721	125000	CREATININE	2.2	mg/dL	0.9-1.4	HIGH	2	R18346401
5	20040202	090000	HEMOGLOBIN	9.7	g/dL	11.1-15.0	LOW	2	R16315901
6	20040505	060100	HEMOGLOBIN	9.6	g/dL	11.1-15.0	LOW	2	R16459801
7	20040505	060100	WBC_SERUM	0.330	Thousand/microL	3.400-9.600	LOW	4	R16459801
8	20040707	110000	HEMOGLOBIN	9.3	g/dL	11.1-15.0	LOW	2	R18831201
9	20050909	155000	WBC_SERUM	4.2	Thousand/microL	4.5-11.0	LOW	1	R16462801
10	20030914	060100	WBC_SERUM	0.330	Thousand/microL	3.400-9.600	LOW	4	R16463001

Access

User Level: Public

Study Level: Lab Union or Lab All

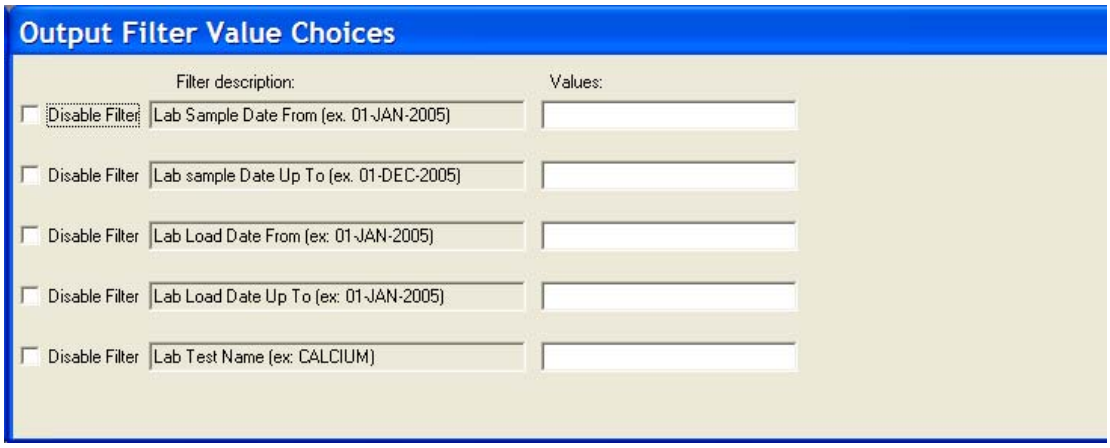
Columns

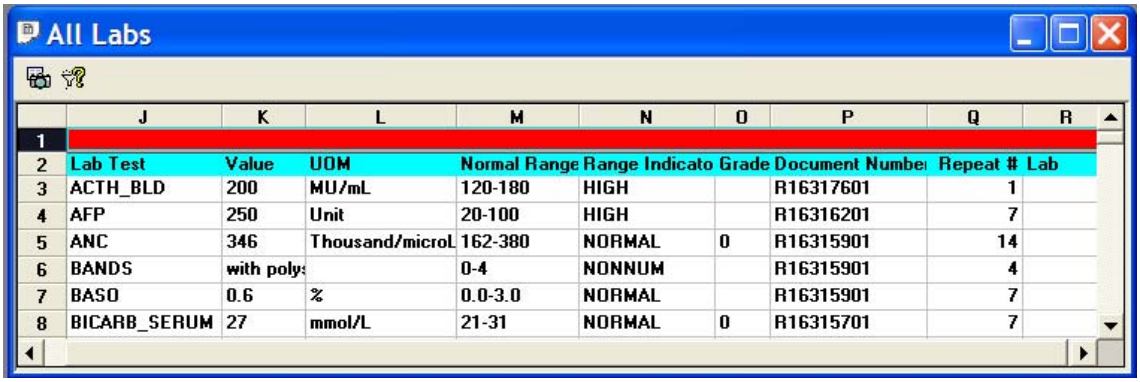
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

All Labs

Description

This report lists all labs per patient, lab test name, in chronological order. Parameters for load and sample date ranges and lab test name.





	J	K	L	M	N	O	P	Q	R
1									
2	Lab Test	Value	UOM	Normal Range	Range Indicato	Grade	Document Numbe	Repeat #	Lab
3	ACTH_BLD	200	MU/mL	120-180	HIGH		R16317601	1	
4	AFP	250	Unit	20-100	HIGH		R16316201	7	
5	ANC	346	Thousand/microL	162-380	NORMAL	0	R16315901	14	
6	BANDS	with poly		0-4	NONNUM		R16315901	4	
7	BASO	0.6	%	0.0-3.0	NORMAL		R16315901	7	
8	BICARB_SERUM	27	mmol/L	21-31	NORMAL	0	R16315701	7	

Access

User Level: Public

Study Level: Lab All

Columns

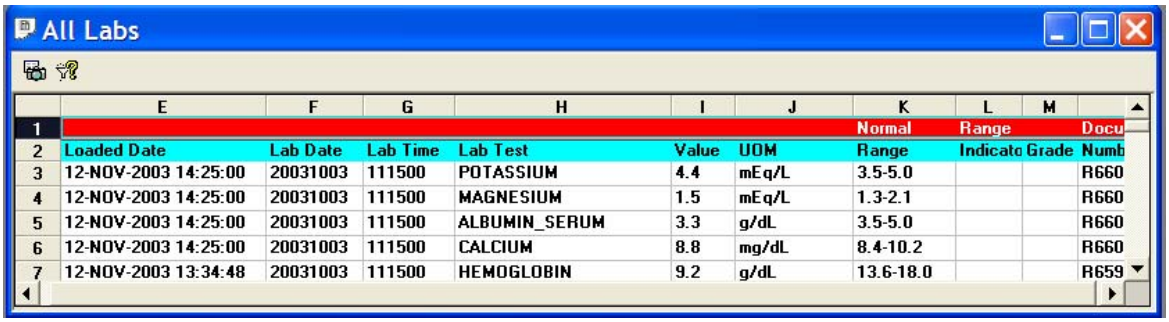
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date and Time	Lab Loading Date and Time
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Course #	The Course Number that This Lab Is Related to

Day in Course (Cycle)	The Day in Course Since the Beginning of Course This Lab Is Related to
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number
Lab	Lab Resource

All Labs

Description

This report lists all labs with values. Do not use patient selection criteria. Use the filter output to set patient, date and other criteria.



	E	F	G	H	I	J	K	L	M	
1							Normal	Range		Docu
2	Loaded Date	Lab Date	Lab Time	Lab Test	Value	UOM	Range	Indicato	Grade	Numb
3	12-NOV-2003 14:25:00	20031003	111500	POTASSIUM	4.4	mEq/L	3.5-5.0			R660
4	12-NOV-2003 14:25:00	20031003	111500	MAGNESIUM	1.5	mEq/L	1.3-2.1			R660
5	12-NOV-2003 14:25:00	20031003	111500	ALBUMIN_SERUM	3.3	g/dL	3.5-5.0			R660
6	12-NOV-2003 14:25:00	20031003	111500	CALCIUM	8.8	mg/dL	8.4-10.2			R660
7	12-NOV-2003 13:34:48	20031003	111500	HEMOGLOBIN	9.2	g/dL	13.6-18.0			R659

Access

User Level: Public

Study Level: Lab Union

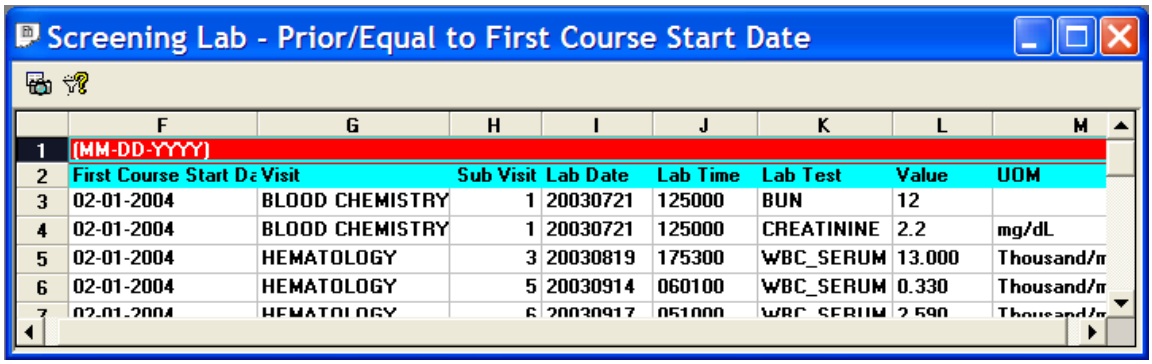
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Screening Labs

Description

This report lists labs prior or equal to the first course start date.



	F	G	H	I	J	K	L	M
1	(MM-DD-YYYY)							
2	First Course Start Da	Visit	Sub Visit	Lab Date	Lab Time	Lab Test	Value	UOM
3	02-01-2004	BLOOD CHEMISTRY	1	20030721	125000	BUN	12	
4	02-01-2004	BLOOD CHEMISTRY	1	20030721	125000	CREATININE	2.2	mg/dL
5	02-01-2004	HEMATOLOGY	3	20030819	175300	WBC_SERUM	13.000	Thousand/m
6	02-01-2004	HEMATOLOGY	5	20030914	060100	WBC_SERUM	0.330	Thousand/m
7	02-01-2004	HEMATOLOGY	6	20030917	051000	WBC_SERUM	2.590	Thousand/m

Access

User Level: Public

Study Level: Lab Union or Lab All

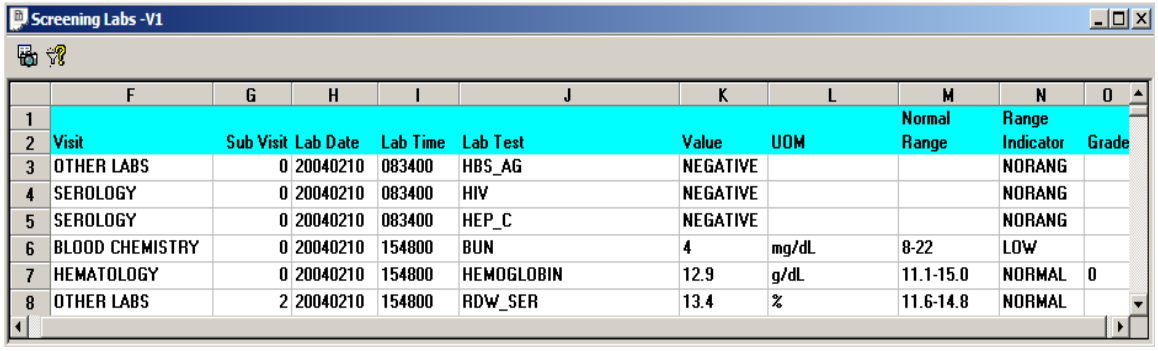
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date of Registration	Date the Patient Was Registered to the Study (Format MM-DD-YYYY)
Date from which to Start Including labs	Date the Lab Loading Start (Format MM-DD-YYYY)
Date Informed Consent Signed	Date the Patient Signed the Informed Consent From (Format MM-DD-YYYY)
First Course Start Date	Date the First Course Started (Format MM-DD-YYYY)
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Screening Labs –V1

Description

This report lists labs prior or equal to the first course start date.



	F	G	H	I	J	K	L	M	N	O
1								Normal	Range	
2	Visit	Sub Visit	Lab Date	Lab Time	Lab Test	Value	UOM	Range	Indicator	Grade
3	OTHER LABS	0	20040210	083400	HBS_AG	NEGATIVE			NORANG	
4	SEROLOGY	0	20040210	083400	HIV	NEGATIVE			NORANG	
5	SEROLOGY	0	20040210	083400	HEP_C	NEGATIVE			NORANG	
6	BLOOD CHEMISTRY	0	20040210	154800	BUN	4	mg/dL	8-22	LOW	
7	HEMATOLOGY	0	20040210	154800	HEMOGLOBIN	12.9	g/dL	11.1-15.0	NORMAL	0
8	OTHER LABS	2	20040210	154800	RDW_SER	13.4	%	11.6-14.8	NORMAL	

Access

User Level: Public

Study Level: Lab Union or Lab All

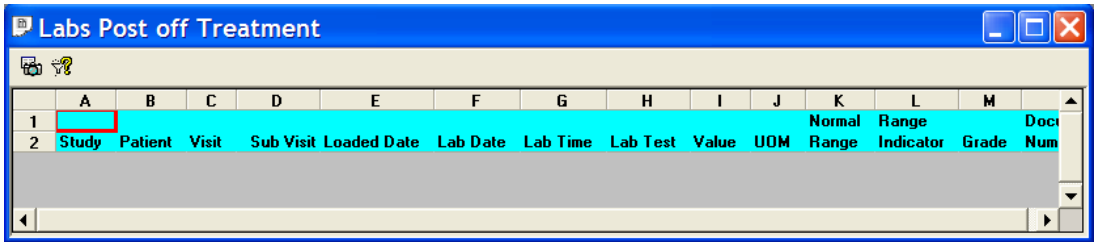
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Date from which to Start Including labs	Date the Lab Loading Start (Format MM-DD-YYYY)
Date Informed Consent Signed	Date the Patient Signed the Informed Consent From (Format MM-DD-YYYY)
First Course Start Date	Date the First Course Started (Format MM-DD-YYYY)
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Labs Post Off Treatment

Description

This report lists labs post off treatment date. Used for Lab Union studies.



Access

User Level: Builder, QA;

Study Level: Lab Union

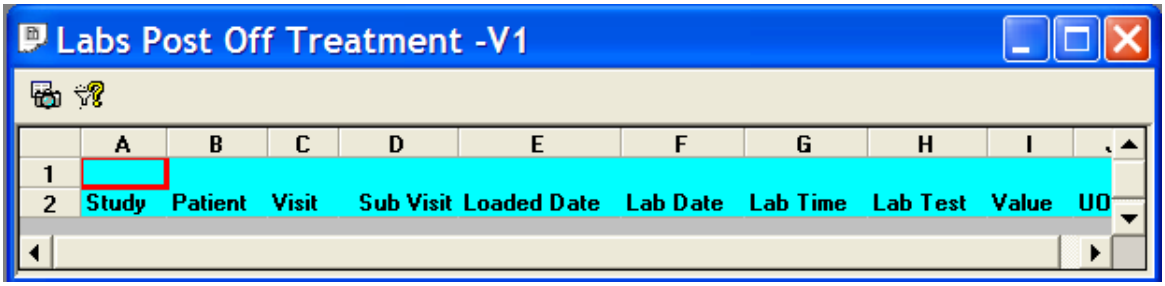
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Labs Post Off Treatment –V1

Description

This report lists labs post off treatment date. Used for Lab All studies. It works on studies that are based on the 3.02 and 3.10 templates.



Access

User Level: Builder, QA;

Study Level: Lab All

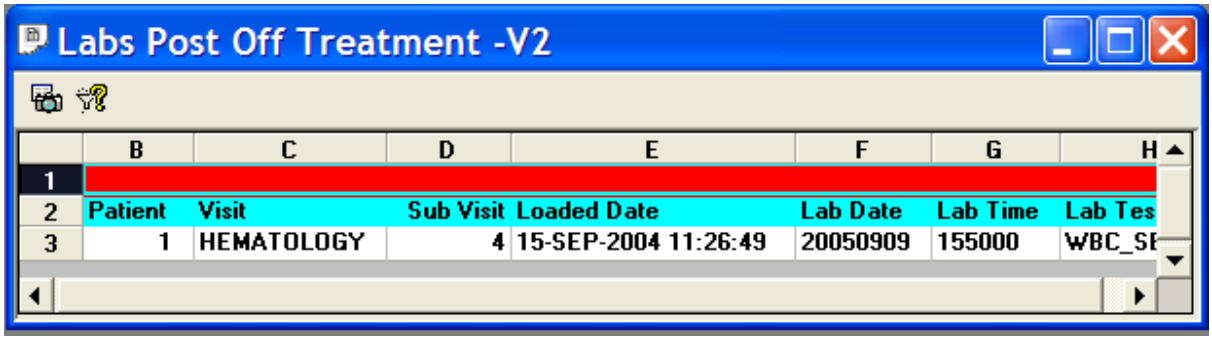
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Labs Post Off Treatment –V2

Description

This report lists labs post off treatment date. Used for Lab All studies. It works on studies that are based on the 3.12 template.



Access

User Level: Builder, QA;

Study Level: Lab All

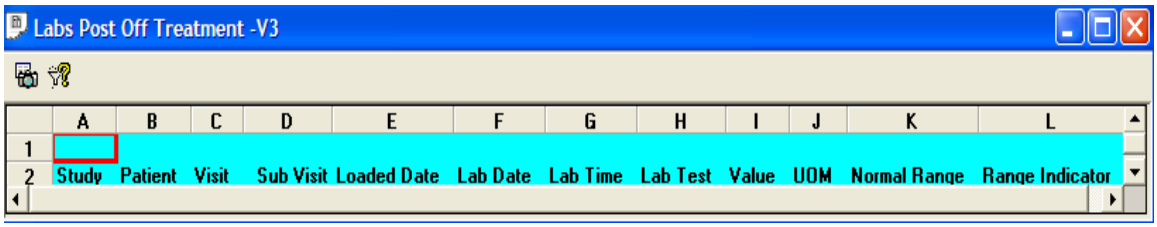
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Labs Post Off Treatment –V3

Description

This report lists labs post off treatment date. Used for Lab All studies. It works on studies that are based on the 2007R1 template.



Access

User Level: Builder, QA;

Study Level: CCR 2007R1 STD, Lab all

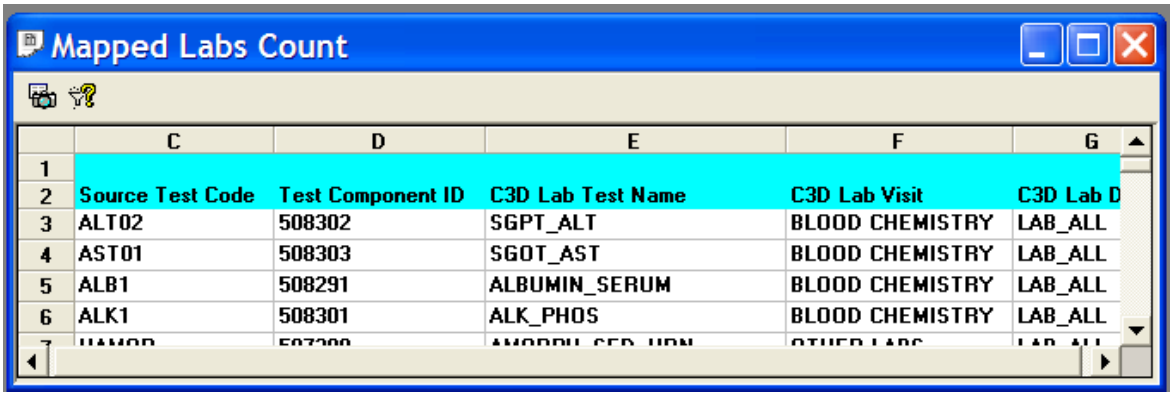
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Visit
Sub Visit	Clinical Sub Visit Number
Loaded Date	Lab Loading/Entry Date
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Lab Test	Lab Test Name
Value	Lab Test Result Value
UOM	Lab Test Unit of Measurement
Normal Range	The Lab Normal Range
Range Indicator	Indicates How the Lab Result Value Compares to The Normal Range
Grade	Grade of This Lab Using CTC Version 2.0 or 3.0
Document Number	System Generated Document Number
Repeat #	The Repeat Sequence Number

Mapping: Mapped Labs Count

Description

This report lists count of mapped labs between CDW and C3D. Load Flags 'C' and 'U' are included.



	C	D	E	F	G
1					
2	Source Test Code	Test Component ID	C3D Lab Test Name	C3D Lab Visit	C3D Lab D
3	ALT02	508302	SGPT_ALT	BLOOD CHEMISTRY	LAB_ALL
4	AST01	508303	SGOT_AST	BLOOD CHEMISTRY	LAB_ALL
5	ALB1	508291	ALBUMIN_SERUM	BLOOD CHEMISTRY	LAB_ALL
6	ALK1	508301	ALK_PHOS	BLOOD CHEMISTRY	LAB_ALL

Access

User Level: Public

Study Level: CCR_Program

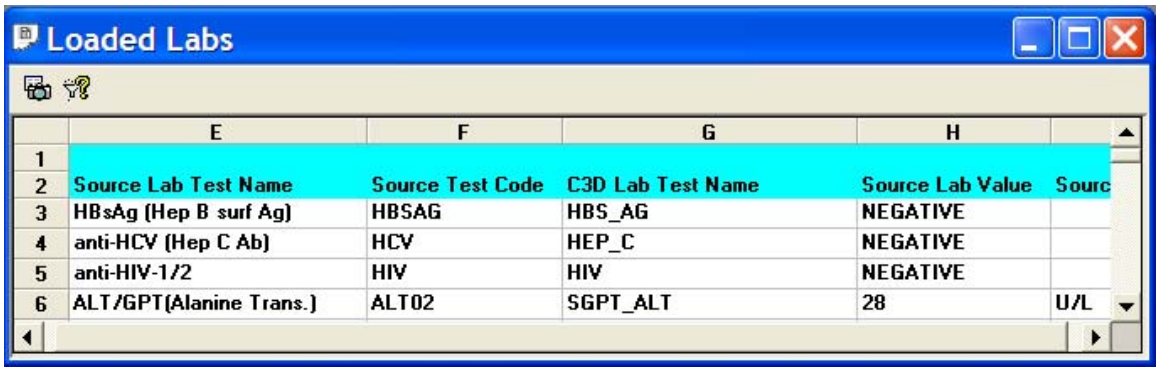
Columns

Field	*Description*
C3D Study	Protocol Number for which Access is being Queried
Source Lab Test Name	CDW Lab Test Name
Source Test Code	CDW Lab Test Code
Test Component ID	CDW Lab Test ID
C3D Lab Test Name	C3D Lab Test
C3D Lab Visit	Lab Visit
C3D Lab DCM	DCM Name
C3D Lab Subset	DCM Subset Name
Count Mapped Lab Results	Number of the Lab Result That Shared the Same Information

Mapping: Loaded Labs Details

Description

This report lists loaded labs from CDW to C3D. Load Flags 'C' and 'U' are included.



Access

User Level: Public

Study Level: CCR_Program

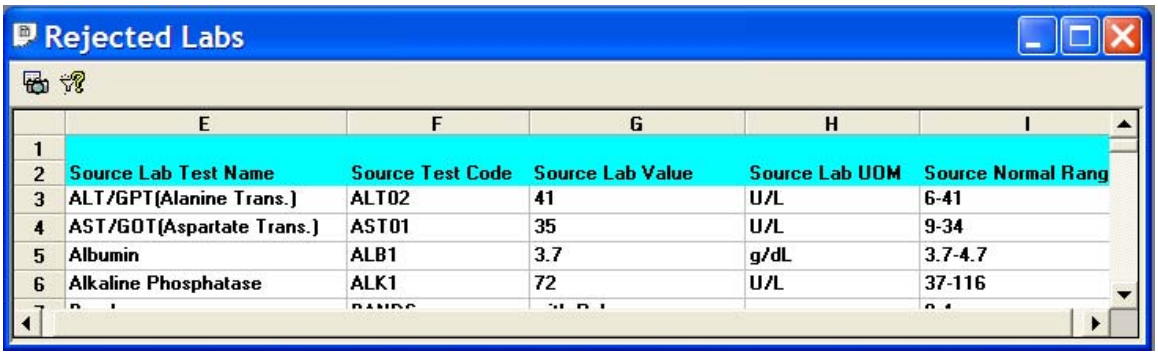
Columns

Field	*Description*
C3D Study	Protocol Number for which Access is being Queried
C3D Patient	C3D Patient ID Displayed on RDC
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Source Lab Test Name	CDW Lab Test Name
Source Test Code	CDW Lab Test Code
C3D Lab Test Name	C3D Lab Test
Source Lab Value	CDW Lab Test Value
Source Lab UOM	CDW Lab Unit of Measurement
Source Normal Range	CDW Lab Normal Range
Source Lab Grade	CDW Lab Grade
Loaded Date	Lab Loading/Entry Date
C3D Lab Visit	Lab Visit
C3D Lab DCM	DCM Name
C3D Lab Subset	DCM Subset Name
Count Mapped Lab Results	Number of the Lab Result That Shared the Same Information

Mapping: Rejected Labs Details

Description

This report lists rejected labs from CDW to C3D. Load Flags 'C' and 'U' are excluded.



	E	F	G	H	I
1					
2	Source Lab Test Name	Source Test Code	Source Lab Value	Source Lab UOM	Source Normal Rang
3	ALT/GPT(Alanine Trans.)	ALT02	41	U/L	6-41
4	AST/GOT(Aspartate Trans.)	AST01	35	U/L	9-34
5	Albumin	ALB1	3.7	g/dL	3.7-4.7
6	Alkaline Phosphatase	ALK1	72	U/L	37-116

Access

User Level: Public

Study Level: CCR_Program

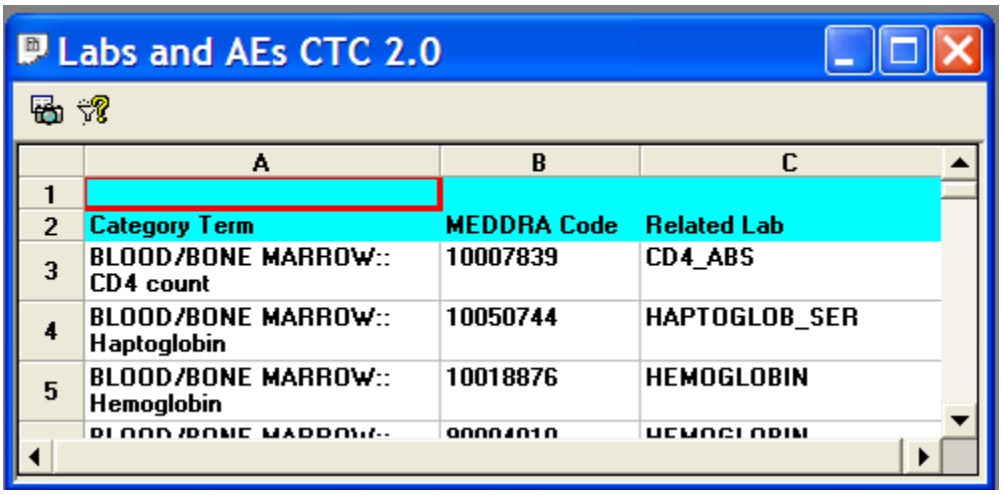
Columns

Field	*Description*
C3D Study	Protocol Number for which Access is being Queried
C3D Patient	C3D Patient ID Displayed on RDC
Lab Date	Date the Lab Sample Was Collected (Format YYYYMMDD)
Lab Time	Time the Lab Sample Was Collected
Source Lab Test Name	CDW Lab Test Name
Source Test Code	CDW Lab Test Code
Source Lab Value	CDW Lab Test Value
Source Lab UOM	CDW Lab Unit of Measurement
Source Normal Range	CDW Lab Normal Range
Received Date	
Error Reason	CDW Lab Grade

Mapping: Labs and AEs CTC 2.0

Description

This report lists the unique link between lab and AE term for version 2.0. Note that if one term is linked to more than one lab test, there is no way to maintain the unique relationship. But one lab can link to more than one AE term.



Access

User Level: Public

Study Level: Global

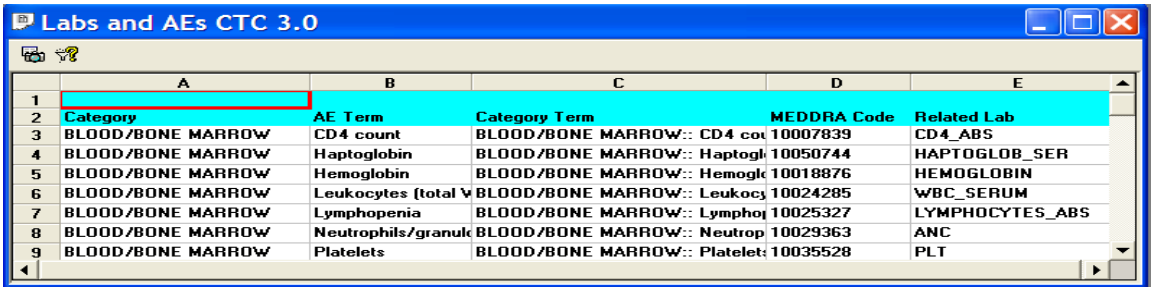
Columns

Field	*Description*
Category Term	CTC Term Expressed by Category::Term
MEDDRA Code	MEDDRA Code for the Corresponding Category Term
Related Lab	The Lab Test That is Uniquely Linked to the Category Term

Mapping: Labs and AEs CTC 3.0

Description

This report lists the unique link between lab and AE term for version 3.0. Note that if one term is linked to more than one lab test, there is no way to maintain the unique relationship. But one lab can link to more than one AE term.



	A	B	C	D	E
1					
2	Category	AE Term	Category Term	MEDDRA Code	Related Lab
3	BLOOD/BONE MARROW	CD4 count	BLOOD/BONE MARROW:: CD4 cou	10007839	CD4_ABS
4	BLOOD/BONE MARROW	Haptoglobin	BLOOD/BONE MARROW:: Haptogl	10050744	HAPTOGLOB_SER
5	BLOOD/BONE MARROW	Hemoglobin	BLOOD/BONE MARROW:: Hemogl	10018876	HEMOGLOBIN
6	BLOOD/BONE MARROW	Leukocytes (total W	BLOOD/BONE MARROW:: Leukocy	10024285	WBC_SERUM
7	BLOOD/BONE MARROW	Lymphopenia	BLOOD/BONE MARROW:: Lymphop	10025327	LYMPHOCYTES_ABS
8	BLOOD/BONE MARROW	Neutrophils/granul	BLOOD/BONE MARROW:: Neutrop	10029363	ANC
9	BLOOD/BONE MARROW	Platelets	BLOOD/BONE MARROW:: Platelet	10035528	PLT

Access

User Level: Public

Study Level: Global

Columns

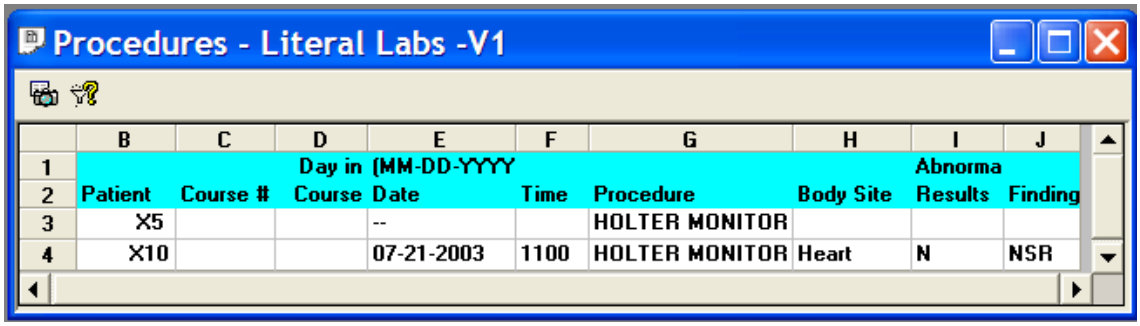
Field	*Description*
Category	Adverse Event Category
AE Term	CTC Term Expressed by Term
Category Term	CTC Term Expressed by Category::Term
MEDDRA Code	MEDDRA Code for the Corresponding Category Term
Related Lab	The Lab Test That is Uniquely Linked to the Category Term

Procedures/Concomitant Therapy Reports

Procedure -Common Literal Labs -V1

Description

This report lists all common literal labs. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	I	J
1			Day in	(MM-DD-YYYY				Abnorma	
2	Patient	Course #	Course	Date	Time	Procedure	Body Site	Results	Finding
3	X5			--		HOLTER MONITOR			
4	X10			07-21-2003	1100	HOLTER MONITOR	Heart	N	NSR

Access

User Level: Public

Study Level: CCR_Program

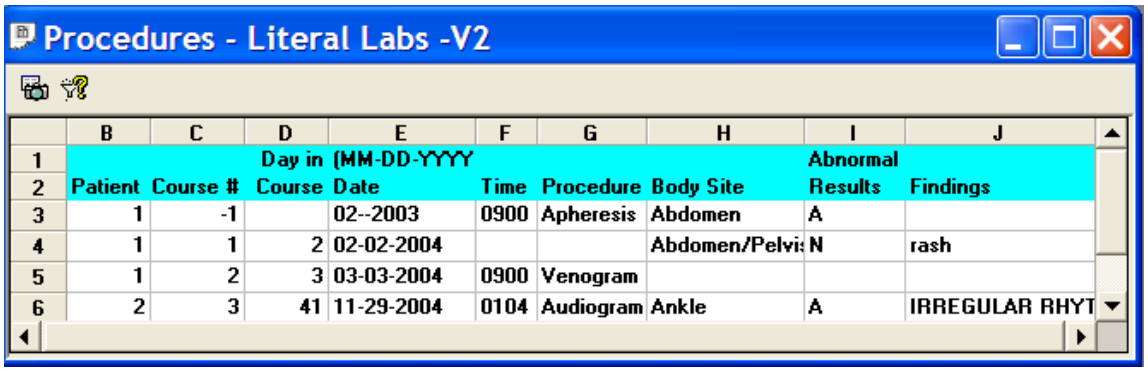
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This Procedure Is Related to
Day in Course	The Day in Course Since the Beginning of Course This Procedure Is Related to
Date	Date the Procedure Was Done (Format MM-DD-YYYY)
Time	Time the Procedure Was Done
Procedure	Name of the Procedure
Body Site	The Applicable Body Site
Abnormal Results	Status of the Finding Results
Findings	Findings of the Procedure
Date	Date the Procedure Was Done. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Procedure -Common Literal Labs –V2

Description

This report lists all common literal labs. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G	H	I	J
1			Day in	(MM-DD-YYYY				Abnormal	
2	Patient	Course #	Course	Date	Time	Procedure	Body Site	Results	Findings
3	1	-1		02--2003	0900	Apheresis	Abdomen	A	
4	1	1	2	02-02-2004			Abdomen/Pelvis	N	rash
5	1	2	3	03-03-2004	0900	Venogram			
6	2	3	41	11-29-2004	0104	Audiogram	Ankle	A	IRREGULAR RHYT

Access

User Level: Public

Study Level: CCR_Program

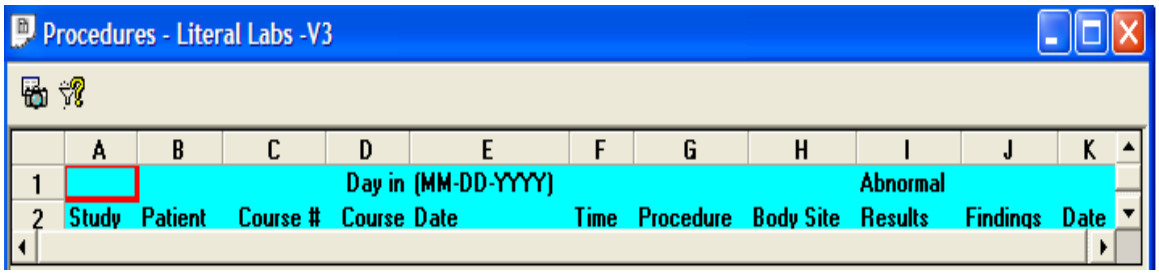
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This Procedure Is Related to
Day in Course	The Day in Course Since the Beginning of Course This Procedure Is Related to
Date	Date the Procedure Was Done (Format MM-DD-YYYY)
Time	Time the Procedure Was Done
Procedure	Name of the Procedure
Body Site	The Applicable Body Site
Abnormal Results	Status of the Finding Results
Findings	Findings of the Procedure
Date	Date the Procedure Was Done. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Procedure -Common Literal Labs –V3

Description

This report lists all common literal labs. It works on studies that are based on the 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

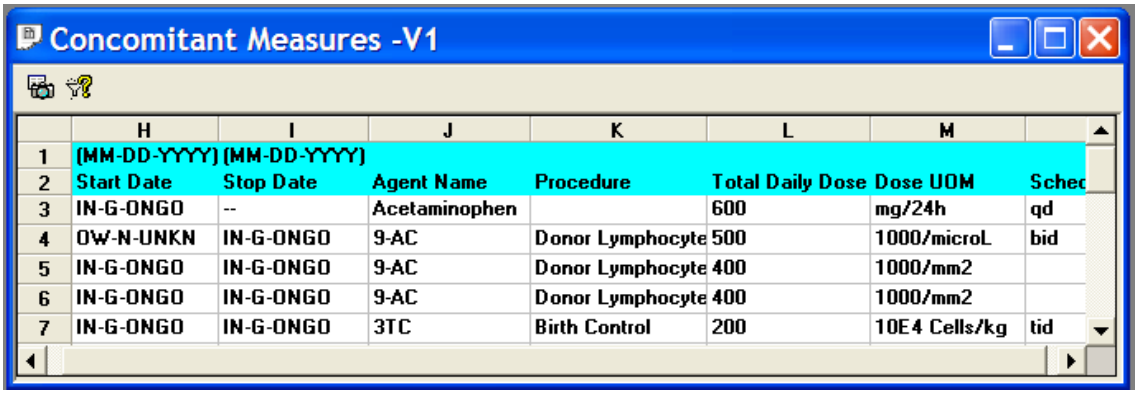
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This Procedure Is Related to
Day in Course	The Day in Course Since the Beginning of Course This Procedure Is Related to
Date	Date the Procedure Was Done (Format MM-DD-YYYY)
Time	Time the Procedure Was Done
Procedure	Name of the Procedure
Body Site	The Applicable Body Site
Abnormal Results	Status of the Finding Results
Findings	Findings of the Procedure
Date	Date the Procedure Was Done. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Concomitant Measures -V1

Description

This report lists concomitant measures/medication. It works on studies that are based on the 3.02 and 3.10 templates.



	H	I	J	K	L	M	
1	(MM-DD-YYYY)	(MM-DD-YYYY)					
2	Start Date	Stop Date	Agent Name	Procedure	Total Daily Dose	Dose UOM	Sched
3	IN-G-ONGO	--	Acetaminophen		600	mg/24h	qd
4	OW-N-UNKN	IN-G-ONGO	9-AC	Donor Lymphocyte	500	1000/microL	bid
5	IN-G-ONGO	IN-G-ONGO	9-AC	Donor Lymphocyte	400	1000/mm2	
6	IN-G-ONGO	IN-G-ONGO	9-AC	Donor Lymphocyte	400	1000/mm2	
7	IN-G-ONGO	IN-G-ONGO	3TC	Birth Control	200	10E4 Cells/kg	tid

Access

User Level: Public

Study Level: CCR_Program

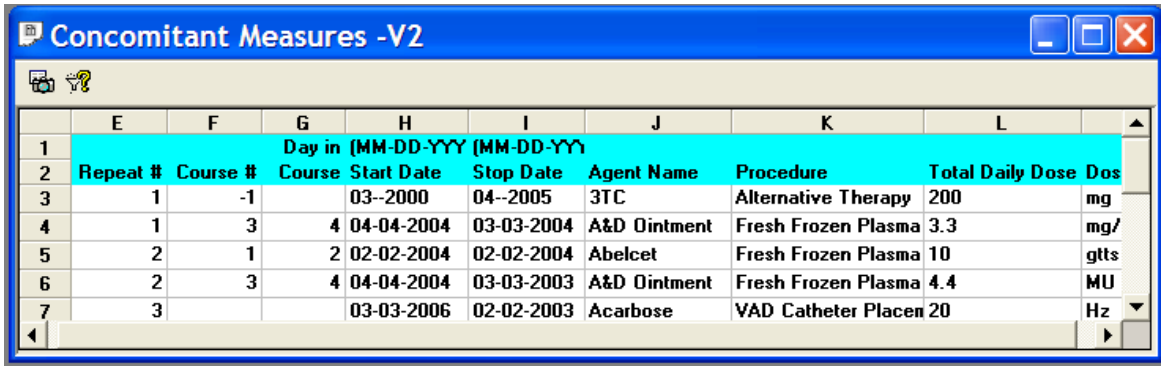
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This Medication or Measure Started
Day in Course	The Day in Course that This Medication or Measure Started
Start Date	State Date of the Measure or Medication (Format MM-DD-YYYY)
Stop Date	Stop Date of the Measure or Medication (Format MM-DD-YYYY)
Agent Name	Name of Medication
Procedure	Name of Procedure/Measure
Total Daily Dose	Total Daily Dose of the Agent
Dose UOM	Total Daily Dose Unit of Measurement
Schedule	Frequency of Medication or Measure
Route	Route the Medication or Measure Given
Reason	Reason the Medication Is Being Administered or Measure Done
Start Date	State Date of the Measure or Medication. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Stop Date of the Measure or Medication. The Original Value Used by System (Form YYYYMMDD)

Concomitant Measures –V2

Description

This report lists concomitant measures/medication. It works on studies that are based on the 3.12 and 2007R1 template.



	E	F	G	H	I	J	K	L	
1			Day in	(MM-DD-YYY	(MM-DD-YY)				
2	Repeat #	Course #	Course	Start Date	Stop Date	Agent Name	Procedure	Total Daily Dose	Dos
3	1	-1		03--2000	04--2005	3TC	Alternative Therapy	200	mg
4	1	3	4	04-04-2004	03-03-2004	A&D Ointment	Fresh Frozen Plasma	3.3	mg/
5	2	1	2	02-02-2004	02-02-2004	Abelcet	Fresh Frozen Plasma	10	gtts
6	2	3	4	04-04-2004	03-03-2003	A&D Ointment	Fresh Frozen Plasma	4.4	MU
7	3			03-03-2006	02-02-2003	Acarbose	VAD Catheter Placen	20	Hz

Access

User Level: Public

Study Level: CCR_Program

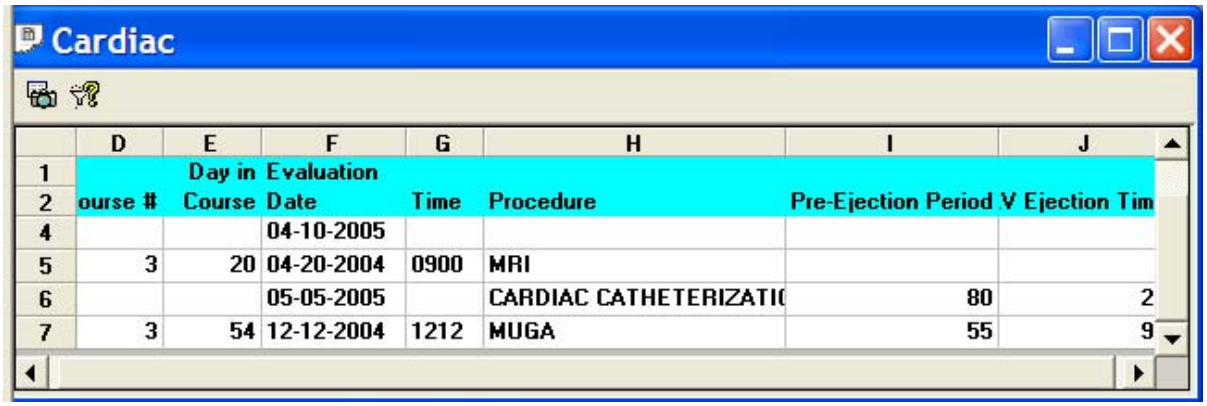
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit #	Clinical Visit Number
Sub Visit	Clinical Sub Visit Number
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This Medication or Measure Started
Day in Course	The Day in Course that This Medication or Measure Started
Start Date	State Date of the Measure or Medication (Format MM-DD-YYYY)
Stop Date	Stop Date of the Measure or Medication (Format MM-DD-YYYY)
Agent Name	Name of Medication
Procedure	Name of Procedure/Measure
Total Daily Dose	Total Daily Dose of the Agent
Dose UOM	Total Daily Dose Unit of Measurement
Schedule	Frequency of Medication or Measure
Route	Route the Medication or Measure Given
Reason	Reason the Medication Is Being Administered or Measure Done
Start Date	State Date of the Measure or Medication. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Stop Date of the Measure or Medication. The Original Value Used by System (Form YYYYMMDD)

Cardiac

Description

This report lists cardiac information.



Access

User Level: Public

Study Level: CCR_Program

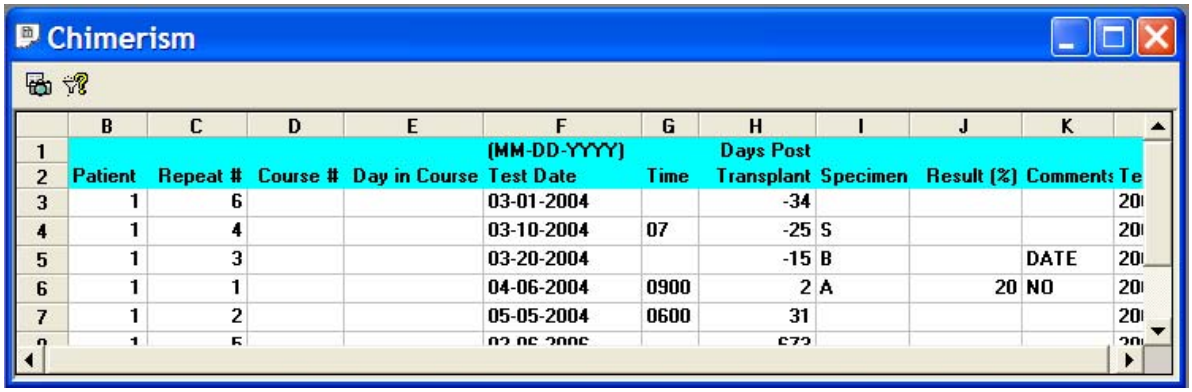
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This Cardiac Ejection Result Is Related
Day in Course	The Day in Course Since the Beginning of Course This Cardiac Ejection Result Is Related
Evaluation Date	Date the Procedure Was Performed (Format MM-DD-YYYY)
Time	Time the Procedure Was Performed
Procedure	Name of Procedure
Pre-Ejection Period	Pre-Ejection Period
LV Ejection Time	Left Ventricular Ejection Time
LV Ejection Fraction %	Left Ventricular Ejection Fraction
Evaluation Date	Date the Procedure Was Performed. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Chimerism –V1

Description

This report lists chimerism information.



Access

User Level: Public

Study Level: CCR_Program

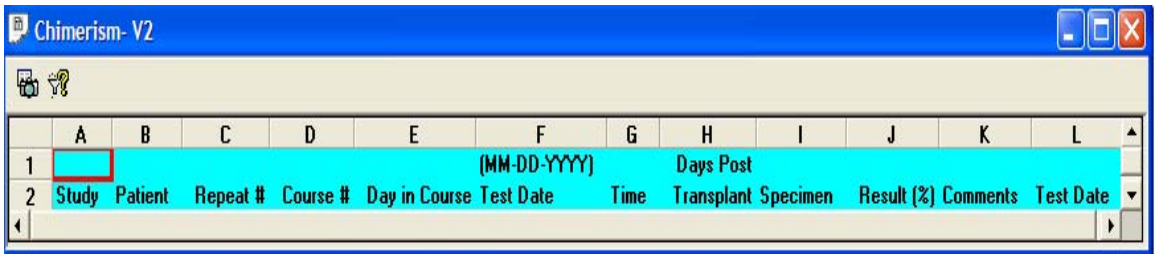
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This Cardiac Ejection Result Is Related
Day in Course	The Day in Course Since the Beginning of Course This Cardiac Ejection Result Is Related
Test Date	Date the Test Was Performed (Format MM-DD-YYYY)
Time	Time the Test Was Performed
Days Post Transplant	Number of Days Before or After the Transplant that the Test Was Done
Specimen	Specimen Type
Result (%)	Test Result
Comments	Comments to the Test
Test Date	Date the Test Was Performed. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Chimerism -V2

Description

This report lists chimerism information. Work for studies based on 2007R1 template.



Access

User Level: Public

Study Level: CCR 2007R1 STD

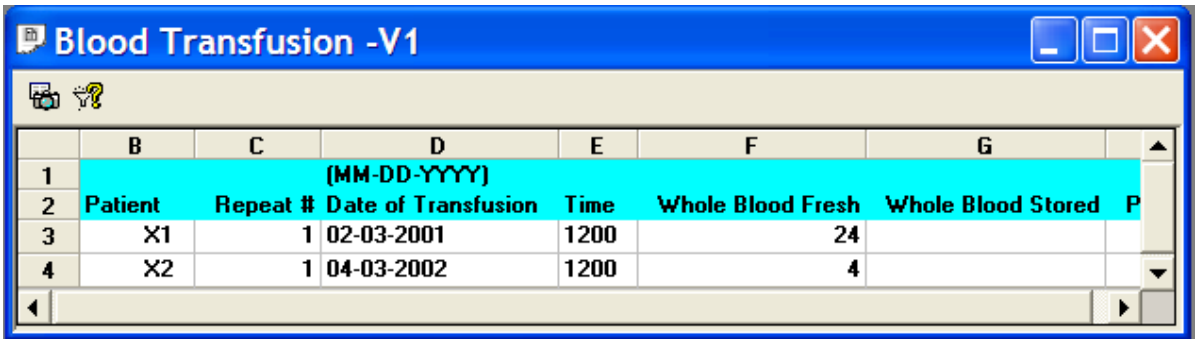
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Course #	The Course Number that This Cardiac Ejection Result Is Related
Day in Course	The Day in Course Since the Beginning of Course This Cardiac Ejection Result Is Related
Test Date	Date the Test Was Performed (Format MM-DD-YYYY)
Time	Time the Test Was Performed
Days Post Transplant	Number of Days Before or After the Transplant that the Test Was Done
Specimen	Specimen Type
Result (%)	Test Result
Comments	Comments to the Test
Test Date	Date the Test Was Performed. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Blood Transfusion –V1

Description

This report lists blood transfusion information. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G
1			(MM-DD-YYYY)			
2	Patient	Repeat #	Date of Transfusion	Time	Whole Blood Fresh	Whole Blood Stored
3	X1	1	02-03-2001	1200	24	
4	X2	1	04-03-2002	1200	4	

Access

User Level: Public

Study Level: CCR_Program

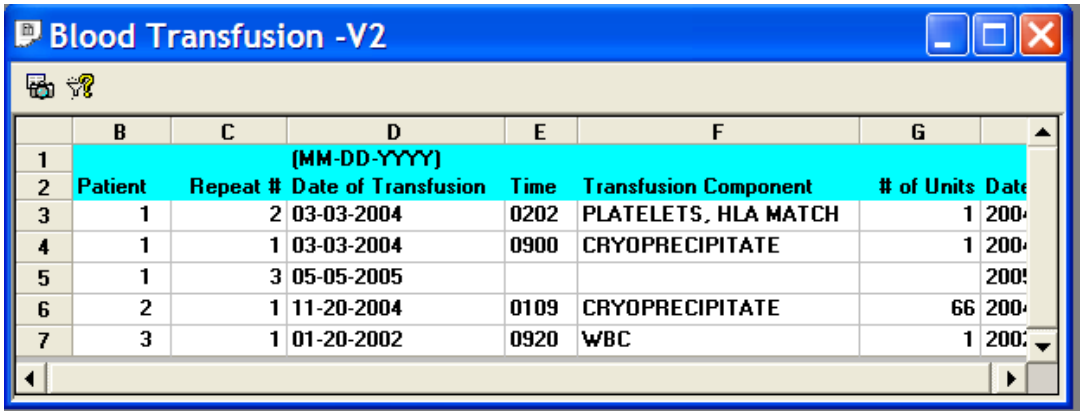
Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Transfusion	Date the Transfusion Was Performed (Format MM-DD-YYYY)
Time	Time the Transfusion Was Performed
Whole Blood Fresh	Unit of Fresh Whole Blood
Whole Blood Stored	Unit of Stored Whole Blood
Packed Red Cells Fresh	Unit of Fresh Packed Red Cells
Packed Red Cells Stored	Unit of Stored Packed Red Cells
Packed White Cells	Unit of Packed White Cells
Platelets	Unit of Platelets

Blood Transfusion –V2

Description

This report lists blood transfusion information. It works on studies that are based on the 3.12 or 2007R1 template.



	B	C	D	E	F	G	
1			(MM-DD-YYYY)				
2	Patient	Repeat #	Date of Transfusion	Time	Transfusion Component	# of Units	Date
3	1	2	03-03-2004	0202	PLATELETS, HLA MATCH	1	200
4	1	1	03-03-2004	0900	CRYOPRECIPITATE	1	200
5	1	3	05-05-2005				200
6	2	1	11-20-2004	0109	CRYOPRECIPITATE	66	200
7	3	1	01-20-2002	0920	WBC	1	200

Access

User Level: Public

Study Level: CCR_Program

Columns

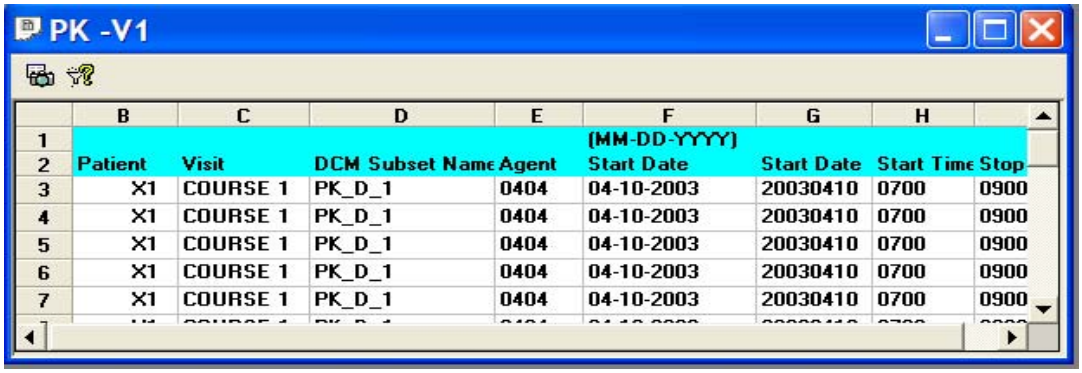
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Repeat #	The Repeat Sequence Number
Date of Transfusion	Date the Transfusion Was Performed (Format MM-DD-YYYY)
Time	Time the Transfusion Was Performed
Transfusion Component	Transfusion Component
# of Units	Unit of the Corresponding Transfusion Component
Date of Transfusion	Date the Transfusion Was Performed. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

PK/Correlative Sciences Report

PK –V1

Description

This report lists pharmacokinetics information. It works on studies that are based on the 3.02 and 3.10 templates.



	B	C	D	E	F	G	H	
1					(MM-DD-YYYY)			
2	Patient	Visit	DCM Subset Name	Agent	Start Date	Start Date	Start Time	Stop
3	X1	COURSE 1	PK_D_1	0404	04-10-2003	20030410	0700	0900
4	X1	COURSE 1	PK_D_1	0404	04-10-2003	20030410	0700	0900
5	X1	COURSE 1	PK_D_1	0404	04-10-2003	20030410	0700	0900
6	X1	COURSE 1	PK_D_1	0404	04-10-2003	20030410	0700	0900
7	X1	COURSE 1	PK_D_1	0404	04-10-2003	20030410	0700	0900

Access

User Level: Public

Study Level: CCR_Program

Columns

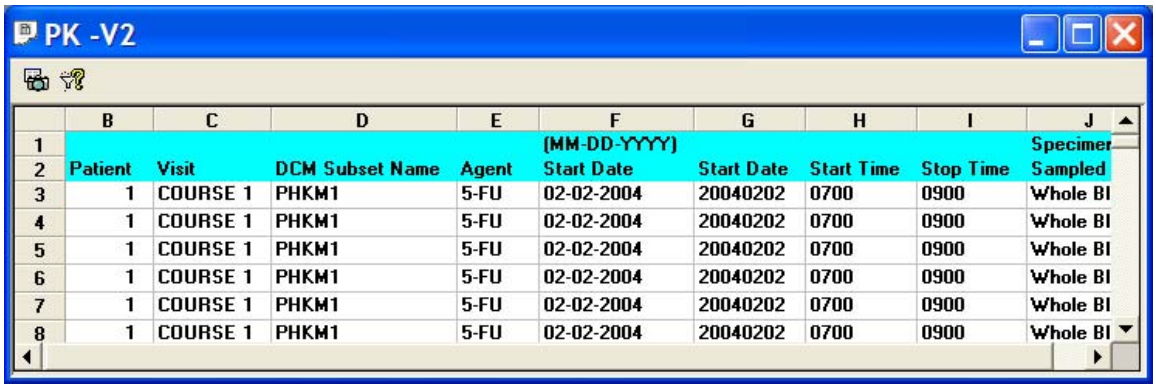
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Agent	Name of Study Agent Which Is the Subject of the Pharmacokinetic Study
Start Date	Date the Study Agent Administration Was Started (Format MM-DD-YYYY)
Start Date	Date the Study Agent Administration Was Started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Start Time	Time the Study Agent Administration Was Started
Stop Time	Time the Study Agent Administration Was Stopped
Specimen Sampled	Body Fluid That Is Being Collected for the Biological Samples
Sample ID	Unique Sample Identification Number for Each Time Point Sample
Planned Interval	Planned Interval on Protocol
Actual Start Date	Specimen Collection Date (Format MM-DD-YYYY)
Actual Start Date	Specimen Collection Date. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Actual Start Time	Specimen Collection Time
Actual Time Interval	Actual Interval From the Study Agent Start Time
Parent Assay 1	Result of Parent Assay for the Study Agent
Parent Assay 2	Second Result of Parent Assay for the Study Agent
Parent Assay Mean	Parent Study Agent mean Concentration
Parent Assay UOM	Parent Study Agent mean Concentration Unit of Measurement
Metabolite Assay 1	First Metabolite Assay Result for the Study Agent
Metabolite Assay 2	Second Metabolite Assay Result for the Study Agent
Metabolite Assay Mean	Metabolite Assay mean Concentration
Metabolite Assay UOM	Metabolite Assay mean Concentration Unit of Measurement

PK –V2

Description

This report lists pharmacokinetics information. It works on studies that are based on the 3.12 template.



	B	C	D	E	F	G	H	I	J
1					(MM-DD-YYYY)				Specimen
2	Patient	Visit	DCM Subset Name	Agent	Start Date	Start Date	Start Time	Stop Time	Sampled
3	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl
4	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl
5	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl
6	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl
7	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl
8	1	COURSE 1	PHKM1	5-FU	02-02-2004	20040202	0700	0900	Whole Bl

Access

User Level: Public

Study Level: CCR_Program

Columns

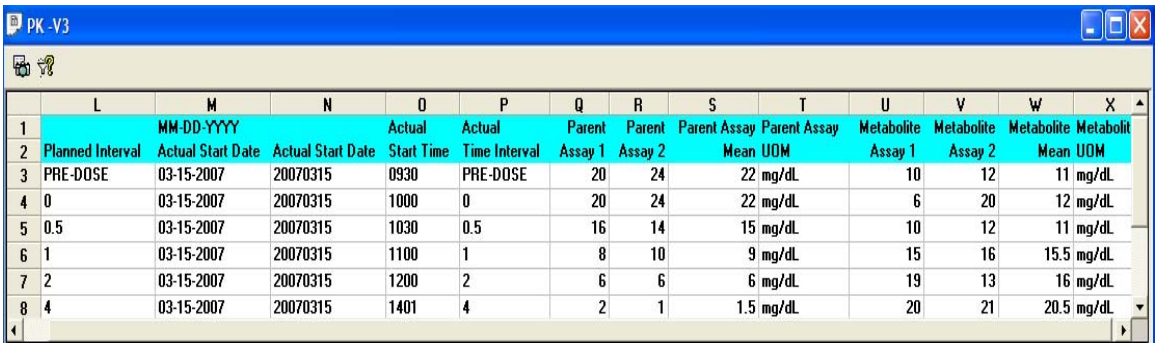
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Agent	Name of Study Agent Which Is the Subject of the Pharmacokinetic Study
Start Date	Date the Study Agent Administration Was Started (Format MM-DD-YYYY)
Start Date	Date the Study Agent Administration Was Started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Start Time	Time the Study Agent Administration Was Started
Stop Time	Time the Study Agent Administration Was Stopped
Specimen Sampled	Body Fluid That Is Being Collected for the Biological Samples
Sample ID	Unique Sample Identification Number for Each Time Point Sample
Planned Interval	Planned Interval on Protocol
Actual Start Date	Specimen Collection Date (Format MM-DD-YYYY)
Actual Start Date	Specimen Collection Date. The Original Value Used by System (Form YYYYMMDD). Used for Sorting
Actual Start Time	Specimen Collection Time
Actual Time Interval	Actual Interval From the Study Agent Start Time
Parent Assay 1	Result of Parent Assay for the Study Agent
Parent Assay 2	Second Result of Parent Assay for the Study Agent

Parent Assay Mean	Parent Study Agent mean Concentration
Parent Assay UOM	Parent Study Agent mean Concentration Unit of Measurement
Metabolite Assay 1	First Metabolite Assay Result for the Study Agent
Metabolite Assay 2	Second Metabolite Assay Result for the Study Agent
Metabolite Assay Mean	Metabolite Assay mean Concentration
Metabolite Assay UOM	Metabolite Assay mean Concentration Unit of Measurement

PK –V3

Description

This report lists pharmacokinetics information. It works on studies that are based on the 2007R1 template.



PK -V3

	L	M	N	O	P	Q	R	S	T	U	V	W	X
1		MM-DD-YYYY		Actual	Actual	Parent	Parent	Parent Assay	Parent Assay	Metabolite	Metabolite	Metabolite	Metabolit
2	Planned Interval	Actual Start Date	Actual Start Date	Start Time	Time Interval	Assay 1	Assay 2	Mean	UOM	Assay 1	Assay 2	Mean	UOM
3	PRE-DOSE	03-15-2007	20070315	0930	PRE-DOSE	20	24	22	mg/dL	10	12	11	mg/dL
4	0	03-15-2007	20070315	1000	0	20	24	22	mg/dL	6	20	12	mg/dL
5	0.5	03-15-2007	20070315	1030	0.5	16	14	15	mg/dL	10	12	11	mg/dL
6	1	03-15-2007	20070315	1100	1	8	10	9	mg/dL	15	16	15.5	mg/dL
7	2	03-15-2007	20070315	1200	2	6	6	6	mg/dL	19	13	16	mg/dL
8	4	03-15-2007	20070315	1401	4	2	1	1.5	mg/dL	20	21	20.5	mg/dL

Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

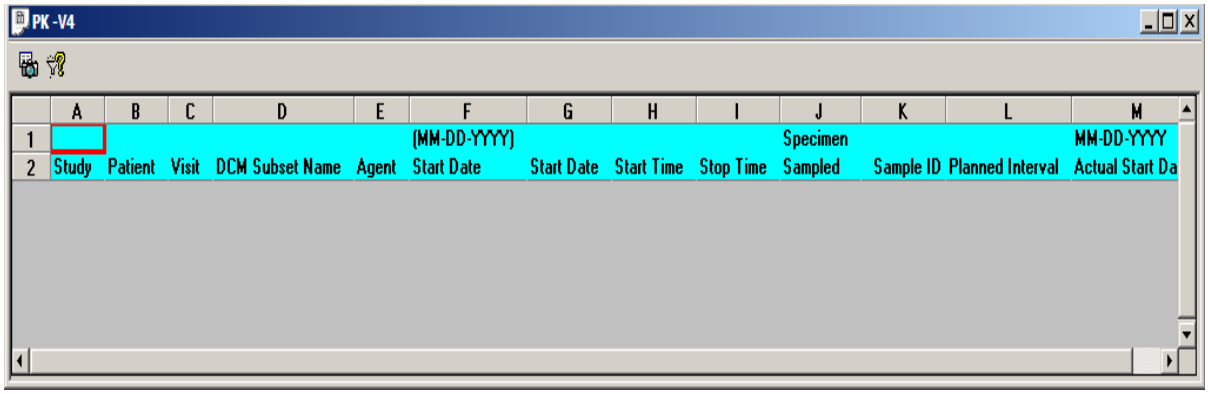
Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Agent	Name of Study Agent Which Is the Subject of the Pharmacokinetic Study
Start Date	Date the Study Agent Administration Was Started (Format MM-DD-YYYY)
Start Date	Date the Study Agent Administration Was Started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Start Time	Time the Study Agent Administration Was Started
Stop Time	Time the Study Agent Administration Was Stopped
Specimen Sampled	Body Fluid That Is Being Collected for the Biological Samples
Sample ID	Unique Sample Identification Number for Each Time Point Sample
Planned Interval	Planned Interval on Protocol
Actual Start Date	Specimen Collection Date (Format MM-DD-YYYY)
Actual Start Date	Specimen Collection Date. The Original Value Used by System (Form YYYYMMDD). Used for Sorting
Actual Start Time	Specimen Collection Time
Actual Time Interval	Actual Interval From the Study Agent Start Time
Parent Assay 1	Result of Parent Assay for the Study Agent
Parent Assay 2	Second Result of Parent Assay for the Study Agent
Parent Assay Mean	Parent Study Agent mean Concentration

Parent Assay UOM	Parent Study Agent mean Concentration Unit of Measurement
Metabolite Assay 1	First Metabolite Assay Result for the Study Agent
Metabolite Assay 2	Second Metabolite Assay Result for the Study Agent
Metabolite Assay Mean	Metabolite Assay mean Concentration
Metabolite Assay UOM	Metabolite Assay mean Concentration Unit of Measurement

PK –V4

Description

This report lists pharmacokinetics information. It works on studies that are based on the 2008V1 template.



Access

User Level: Public

Study Level: CCR 2008V1 STD

Columns

Field	*Description*
Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Visit	Clinical Event
DCM Subset Name	DCM Subset Name on RDC
Agent	Name of Study Agent Which Is the Subject of the Pharmacokinetic Study
Start Date	Date the Study Agent Administration Was Started (Format MM-DD-YYYY)
Start Date	Date the Study Agent Administration Was Started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Start Time	Time the Study Agent Administration Was Started
Stop Time	Time the Study Agent Administration Was Stopped
Specimen Sampled	Body Fluid That Is Being Collected for the Biological Samples
Sample ID	Unique Sample Identification Number for Each Time Point Sample
Planned Interval	Planned Interval on Protocol
Actual Start Date	Specimen Collection Date (Format MM-DD-YYYY)
Actual Start Date	Specimen Collection Date. The Original Value Used by System (Form YYYYMMDD). Used for Sorting
Actual Start Time	Specimen Collection Time
Actual Time Interval	Actual Interval From the Study Agent Start Time

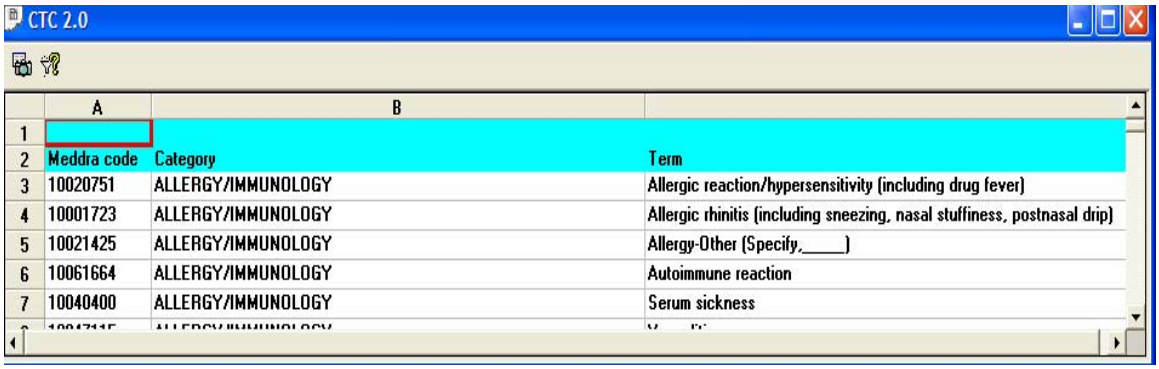
Parent Assay 1	Result of Parent Assay for the Study Agent
Parent Assay 2	Second Result of Parent Assay for the Study Agent
Parent Assay Mean	Parent Study Agent mean Concentration
Parent Assay UOM	Parent Study Agent mean Concentration Unit of Measurement
Metabolite Assay 1	First Metabolite Assay Result for the Study Agent
Metabolite Assay 2	Second Metabolite Assay Result for the Study Agent
Metabolite Assay Mean	Metabolite Assay mean Concentration
Metabolite Assay UOM	Metabolite Assay mean Concentration Unit of Measurement

Standardized Pick Lists

CTC 2.0

Description

This report lists the CTEP CTC version 2.0 for Adverse Events.



	A	B	
1			
2	Meddra code	Category	Term
3	10020751	ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)
4	10001723	ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)
5	10021425	ALLERGY/IMMUNOLOGY	Allergy-Other (Specify,_____)
6	10061664	ALLERGY/IMMUNOLOGY	Autoimmune reaction
7	10040400	ALLERGY/IMMUNOLOGY	Serum sickness

Access

User Level: Public

Study Level: Global

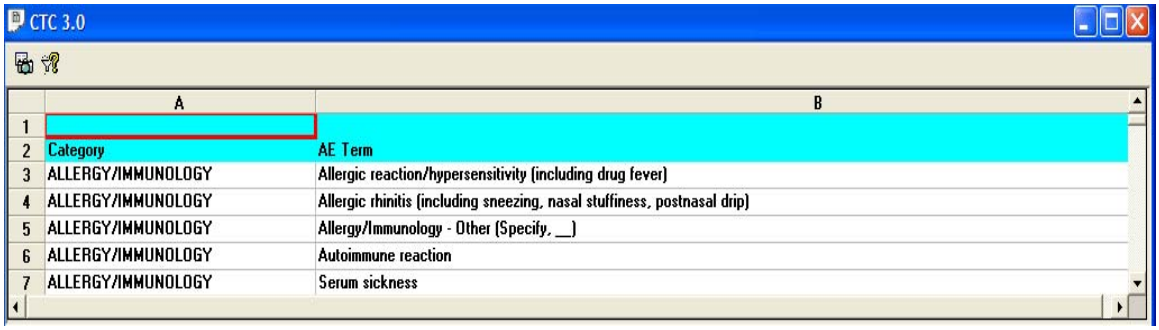
Columns

Field	*Description*
Meddra Code	MEDDRA Code for the Corresponding Category Term
Category	Adverse Event Category
Term	CTC Term Expressed by Category: Term
Description Required	If Term requires further description, for example if term is Allergy- other (specify,--) then further details are required
Related Lab	Name of the Related C3D Lab Test

CTC 3.0

Description

This report lists CTEP CTC version 3.0 for Adverse Events.



	A	B
1		
2	Category	AE Term
3	ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)
4	ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)
5	ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, __)
6	ALLERGY/IMMUNOLOGY	Autoimmune reaction
7	ALLERGY/IMMUNOLOGY	Serum sickness

Access

User Level: Public

Study Level: Global

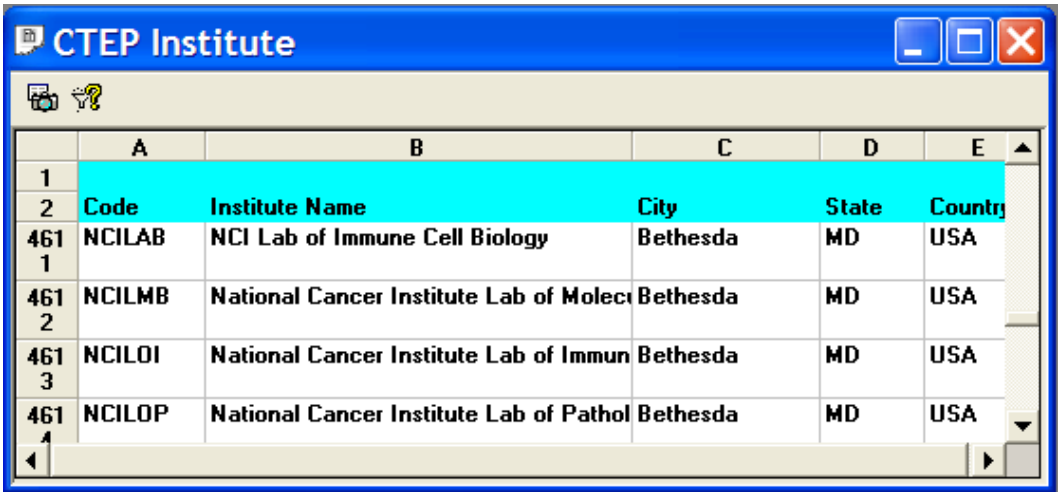
Columns

Field	*Description*
Category	Adverse Event Category
AE Term	CTC Term Expressed by Term
Category Term	CTC Term Expressed by Category: Term
MEDDRA Code	MEDDRA Code for the Corresponding Category Term
MEDDRA TERM	Description of MEDDRA code term
Related Lab	Name of the Related C3D Lab Test
Description Required	If Term requires further description, for example if term is Allergy- other (specify,--) then further details are required

CTEP Institute

Description

This report lists all the CTEP institutes.



	A	B	C	D	E
1					
2	Code	Institute Name	City	State	Countr
4611	NCILAB	NCI Lab of Immune Cell Biology	Bethesda	MD	USA
4612	NCILMB	National Cancer Institute Lab of Molec	Bethesda	MD	USA
4613	NCILOI	National Cancer Institute Lab of Immun	Bethesda	MD	USA
4614	NCILOP	National Cancer Institute Lab of Pathol	Bethesda	MD	USA

Access

User Level: Public

Study Level: Global

Columns

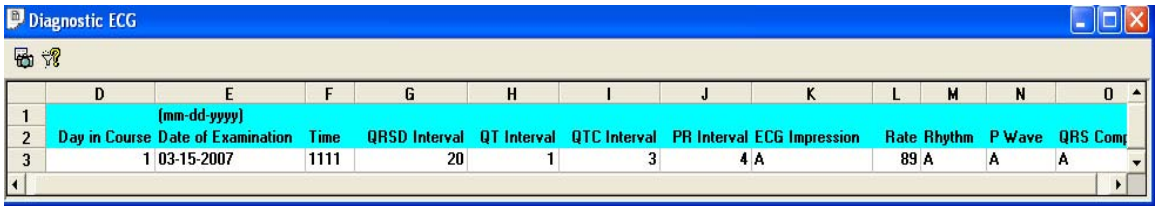
Field	*Description*
Code	Code of the Institute
Institute Name	Name of the Institute
City	City Where the Institute Locates
State	State Where the Institute Locates
Country	Country Where the Institute Locates

Ongoing

Diagnostic ECG

Description

This report lists diagnostic ECGs. It works for studies that are based on the 2007R1 templates.



Access

User Level: Public

Study Level: CCR 2007R1 STD

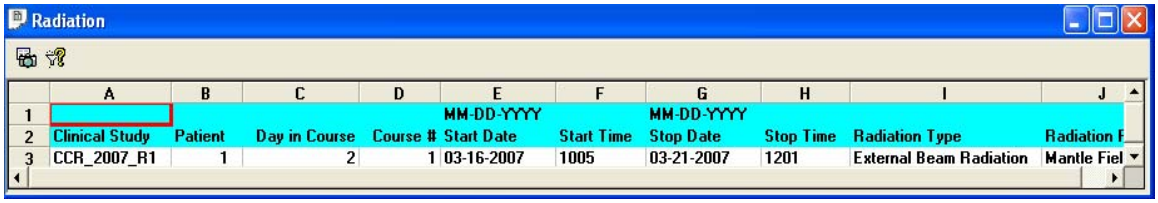
Columns

Field	*Description*
Clinical Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Course #	The Course Number that This ECG Is Related to
Day in Course	The Day in Course Since the Beginning of Course This ECG Is Related to
Date of Examination	Date the ECG was done (Format MM-DD-YYYY)
Time	Time the ECG Was Done
QRSD Interval	QRS duration (QRSD) interval in milliseconds
QT Interval	QT interval in milliseconds
QTC Interval	QTC interval in milliseconds
PR Interval	PR interval in milliseconds
ECG Impression	Summary finding
Rate	Patient's pulse rate
Rhythm	Rhythm finding
P Wave	P Wave finding
QRS Complex	QRS complex finding
ST Segment	ST Segment finding
Arrhythmia Type	Patient's arrhythmia type
Comments	Comments applicable to the ECG.
Date of Examination	Date the examination was Done. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Radiation

Description

This report lists details of Radiation therapy. It works for studies that are based on the 2007R1 templates.



Access

User Level: Public

Study Level: CCR 2007R1 STD

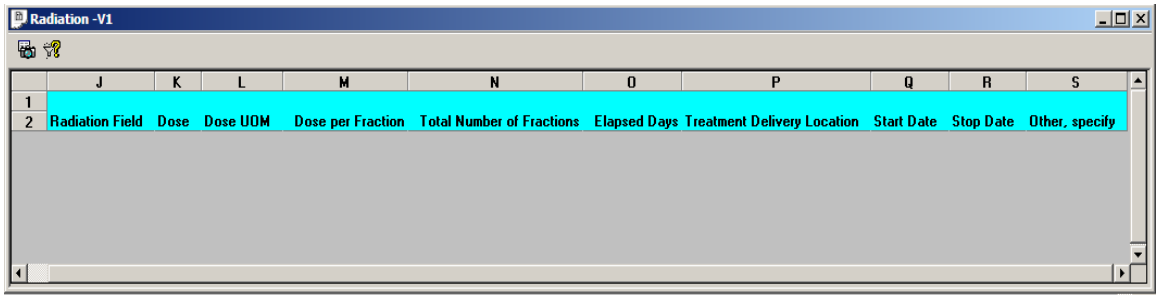
Columns

Field	*Description*
Clinical Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Day in Course	The Day in Course Since the Beginning of Course This radiation therapy Is Related to
Course #	The Course Number that This therapy Is Related to
Start Date	Date the radiation therapy started (Format MM-DD-YYYY)
Start Time	Start time of radiation therapy
Stop Date	Date of last dose of the radiation therapy(Format MM-DD-YYYY)
Stop Time	Stop time radiation therapy
Radiation Type	Type of radiation therapy
Radiation Field	Site of Radiation therapy
Dose	Total radiation dose patient received during treatment period
Dose UOM	Radiation dose unit of measurement
Dose per Fraction	Fractionated dose of radiation therapy administered to a treatment field or site
Total Number of Fractions	Number of dose portions or fractions of radiation therapy actually administered
Elapsed Days	Actual number of days radiation therapy administered
Treatment Delivery Location	Institute where radiation therapy was administered
Start Date	Date the radiation therapy was started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Date the last dose of radiation therapy was last taken. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

Radiation –V1

Description

This report lists details of Radiation therapy. It works for studies that are based on the 2008V1 templates.



Access

User Level: Public

Study Level: CCR 2008V1 STD

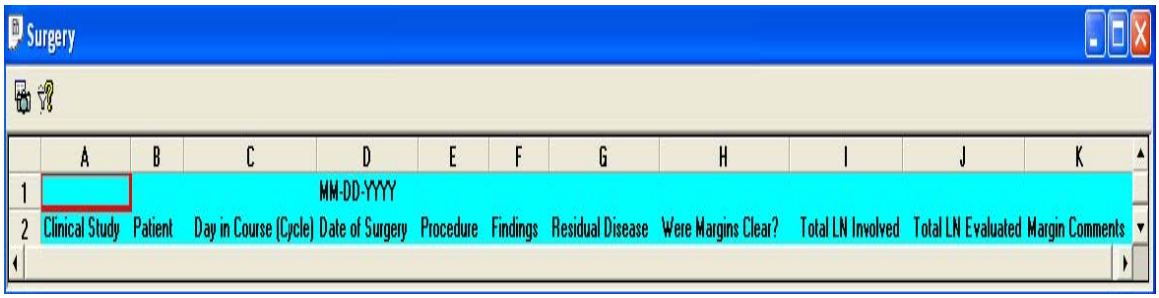
Columns

Field	*Description*
Clinical Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Day in Course	The Day in Course Since the Beginning of Course This radiation therapy Is Related to
Course #	The Course Number that This therapy Is Related to
Start Date	Date the radiation therapy started (Format MM-DD-YYYY)
Start Time	Start time of radiation therapy
Stop Date	Date of last dose of the radiation therapy(Format MM-DD-YYYY)
Stop Time	Stop time radiation therapy
Radiation Type	Type of radiation therapy
Radiation Field	Site of Radiation therapy
Dose	Total radiation dose patient received during treatment period
Dose UOM	Radiation dose unit of measurement
Dose per Fraction	Fractionated dose of radiation therapy administered to a treatment field or site
Total Number of Fractions	Number of dose portions or fractions of radiation therapy actually administered
Elapsed Days	Actual number of days radiation therapy administered
Treatment Delivery Location	Institute where radiation therapy was administered
Start Date	Date the radiation therapy was started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Stop Date	Date the last dose of radiation therapy was last taken. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date
Other Specify	Description of 'Other'

Surgery

Description

This report lists details of Radiation therapy. It works for studies that are based on the 2007R1 templates.



Access

User Level: Public

Study Level: CCR 2007R1 STD

Columns

Field	*Description*
Clinical Study	Protocol Number for which Access is being Queried
Patient	C3D Patient ID Displayed on RDC
Day in Course	The Day in Course Since the Beginning of Course This radiation therapy Is Related to
Date of Surgery	Date of Surgical procedure(Format MM-DD-YYYY)
Procedure	Procedure performed to diagnose /to treat patient's disease
Findings	Findings of the procedure
Residual Disease	Extent of residual disease at the conclusion of the operation
Were Margins Clear?	Result of tissue margin examination
Total LN Involved	Number of Lymph nodes involved with disease as determined by pathologic examination
Total LN Evaluated	Total number of Lymph nodes removed and pathologically assessed for disease.
Margin Comments	Comment for margin examination
Date of Surgery	Date the radiation therapy was started. The Original Value Used by System (Form YYYYMMDD). Used for Sorting to Avoid the Problem Caused by Invalid/Partial Date

I-Review Fields

I-Review Date types

RDC Date	Actual Value		Oracle Date		Oracle Date (mm-dd-yyyy)		Oracle Date (dd-mm-yyyy)	
	I-Review	Exported Excel File	I-Review	Exported Excel File	I-Review	Exported Excel File	I-Review	Exported Excel File
10-FEB-2004	20040210	text, can use formula to convert to date	10-Feb-04	date	02-10-2004	text, can use formula to convert to date	10-02-2004	text, can use formula to convert to date

Common fields

Question	Useful?	Description	Example
Clinical Study		Study number.	00_C_0079
DCM Name	Probably	Data Collection Module name.	ADVERSE EVENTS
DCM subset Name	Maybe	Data Collection Module subset name.	ALLAES
DCM Subset Number	Maybe	Data Collection Module subset number.	2
Document Number	Yes	Document Number. Unique eCRF identifier. Important when joining two or more DCMs of the same eCRF. First character indicates if record was batch loaded (D) or manually entered ®.	R14011234 OR D12345678
Site		Site. Not very useful because we only have intramural studies with one site.	SITE_01
Investigator		Name of the Principal Investigator.	INV_17
Patient	Yes	Patient ID that appears on the left of the C3D RDC spreadsheet.	3
Accessible TS		Accessible timestamp.	
Login TS		Login timestamp.	
LstChg TS		Last changed timestamp.	
CPE Name	Maybe	Clinical Planned Event name. This is the C3D RDC Visit label that appears when the Tab 'Visit' is selected.	ONGOING, SCREENING, Etc.
Entered By		User that entered the data.	
Data Lock Flag		Indicates if the data has been locked.	N
DCM Date	Yes	Visit Date.	20050128
DCM Time	Yes	Visit Time. Only meaningful for labs.	150345
Repeat #	Yes	Record number in the repeating group.	3
Actual Event	Maybe	Combination of Visit and Sub Event. Useful Labs and unplanned visits. For example: 60.01.	13
Sub Event	Maybe	Sequence number within a visit. See Actual Event.	2
Visit	Maybe	Number of the visit. This is the number displayed on the C3D RDC spreadsheet between the Phase and the DCI (eCRF) name.	13
Qualifying Value	Yes	Two or three letter abbreviation of the eCRF the data belongs to. For example: BC for Blood Collection.	BC, HM, UE, etc.
Qualifying Question		Internal identifier number. Only useful for sophisticated reports.	
Lab	Yes	Location the lab was performed.	DLM, OUTSIDE, Duke, Georgetown, etc. For Example: DLM is the one for Dept of Lab Medicine - from the Clinical Center and available from CRIS. Other values are: OUTSIDE, Duke, Georgetown, etc.
Lab Range Subset Number		Internal use only	
Lab Assignment Type Code		Internal use only	
Lab Id		Internal identifier number. Only useful for sophisticated reports.	
DCM Id		Internal identifier number. Only useful for sophisticated reports.	
DCI Id		Internal identifier number. Only useful for sophisticated reports.	
Received DCM Id		Internal identifier number. Only useful for sophisticated reports.	
Received DCI Id		Internal identifier number. Only useful for sophisticated reports.	
Patient Position Id		Internal identifier number. Only useful for sophisticated reports.	
Clinical Study Id		Internal identifier number. Only useful for sophisticated reports.	

Patient visit Date-Time Fields

DCM	Question Group	Date	Time	Date	Time
Adverse Events	Adverse Events	Date of Onset	-	Date Resolved	-
Baseline Medical History	Non-Repeating Data	Date of Examination	-	-	-
Baseline Medical History	Baseline Medical History	-	-	-	-
Baseline Symptoms	Baseline Symptoms	Date of Onset	-	Date Resolved	-
Cardiac	Cardiac Details	Eval Date	Time	-	-
Chimerism	Chimerism	Test Date	Time	-	-
Chimerism	Non-Repeating Data	Date of Transplant	-	-	-
Comments	Comments	Date	-	-	-
Concomitant Measures/Medications	Concomitant Measures/Medications	Start Date	-	Stop Date	-
Course Assessement	Non-Repeating Data	Start Date of Course	-	End Date of Course, Date of Progression, Date of Response	-
Course Initiation	Non-Repeating Data	Start Date of Course	-	Stop Date of Course	-
Eligibility Checklist	Eligibility Criteria	-	-	-	-
Eligibility Checklist	Non-Repeating Data	Effective Date	-	-	-
Enrollment	Non-Repeating Data	Date Informed Conset Signed	-	Date of Registration	-
Extent of Disease	Extent of Disease - Lesion Identification	-	-	-	-
Extent of Disease	Extent of Disease - Lesion Measurement	Eval Date	-	-	-
Follow-up	Patient Follow-up	Date of Last Contact	-	-	-
Infection Episode	Infection Episode	Date of Onset	-	-	-
LAB_ALL	Non-Repeating Data	DCM Date	DCM Time	-	-
LAB_ALL	Repeating Lab Group	DCM Date	DCM Time	-	-
LAB_LL	Procedures	Date of Evaluation	Time	-	-
Off Treatment/Study	Non-Repeating Data	Date Off Treatment	-	Date Off Study, Date of Last Medication Administration, Date of Progression, Date of Response	-
Patient ID	Patient Identification	-	-	-	-
Pharmacokinetics	Non-Repeating Data	Start Date	Start Time	-	Stop Time
Pharmacokinetics	Pharmacokinetics	Sample Date	Sample time	-	-
Pharmacokinetics	Pharmacokinetics	-	-	-	-
Physical Exam	Non-Repeating Data	Date of Examination	-	-	-
Physical Exam	Physical Exam	-	-	-	-
Prior Radiation Supplement	Prior Radiation Supplement	Date of First Dose	-	Date of Last Dose	-
Prior Surgery Supplement	Prior Surgery Supplement	Date of Surgery	-	-	-
Prior Therapy Supplement	Prior Therapy Supplement	Date of First Dose	-	Date of Last Dose	-

Prior Treatment Summary	Prior Treatment Summary	Date of Last Dose	-	-	-
Scintigraphy	Non-Repeating Data	Sample Collection Date	-	-	-
Scintigraphy	Scintigraphy (Samples)	-	-	-	-
Study Medication Administration	Study Medication Administration	Start Date	Start Time	Stop Date	Stop Time
Study Medication Missed	Study Medication Missed	Date of Missed Dose	-	-	-
Survival	Non-Repeating Data	Date of Death	-	-	-
Survival	Patient Autopsy - Sites	-	-	-	-
Transfusion	Transfusion	Date of Transfusion	Time	-	-
Urinary Excretion	Non-Repeating Data	Date of Dosing	Start Time of First Injection	-	-
Urinary Excretion	Urinary Excretion	Date	Start Time	Stop Date	Stop Time
Vital Signs	Vital Signs	Date	Time	Vitals Date(Enroll), Course Start Date	-

Glossary

C3D

Cancer Centralized Clinical Database

CDW

Clinical Data Warehouse

CDR

Clinical Data Registry

CTEP

Cancer Therapy Evaluation Program

IDE

Investigational Device Exemption

IND

Investigational New Drug

IRB

Institutional Review Board

NAL

NIH's Application Launcher

RDC

Oracle Clinical Remote Data Capture