Urinary Excretions

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Purpose

Record detailed information about the collection of urine samples for analysis of the presence and quantity of the study medication and/or its metabolites.

> ⓘ Note: This CRF will be put on the cycle section.

Urinary Excretion eCRF

Field Name	Description / Instructions	Format
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Dosing field.	DD-MMM-YYYY
Course Number[d]	Indicates the course number that this urinary excretion sample is related to as derived from the course initiation start date.	5 digits
Day in Course[d]	Indicates the day since the beginning of course that this urinary excretion sample is related to as derived from the course initiation start date.	5 digits
Start Date of Dosing[m]	Enter the date the study agent was administered.	DD-MMM-YYYY
Start Time of First Injection[m]	Enter the time of the first injection of the study agent, or if appropriate, for taking the study agent via any "non-IV" route of administration (for example, enter the time that the agent is administered orally or rectally).	HH(24):MM
Study Agent[m]	Enter the name of the study agent (investigational or commercial) which is the subject of the urinary excretion study. > ⓘ Note: Only one study agent is allowed per case report form. Separate forms should be used when more than one study agent is being studied.	Use pick list.

ⓘ

Stop Date of Dosing	Enter the date the study agent administration was stopped. ⓘ Note: This field will be used for infusional therapies only.	DD-MMM-YYYY
Stop Time of First Injection	Enter the stop time of the first injection of the study agent, or if appropriate, for taking the study agent via any "non-IV" route of administration (for example, enter the time that the agent is administered orally or rectally). ⓘ Note: This field will be used for infusional therapies only.	HH(24):MM
Planned Interval	Planned interval pre-determined per protocol.	80 characters
Sample Collected?(m)	Indicate whether or not the specimen is collected. YES - then the Start Date, Time and Urine Volume should be entered NO UNKNOWN	Use pick list.
Start Date	Enter the collection start date.	DD-MMM-YYYY
Start Time	Enter the collection start time even if the assay results are not available.	HH(24):MM
Stop Date	Enter the collection end date.	DD-MMM-YYYY
Stop Time	Enter the collection end time even if the assay results are not available.	HH(24):MM
Urine Volume	Enter the urine volume collected in milliliters.	4 digits.
Parent Study Agent Assay 1	Enter the first parent study agent assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Parent Study Agent Assay 2	Enter the second parent study agent assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Parent Study Agent Assay Mean Concentration	Enter the parent study agent assay mean concentration, if available.	8 digits and 3 decimals
Parent Study Agent in Void	Enter the parent study agent assay in void results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Parent Study Agent UOM	Select the appropriate Study Agent units of measurement (e.g.: mg/dL or mmol/l).	Use pick list.
Metabolite Assay 1	Enter the first metabolite assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite Assay 2	Enter the second metabolite assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite Mean Concentration	Enter the metabolite mean concentration, if available.	8 digits and 3 decimals
Metabolite in Void	Enter the metabolite in void results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite UOM	Enter the appropriate Metabolite units of measurement (e.g.: mg/dL or mmol/l).	Use pick list.

Validations

Code	Description	Resolutions
UE01, UE02, UE07, UE15	Urinary excretion dates are in the future.	Enter dates that are equal to or prior to the current date.
UE06	Collection End Date/Time is prior to the collection Start Date/Time.	Collection End Date/Time must be after the collection Start Date/Time.
UE08	Start Date / Time and Stop Date / Time pair appears more than once – duplicate entry.	Remove the duplicate record or correct the Start Date / Time and Stop Date / Time of one of them.
UE11	Study Agent UOM entered, but Assay 1, Assay 2, Mean Concentration and Amount in Void are missing.	Enter a Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void.
UE12	Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void entered, but UOM is missing.	Enter the Study Agent UOM.
UE13	Metabolite UOM entered, but Assay 1, Assay 2, Mean Concentration and Amount in Void are missing.	Enter a Metabolite Assay 1, Assay 2, Mean Concentration and/or Amount in Void.
UE14	Metabolite Assay 1, Assay 2, Mean Concentration and/or Amount in Void entered, but UOM is missing.	Enter the Metabolite UOM.
UE16	Collected Urinary Excretion sample does not have corresponding Start Date, Time and Urine volume.	Enter Start Date, Time and Urine Volume if 'Sample Collected' is 'YES'.

Derivations

Code	Field Name	Description
UE1001	Course #	Course number is derived based on the course initiation start dates and the infection episode onset date.
UE1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the infection episode onset date.