Introduction

At the end of 2003, the National Cancer Institute's Center for Cancer Research (CCR) developed and started using the Cancer Central Clinical Database (C3D) - a client-server computer system - to capture data for oncology clinical trials research trials conducted at the CCR.

This manual contains the instructions for the completion of the NCI's standard Case Report Forms used in C3D.

The eCRF instruction manual is preceded by a General Instructions section which describes topics applicable to all eCRFs. This is followed by instructions for each form which include how to complete each field, what the validation rules are for the CRF, and what fields will be derived by the database. The Appendices include conversion tables and useful Internet and Intranet references and standard lab panels.

For BTTC Studies, refer to the BTTC eCRFs Instructions Manual.

Changes to Case Report Forms since Last Version of the Manual

Previous Versions of the eCRFs Instructions Manual

2013 Version in a single PDF (outdated!). (No large CRF screenshots!)
Case Report Forms Instructions

General Instructions
★ updated

Adverse Events ★ Baseline Medical History Baseline Symptoms Cardiac Chimerism Concomitant Measures and Medications Course Assessment Course Initiation Consults (new) ECG Eligibility Checklist Enrollment ★ Extent of Disease ★ Extent of Disease (Neuro Oncology Branch) (new) Follow up Infection Episode Labs ★ Medical Record Numbers Off Study ★ Off Treatment Pathology Report (new) Pharmacokinetics Physical Exams - Screening Physical Exams - Courses PI Signoff Prior Radiation Supplement Prior Surgery Supplement Prior Therapy Supplement Prior Treatment Summary Procedures Radiation Study Medication Administration Storage (new) Surgery Survival Transfusions Urinary Excretions Vital Signs

Appendices

Appendix I - Conversion Tables
Appendix II - Useful References
Appendix III - Lab Panels
Appendix IV – Lab Load Interface (LLI) Tool

Case Report Forms for GVHD Studies

Under Development
cGVHD - Activity Assessment Clinician
cGVHD - Activity Assessment Patient Self Reported
cGVHD - Characteristics at Enrollment
cGVHD - Composite Assessment Scale
cGVHD - Composite Assessment Scale (Continuation)
cGVHD - Patient Symptom Scale
cGVHD - Qualitative Research Questions
cGVHD - Treatment History

GVHD
Changes to Case Report Forms since Last Version of the Manual

New Standard eCRFs

- Consults
- Extent of Disease (Neuro Oncology Branch)
- Pathology Report
- Storage

Updated eCRFs

Adverse Events

- Serious instructions clarified.
- Added Expedited to Manufacturer.

Chimerism

- Specimen picklist updated.

Enrollment

- Gender picklist updated.
- Disease Term picklist using CTep Simplified Disease Code list.

Extent of Disease

- eCRF broken into two: one for the Lesion Identifications and another for the Lesion Measurements.

Labs

- Added 2 new eCRF Lab Panels: HLA and Chimerism.

Off Study

- Removed Reason ‘O’ from Off study Reason Picklist used in studies that have Follow-up period.