C3D BTTC eCRFs Instructions Manual

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Manual for the Completion of the NCI / CCR / C3D BTTC Case Report Forms

To register for C3D training, please visit: C3D Training Schedule

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 was developed for data managers and study coordinators responsible for capturing patient data from BTTC clinical trials into C³D. It contains general instructions on how to complete the Standard Case Report Forms (eCRF) developed for BTTC trials, such as time frames for data entry. It also includes specific details on how to complete each eCRF, defining the required fields, pick lists available and validations to assist with data entry.

If you have questions or comments, please forward your feedback on this manual to the NCI Brain Tumor Trials Collaborative.

Case Report Forms Instructions General Instructions for completion of all Case Report Forms **BTTC Adverse Events BTTC** Baseline Disease Assessment **BTTC Baseline Medical History BTTC Baseline Symptoms BTTC Concomitant Measures and Medications BTTC Course Assessment BTTC Course Initiation** BTTC Eligibility Checklist **BTTC Enrollment BTTC Extent of Disease** BTTC Follow up **BTTC** Labs BTTC MDASI-BT BTTC MDASI-Simplified BTTC MDASI-SP **BTTC Neurological Assessment** BTTC Off Study **BTTC Off Treatment BTTC Overall Survival** BTTC Physical Exams - Courses BTTC Physical Exams - Screening BTTC Physical Exams - Simplified **BTTC Post Treatment Medication** BTTC Prior Radiation Supplement **BTTC Prior Surgery Supplement BTTC Prior Therapy Supplement BTTC Prior Treatment Summary BTTC Procedures** BTTC Seizure Activity Summary **BTTC Specimen Status** BTTC Study Medication Administration

Appendices

Appendix III - Lab Panels