BTTC Post Treatment Medication

Contents

Purpose

This Case Report Form (CRF) is required when a patient stops treatment and begins a new anticancer therapy. Record details of post therapies related to the disease being studied (i.e. brain tumor). You may also record any treatment details that would be clinically significant for the evaluation of this study as indicated on the Post Treatment Summary CRF.

Post Treatment Supplement eCRF

Field Name	Description / Instructions	Format
Visit Date(m)	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Start Date(m)	Enter the date the patient received the first dose of the new anti-cancer therapy (i.e. the next post-protocol therapy). Partial dates are acceptable when the day is not known.	DD-MMM-YYYY or MMM-YYYY
Stop Date	Enter the date the patient received the last dose of the post-protocol therapy. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received.	DD-MMM-YYYY, MMM-YYYY
Therapy Type	Term to describe the number of agents included in therapy regimen: - MULTIPLE AGENTS - SINGLE AGENT - UNKNOWN	Use pick list.
Post-Therapy Followup Agent Name	Select the generic name of the agent that was used. ℹ Note: For standard regimen (multiple agents given as one regimen), enter one record for each agent.	Use pick list.
Total Dose	Enter the total dose of the agent.	8 digits, 3 decimal
Total Dose UOM	Enter the total dose units of measurement.	16 digits
Schedule	Select the schedule on which the agent (or combination) was given. (Optional field)	24 characters
Route	Select the route from the list.	16 characters

Duration(m)	Enter the duration calculated from the start date/time and stop date/time.	6 digits, 2 decimal
Duration UOM(m)	Select the units of measurement so that the duration can be derived. DY - Days HR - Hours MN - Minutes MO - Months WK - Weeks SEC- Seconds	Use pick list.
Best Response	Select the best response encountered: CR - Complete Response PD - Progressive Disease PR - Partial Response SD - Stable Disease UK - Unknown **Leave this field blank if the treatment is ongoing.**	Use pick list.

Legend: (m) RDC mandatory.

Validations

Code	Description	Resolutions

Derivations

Code	Field Name	Description