BTTC Concomitant Measures and Medications

Contents

Purpose

Record all concomitant medications from baseline as specified in the protocol. If a patient receives treatment or therapy for an adverse event, also record the specific medications or therapies prescribed to treat adverse events on this CRF.

If a patient is taking a medication PRN, do not use a separate line for each time the medication is taken, instead report the first and last dates taken.

Concomitant Measures / Medications eCRF

Field Descriptions and Instructions

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 Start Date field.	DD-MMM-YYYY
Course # (d)	Indicates the course number that this concomitant measure / medication started in as derived from the course initiation start date.	5 digits
Day in Course (d)	Indicates the day since the beginning of course that this concomitant measure / medication started as derived from the course initiation start date.	5 digits
Start Date (m)	Enter the start date of the measure or medication. ⓘ Note: Partial date is only acceptable for baseline measure or medication.	DD-MMM-YYYY or MMM-YYYY
Stop Date	Enter the stop date of the measure / medication. ⓘ Note: Partial date is only acceptable for baseline measure or medication.	DD-MMM-YYYY or MMM-YYYY

Agent Name	In the case of agents, state the generic name of the medication administered, or, in the case of combinations such as trimethoprim / sulfamethoxazole, state the brand name (i.e., Bactrim). ⓘ Note: This pick list does not show all the Agents. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched Agents. Ex: type %ydro% to list all the agents that include the lower characters 'ydro' somewhere in the agent's name. ⓘ Note: Pre and post medications specified in the protocol and administered as part of the patient's treatment, must be entered in the Study Medication Administration case report form. ⓘ Note: Do not select an agent name if a procedure has been entered.	Use pick list.
Procedure /Measure	If a procedure/measure, state e.g., oxygen administration, pleural tapping, etc. ⓘ Note: Do not select a procedure if an agent name has been entered.	Use pick list.
Dose (m) (	Enter the dose of the agent as appropriate. ⓘ Note: This field is mandatory for agents. If a procedure/measure, leave blank. In the case of combinations such as Bactrim, enter the single dose. Ex: Dose 1, Unit tab, schedule bid. When the schedule is PRN (For example: taking 2 tabs of Percocet PRN every four hours) enter the single dose Ex: Dose 2, Unit tab, q4hr PRN.	100 characters
UOM	Select the total daily dose units of measurement. ⓘ Note: If a procedure/measure, leave blank.	Use pick list.
Schedule	Enter the frequency of medication administration or measure under schedule.	24 characters
Route	Select the route given: IM - intramuscular ID - intradermal IV - intravenous bolus (less than 30 minutes) IVI - intravenous infusion (greater than 30 minutes, but less than 24 hours) CIV - continuous intravenous infusion (greater than 24 hours) IA - intra-arterial IT - intrathecal IP - intraperitoneal IH - intrahepatic IHI - intrahepatic infusion SC - subcutaneous T - topical PO - oral RT - radiation	Use pick list.
Reason (m)	Select the reason the medication is being administered or why measure done. For example, if Bactrim is being given as a prophylactic, select "pneumocystis prophylaxis". ⓘ Note: Do not enter the pharmacological classification of the medication (e.g. antibiotic, analgesic, etc.)	Use pick list.

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Validations

Code	Description	Resolutions
CM01	Agent and Procedure are missing.	An Agent or Procedure must be present.
CM02	Both Agent and Procedure are filled.	Agent and Procedure cannot be both selected at the same time.
CM03	Stop Date is before the Start Date.	Stop Date must not be earlier than Start Date.
CM04	Agent entered and Dose and/or Units of Measurement are/is missing.	If Agent is entered, Dose and Unit of Measurement must be present.
CM05	Dose and/or Unit of Measurement entered and Procedure also entered.	If Procedure is entered, Agent, Dose and Unit of Measurement must not be present.
CM06, CM07	Start and/or Stop Date are/is in the future.	Enter a date that is equal to or prior to the current date.
CM10, CM11	Partial Start Date and/or Stop Date are/is after the first Course Initiation Date.	Partial Start and Stop Dates are only acceptable for baseline measures and/or procedures.
CM12	Dose is not a valid numeric value.	Enter a valid numeric value.

Derivations

Code	Field Name	Description
CM1001	Course #	Course number is derived based on the course initiation start dates and the concomitant measure / medication start date.
CM1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the concomitant measure / medication start date.