Follow up

Contents

Purpose

Record each follow-up contact as identified in the protocol.

There is no need to complete this Case Report Form if the patient died during the treatment portion of the study. Survival CRF still needs to be completed.

Follow-up 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 Last Contact field.	DD-MMM-YYYY
Date of Last Contact(m)	Enter the date the patient was last contacted. If the patient is being considered lost to follow-up (i.e.: unsuccessful contact with the patient / family / health care provider), please indicate the date that no further follow-up will be attempted.	DD-MMM-YYYY
Type of Contact(m)	Select how the information was obtained: 1. Telephone contact with patient 2. Telephone contact with patient's family 3. Telephone contact with patient's local physician 4. Social Security Death Index (SSDI) 5. Clinic Appointment 6. Mail contact with the patient 7. E-Mail contact with the patient	Use pick list.
Received Treatment Since Last Contact?(m)	If the patient has received further treatment since the last contact, select Y - Yes N - No ⓘ Note: When answering 'Yes' and the patient has died during the follow-up period, only the Date of Death, entered on the Survival case report form, is sent to CTMS. Cause of Death and Autopsy information are not sent.	Use pick list.
Patient Status(m)	Select one of the options below that indicates the patient's last known status. If the patient has died, enter the date in the Date of Death field. If status is unknown, enter some explanation on the field labeled "Unknown (explain)". 1. Alive with disease 2. Alive with no evidence of disease 3. Alive disease status unknown 4. Unknown (Explain) 5. Died	Use pick list.
Explain 'Unknown' Patient Status	If Patient Status is unknown, enter some explanation here. Include what attempts were made and how many attempts where made in order to obtain the patient's status (i.e.: no response to 5 messages left).	24 characters

Validations

Code	Description	Resolutions
FLW05	Date of Last Contact is in the future.	Enter a date earlier than, or equals to, the current date.
FLW06	Date of Last Contact is not within the Date Off Treatment and Date Off Study.	Date of Last Contact must fall between the Date Off Treatment and Date Off Study.
FLW07	Duplicate Date of Last Contact.	Date of Last Contact must be unique.
FLW08	Patient Status is "Unknown" and explanation is missing.	Patient Status "Unknown" requires an explanation.
FLW09	Explain "Unknown" Patient Status was provided, but Patient Status is not "Unknown".	Patient Status "Unknown" is required if an explanation for "Unknown" Patient Status is provided.