Automated Forms Tracking

Changes to the Forms Tracking System

- Expected form dates will be generated by a computer program rather than entered manually by the Quality Control specialists (QCS)
- Key study parameters will be entered prior to the start of the study. These parameters will define when forms are expected and the cycle length for the given phase of the study (Active Treatment, Observation)

  Example

  Registration & On-Study Material
  Expect the On-study Form once at registration
  Active treatment
  Expect the Measurement Form, Evaluation Treatment Form, and Nadir Adverse Event Form for each cycle (for example, every 28 days)

- Expected dates will be adjusted based on data received.

  Example

  When a Nadir Adverse Event form is received and entered in the database, the date of evaluation will be used to adjust the date that the next cycles of forms are expected. For example, in a trial where the cycle length is 28 days, if treatment is delayed for cycle 2, the cycle 3 Nadir Adverse Event Form will not be expected until 28 days after the date of evaluation for cycle 2.

- We will continue to give a 30 day grace period to send in all forms. Thus, the form is not overdue until 30 days past the expected date.

- Forms required when a particular event occurs will not be tracked

  Example

  End of Active Treatment Form – We do not know when to expect this form since it is submitted when a patient goes off active treatment.

How Changes Affect Overdue Report

- You will see all missing forms not just the next missing form
- Initially you will receive the NCCTG Study Materials Monitoring Report on the same schedule, the goal is to eventually place this report on the web and update it nightly
- The report will be as accurate as the data you submit to the research base

Example

If you do not submit an End of Active Treatment Form in a timely fashion, you will continue to see active treatment forms expected even after your patient has gone off treatment

If you submit an End of Active Treatment Form that indicates the patient is going to the Observation Phase and the patient is actually in the Event Monitoring Phase, you will receive overdue notices for Event Monitoring Forms in error and will not receive any notices of missing Observation forms.

Key Forms and Variables

- Key Form - End of Active Treatment Form

  Key Field - Date off last treatment dose on this study
  Date decision was made to end active treatment

  Key Field – The patient will now go to
  1- Observation
  2- Event Monitoring

  Note: Look at the schema, test schedule, Section 13 & 18 for direction on if patient should be going to observation or event monitoring phase. If there is confusion, consult the QCS for the study.

  Reminder: New Primary does not constitute progression and therefore does not necessarily result in the patient going to the Event Monitoring phase.

- Key Form – Evaluation Treatment Form
  Key Field – Check One: Treatment/Observation
  Indicate if End of Observation

- Key Form – Nadir Adverse Event Form

  Key Field – Evaluation Date (typically used to adjust cycle length)

Miscellaneous Notes

- Always note the date of the report when viewing the Study Materials Monitoring Report. If you have submitted data just prior or after this date either remotely, via fax, or mail, the report will not reflect the recently entered/received data.