IMPAACT 2000 CRF Overview
Data Management Center
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Agenda

- Review the Data Collection Forms Schedules (DCFS)
- Examine specific CRFs
- Study notes
- Questions
This is the DCFS for the Screening, Inoculation and Week 1 visits. This slide is to highlight important aspects of data collection for this study.

X on the schedule = the form is required to be completed at that visit
V on the schedule = Non-ARV concom meds, Signs and Symptoms, Diagnoses, and Episodic Fever Tracking forms are V’d

These forms with a V are “event directed” forms, the completion of these forms is directed from the SVW0262-Study Event Tracking form

These forms are required to be completed (X) ONCE per visit week (look at the column for Week 1, Day 7)
During the visit week, collect data either on this form or in your source documents, then on the last day of the visit week, fill out the V’d form and key to the database
We’ll cover the V’d forms individually later on

The SVW0262 CRF is required to be complete every visit (X), as this form directs the completion of other forms (V’d)

The ADM0040 and F3008 are only required about 3 times a week (X)

We have a new form called the Episodic Fever Tracking form, which will collect episodes of fever. We’ll cover this form in more detail later on. This form is required to be completed on the day the episode of fever has resolved.

The schedules have a PRN section, which includes forms that should be completed ONLY if they’re needed. The PRN forms are hospitalization, specimen consent/deconsent, hematology, chemistry, and event evaluation forms
DCFS for Weeks 4, 5 and 8:

This schedule has a column called “Sick Visit.” This column only appears on this schedule and on the Pre-RSV, Seasonal Surveillance, Post-RSV Schedule

A “Sick Visit” is one that occurs outside of a regularly scheduled clinic visit. If a child is sick (meets illness criteria) at a regularly scheduled clinic visit, this is NOT a “sick visit.”

The forms required at a Sick Visit include the visit status report, master specimen tracking, and study event tracking forms. The V’d forms MAY be required, depending on how the questions are answered on the study event tracking form.

You will need to calculate the FORM WEEK for the header information on the forms required at a sick visit.

The calculation for FORM WEEK is,

Form Week of the last visit + the number of weeks since that visit

Example: the form week of the last visit (Week 8) + it has been 3 weeks since that week 8 visit = (8+3) Form Week 11
Please make sure you pay attention to all instructions and study specific notes on the CRFs.
The Visit Status Report and Master Specimen Tracking forms are required to be completed at the same visits.

On the Visit Status Report form:
The instructions tell you when to complete the form, but also follow the DCFS
Be aware of the study specific note under Question 1, which tells you how to complete question 1 for a Sick Visit.

On the Master Specimen Tracking form:
Question 1 has a study specific note instructing on the completion of question 1 for a Sick Visit. Don’t forget to complete all required tests and question 4b3 at a sick visit!
Question 2 should always be equal to “2-No.”
After you tab out of question 4b3, eData will take you to the last question on the form (5). You don’t have to tab all the way through pages 2, 3 and 4 to get to the end.
The V’d forms (visit directed, V’d on the DCFS)

The Non-ARV Concomitant Medications form is required to be completed (X) at the Inoculation Visit and on the last visit day of the each visit week

How do you complete this form?
During the visit week, you will collect the data that is required for this form. On the last visit day of the visit week, you will record the data from the entire week on ONE CRF.

If you run out of space to record data (the data exceeds lines a-i), continue to record on an additional form. The sequence number on this form will be “2.”
If you do continue on to an additional form, the header date must be the same for each form.

The header date will be the date of the last visit of the visit week.
Another V’d form-Signs and Symptoms:

Please be aware of the study specific instructions on Page 2 of this form. There is a reference to Table 5 of the Protocol, which provides instructions on recording AE Signs and Symptoms on CRFs. The instructions also reiterate how to complete the V’d forms.

There are specific instructions on when to EVALUATE a sign/symptom recorded on this form, as well as specific grading instructions.

Be aware of the study specific note under Question 1: answer the study specific question only at the inoculation visit.

How do you complete this form?
During the visit week, you will collect the data that is required for this form. On the last visit day of the visit week, you will record the data from the entire week on ONE CRF.

If you run out of space to record data (the data exceeds lines a-g), continue to record on an additional form. The sequence number on this form will be “2.”
If you do continue on to an additional form, the header date must be the same for each form.

The header date will be the date of the last visit of the visit week.
Another V’d form-Diagnoses CRF

This form has the same instructions as the Signs/Symptoms form, and should also be completed in the same way as the Signs/Symptoms and Non-ARV Con Meds forms.

Please be aware of the study specific note under Question 1, again, answer that question only at the inoculation visit.
These are snippets of Table 5 and Appendix 4 from the Protocol. Appendix 4 gives the definitions of Adverse Events, while Table 5 tells you WHICH AEs to record on the CRFs and WHEN (what phase of the study) to record them.
Tables 3 and 4 from the Protocol. These are the specific grading tables referenced on the Signs/Symptoms and Diagnoses CRFs.
Study Event Tracking form: required to be completed at every visit (in-person and not in-person)

Question 1: this is how we tell in which phase of the study the visit occurred, and what type of visit occurred. Only answer question 1a for participants on study between days 0-56.

Visit day refers to the study visit day listed on the Data Collection Forms Schedules

If you answer “Yes” to Question 2, you will be directed to complete the Signs/Symptoms form. IN ADDITION, this question will direct you to complete the Episodic Fever Tracking form IF an EPISODE of fever has RESOLVED.

This is the only place on the forms that you will be directed to complete the Episodic Fever Tracking Form

If you answer “Yes” to Question 3, you will be directed to complete the Diagnoses form

If you answer “Yes” to Question 4 (next screen) you will be directed to complete the Non-ARV Concomitant Medications form will direct you to complete the ARV Concomitant Medications form
Under the Laboratory Section, the note refers you to the PRN section for the Chemistry and Hemtology forms. These forms should only be completed if there are any abnormal chemistry or hematology results available that are associated with any AE being EVALUATED.

Question 5 and 6 will refer you to complete the Master Specimen Tracking form if they are answered “Yes.”

Please remember to complete question 4b3 if an adventitious agent assay is required.
Forms in the PRN Section: Event Evaluation form

There are a few study specific notes throughout this form. Under question 3, there is a study specific question.

Question 7 should always be answered as “1-Study participant AE”
The note under Question 6 is to remind you that any event being evaluated on the Event Evaluation form must also be recorded on the corresponding diagnoses, signs/symptoms, chemistry or hematology form.

On the chemistry and hematology forms, there is a study specific note to remind you that you should only be completing these forms if the lab results are associated with a primary event that is being evaluated.
The Episodic Fever Tracking form:

The completion of this form is directed from the Study Event Tracking form. This form should be completed ONLY if an EPISODE of fever has RESOLVED.

When the fever episode has resolved you will fill out this form and submit it to the database on the same day.
Just a reminder: this form should only contain information pertaining to the study product (RSV LID ΔM2-2 vaccine/placebo). All other medications/therapies should be recorded on the Non-ARV Concomitant Medications form.
Call/email us anytime!

Thanks!