IMPAACT 2011 CRF Overview

Data Management Center
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Agenda

- Data Collection Forms Schedules (DCFS)
- Case Report Forms (CRFs)
- Study-specific instructions and CRF completion
- Questions, comments
Data Collection Forms Schedules (DCFS)
What is the meaning of X?
► Forms that are required for that visit

Data Collection Forms Schedules (DCFS)

What is the meaning of V?
► Data collection on these forms may be required; "event directed"
► The SVW0286 - Study Event Tracking form directs completion of the V’d forms, when appropriate
► Collect information for the entire visit week, and record on ONE form
► Key to the database on the required days of the visit week: Days 7, 14, 17, and 28, or unless otherwise specified
ADM0040 - Visit Status Report / F3008 - Master Specimen Tracking
- Completed at Inoculation, any other visit marked with an X, or if directed by SVW0286 - Study Event Tracking form

SVW0286 – Study Event Tracking
- Tracks study visits/contacts and events (replaces the need to key the ADM0040 at every visit)
- Directs completion of other CRFs
- Complete on every day marked with an X

TRK0167 - Episodic Fever Tracking
- Tracks episode(s) of fever
- Completion directed from the SVW0286 - Study Event Tracking form
CRF Completion and Protocol 2011 Notes

 PLEASE:

► Be sure to read ALL of the instructions on each form for properly filling out CRFs.
► Be sure to also pay attention to ALL 2011 study-specific notes on the CRFs.
For Protocol 2011…” Notes

Forms that contain IMPAACT 2011 protocol-specific instructions include:

- ADM0040 - Visit Status Report
- F3008 - Master Specimen Tracking
- PE0032 - Detailed Vital Signs
- PE0414 - Non-ARV Concomitant Medications
- PE6833/PE6853 - Signs and Symptoms/Diagnoses
- PE6866 - Event Evaluation
- PE6813/PE6818 - Chemistry/Hematology
- SVW0286 - Study Event Tracking
- TRK0167 - Episodic Fever Tracking
- VAC003 - Nasal Vaccine Record

### INSTRUCTIONS:

- This form will indicate if any events defined by the study have occurred since the last visit or at this visit.
- This includes new information about study status, event reporting (includes signs and symptoms, diagnoses and abnormal lab results), concomitant medications.
- Complete this form at each visit.

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**For Protocol 2011:**

- Use only one F0414 form for each visit week. Complete another sequence if the number of medications/therapies entered for the visit week exceeds lines a-i.
- The header date of the form should match the visit date.
- For events not recorded on the Signs and Symptoms - IV form (PE6833), sites should add “Did not meet criteria” in the “Specify reason for use” field for given medication.
- During the visit week corresponding to each visit, record in source documents all medications/therapies with Start Dates and Stop Dates.
- As needed throughout the study, record on this CRF all required medications/therapies that were started, stopped, or ongoing during that week. Key this form at the end of each visit week on Days 7, 14, 17, and 28.
- During the RSV Surveillance period, record only those medications/therapies related to medically attended fever, URI, LRI, or otitis media.
Case Report Forms (CRFs)
Depending on which Data Collection Forms Schedule the participant is currently following, enter the appropriate visit type* in Question 1
- Day 0 - Day 56 → [Books 1-4]
- Pre-RSV Season, Seasonal Surveillance, and Post-RSV Season → [Book 5]

For Question 1b., fill in the appropriate Study Day
- This only applies to visits that fall within Study Day 0 - Day 56
  - If past Day 56, enter a “-1”

*If this is a missed visit/contact, use the appropriate code and then complete Question 1a. and specify the reason for missed visit before continuing.
Directs the completion (or continuation) of other forms, if necessary:

- F3008 - Master Specimen Tracking
- PE6818 - Chemistries
- PE6813 - Hematologies
- PE6833 - Signs and Symptoms
- PE6853 - Diagnoses
- PE6866 - Event Evaluation
- PE0414 - Non-ARV Concomitant Medications
- TRK0167 - Episodic Fever Tracking
Remember to complete the F3008 for:

- samples obtained for immunologic assays
- nasal wash for viral detection and quantification

If an adventitious virus assay is required at a visit, remember to indicate on the SVW0286, and then fill out the corresponding F3008 including question 4b3.
Illness Visit Instructions

Question 2: For 2011, ALWAYS answer as “2-No”
This form is event-directed from the SVW0286 - Study Event Tracking.

The PE0414 is required at Inoculation and thereafter, it may be required if there are new medications required to be reported per the protocol.

As outlined by the DCFS, key this form ONCE at the end of the visit week.

If the data exceeds the available space (a-i), complete an additional form sequence.

Each additional sequence should have the same corresponding header date (date of last visit day of visit week).

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**PE0414 - Non-ARV Concomitant Medications/Therapies**

<table>
<thead>
<tr>
<th>Form Data</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Number</strong>:</td>
<td>Enter patient number.</td>
</tr>
<tr>
<td><strong>Date of Patient Visit</strong>:</td>
<td>Enter date of patient visit.</td>
</tr>
<tr>
<td><strong>Protocol Number</strong>:</td>
<td>Enter protocol number.</td>
</tr>
<tr>
<td><strong>Form Week</strong>:</td>
<td>Enter form week.</td>
</tr>
</tbody>
</table>

- **Specify Drug [70]**
  - **Date Started**: Enter date started.
  - **Date Stopped**: Enter date stopped.
  - **Status**: Enter status.
  - **Route**: Enter route.
  - **Frequency**: Enter frequency.
  - **Specify Reason for Use [70]**

- **Tab Key after the last entry.**

- **Complete an additional form sequence.**

- **Each additional sequence should have the same corresponding header date (date of last visit day of visit week).**
PE0414 - Non-ARV Concomitant Medications/Therapies
“For Protocol 2011…” Highlights

- Generic form instructions provide basic information on what should be reported on the PE0414 throughout the study.

- Protocol-specific instructions outline when this form should be keyed into the database.

INSTRUCTIONS:

- **STUDY MEDICATIONS** that start prior to enrollment should be recorded as history/entry with a stop date the day before enrollment. Do not report STUDY MEDICATIONS on this form after enrollment.
  - When recording blinded study medications from another protocol, specify the word blinded in the specify field, specify the group (e.g., IMPAACT, ACTG, etc.) and the protocol number.
  - If complete date is not known, estimate date(s) according to “Date Conventions”.

For Protocol 2011:

- Record on this CRF all required medications/therapies that were started, stopped, or ongoing during that week. Key this form at the end of each visit week on Days 7, 14, 17, and 28.
  - The header date of the form should be the date of the last visit of the week, while dates in the body should correspond to the medication Start Dates and Stop Dates.
  - For events not recorded on the Signs and Symptoms - IT form (PE6833), sites should add “Did Not Meet Criteria” (DNMC) in the “Specify reason for use” field for given medication.
  - During the visit week corresponding to each visit, record in source documents all medications/therapies with Start Dates and Stop Dates.
  - During the RSV Surveillance period, record only those medications/therapies related to medically attended fever, URI, LRI, or otitis media.
PE6833 - Signs and Symptoms

► This form is also directed from the SVW0286 - Study Event Tracking.

► The PE6833 is required at Inoculation and thereafter, it may be required if there are new signs/symptoms required to be reported per the protocol.

► If the data exceeds the available space (a-g), complete an additional form sequence.
  ► Each additional sequence should have the same corresponding header date (date of last visit day of visit week).

► If required per protocol, fill out the PE6866 - Event Evaluation form for the corresponding signs/symptoms
The reporting criteria for the PE6833 and PE6853 are nearly synonymous.

Data collection, reporting, and AE instructions

Fever grading, SAE reporting criteria
The VAC0003 is only required at the Inoculation visit (Day 0).

Only information regarding the study product (RSV LID ΔM2-21030s vaccine/placebo) should be recorded on this form.
Completion of this form is directed from the SVW0286 - Study Event Tracking.

The occurrence of a fever will be recorded and on the PE6833 - Signs and Symptoms form (new and resolved).

Only complete the TRK0167 if an episode of fever has RESOLVED:
- Record the start and stop date of the fever EPISODE
- Record the MAXIMUM temperature of the fever that occurred during the episode

- Should the number of episodes for a participant exceed Line C during a visit week, then complete an additional sequence.
- Complete and key this form when the episode RESOLVES.
- An episode may span across two visit weeks.
Illness Visits
Illness Visit

- May occur outside of a scheduled visit or concurrently. Complete the regular visit as well any additional evaluations and required samples.
- To calculate the Form Week for the Header:

  \[
  \text{Form Week} = \text{Form Week of the last visit} + \text{the number of weeks since that visit}
  \]

The following forms are required at an Illness Visit (X):
- AMD0040 - Visit Status Report
- F3008 - Master Specimen Tracking
- PE0032 - Detailed Pediatric Vital Signs
- SVW0286 - Study Event Tracking

The following forms are directed from the Study Event Tracking and may need to be completed and (V):
- PE0414 - Non-ARV Concom Meds
- PE6813 - Chemistries
- PE6818 - Hematologies
- PE6833 - Signs and Symptoms
- PE6853 - Diagnoses
- PE6866 - Event Evaluation
- PE9905 - Hospitalization Record
- TRK0167 - Episodic Fever Tracking
Protocol Reporting Criteria

When in doubt, read the protocol!
## Solicited AE Grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Defined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade (0) None</td>
<td>None</td>
<td>No medical intervention required; may include use of over-the-counter medications managed by the caregiver for treatment of symptoms</td>
</tr>
<tr>
<td>Grade (1) Mild</td>
<td>Outpatient medical intervention by a health care provider required; may include use of over-the-counter and/or prescription medications</td>
<td></td>
</tr>
<tr>
<td>Grade (2) Moderate</td>
<td>Prolonged medical intervention and/or hospitalization required</td>
<td></td>
</tr>
<tr>
<td>Grade (3) Severe</td>
<td>Illness requiring hospitalization with intensive care</td>
<td></td>
</tr>
<tr>
<td>Grade (4) Life threatening</td>
<td>Event resulting in fatal outcome to the participant</td>
<td></td>
</tr>
</tbody>
</table>

## Fever Grading: Temperature Measurement

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Defined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade (0)</td>
<td>≥100.0°F but &lt;100.4°F (≥37.8°C but &lt;38°C)</td>
<td></td>
</tr>
<tr>
<td>Grade (1)</td>
<td>≥100.4°F but ≤101.4°F (≥38°C but &lt;38.6°C)</td>
<td></td>
</tr>
<tr>
<td>Grade (2)</td>
<td>≥101.5°F but ≤102.4°F (≥38.6°C but &lt;39.1°C)</td>
<td></td>
</tr>
<tr>
<td>Grade (3)</td>
<td>≥102.5°F but ≤104.8°F (≥39.2°C but &lt;40.4°C)</td>
<td></td>
</tr>
<tr>
<td>Grade (4)</td>
<td>≥104.9°F (≥40.5°C)</td>
<td></td>
</tr>
</tbody>
</table>

*Applies to any modality of temperature measurement Expedited AE Reporting Period*
**IMPAACT 2011 Grading Tables Protocol Section 7**

**Table 2: AE CRF Recording Requirements**

<table>
<thead>
<tr>
<th>Event Phase</th>
<th>Onset Date</th>
<th>AEs to record on CRFs</th>
<th>Concurrent Medications to Record on CRFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0 through midnight of 28th day following inoculation (Acute Phase)</td>
<td>ANY</td>
<td>All SAEs, All solicited AEs that meet Appendix IV criteria, All unanticipated AEs (Grade 1-6), with the exception of the following conditions if not treated with prescription medications or OTC medications with antipyretic properties: diarrhea, rash, itching, sunburn, and spitting up. Note: SAEs and LRIs must be reported via DAIDS Adverse Events Reporting System (DAERS); see Section 7.3.4.</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
<tr>
<td>From 12:01 am on 29th day after inoculation to midnight of the 56th day following inoculation (Post-Acute Phase)</td>
<td>ANY</td>
<td>All SAEs. Note: SAEs must be reported via DAERS (see Section 7.3.4).</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
<tr>
<td>After Day 56 Visit and until RSV Session Surveillance Period</td>
<td>Up to October 8 in year of inoculation</td>
<td>Grade 3 or SAE that is deemed related to Pre-RSV Session Study Visit procedures.</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
<tr>
<td>RSV Session Surveillance Period</td>
<td>November 1st to March 31 following inoculation</td>
<td>Fever, LRI, URI, and/or other illness that are medically attended. All SAEs</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
<tr>
<td>Post-RSV Season</td>
<td>April 1st to April 30th in the year after the inoculation</td>
<td>Grade 3 or SAE that is deemed related to Post-RSV Session Study Visit procedures.</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
<tr>
<td>Throughout study</td>
<td>ANY</td>
<td>Unresolved AE or SAE with onset date during Day 0 to midnight of the 25th day after inoculation. Unresolved SAE with onset date prior to midnight on the 56th day following inoculation. Unresolved SAE with onset date during RSV Surveillance Period or related to the Pre- or Post-RSV Session Study Visit.</td>
<td>All coexistent medications related to the recorded event.</td>
</tr>
</tbody>
</table>

**Notes:**
- SAEs and LRIs must be reported via DAIDS Adverse Events Reporting System (DAERS); see Section 7.3.4.
- Medically attended illness should be documented in source notes.

**Specifications:**
- **WHICH Adverse Events to record**
- **WHEN to record Adverse Events**
Questions? Comments? Concerns?

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