IMPAACT 2013 CRF Overview

Data Management Center
Ben Johnston and Linda Marillo
March 2017
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

What is the meaning of V?
- Data collection on these forms may be required; “event directed”
- The SVW0291 - 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
**TRK0175 - Episodic Fever Tracking**
- Tracks episode(s) of fever
- Completion directed from the SVW0291 - Study Event Tracking form

**SVW0291 – 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

**ADM0040 - Visit Status Report / F3008 - Master Specimen Tracking**
- Completed at Inoculation, any other visit marked with an X, or if directed by SVW0291 - Study Event Tracking form

---

**Data Collection Forms Schedules (DCFS)**

![Data Collection Forms Schedule](image_url)
CRF Completion and Protocol 2013 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 2013 study-specific notes on the CRFs
For Protocol 2013…” Notes

Forms that contain IMPAACT 2013 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
- SVW0291 - Study Event Tracking
- TRK0175 - Episodic Fever Tracking
- VAC0003 - 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.

**For Protocol 2013:**

- Record on the 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 - 11 form (PE8833), sites should add “Did Not Meet Criteria” (DNMC) in the “Specify reason for use” field for given medication.
- For medications associated with signs and symptoms, diagnoses or abnormal labs not required to be reported on CRFs, in the “Specify reason for use” field include DNMC with the condition listed.
- 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, URI, 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
- TRK0175 - 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 SVW0291, and then fill out the corresponding F3008 including question 4b3.
**Question 2:**
For 2013, ALWAYS answer as “2-No”
This form is event-directed from the SVW0291 - 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).

---

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

<table>
<thead>
<tr>
<th>Non-Antiretroviral Concomitant Medications/Therapies</th>
<th>Protocol Number</th>
<th>Patient Number</th>
<th>Data of Patient Visit</th>
<th>Protocol</th>
<th>Form Week</th>
<th>Seq No</th>
<th>Step No</th>
<th>Key Operator Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **Patient Information**
   - **Patient Number**: [ ]
   - **Data of Patient Visit**: [ ]

2. **Form Information**
   - **Protocol Number**: [ ]
   - **Protocol**: PE0414
   - **Form Week**: [ ]
   - **Seq No**: [ ]
   - **Step No**: [ ]
   - **Key Operator Code**: [ ]

3. **Medications/Therapies**
   - **Vaccines**
     - **Date Started/Date Stopped**: [ ]
     - **Status**: [ ]
     - **Route**: [ ]
     - **Frequency**: [ ]
     - **Specify Reason for Use**: [ ]

4. **Non-Antiretroviral Therapies**
   - **Specify Drug**: [ ]
   - **Date Started/Date Stopped**: [ ]
   - **Status**: [ ]
   - **Route**: [ ]
   - **Frequency**: [ ]
   - **Specify Reason for Use**: [ ]

---

**Legends**
- (1-No, 2-Yes)
- Key this form ONCE at the end of the visit week.
**PE0414 - Non-ARV Concomitant Medications/Therapies**

“For Protocol 2013…” 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.
PE6833 - Signs and Symptoms

► This form is also directed from the SVW0291 - 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 (D46/NS2/N/ΔM2-2-HindIII, Lot RSV#011B,) should be recorded on this form.
Completion of this form is directed from the SVW0291 - 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 TRK0175 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
  - SVW0291 - 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
  - TRK0175 - Episodic Fever Tracking

![Data Collection Forms Schedule](image-url)
Protocol Reporting Criteria

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

<table>
<thead>
<tr>
<th>Severity</th>
<th>Defined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade (0) 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>
</tr>
<tr>
<td>Grade (2) Moderate</td>
<td>Prolonged medical intervention and/or hospitalization required</td>
</tr>
<tr>
<td>Grade (3) Severe</td>
<td>Illness requiring hospitalization with intensive care</td>
</tr>
<tr>
<td>Grade (4) Life threatening</td>
<td>Event resulting in fatal outcome to the participant</td>
</tr>
</tbody>
</table>

**Fever Grading: Temperature Measurement**

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

*Applies to any modality of temperature measurement Expedited AE Reporting Period*
### Table 2: AE CRF Recording Requirements

<table>
<thead>
<tr>
<th>Event Time Period</th>
<th>Record at Event Onset</th>
<th>Concomitant Medications Related to the Recorded Event</th>
</tr>
</thead>
</table>
| **Days 0 through midnight of 28th** | ANY | • All cough and cold remedies including decongestants, cough suppressants, antibiotics • All nasal sprays (except salmeterol) | £
| **day following inoculation (Acute Phase)** | | • All antihistamines • All antipyretics • All prescription medications | £
| **From 12:01 am on 29th day after inoculation to midnight of the 56th day following inoculation** | ANY | • All SAEs Note: SAEs must be reported via DAIDS Adverse Experience Reporting System (DAERS) see Section 7.3.4. | £
| **Post Acute Phase** | | • All concomitant medications related to the recorded event | £
| **After Day 56 Visit and until RSV Session Surveillance Period** | Up to October 31st in year of inoculation | Grade ≥3 AE or SAE that is deemed related to Pre-RSV Session Visit procedure. | £
| **RSV Session Surveillance Period** | November 1st – March 31st following inoculation | • Fever, LRI, URI, and/or other illnesses that are medically attended • All SAEs Note: these events do not need to meet the Appendix IV criteria. SAEs and medically attended LRI s must be reported via DAERS (see Section 7.3.4). | £
| **Post-RSV Session** | April 1st – April 30th in the year after the inoculation | Grade ≥3 AE or SAE that is deemed related to Post-RSV Session Study Visit procedure. | £
| **Throughout Study** | ANY | • All concomitant medications related to the recorded event | £

**Notes:**
- SAEs and LRI s must be reported via DAIDS Adverse Experience Reporting System (DAERS), see Section 7.3.4.
- For SAE and LRI, all concomitant medications related to the recorded event.
- All concomitant medications related to the recorded event.

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

Linda Marillo
marillo@fstrf.org
716-834-0900 ext. 7257

Ben Johnston
johnston@fstrf.org
716-834-0900 ext. 7407