IMPAACT Network Reportable Protocol Deviations

Frequently Asked Questions

Please send any questions about IMPAACT deviations to: impaact.deviation@fstrf.org

1. **Sites are expected to report reportable protocol deviations (PD) within 5 days of awareness. How is a "reporting day" defined?**
   Reporting days are those that count towards the timeline provided for reporting of PDs to DAIDS via the electronic case report form (eCRF) or protocol deviation reporting system (PDRS). Reporting days for reportable PDs follow the same requirements as reporting days for expedited adverse events. The criteria used to determine reporting days are described in the Cross-Network Protocol Deviation Reporting Guide, as follows:
   - A reporting day starts at 12:00 AM (midnight) and ends at 11:59 PM local time.
   - A day is counted as a reporting day regardless of the time of day that awareness occurred.
   - The day a site indicates that site personnel became aware of a PD that meets reporting criteria shall count as day 1 if that day occurs on a reporting day (i.e., Monday through Friday).
   - If that day occurs on a non-reporting day (i.e., Saturday or Sunday), then the next reporting day shall count as day 1.
   - Monday through Friday count as reporting days.
   - Saturday and Sunday are not considered reporting days.
   - Any holiday (U.S. or in-country/local) that occurs on a Monday through Friday counts as a reporting day.

2. **Please clarify what is considered the date of site awareness of a protocol deviation.**
   The day a site becomes aware that a deviation occurred is considered day 1 of the awareness period. In cases where a site first consults the protocol team to determine whether a deviation is reportable, the day that the deviation is assessed as reportable is considered day 1 of the awareness period.

3. **What occurs when a site does not report a reportable PD within the 5-day reporting period?**
   This will be addressed on a case-by-case basis and will depend on the specific nature of the case. Sites should adequately document all deviations in source records and provide details accounting for any delays in reporting.

4. **Is the DAIDS OCSO Program Officer informed of reportable deviations?**
   Yes, the IMPAACT Operations Center shares all reportable PD reports with Network leadership and a subset of study team members, as well as with the applicable site DAIDS OCSO PO (for NIAID-supported sites; the Westat site contact is copied for NICHD-supported sites). The

IMPAACT Manual of Procedures (MOP), Section 12.5, includes a list of all individuals to whom reportable PD reports are distributed.

5. **Should sites email non-reportable deviation reports to the IMPAACT Operations Center?**
   No, only reportable PD reports—as recorded in the eCRF or PDRS—should be submitted to the IMPAACT Operations Center. Non-reportable PD reports should be retained among site records.

6. **When will the updated Protocol Deviation eCRF be implemented?**
   IMPAACT Protocol Data Managers will communicate the eCRF updates as they are completed, on a study-by-study basis. Each study will receive an eCRF memo outlining the applicable updates.

7. **A participant consented to participate in a study. They were offered a copy of the signed/dated informed consent form but decided to receive a blank ICF (not the signed and dated version). Is this a protocol deviation?**
   This would likely not be a PD. Sites should offer a copy of the signed and dated ICF to participants; however, participants may choose to receive a blank copy or no copy at all, for privacy or other reasons. It is recommended that sites' Standard Operating Procedures allow for flexibility around whether participants will receive a copy of the ICF. The DAIDS SCORE manual includes an appendix outlining site requirements for the informed consent process SOPs; notably, procedures must include confirmation that the participant/legally authorized representative received a copy of the signed ICF and if applicable, reasons the participant/legally authorized representative declined or did not receive a copy of the ICF.

8. **In the quiz component of the presentation, please clarify what is meant by the terms "likely reportable" and "likely not reportable".**
   The scenarios posed in the quiz are discrete, brief examples that do not consider the full context of a protocol. The reportability of a protocol deviation will depend on the specifications of a given protocol. The terms "likely reportable" and "likely not reportable" are used to account for the possibility of a different categorization being made in practice.

9. **Would frequent reporting of PDs be considered a trend and could this incur negative consequences?**
   If sites are frequently submitting PDs that are not considered reportable, the IMPAACT Operations Center, along with study teams, will work with them on a case-by-case basis to address frequent reporting of PDs. However, frequent reporting of PDs would generally not be considered a trend nor have negative ramifications for sites. If sites are frequently submitting reportable PDs, this trend may be escalated per the procedures noted in the IMPAACT MOP, Section 13.7.

10. **What resources can sites use to help determine whether a PD is reportable or not reportable?**
    Sites may review the PD examples provided in the PD process training presentation dated August 2023, as well as those provided in the Cross-Network Protocol Deviation Reporting Guide. Sites are encouraged to consult the protocol team for assistance in determining whether a deviation

has occurred and whether it is reportable or not reportable. The IMPAACT Operations Center deviations team is also available to assist in this capacity.

11. **Should reports of reportable PDs be submitted to the study Clinical Management Committee?**
    It may be necessary to submit reportable PD reports to the CMC, depending on the individual study requirements. Submission to study CMCs is not a general requirement of the IMPAACT PD reporting process.

12. **The presentation provides an example of a PD consisting of intentionally reporting unreliable lab results. What does this entail?**
    This scenario could entail a site being aware of a lab-related issue that is in breach of Good Clinical Laboratory Practices and not reporting or rectifying the issue.

13. **The Cross-Network Protocol Deviation Reporting Guide states that the final decision on whether a protocol deviation is reportable will be determined by the study sponsor. How will this be operationalized?**
    Sponsor involvement in determining the reportability of PDs is still to be defined. The IMPAACT Network is consulting with DAIDS for clarification on how this will be operationalized.