Protocol Deviations

**Initiative Status:**
Last Update: May 2020

**Benefits:**
- Improves identification of important Protocol Deviations and reduced noise
- Creates a focused and efficient risk-based approach to management of PDs which could directly impact patient safety, reliability of study data, human subject’s protections and/or data quality
- Reduces burden in PD definitions and associated site processes for management, reducing confusion and increasing speed of identifying important violations

**Solutions:**

**PD Process Guide (Q1 2020):**
A proposed framework describing flexible PD management approaches, elements for consideration based upon proposed interpretation of the ICH E3 definition for important protocol deviations and other associated PD Guidance with links to the PD Process Map

**PD Process Map (Q1 2020):**
A map of the PD management process containing proposed processes for both important and non-important deviations

**PD Assessment Plan Template (Q1 2020):**
A template to assist in the identification of documentation of protocol specific “important deviations”

**PD Publications (Q3 2020):**
A manuscript culminating the methodology for creating the PD Process Guide, Process Map and Assessment Template

Working with relevant Health Authorities to create a Protocol Deviation (PD) Management Toolkit designed to help sponsors conducting clinical research improve PD classification, collection, analysis, and reporting processes.