The CDASH Model establishes a standard way to collect data across studies. Guidance in this section implements the CDASH Model for the TIG Product Impact on Individual Health use case and provides

- basic data collection guidance and best practices;
- guidance for developing, managing, and using CRFs, irrespective of the inclusion of collected data in subsequent tabulation datasets; and
- guidance for mapping data collected via CRFs to tabulation datasets be used to as applicable with guidance in Section 2.8, Standards for Tabulation.

The TIG supports development of CRFs but does not formally address data collection via other sources. Guidance in this section suggests a format to be presented to those entering collected data using CRFs but does not dictate any data structure or system in which to store the collected data. Applicants may choose to develop libraries of CRFs for organizational use. In such cases, following both the CDASH Model and TIG recommendations, taking into consideration both scientific and regulatory requirements, is recommended. To gain the greatest benefit, CRFs should not be developed on a study-by-study basis within the implementer organization, but rather be brought into a study from a library of approved CRFs based on the CDASH Model and the TIG, whenever feasible.