Paper DS08 – PHUSE US 2020

CDISC Implementation Primer

Bess LeRoy, CDISC, Austin, TX, USA
Rebecca Baker, CDISC, Austin, TX, USA

ABSTRACT

As the CDISC implementation community increases, new implementers, especially those not directly connected to the pharmaceutical industry and regulators, need a starting point for their implementation journey. At the 2018 PHUSE Computational Science Symposium (CSS), the CDISC Implementation Primer project was launched as part of the PHUSE working group "Optimizing the use of Data Standards". The goal of the project was to provide new CDISC implementers a primer to start their journey. This Primer is being developed to address these implementation needs and will be made freely available to the public through the CDISC and PHUSE websites. Topics addressed will include: how to get started with CDISC, understanding the linking of models and implementation guides, compliance, and traceability. The CDISC Implementation Primer will be launched in mid-2020.

INTRODUCTION

The CDISC Implementation Primer was designed to provide new CDISC implementers a way to assemble, organize and surface useful information to make using CDISC standards easier. In this paper, we discuss the purpose, the journey, and the content of the Primer. We will take you along with us starting with the 2018 PHUSE CSS, where the idea was sparked, to the tool that will soon be available on the CDISC website with linkage to the PHUSE website and vice versa. The topics: how to get started with CDISC, understanding the linking of models and implementation guides, traceability, and compliance—will guide new comers around the rich available resources towards helpful content directed according to their role and specific needs. The landing page, *"How to get started with CDISC"* will serve as an entry point for directing users to explore the content by role, standard, organization type. There will be a series of 3-minute videos providing general overviews of the core CDISC models, Implementation Guides, and the fundamental principles for each. These will be linked to existing CDISC content as well as links to additional topics developed for the Primer.

THE JOURNEY

At the 2018 PHUSE CSS the PHUSE working group, "Optimizing the use of Data Standards" noted there was a gap in tools for new comers. The CDISC website with the

rich treasure trove of information and documents can prove overwhelming for someone new to CDISC standards. The PHUSE team wanted to understand the gaps and fill the missing void thus, the CDISC Implementation Primer idea was born. The team led by Beate Hientzch, Yvoone Moores, Wendy Dobson, and Bess LeRoy is composed of over 20 volunteers from a variety of stakeholders including CROs, pharmaceutical companies, CDISC, and PHUSE. The members decided to first focus on the following four topics: how to get started with CDISC, understanding the link between the CDISC documents, compliance and traceability. Over the next two years the team further fleshed out the topics and the initial content will be available for members in mid-2020.

IMPLEMENTATION PRIMER TOPICS

The Primer is based on four main concepts and will be able to be navigated by role, CDISC standard, and by organization type. The Primer is set up to guide the user to helpful information according to the topics they choose.

HOW TO GET STARTED WITH CDISC

This section serves as the entry point to the Primer. Individuals will be able to explore the Primer by role, clinical research process, or organization type (mock up show below in Figure 1). For each role, standard, and organization type, a variety of content which includes short videos, links to existing CDISC content, and links to the additional topics currently under development for the Primer will be made available in an easy to navigate format.

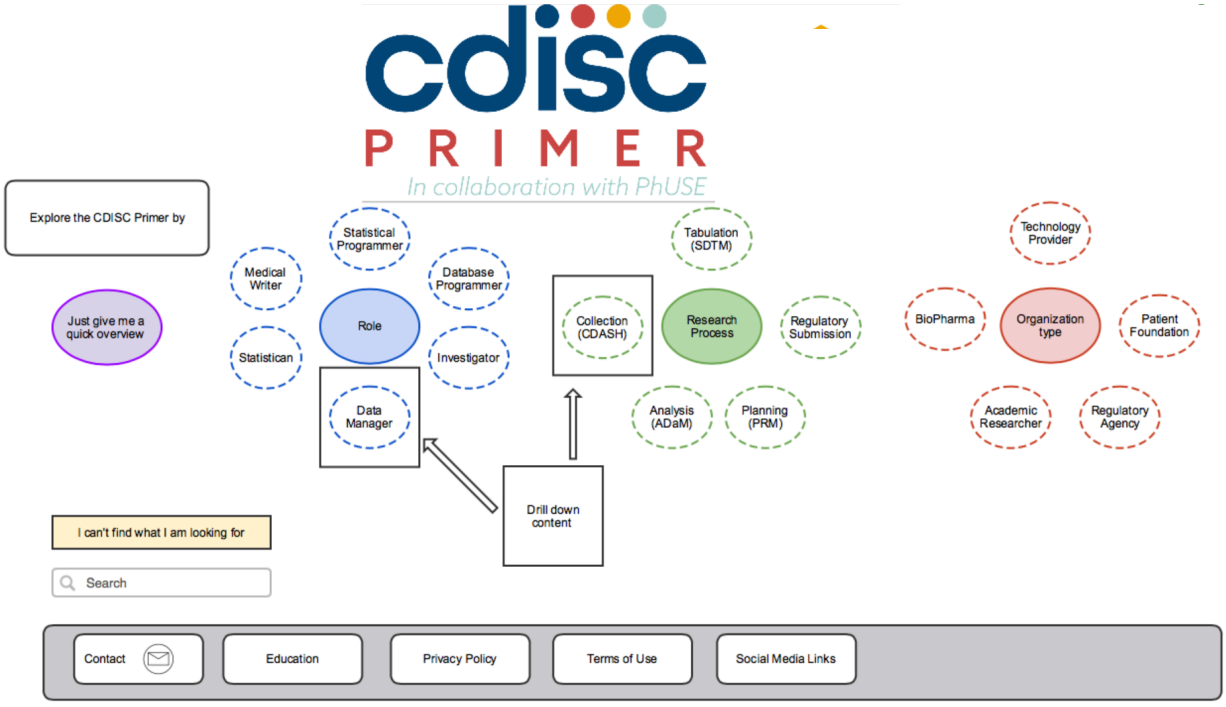

Figure 1. Draft Primer Layout

COMPLIANCE

What does it mean for a submission to be CDISC compliant? This section of the CDISC Implementation Primer focuses on compliance from different perspectives including CDISC, US Food & Drug Administration (FDA), the Pharmaceutical and Medical Devices Agency (PMDA) in Japan and vendors such as PINNACLE21 (P21). This section will include frequently asked compliance questions implementers may have regarding domains, terminology, required and expected variables, versioning, models, and regulatory requirements versus CDISC requirements as well as data cleaning, data checks, and using the P21 validator.

UNDERSTANDING THE LINK BETWEEN CDISC STANDARDS

Understanding how CDISC Standards link together is often a point of confusion for newcomers. This section of the CDISC Implementation Primer focuses on explaining how CDISC Standards connect to each other using both click-through text and click-through diagrams like the one shown below (Figure 2).

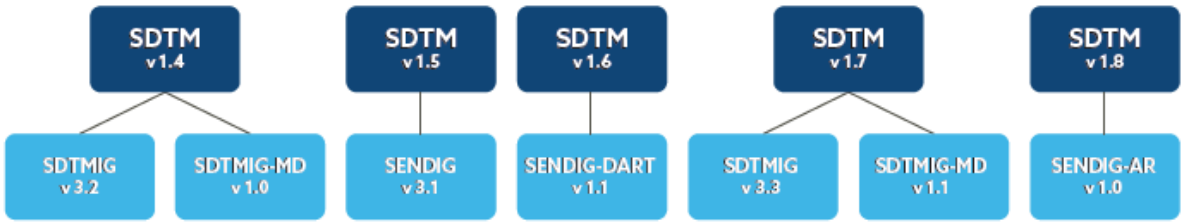

Figure 2. Relationship of CDISC SDTM Standards

This figure illustrates the relationship between various SDTM models and Implementation Guides. For example, the Study Data Tabulation Model v1.4 supports the SDTM Implementation Guide v3.2, SDTMIG v3.2, and the SDTM Implementation Guide for Medical Devices v1.0, SDTMIG-MD v1.0. The SDTM v1.5 supports the implementation guide for Standard for Exchange of Nonclinical Data Implementation Guide, SENDIG v3.1. The rest of the diagram follows the same logic and the Primer will explain how these fit together.

TRACEABILITY

Documenting the relationships between CDISC datasets from analysis to source data is important to ensure traceability. This section of the Primer focuses on introducing the concept of traceability, including data-point traceability and metadata traceability. Traceability means using the same variable names, domain names, and controlled terminology. This way it is apparent how and when transformations and derivations occurred and the same data assumptions were followed. In the diagram below (Figure 3), the documented path of a piece of data or metadata from its final location back through all transfers and transformations to its source.

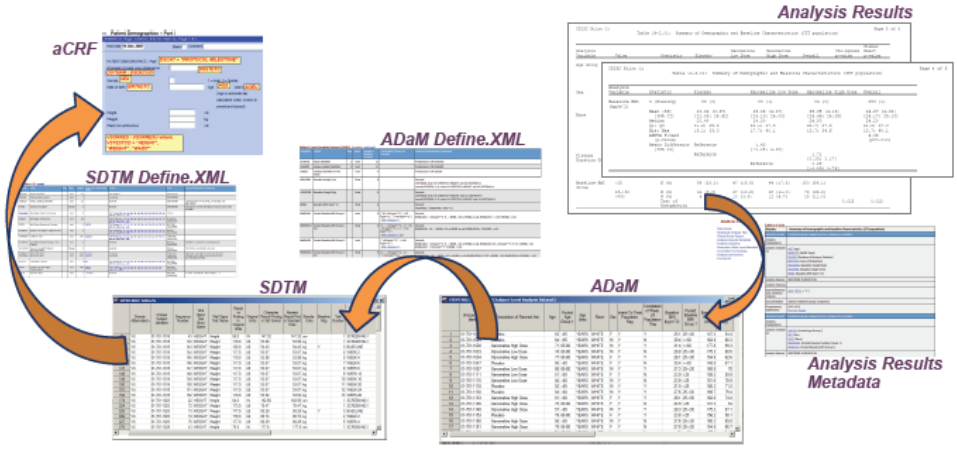

Figure 3. CDISC Standards Data Flow Traceability

CONCLUSION

The CDISC Implementation Primer is being developed to provide new CDISC implementers a primer to start their journey. The Primer provides a guide to assemble, organize and surface useful information to make using CDISC standards easier. This enables the CDISC implementation community, especially those not directly connected with the pharmaceutical industry and regulators, a map for their journey and simple introduction to fill the gap between existing documents. PHUSE heard the concerns of the community; CDISC collaborated and will provide a tool to help educate new implementers as they start their journey freely available through the PHUSE and CDISC websites.

ACKNOWLEDGMENTS

The authors wish to acknowledge the CDISC Implementation Primer Team.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Bess LeRoy
CDISC
401 West 15th Street, Suite 800
Austin, TX 78701
bleroy@cdisc.org
cdisc.org

Clear Data. Clear Impact.

.