



Implementation Primer Overview and Update

Introduction

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. The goal of the project is to provide new CDISC implementers a primer to start their journey. This Primer will be developed to address these implementation needs and will be made freely available to the public through the PhUSE website.

The CDISC Implementation Primer project was launched at the 2018 PhUSE CSS as part of the PhUSE working group "Optimizing the use of Data Standards". The members of the team 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.

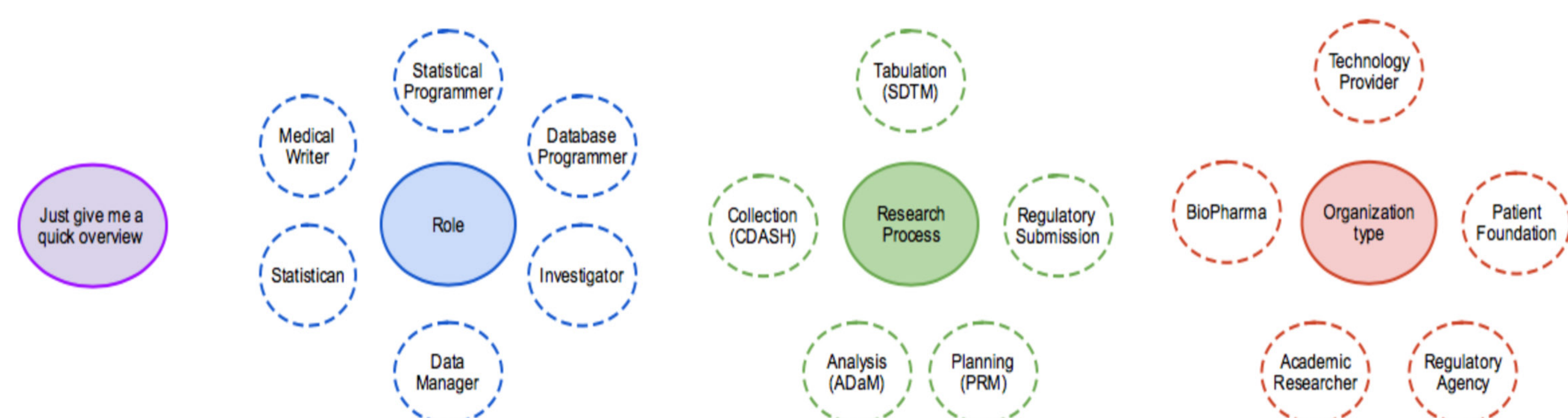
The team is led by Beate Hientzsch, Yvonne Moores, Wendy Dobson, and Bess LeRoy and is composed of over 20 volunteers from a variety of stakeholders, including CROs, pharmaceutical companies, CDISC, and PhUSE.

The CDISC Implementation Primer is anticipated to be completed in the fall of 2019.

Implementation Primer Topics

How to get started with CDISC

This section will serve as the entry point to the CDISC Implementation Primer. Individuals will be able to explore the Primer by role, clinical research process, or organization type (mock-up shown below). For each role, standard, and organization type, a variety of content will be developed, including short videos, links to existing CDISC content, and links to the additional topics currently being developed for the Primer.

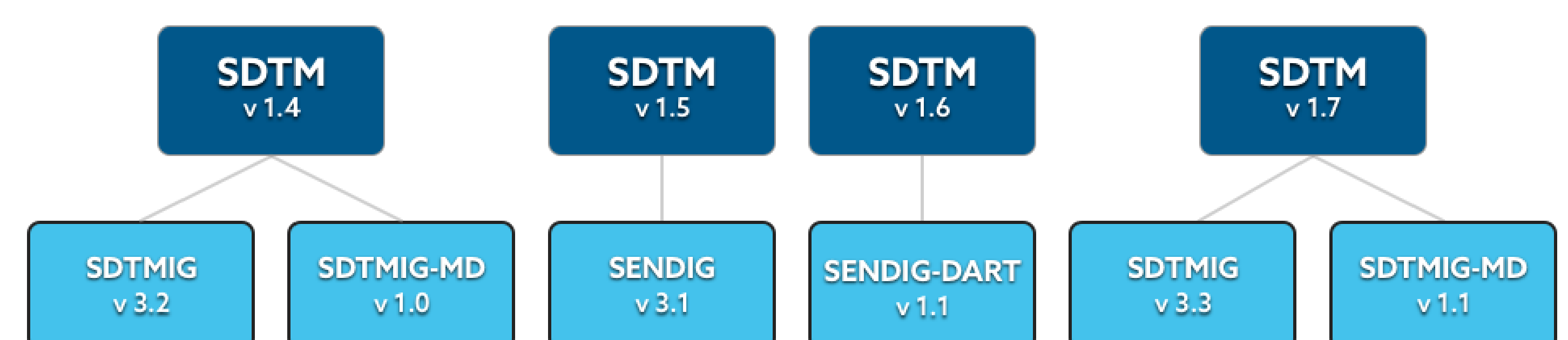


Compliance

What does it mean for a submission to be CDISC compliant? This section of the CDISC Implementation Primer will focus on compliance from different perspectives including CDISC, FDA, PMDA, and vendors such as P21.

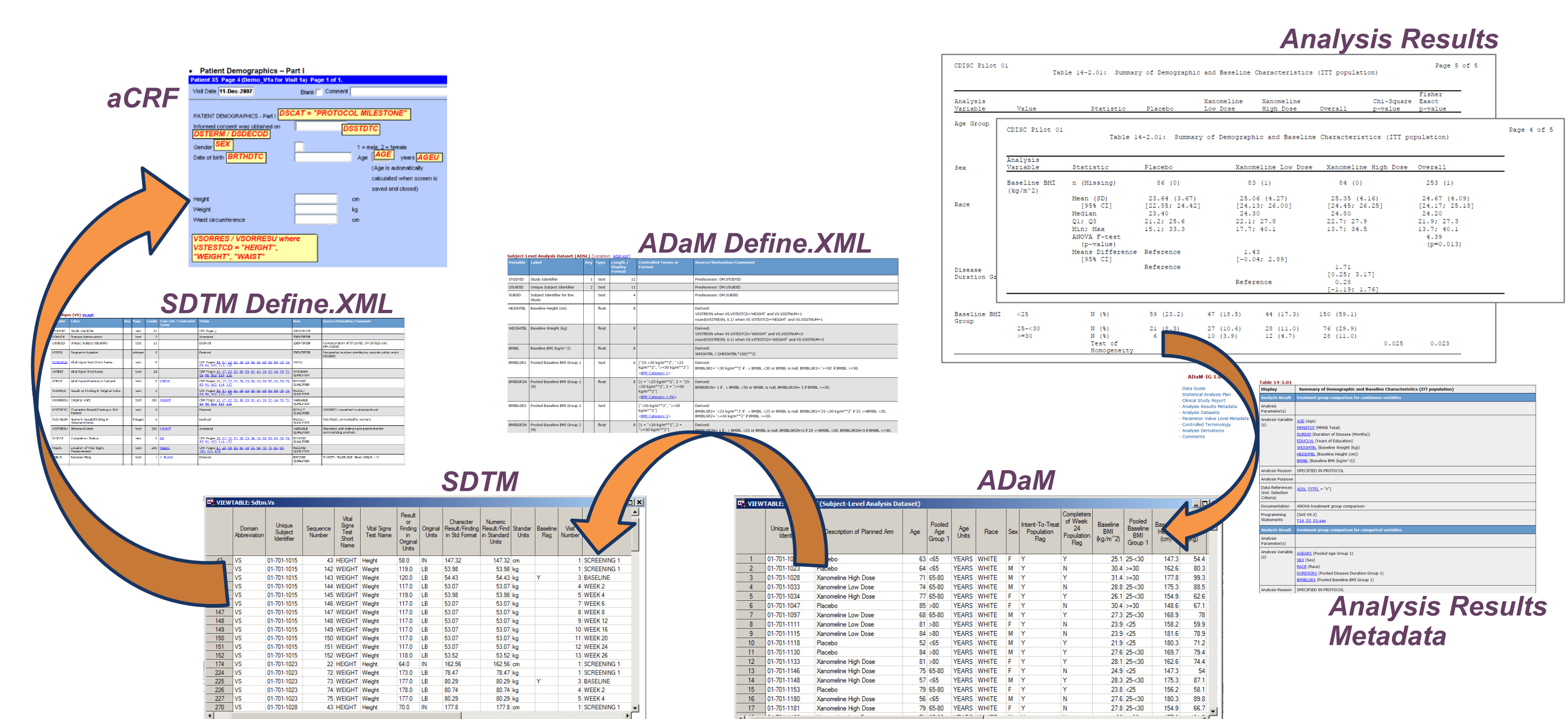
Understanding the link between the CDISC Standards

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



Traceability

Documenting the relationships between CDISC datasets from analysis to source data is important to ensure traceability. This section of the CDISC Implementation Primer will focus on introducing the concept of traceability, including data-point traceability and metadata traceability.



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