



Crohn's Disease WP1 Targeted Review with CDASH to SDTM Data Representations Public Review Webinar

Crohn's Disease Development Team

14th Jan 2021





Crohn's Disease WP1 Targeted Review with CDASH to SDTM Data Representations Public Review Webinar

Presented by

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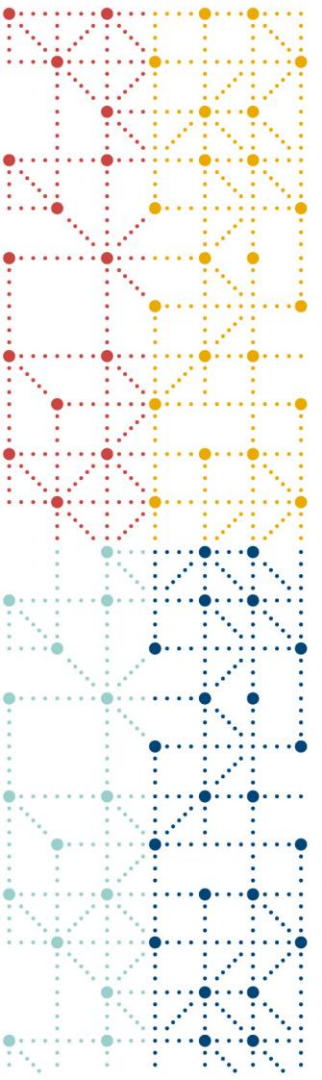
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14th Jan 2021





Crohn's Disease Project Update

Crohn's Disease

Work Package 1

- QRS Instruments
- Prior, Baseline and On-Study medications
- Disease Classification

Public Review completed Nov 2020

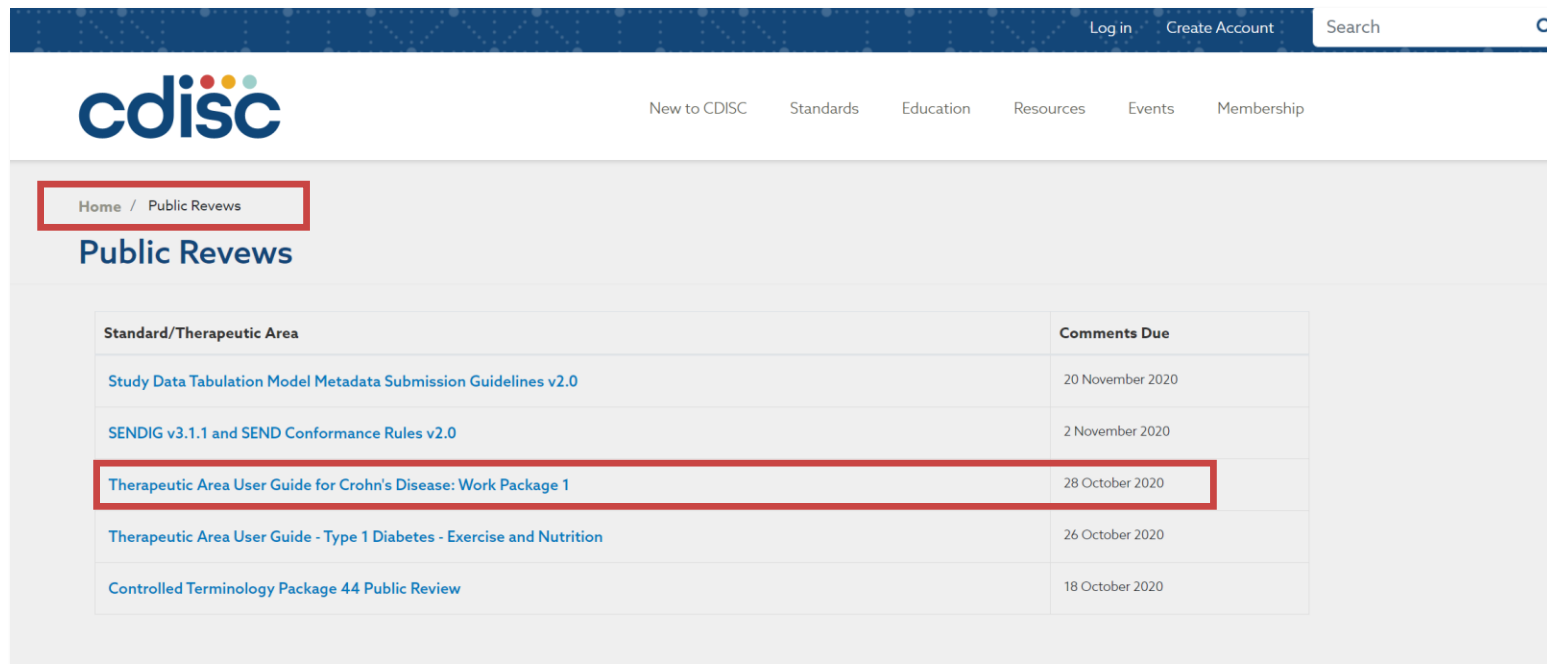
Focused Public Review – mid Feb

Work Package 2

- Endoscopy
- Cross Sectional Imaging
- Histopathology
- Biomarkers
- Analysis

Public Review completed Dec 2020

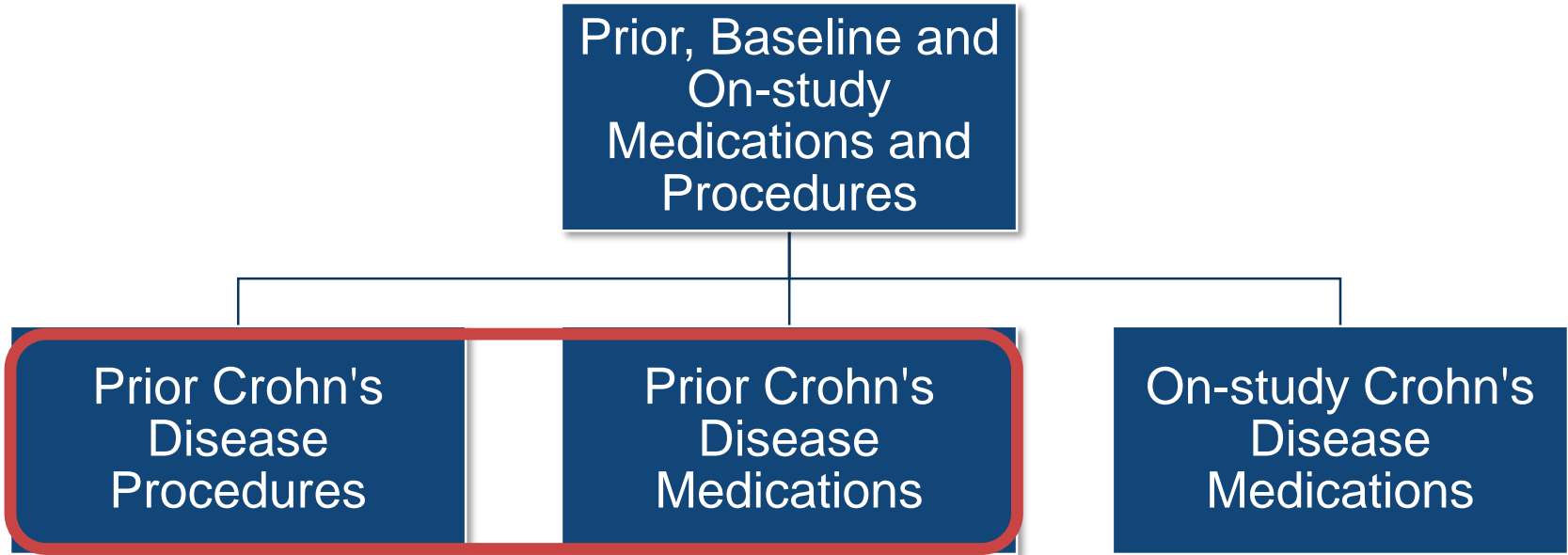
WP1 Targeted Review 2 – Public Review Documents



The screenshot shows the CDISC website interface. At the top, there is a navigation bar with 'Log in', 'Create Account', and a search box. Below this is the CDISC logo and a main navigation menu with links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', and 'Membership'. The main content area features a breadcrumb trail 'Home / Public Reviews' and a heading 'Public Reviews'. A table lists various public review documents with their respective comment due dates. The row for 'Therapeutic Area User Guide for Crohn's Disease: Work Package 1' is highlighted with a red border.

Standard/Therapeutic Area	Comments Due
Study Data Tabulation Model Metadata Submission Guidelines v2.0	20 November 2020
SENDIG v3.1.1 and SEND Conformance Rules v2.0	2 November 2020
Therapeutic Area User Guide for Crohn's Disease: Work Package 1	28 October 2020
Therapeutic Area User Guide - Type 1 Diabetes - Exercise and Nutrition	26 October 2020
Controlled Terminology Package 44 Public Review	18 October 2020

Overview of Module





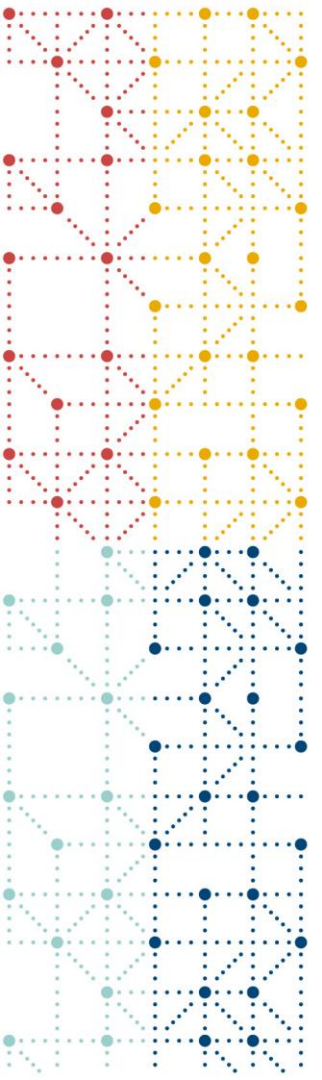
Targeted Public Review 2

Prior Crohn's Disease Procedures - Example 1

- CDASH to SDTM Data Representation

Prior Crohn's Disease Medications - Example 3

- Immunomodulators - Immunosuppressives



CDASH to SDTM Data Representation

Review Part 1



Crohns WP 1 - Review 2 - Targeted Review with CDASH to SDTM Data Representation

Created by Rebecca Baker last modified on Jan 07, 2021

This review is for Crohn's Disease TAUG WP1 and there are two updated sections for review:

- Review Part 1 - CDASH to SDTM data representation, and
- Review Part 2 - Updates to the Immunomodulator - immunosuppressive prior medication examples.

Review Part 1

The module links are provided below for convenience, the entire content of the module does not need reviewed, however, these links have been provided for context. Explanation of the content for review is provided below. Please refer to the [Instructions for Reviewers](#) page for details of how to record any review comments.

Links to the modules

- Prior, Baseline, and On-study Medications and Procedures
- Prior Crohn's Disease Procedures

The target for the review is for the CDASH to SDTM data representation included in the "View CDASH Data Representations" expanding section nested within the example CRF found in **Example 1** of the **Prior Crohn's Disease Procedures** section located in the **Prior, Baseline and On-study Medications and Procedures** module. However, to aid review, **Example 1** is re-represented below for optimal identification of what to review. Review comments can be made directly in the representation of Example 1 below.

The content for review is found by expanding the "aCRF Prior Crohn's Disease Surgery" section (Figure 1 below) and then expanding the "View CDASH Data Representations" section found immediately below the example CRF (Figures 2 and 3 below).

Please review the entire CDASH Data Representations section, including the introductory text and the four subsections:

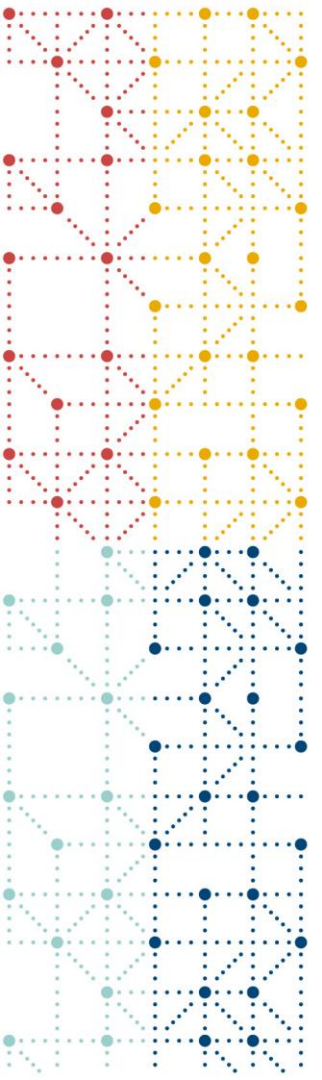
- Vertical Structure - Separate Tables
- Vertical Structure - Single Table
- Horizontal Structure
- Mapping to SDTM

Figure 1

Figure 2

Figure 3

Added CDASH data representations to aid in understanding of the magic that happens between CDASH metadata and SDTM



Immunomodulators - Immunosuppressives



Review Part 2

Review Part 2

The target for the second review is **Example 3** of the **Prior Crohn's Disease Medications** section located in the **Prior, Baseline and On-study Medications and Procedures** module. However, to aid review, the example is re-represented as **Example 2** below for optimal identification of *what* to review. Review comments can be made directly in the representation of the example below.

The changes to the immunomodulator - immunosuppressive class examples were:

- Change from "primary" and "secondary" *non-response* to *non-response*
- Addition of an "adequate treatment indicator" to reflect whether or not the past treatment with immunomodulators met the protocol defined criteria

To review the content within context please refer to the [Prior Crohn's Disease Medications](#) section.

Example 2

This example CRF collects information on the use of prior immunomodulator medications for Crohn's disease that were discontinued prior to study start.

> aCRF Prior Crohn's Disease Medications - Immunomodulators

> cm.xpt

Information about maximum and final dosing amounts of prior immunomodulator **CROHNS-443 IN PROGRESS** treatment for Crohn's disease is recorded in the FACM dataset.

> facm.xpt

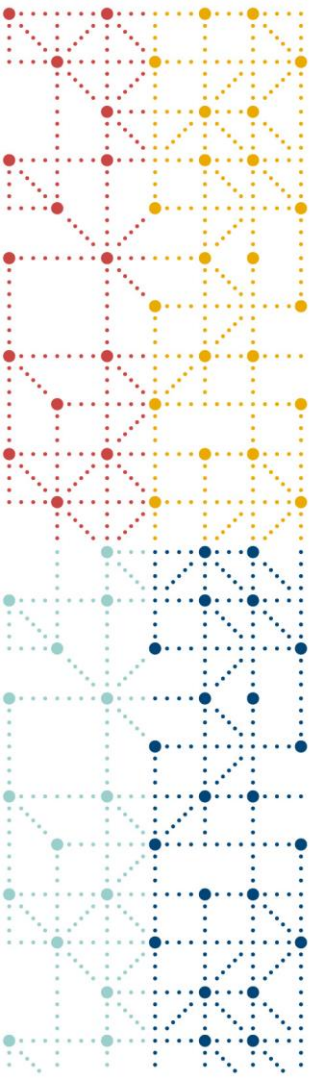
Conditions indicating intolerance to prior immunomodulators are recorded in the MH domain.

> mh.xpt

The RELREC dataset shows the relationship between the discontinued immunomodulator medications, which are recorded in the CM dataset, and both the dosing information (recorded in the FACM dataset) and the prior reactions to immunomodulator (in the MH dataset). The --SPID variables were used to relate the records in CM and FACM, whereas records in the CM and MH datasets are related by matching values in the CMSPID and MHLNKID variables.

> relrec.xpt

- Change from "primary" and "secondary" *non-response* to *non-response*
- Addition of "adequate treatment indicator" to reflect past treatment met protocol defined criteria



Thank You!

