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

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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

Public Review completed Nov 2020

Public Review completed Dec 2020
WP1 Targeted Review 2 – Public Review Documents

- **Study Data Tabulation Model Metadata Submission Guidelines v2.0**
  - Comments Due: 20 November 2020

- **SENDIG v3.1.1 and SEND Conformance Rules v2.0**
  - Comments Due: 2 November 2020

- **Therapeutic Area User Guide for Crohn’s Disease: Work Package 1**
  - Comments Due: 28 October 2020

- **Therapeutic Area User Guide - Type 1 Diabetes - Exercise and Nutrition**
  - Comments Due: 26 October 2020

- **Controlled Terminology Package 44 Public Review**
  - Comments Due: 18 October 2020
Overview of Module

Prior, Baseline and On-study Medications and Procedures

- Prior Crohn's Disease Procedures
- Prior Crohn's Disease Medications
- On-study Crohn's Disease Medications
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
Added CDASH data representations to aid in understanding of the magic that happens between CDASH metadata and SDTM
Immunomodulators - Immunosuppressives
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 - SPIID 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 MH-LNKID 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!