

2.4 Form Library (CDASH)

The Form Library consists of ready-to-use, CDISC CDASH-compliant eCRF templates that can be customized or imported as-is to the OpenClinica EDC platform. The eCRF templates cover most of the key standard forms that are used across the majority of studies. In order to make customizations, download the template and make edits within Microsoft Excel, or use the OpenClinica Form Designer. Please preview each CRF before use to make sure that all the items are adequate for data collection.

Download All Files (.zip):

• CDISC

CDISC Sample Forms:

Foundational CRFs

Common Repeating

- CE Clinical Events
- HO Healthcare Encounters
- MH Medical History
- AE Adverse Events
- PR Procedures
- CM Concomitant Medications

Common 1 - Common Forms with leading prompt

- CE Clinical Events Including Prompt
- CM Concomitant Medications Including Prompt
- PR Procedures Including Prompt
- HO Healthcare Encounters Including Prompt
- AE Adverse Events- Including Prompt
- MH Medical History- Including Prompt

Visit

- EG CENTRAL ECG Test Results- Central Reading
- MB CENTRAL Microbiology Specimen Central Processing
- LB LOCAL Laboratory Test Results- Local Processing
- IE Inclusion Exclusion Criteria

- RP Reproductive System Findings
- DA_H_RETURNED Drug Accountability Horizontal- Returned Amount
- MI CENTRAL Microscopic Findings Central Processing
- **DM Demographics**
- DA VERTICAL Drug Accountability Vertical
- LB CENTRAL Laboratory Test Results- Central Processing
- MB LOCAL Microbiology Specimen Local Processing
- **DS Disposition**
- PC FIXTIME Pharmacokinetics Sampling at Fixed Time Points
- DD Death Details
- FA Finidngs About Events or Interventions
- SU TOBACCO Substance Abuse-Tobacco
- EC Exposure as Collected
- PC_OVERTIME Pharmaconkinetics Sampling Over a Time Interval
- EG LOCAL ECG Test Results- Local Reading
- LOG Log Form Prompt
- VS HORIZONTAL Vital Signs
- PE Physical Examination- Recommended
- MI LOCAL Microscopic Findings Local Processing
- DA H DISPENSED Drug Accountability Horizontal Dispensed Amount

Crohn's Therapeutic Area

Crohn's Common

- CD ENPRB Endoscopy Procedure Biopsies
- CD_CM5ASA Prior Crohn's Disease Medication Aminosalicylates
- CD CMIM Prior Crohn's Disease Medication Immunomodulators
- CD CMBIO Prior Crohn's Disease Medication Biologics
- CD CMCS Prior Crohn's Disease Medication Corticosteroids
- CD PRSGD Prior Crohn's Disease Surgery Details
- CD_CMNSD On-Study Crohn's Disease Background Medication, Non-study Drugs-1

Crohn's Visit CRFs

- CD ENPR Endoscopy Procedure
- CD PREBD Prior Crohn's Disease Endoscopic Balloon Dilation
- <u>CD_CMNSDC On-Study Crohn's Disease Background Medication, Non-study Drug Changes-1</u>
- CD CMDCS Prior Crohn's Disease Corticosteroids Alternative Dependency
- CD PRRLOC Prior Crohn's Disease Resections, by Locations
- CD CMHL Prior Crohn's Disease Medication Classes
- CD GHAS Global Histologic Disease Activity Score (GHAS)
- CD MHCD History of Crohn's Disease
- CD PRSG Prior Crohn's Disease Surgery
- CD PREIP Prior Crohn's Disease Endoscopic Interventional Procedures
- CD_PREGSI Prior Crohn's Disease Endoscopic Gastrointestinal Stent

Insertion

- $\circ \ \underline{\textbf{CD_PAUI Procedure Agents Related to Imaging Procedures}}$
- CD_ENQM Endoscopy Quality and Measurements

Approved for publication by Riley Bianchi. Signed on 2022-07-28 9:04AM

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