

Clinical Data Acquisition Standards Harmonization (CDASH) Standard Version 1.0

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ABSTRACT

The aim of CDISC's Clinical Data Acquisition Standards Harmonization (CDASH) project is to describe recommended basic standards for the collection of clinical trial data. This document is intended to be used by those functions involved in the planning, collection, management and analysis of clinical trials and clinical data, for example, Clinical Investigators, Medical Monitors, Clinical Research Associates (Monitors), Clinical Research Study Coordinators, Clinical Data Managers, Clinical Data and Statistical Programmers, Biostatisticians, Drug Safety, Case Report Form (CRF) designers and other functions tasked with the responsibility to collect, clean and ensure the integrity of clinical trial data.

Sponsors will need to determine what additional data fields will need to be added to address study-specific requirements based on regulatory and applicable business practices. Until therapeutic area (TA) specific data fields have been standardized, sponsors will need to add these fields to the CDASH recommendations to fulfill their protocol-specific requirements.

The standard includes Best Practice recommendations and methodologies for creating data collection instruments and CDASH Domain Tables for Adverse Events (AE), Inclusion and Exclusion Criteria (IE), Comments (CO), Laboratory Test Results (LB), Prior and Concomitant Medications (CM), Medical History (MH), Demographics (DM), Physical Examination (PE), Disposition (DS), Protocol Deviations (DV), Drug Accountability (DA), Subject Characteristics (SC), ECG Test Results (EG), Substance Use (SU), Exposure (EX) and Vital Signs (VS) and can be downloaded from: <http://www.cdisc.org/standards/cdash/index.html>.

Contact Information

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