

1. [CDASH Home on the CDISC Website](#)
2. [CDASH Home on the CDISC Wiki](#) (Access may be restricted to CDASH Team Members)

<p align="center">CDASH Co-Leads</p> <p>Michael J. Ward and Jerry Salyers</p>
<p align="center">CDASH Extended Leadership Team (CELT)</p> <p>The CELT is comprised of the CDASH Sub-team Leads and the Therapeutic Area (TA) Standards Leads. The CELT meets on a monthly basis in order to address cross-team issues, share relevant information, and ensure efficient resource utilization.</p>
<p align="center">CDASH Team</p> <p>The CDASH team maintains its membership through recruitment of volunteer subject matter experts who can contribute to its various sub-teams with technical and/or therapeutic-based knowledge.</p> <p>Subteams:</p> <ul style="list-style-type: none"> • CDASH Model members develop the content for the model metadata that is used for the basis of the CDASHIG domains. • CDASHIG members develop the content for the domain level content of the CDASH standards. • CDASHIG aCRF members specialize in using the CDISC Wiki tools and macros to develop metadata and drive annotated CRF examples to support the CDASHIG. • CELT (CDASH Extended Lead Team) members determine the strategy and set the priorities and timelines for updates to the CDASH suite of standards components.
<p align="center">CDASH Education</p> <p>The CDASH training team works cooperatively with CDISC Education to develop course materials, identify and qualify new instructors, and deliver authoritative training on the CDASH standard through classroom and online courses. This team is comprised of CDASH members who are authorized CDISC trainers.</p>

<p align="center">Team Mission</p> <p>To develop and maintain data acquisition standards, therapeutic area user guides and an implementation guide to enable the efficient and standardized recording, exchange, analysis, submission, and archiving of clinical research data and metadata.</p>
<p align="center">Scope</p> <p>The CDASH team develops data acquisition standards for clinical research that:</p> <ul style="list-style-type: none"> • Address the needs of multiple stakeholders; • Permit optimal data entry for subjects and site staff; • Facilitate the review of collected data to enhance the quality of submission data; • Maintain transparency from data capture to data reporting.
<p align="center">History</p> <p>CDASH was formed in 2006 as a collaborative effort between CDISC and the Association of Clinical Research Organizations (ACRO) to specifically address FDA's Critical Path Initiative Opportunity #45, <i>Consensus on Standards for Case Report Forms</i>. The first version of the basic content standards was published in 2008. Subsequently, the team released version 1-1.1 of the CDASH User Guide (available as ODM forms) in April 2012. Subsequently, CDASHIG v2.0 and CDASH Model v1.0 were released in September 2017, including the publication of its metadata in SHARE.</p>
<p align="center">Current Focus</p> <p>The team will continue to update the CDASH Implementation Guide, CDASH Model and education materials in order to support revisions to other CDISC standards; incorporate new domains and variables resulting from the Therapeutic Area User Guide development; and address new regulatory requirements.</p>

<p align="center">Stakeholders & Constituencies</p> <ul style="list-style-type: none"> • Academic Researchers • Biotechnology • Biopharmaceutical & Pharmaceutical Sponsors • CFAST • Contract Research Organizations & Consultants • Medical Devices, Diagnostics • Regulatory Authorities • Clinical Research Sites • Standards Development Organizations • TransCelerate Biopharma Inc.
<p align="center">Collaborations</p> <p>CDASH works closely with all of the CDISC foundational standards teams, Therapeutic Area User Guide teams, NCI-EVS, and other industry groups in order to ensure the CDASH Standard provides the highest quality and most current data capture guidance available. The CDASH team includes representatives from all facets of the clinical trial industry in order to ensure the CDASH Model and CDASH Implementation Guide are easily adoptable and usable by all parties.</p>
<p align="center">Operation Model & Meetings</p> <ul style="list-style-type: none"> • The CDASH Extended Lead Team (CELT) meets on the 2nd and 4th Monday of every month. • CDASH "All Hands" meets each quarter, on the 4th Monday of the month that begins the quarter. • The CDASHIG team meets every Thursday. • The individual sub-teams leads determine the frequency of the sub-teams meetings.