Clinical Data Acquisition Standards Harmonization (CDASH)
2014 Team Charter

CDASH Co-Leads
Lauren Shinaberry and Trisha Simpson

CDASH Expanded Leadership Team (CELT)
The CDASH Sub-team Leads and CDASH CFAST TA Standards Leads form the Expanded Leadership Team. The CELT meets on a monthly basis in order to address cross-team issues, share relevant information, and ensure efficient resource utilization.

CDASH Sub-team Leads

CDASH v1.2 & 2.0	Lauren Shinaberry
CDASH Model:	Shannon Labout
CDASH Terminology:	Alec Vardy
Devices:	Kit Howard
DILI:	Kim Truett
Education:	Shannon Labout
PK:	Gary Walker & Joris De Bondt
SHARE:	Mike Ward

CDASH CFAST TA Standards Leads
*(**C**oalition **F**or **A**ccelerating **S**tandards & **T**herapies)*

CFAST Team Coordination	Dan Crawford & Dawn Kaminski
Alzheimer's:	Lorraine Spencer
Cardiovascular:	Kathy Mellars
COPD:	*To Be Determined*
Diabetes:	Rachael Zirkle
Dyslipidemia:	*To Be Determined*
Hepatitis C:	Karen Dhami
Multiple Sclerosis:	Bev Mersing
Oncology (Breast Cancer):	Elizabeth Langevin

CDASH Team
The CDASH team maintains its membership through careful selection of volunteer experts who can contribute to its various sub-teams with technical or therapeutic-based knowledge.

Team Mission
To develop and maintain data acquisition standards and user guides that allow for the efficient recording, exchange, submission, analysis, and archival of clinical research data and metadata.

Scope
The CDASH team develops data acquisition standards needed for the submission of Study Data Tabulation Model (SDTM) data-sets while keeping in mind the needs of the investigational sites.

History
CDASH formed in 2007 as a collaborative effort between CDISC and the Association of Clinical Research Organizations (ACRO) to specifically address FDA's Critical Path Initiative Opportunity #45, *Consensus on Standards for Case Report Forms.* 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.

Current Focus
The team will continue to update the CDASH standard, User Guide, and education materials in order to support revisions to other CDISC standards; incorporate the CFAST Therapeutic Area domains; address new regulatory requirements; and take advantage of advancing data capture technologies.

2014 Deliverables
- Diabetes TA CRFs for the TA User Guide *(TAUG)* (Q2)
- Hepatitis C TA CRFs for the TAUG (Q3)
- PK CRFs (Q3)
- CDASH v2.0, incorporating new SDTM domains (Q4)
- CDASH Model, primary domains (Q4)
- Device CRFs (Q4)
- SHARE CDASH content for v2.0 (Q4)

Stakeholders/Constituency
- Academic Researchers
- Biotechnology
- Biopharmaceutical & Pharmaceutical Sponsors
- CFAST TA Teams
- Contract Research Organizations & Consultants
- Medical Devices, Diagnostics
- Regulatory Authorities
- Society for Clinical Research Sites (SCRS)
- Standards Development Organizations
- TransCelerate

Collaborations
CDASH works closely with all of the CDISC and CFAST teams NCI-EVS, and other relevant industry groups in order to ensure the highest quality and usability of the CDASH standard for all parties.

Operating Model & Meetings
- The CELT meets on the third Monday of every month.
- CDASH "All Hands" meets each quarter.
- The individual sub-teams leads determine the frequency and duration of the sub-team meetings.