### 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
(Coalition For Accelerating Standards & Therapies)
- **CFAST Team Coordination**: Dan Crawford & Dawn Kaminski
- **Alzheimer’s**: Lorraine Spencer
- **Cardiovascular**: Kathy Mellars
- **COPD**: To Be Determined
- **Diabetes**: Rachel Zirkle
- **Dyslipidemia**: To Be Determined
- **Hepatitis C**: Karen Dhami
- **Multiple Sclerosis**: Bev Mersing
- **Oncology (Breast Cancer)**: Elizabeth Langevin

### 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) datasets 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.

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**Clinical Data Acquisition Standards Harmonization (CDASH)**

**2014 Team Charter**