Abstract

CFAST is an initiative of CDISC and the Critical Path Institute to accelerate clinical research and medical product development by facilitating the creation and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health. CFAST was established in June 2012 and collaborators include the U.S. Food and Drug Administration (FDA), TransCelerate BioPharma (TCB) and the National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), with participation and input from many C-Path and CDISC members as well as other organizations.

Mission

CFAST aims to develop data standards, tools, and methods to guide the development of new therapies in areas important to public health based on those areas called out in FDA’s prioritized therapeutic area list.

For each therapeutic area, CFAST aims to create the following products:
• User/implementation guide

• Core data elements with definitions, data types, Biomedical Research Integrated Domain Group (BRIDG)/Study Data Tabulation Model (SDTM) mappings

• SDTM domains and examples

• Controlled terminology/allowable value sets; along with definitions and data types, all efforts should be made to identify existing work that can be adopted or adapted to meet the requirements before new controlled terminologies or element definitions are developed

• Standard CDASH case report forms (CRFs) and SDTM annotations

• Examples of Standard for Exchange of Nonclinical Data (SEND) nonclinical data, where appropriate

These tools aim to provide a defined and consistent way to collect, store, and submit clinical trial data, allowing researchers to combine and evaluate data from multiple studies using a common approach. In addition to accelerating basic research, these standards also aim to enhance the design of clinical trials and the evaluation of new medical products, such as clinical trial simulation models and methods to evaluate treatment endpoints. All of the tools created by CFAST aim to enable researchers to guide the organization, structure, and format of standard clinical trial tabulation datasheets that are submitted to a regulatory authority.

**Consortium History**

2012

• CFAST was created as a joint initiative of C-Path and CDISC and standards for tuberculosis, virology and pain were delivered to the research community
2013

- Parkinson’s disease, polycystic kidney disease, Asthma and Alzheimer’s disease v2 (v1 pre-dated CFAST) therapeutic area standards were published.

2014

- Multiple sclerosis, diabetes, Cardiovascular endpoints, Influenza and QT Studies, therapeutic area standards were published.

2015

- Chronic Hepatitis C, Schizophrenia, Dyslipidemia and Virology v2 standards have been published. Standards for traumatic brain injury, COPD, Breast Cancer, Tuberculosis v2, CV imaging, Diabetic Kidney disease, and Rheumatoid arthritis are under development, with prostate cancer, major depressive disorder and kidney transplant standards also starting development in 2015.

Structure & Governance

CFAST has several co-directors who are senior executives of C-Path and CDISC. They are supported by assistant directors and project managers from C-Path and CDISC.

The CFAST Therapeutic Area Program Steering Committee (TAPSC) prioritizes, reviews status, and approves CDISC TA standards development projects.

The CFAST Scientific Advisory Council (SAC) provides scientific guidance and advice to the CFAST TAPSC and other CFAST project-related teams as needed.
**Financing**

CFAST is funded primarily by grants from the U.S. Food and Drug Administration. Some projects are also supported by separate, incremental funding provided by other organizations and/or in-kind contributions from other organizations.

**Intellectual Property**

Any clinical data standards produced under this partnership will be created under the CDISC standards development process, and those standards will then be published openly on the CDISC website as a global CDISC standard.

**Patent Engagement**

CFAST has a clear focus on the patient and clinician communities, through the continued development of CDISC Therapeutic Area (TA) Standards development projects, which incorporate input from patient advocacy organizations, clinicians and researchers as well as regulatory authorities.

CFAST has already published fifteen (15) CDISC therapeutic area standards (with two updated to v2, for 17 total) and is currently working on ten (10) more. Published therapeutic area user guides include: Asthma, Alzheimer’s disease v2, Cardiovascular Endpoints, Chronic Hepatitis C, Diabetes, Dyslipidemia, Influenza, Multiple Sclerosis, Pain, Parkinson's Disease, Polycystic Kidney Disease, QT Studies, Schizophrenia, Tuberculosis and Virology v2.

**Data Sharing**

CFAST’s goal is to develop data standards, tools and methods that enable more efficient and effective sharing of data for conducting research and preparing regulatory submissions in therapeutic areas important to public health. It brings together the clinical data standard-setting organization, CDISC, with the regulatory science expertise and consortium management capabilities of C-Path. CDISC standards are vendor-neutral, platform-independent, and openly available via the CDISC website.
Links/Social Media Feed

- C-Fast Therapeutic Area Standards: [http://www.cdisc.org/therapeutic](http://www.cdisc.org/therapeutic)
- Twitter: [@CDISC](http://twitter.com/CDISC)

Points of Contact

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Sponsors & Partners

- Association of Clinical Research Organizations (ACRO)
Clinical Data Interchange Standards
Consortium (CDISC)
Critical Path Institute (C-Path)
Innovative Medicines Initiative (IMI)
National Cancer Institute – Enterprise Vocabulary Services (NCI-EVS)
National Institutes of Health (NIH)
TransCelerate BioPharma Inc. (TCB)
U.S. Food and Drug Administration (FDA)

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