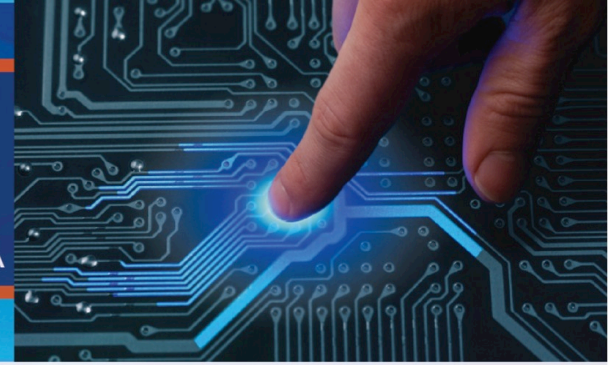




**FDA/PhUSE Annual
Computational Science Symposium**

March 19 - 20th 2012

Silver Spring Civic Center | Silver Spring Maryland, USA



CDER's Computational Science Center Progress Update

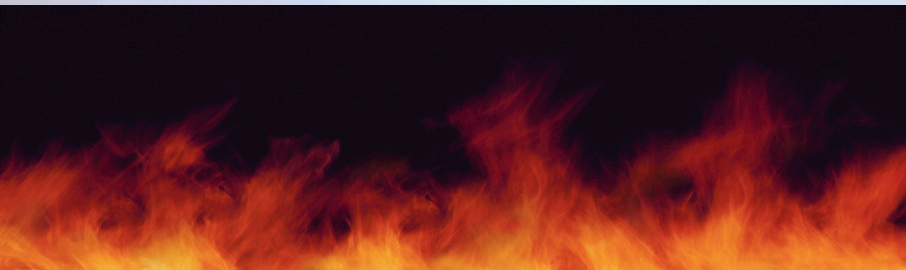


Better Data, Better Tools, Better Decisions



Great Baltimore Fire of 1904

- 1,231 firefighters were required to bring the blaze under control.
- Destroyed a major part of central Baltimore, including over 1,500 buildings covering an area of some 140 acres
- One reason for the fire's duration was the lack of national standards in fire-fighting equipment. Although fire engines from nearby cities (such as Philadelphia and Washington, D.C. as well as units from New York City, Virginia, Wilmington, and Atlantic City) responded, many could not help because their **hose couplings could not fit Baltimore's hydrants.**





The CSC Mission and Vision

CSC Mission

To support CDER in continually improving the optimal drug evaluation and review process for the entire drug lifecycle while addressing the dynamic nature of the healthcare system

CSC Vision

The CSC will support CDER decisions by high-quality quantitative analysis of information regarding efficacy, safety and product quality over the product life cycle



CSC Progress

2008

- Interest groups
- Needs assessment
- Sporadic support



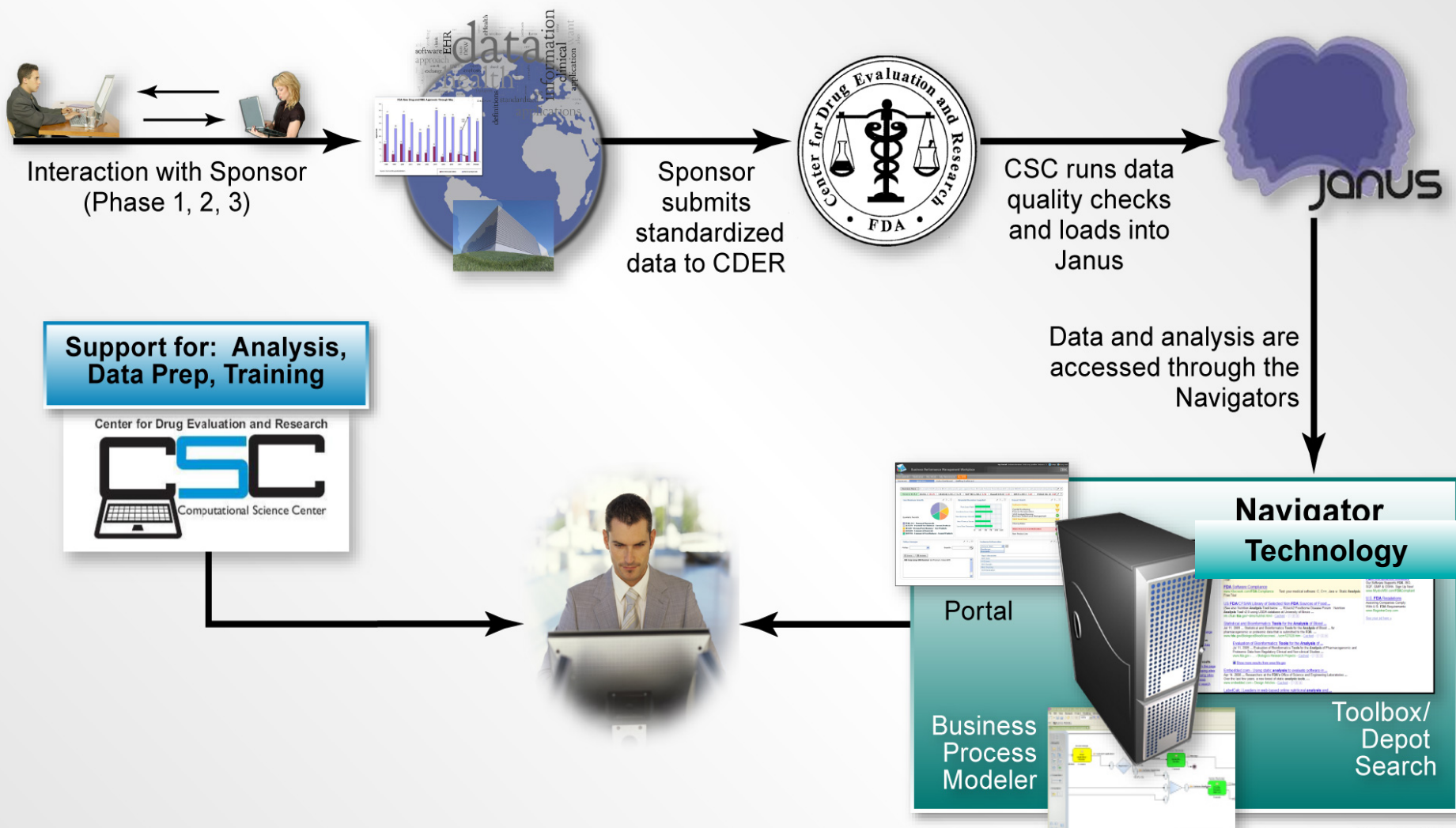
2012

- Increased visibility
- Training
- Outreach
- Tools Development/
Support



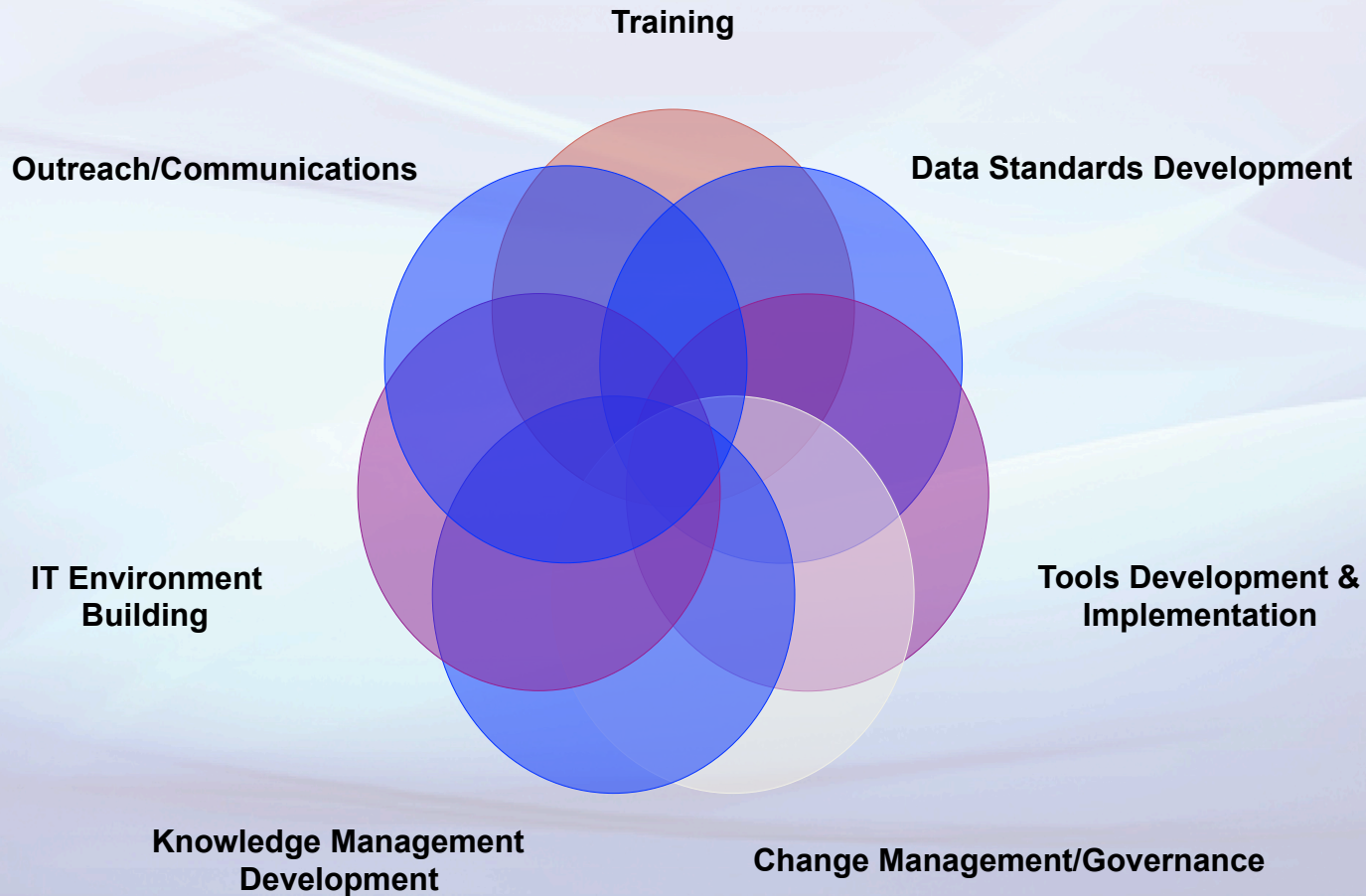


Future State



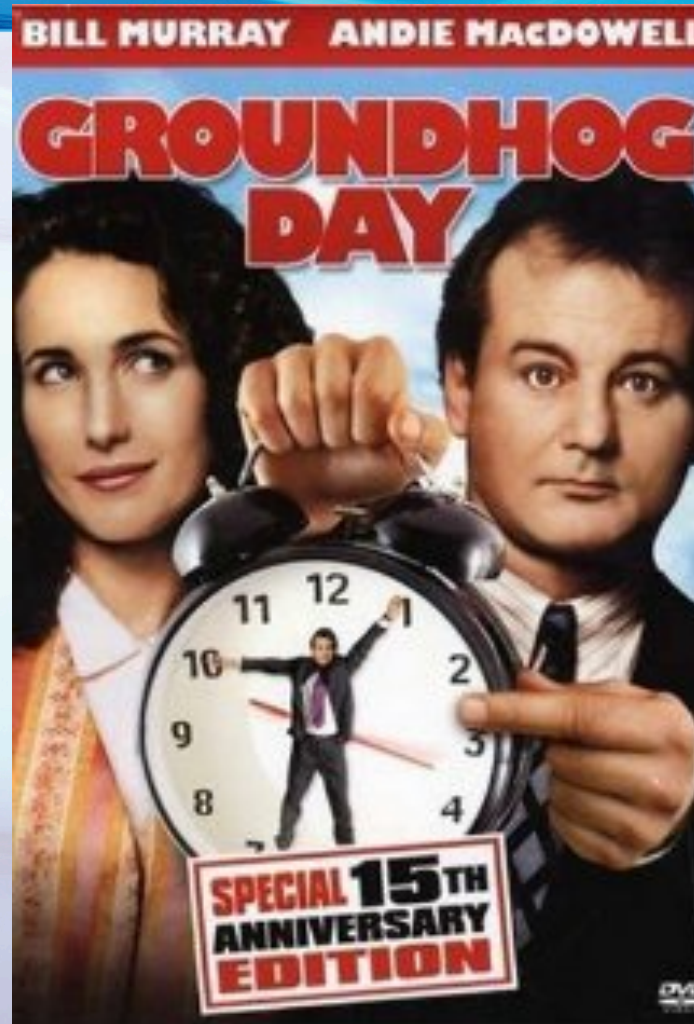


How do we get there?





Avoiding Groundhog Day...





2011

2012





What have we accomplished?

- Revised the PDUFA IT 5-year plan to clarify for key stakeholders FDA plans for continued and expanded use of regulatory submissions using standardized data through FY 2013 and beyond.
- Initiated discussion of new regulatory requirements for electronic submissions of all study data included in submitted NDAs, BLAs, and ANDAs.
- Established a CDER Data Standards Program Board (DSPB) to oversee all CDER data standards projects and activities.
- Developed a baseline inventory of data standards needs for all of CDER regulatory operations.
- Established a basic set of clear processes to support data standards development and implementation that would engage all key stakeholders.



Salient Activities for 2011

- Publication of the production v3.0 SEND Implementation Guide for nonclinical studies
- Suggestions for and review of proposed changes to CDISC standards
- Collaboration with data standards efforts sponsored by entities such as the National Institutes of Health and Critical Path Institute
- Legacy data conversion activities
- CDER championed efforts for research and demonstration activities (continued work on CDISC-HL7 standards), and the Cardiovascular Imaging Data Standards Initiative



CDER Data Standards Grant Program

- In May 2011, CDER announced a new small grant program to fund projects that develop disease/domain specific therapeutic area data standards. Funding preference will be given to projects that address existing data standards challenges and aim to create standards under the CDISC and HL7 processes.



CDER Study Data Common Issues Document

- The goal of this document is to communicate general CDER preferences and experiences regarding the submission of standardized data to aid sponsors in the creation of standardized datasets. The document is not intended to replace the need for sponsors to communicate with review divisions regarding data standards implementation approaches or issues, but instead, it is designed to complement and facilitate the interaction between sponsors and divisions.

Training

- Study Data Standards eResource modules have been developed to provide on-demand resources for reviewers who have not yet attended the classroom training and/or need a quick overview when they receive a new submission in standardized format.

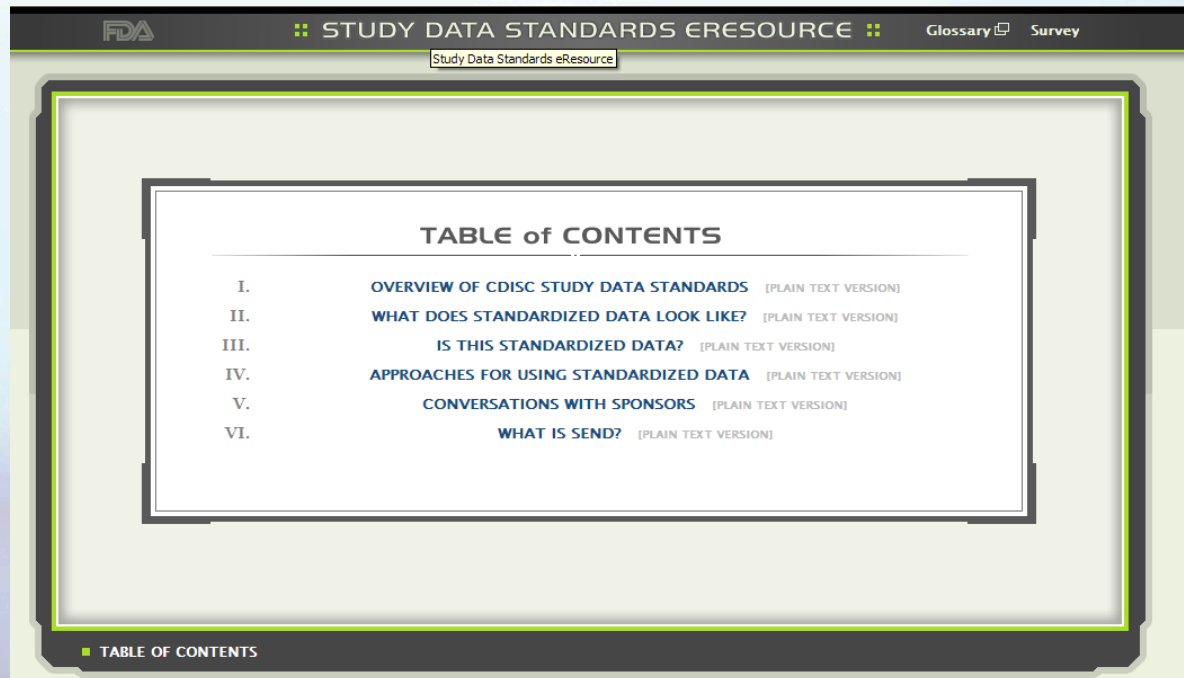
A screenshot of the "STUDY DATA STANDARDS ERESOURCE" website. The page has a dark blue header with the FDA logo on the left, the title "STUDY DATA STANDARDS ERESOURCE" in the center, and links for "Glossary" and "Survey" on the right. Below the header is a light green banner with the text "Study Data Standards eResource". The main content area is a white box with a black border, titled "TABLE of CONTENTS". It lists six items, each with a Roman numeral, a title, and a link to a plain text version. At the bottom of the page, there is a small green square followed by the text "TABLE OF CONTENTS".

TABLE of CONTENTS		
I.	OVERVIEW OF CDISC STUDY DATA STANDARDS	[PLAIN TEXT VERSION]
II.	WHAT DOES STANDARDIZED DATA LOOK LIKE?	[PLAIN TEXT VERSION]
III.	IS THIS STANDARDIZED DATA?	[PLAIN TEXT VERSION]
IV.	APPROACHES FOR USING STANDARDIZED DATA	[PLAIN TEXT VERSION]
V.	CONVERSATIONS WITH SPONSORS	[PLAIN TEXT VERSION]
VI.	WHAT IS SEND?	[PLAIN TEXT VERSION]

■ TABLE OF CONTENTS



Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Standardized Study Data

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Kieu Pham at 301-796-1616, (CBER) Office of Communication, Outreach and Development (OCOD) at 301-827-1800 or 1-800-835-4709, or (CDRH) Terrie Reed at 301-796-6130.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

February 2012
Electronic Submissions



Facilitating Data Standards Conformance Checks at Submission

- Development and testing of validation specifications using OpenCDISC
- Post-review Debrief Templates to Assess Reviewer Experience with Standardized Data
- Structured Database for Implementation Problems and Insufficiencies



Additional Activities

- Established Division Data Standards Leads Working Group
- Established a Data Standards Questions Team and Supporting Processes
- Frequently Asked Questions Database
- Exploring SAS Clinical Data Integration
- Developing Study Data Quality Assessment Score
- Continuing CDISC-HL7 Research and Development Activities



Communication/Outreach

CDER's Data Standards Program webpage	New in 2011, this is the main page for information on CDER's comprehensive data standards program.
Study Data Standards Submission to CDER webpage	New in 2011, houses study data resources specific to CDER submissions, including links to CDISC standards and implementation guide resources.
Study Data Specifications Document	Updated in 2011 to include specifications for general toxicology and carcinogenicity data tabulation datasets.
CDER Study Data Common Issues Document	Information for reviewers and sponsors on best practices for submitting CDISC-compliant data sets and avoiding common errors and omissions.
Study Data Catalog	A listing of various data standards (including versions of those standards) currently supported at FDA. By supported, we mean that the FDA component listed in the catalog has established processes and technology infrastructure to support the receipt, processing, review, and archive of study data using these standards.
CDER Study Data Standards Research and Development webpage	New in 2011, this webpage provides details about CDER's ongoing efforts to support development of robust data exchange and therapeutic area standards. The list of 57 top priority therapeutic areas for standardization is found on this page.
PDUFA IV 5-year IT Plan and related documents	The PDUFA IV IT Plan and annual assessments describe the FDA approach to data standards and provide status reports on various initiatives.
FDA Data Standards webpage	Study data resources maintained by the FDA Data Standards Council and the cross-Center Study Data Resources Change Control Group.



“As we work to accelerate innovation and strengthen regulatory science, it is increasingly clear that our most effective strategies are grounded in partnership.”

Margaret Hamburg, FDA Commissioner
November 10, 2011





WE WANT YOU!