



The Path of CSS Collaboration in CBER

Ginny Hussong

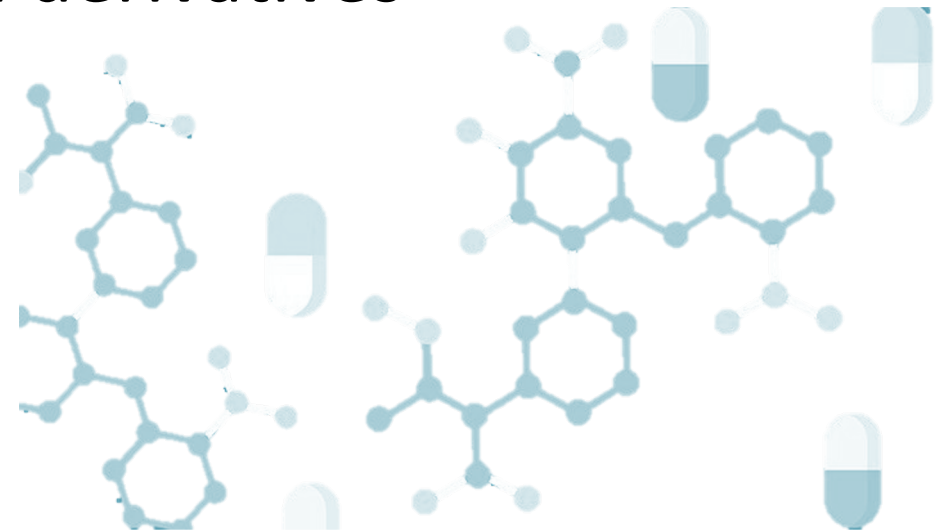
Chief (acting), Data Standards

Center for Biologics Evaluation and Research, FDA

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CDER Overview – Products We Regulate

- Vaccines (preventative and therapeutic)
- Blood, blood components, and derivatives
- Allergens
- Cell and Gene Therapies
- Tissues
- Xenotransplantation Products
- Related Devices (including certain *in vitro* diagnostics)





In the beginning

- CDER's data standards program started in 2010
 - published the first Data Standards Plan and established a Data Standards Program Board
- FDA Data Standards Catalog was published 2011
- 2012 FDASIA / 745A Statute spurred Internal and External Collaboration
 - Led to required standardized study data, e.g., CDISC SDTM, but also...
 - Brought CBER & CDER closer together in the world of study data
 - This collaboration was a gateway to greater involvement with PHUSE and other external organizations.



CBER's Presence at the CSS



- CBER's first presented at PHUSE CSS in 2012 ...
 - Legacy vaccine study conversion to SDTM and creating analysis datasets
 - Collecting lessons learned to improve business processes, provide input to the standard development/maintenance process
 - Spotfire pilot; Amalga project with CDRH to evaluate standardize vs. nonstandard data
 - Gaps in SDTM Identified, such as
 - Reproductive, macroscopic, microscopic, non-subject findings
 - Elimination/continuation criteria; procedures
 - Sponsors want a define.xml for ADaM
 - Reviewers want to print the define.xml

In the beginning

CBER's Past CSS Collaboration



CBER's presentations at PHUSE CSS in 2012, cont'd.

- Need for business rules identified; use of SUPPQUAL
- MedDRA coding – how to handle certain codes
- Documentation Rules – handling of certain variables; annotated CRF and define.xml
- Analysis Traceability; Validation Results – as a result of legacy data conversion; gaps in standard; rules not written properly to obtain desired result
- General challenges outlined:
 - Evolving standards; changes in science; all clinical trials not created equal; lack of tools, training and support
 - XPT as a transport mechanism ineffective
 - Few staff to work on data standards

In the beginning

CBER's Past CSS Collaboration

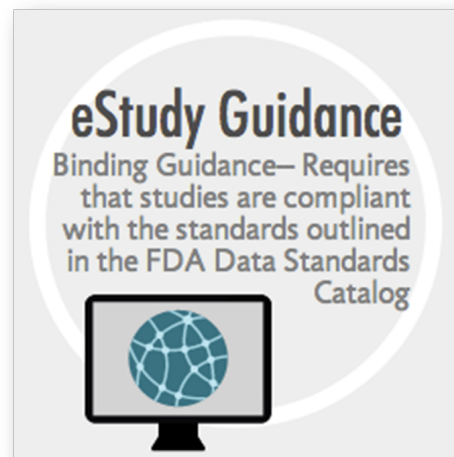
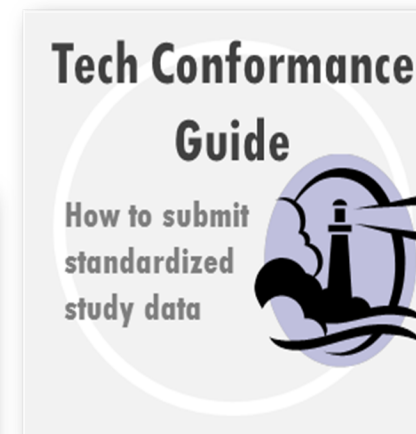


CBER's presentations at PHUSE CSS in 2012, cont'd.

- Computational Science has significant impacts on CBER Regulatory Review and Science by allowing CBER to do more in protecting public health
- Computational Science blurs the line between regulatory review and regulatory science
- CBER is working to develop an integrated strategic plan for information technology
- CBER will continue to work with other Centers and stakeholders to contribute to and to leverage data standards, patient-centered outcome research, and tools in support of public health

2014

Putting Together the Pieces of the Regulatory Framework for Standardized Study Data



- The Guidance
- The Catalog
- The Technical Conformance Guide



Growth Spurt



2014

- Original eStudy Data Guidance draft & final was published – the first FDA binding guidance under 745A
- Original Technical Conformance Guide was published

2016

- CBER's data standards program was launched
- Key staff members hired in 2016-2018 to further build the program

2017

- CBER adopted DataFit Validation for BLAs
- The CBER Appendix was added to the SDSP
- We began the CBER SEND project, evaluation and testing of SEND

Beginning of New Era

2018

- Vaccine TAUG was republished by CDISC
- CBER Vaccine Technical Specifications Document was published
- CBER & CDER published a Joint data standards strategy in 2018, aligned with PDUFA
 - It focused not only on study data, but encompassed a much broader set of data standards
 - Strong collaboration with CDER and CBER allowed for more uniform, integrated collaboration externally with CDISC and PHUSE
 - Aid to industry since many guidances and FRN notices were joint rather than center-specific

Moving Forward



- At the 2019 CSS, CBER's Office of Tissues and Advanced Therapies and Office of Vaccines Research and Review presented on clinical and nonclinical data submissions
- CBER continued to train reviewers on study data standards and use of analytic tools, and support staff was added
- CBER's validation process continued to be refined and streamlined to be more useful to reviewers

Multi-Center Collaboration

- Data Standards Catalog via the Data Standards Advisory Board (DSAB). For example,
 - Fosters a uniform collaboration with HL7 for standardized exchange formats (FHIR),
 - with ISO for IDMP development, and
 - with IEEE for BioCompute (agency genomics working group) all done as cross-agency initiatives.
- PDUFA VI continued the collaboration on various joint projects, ESG, eCTD, Technical Rejection of Study Data, IDMP, PQ/CMC, Study Data Standards, RWD/RWE, IND Safety.
- PDUFA VII draft commitment letter (now public) describes even more collaboration and will be used as a foundation for the next iteration of our Data Standards Strategy for 2023-2027.



THANK YOU!

Questions?

CBER-eDATA@fda.hhs.gov