DCRI **CDISC**

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Defining the Standards

WHO WE ARE

The Duke Clinical Research Institute (DCRI), the world's largest academic research organization (ARO) and part of the Duke University School of Medicine, is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research.

CDISC SERVICES

The DCRI has been collaborating with CDISC and providing standards implementation services since 2001. We monitor CDISC and FDA advances so that we can proactively provide the latest CDISC deliverables. We have produced dozens of SDTM databases, as well as numerous ADaM and define-file submissions.

PROACTIVE, NOT REACTIVE

DCRI CDISC processes are metadata-driven. We regard a define file not as an end product, but as a deliverable that can drive downstream production processes efficiently and proactively.

Our define files can be generated before any data transformation code is constructed, and each define file helps to generate automated transformation programming.

EXPERIENCE WITH PINNACLE 21 VALIDATION

Our expertise using the Pinnacle 21 OpenCDISC Validator tool with the CDISC models ensures that the results are model-compliant and submission-ready for the FDA.

When there are issues with the OpenCDISC Validator results, we ensure that they are explained in the appropriate study data or analysis data reviewer's guide.

CDISC SUBMISSION REQUIREMENTS

Clinical trials starting after December 17, 2016, and submitted to the FDA must adhere to the Clinical Data Interchange Standards Consortium (CDISC) data-submission standards (e.g., SDTM, ADaM, and define-xml).

Partnering with our sponsors to:

- Adopt sponsor-controlled terminology.
- Import sponsor metadata from various file formats.
- Collaborate on the subjective areas of CDISC.
- Deliver compliant data submission packages.

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Find out more about data standards at the DCRI.

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WHY THE DCRI FOR CDISC?

- Independent, not-for-profit ARO focused on its mission to develop and share knowledge that improves the care of patients around the world through innovative clinical research
- Close integration of the academic faculties of Duke University—peer-acclaimed thought leaders and health innovators in many therapeutic areas
- Active involvement in many national and international initiatives for healthcare improvements, including the Clinical Trials Transformation Initiative
- Integrated clinical trial capabilities, experience, and competencies covering all aspects of trial design, implementation, and management
- Long history of designing and managing successful trials with Data-Driven Trial Management (DDTM) principles
- Impressive track record of participation in clinical studies and mega trials for many different healthcare products, technologies, and indications
- World-renowned and experienced biostatistics group, with faculty recognized as innovators and thought leaders in biostatistical and analytical methods in medical and clinical research relevant to DDTM, including:
  - Trial design
  - Clinical trial analytics
  - Independent Data Monitoring Committee (IDMC/DSMB)
  - CDISC
  - Research/predictive analytics leveraging multiple data sources
  - Manuscripts and publications

ADaM LEADERSHIP AND CDISC EXPERTISE

The DCRI's Jack Shostak, associate director of Statistical Programming, is one of the CDISC ADaM team leaders. Jack has been instrumental in developing ADaM and regularly consults with FDA reviewers on ADaM-related topics. He teaches ADaM courses for CDISC nationwide as well to FDA reviewers, has written a book on CDISC, and keeps the DCRI abreast of CDISC and FDA developments.

Jack Shostak
Associate Director,
Statistical Programming

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

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