Medidata Rave and CDISC: Implementation Update

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Introduction

- The SDMC is actively transitioning to a commercial Clinical Trials Data Management System (CTDMS)
  - Medidata Rave
- In parallel, we are introducing CDISC data collection standards for new Rave studies

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Clinical Data Interchange Standards Consortium (CDISC)

- CDISC has established standards for acquisition, exchange, submission and archive of clinical research data and metadata
  - CDISC compatibility mandated by DAIDS in the last recompetition
  - Per FDA, any regulatory study that starts after 12/16/2016 will be required to be submitted using CDISC standards

Functionalities of Rave

- Data entry available on any computer or tablet with an Internet connection
- Data enter database in real time
- Query and error resolution integrated into data entry screens
- Built-in reporting capabilities
- Site monitors have eCRF access and can query data

Limitations of Rave

- Available only as a cloud application
  - Sites with frequent internet outages may need to adjust workflow
- Rave is study-oriented
  - Difficult to look at information across studies, such as a site-wide accrual report
  - Cross-study reports will continue to be accessed via the DMC Portal
- The DMC cannot customize the software

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Site internet requirements

- Internet connection is required for all work
  - There is no offline option
- 128kbps minimum connection speed for Rave
- FSTRF conducted a site survey in March 2015 to assess internet capability; results were shared with DAIDS
  - 38/44 sites have appropriate connection speeds
    - 6 sites did not provide enough data to fully assess speed

FSTRF CTDMS

- Rave will replace several existing FSTRF systems
  - eData (EDC software)
  - Delinquency
  - Query System
  - Resolve
  - Some study-specific Portal reports

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What isn't changing?

- Registration/Randomization
  - Current system will be the single study entry point for all studies
  - Data will be copied into Rave in real time
- Laboratories will continue to use the LDMS
- Other data submission systems for electronic result files and sequencing data
- Data from these systems will continue to be stored in the DMC central database

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Overall Approach

- Open studies that will close to follow-up in or before 2017 will continue to use the FSTRF CTDMS
- Studies active past 2017 are candidates for migration into Rave
  - We will collect the same data points for migration studies (CDISC will not be used), but eCRFs in Rave will look different
- As of February 2016, all newly approved, developing studies are being implemented in Rave/CDISC

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Impact on sites

- During the transition, site staff will have to work in both the FSTRF CTDMS and Rave
- The data collection paradigm has changed for new studies implemented in Rave/CDISC
  - More dynamic data entry screens
  - Different organization, with greater emphasis on log-style forms and less site coding

Impact on sites

- Paper CRFs will no longer be produced by the DMC
  - Full set of blank eCRFs will be posted to the DMC Portal
  - Sites can print eCRFs as needed directly from Rave
- DMC will publish an eCRF completion guide (per study) before screens are available in Rave
  - Facilitate IRB submission
  - Allow sites to plan for data collection and develop source documentation for their workflow

Changes to site data management

- Sites encouraged to explore moving to direct data entry (eliminating completion of printed eCRFs)
  - Many sites already have experience with Rave for industry studies and have experience preparing worksheets and source documentation for this purpose
  - DMC is collaborating with sites to promote cross discussion for further education and training

Site data management metrics

- Some changes needed to current site performance evaluation metrics, specifically to error rate calculations based on how Rave triggers edit checks in real time as data are keyed and saved to the database
- The DMC will work closely with the ACTG PEC and IMPAACT NEG to evolve metrics appropriately
- Sites currently not being evaluated on Rave study activity

Implementation progress - ACTG

- A5350 and A5352S - first studies live in Rave/CDISC
  - 8 additional ACTG studies in development for Rave/CDISC
- A5322 - first ongoing study migrated to Rave
  - First site (2701) went live in January 2016
  - 11 additional ACTG long-term studies are migration candidates

Implementation progress - IMPAACT

- Four IMPAACT studies in development for Rave/CDISC
  - 2004, 2006, 2009 and 2010
- P1115 - first ongoing study migrating to Rave
  - First sites expected to go live this month
  - 4 additional IMPAACT long-term studies are migration candidates

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Site training

- eLearning modules provided by Medidata
  - Site staff are required to pass eLearning courses before they are activated for Rave
- DMC-led webinars prior to site initiation
- Training materials available on DMC Portal > Medidata Rave Resources link

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Network education and training

- DMC Newsline articles describe implementation plans and highlight Rave features
- Plenary presentations, Demo Room sessions and other presentations at network meetings
- Rave site focus group established in July 2015
  - U.S. and non-U.S. members
- Collaboration with network data management and forms committees

Impact on the Network

- Committees involved in site data management operations will face more demands on their time over the next year
- Study teams and site staff will have to develop some sense of CDISC and become familiar with new data collection concepts

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Site monitoring in Rave

- A5350 and P1115 will be the first studies to pilot the Targeted Source Documentation Verification (TSDV) module for site monitoring in Rave
  - Provides monitors with direct access to eCRFs and reports
  - Monitors can trigger queries to sites
- DMC is actively working with DAIDS, PPD, and Westat on TSDV implementation

Questions

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