

External Data Transfers to the DMC

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Agenda

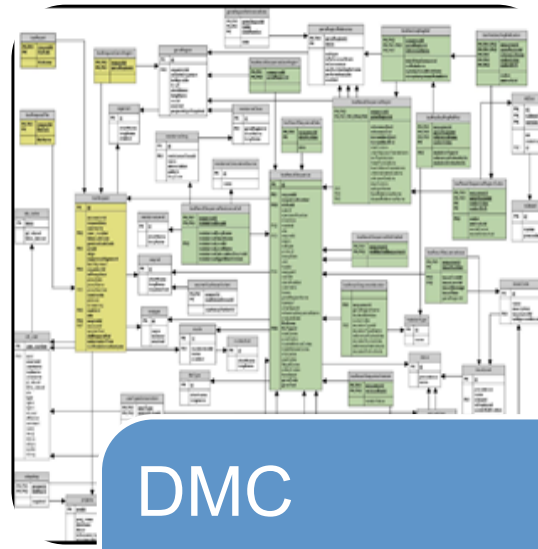
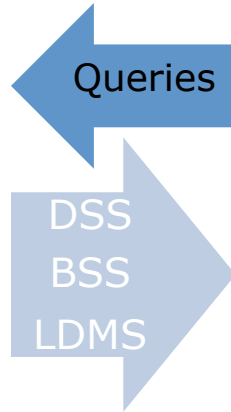
- Background: External Data Transfers
- New: Data Transfer Agreements (DTAs)
- New: Signatures for External Data Transfers

Background: External Data Transfers



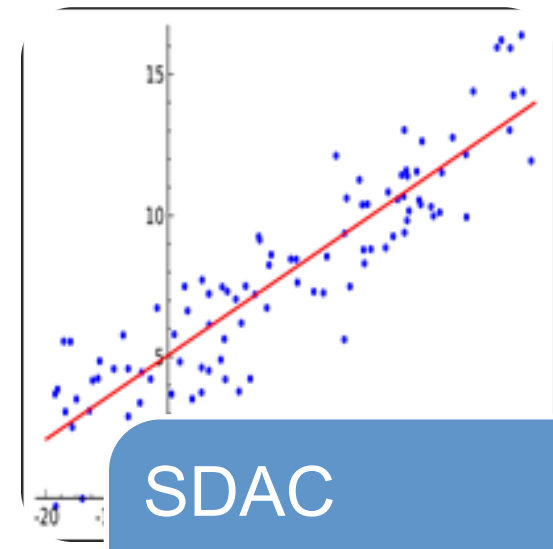
Data Submitter

- Laboratory
- Clinic
- Central ECG Reading Center
- Pharmacologist



DMC

- Screen data
- Transform data
- Load data
- QC data
- Map to SDTM



SDAC

- Analyze data
- Report on data

Tools for Receiving External Data Transfers

- Laboratory Data Submission System (LDMS)
- Biological Sequencing System (BSS)
- Data Submission System (DSS)
- During the last reporting year (Sept 2016 - Aug 2017), the DMC received:
 - 759 DSS/BSS submissions for ACTG & IMPAACT
 - containing 1,326 data files
 - across 63 different studies
 - from 64 different laboratories

Good Clinical Data Management Practices (GCDMP)

Laboratory Data Handling – Best Practices

- Develop a data transfer agreement for electronic transfers and perform quality control of the test transfer.
- Document and confirm all lab variables prior to signing off on data transfer specifications.

Good Clinical Data Management Practices (GCDMP)

Laboratory Data Handling - Lab Processes in Studies

“When using a central lab (or any lab that transfers data electronically), the lab and sponsor will complete a data transfer agreement (DTA) during study setup. The DTA defines the format of files, frequency of data transfer, file naming conventions, encryption levels, method of transfer, type of transfer (complete versus partial), recipient, test names, formats, high and low value flags or alerts, and any additional information concerning the lab data.”

Data Transfer Agreements (DTAs)

- Communication tool between DMC and submitting institution
- Key components: format, frequency, method of transfer, variable specifications, blinding requirements, data reconciliation process
- For DSS data only (not BSS or LDMS)
- Plan to pilot DTAs with a few studies
- See draft DTA template

Freezing/Locking

- DMC proposes to capture signatures from submitting institutions
- DMC will send cumulative data plus signature page
- For all non-CRF data, including LDMS, BSS, and DSS
- See draft signature page

Questions?

