



National Institute of
Diabetes and Digestive
and Kidney Diseases



Principles of Data Collection and Management

Matt Breymaier, Sai Theja, & Ken Wilkins

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Data Management And Electronic Data Capture (EDC)

REDCap and Data Management



- Data Management spans protocol conception to completion
 - Protocol Development - Pre collection
 - Protocol Execution – Collection
 - Analysis – Post collection



Pre collection Data Management

- Pre collection
 - Data Management and Sharing plan, define endpoints
 - Consider using standardized forms and common data elements (CDE's)
 - Collaborating with external institutions or conducting a multi site study
 - Regulatory considerations – FDA oversight? IND?
 - Regulatory Binder - Electronic or Paper, Shared Drive or One Drive
 - Organization - will the collection facilitate sharing



Pre collection Data Management

- Pre collection -
 - Source data map - where will data be collected and stored. CRIS, REDCap, Outside labs, biospecimen core analysis

Source data map					
Please utilize this spreadsheet to map the location of all source data collected. This is the first place the data is collected and documented as well as					
				Version 1_DDMMYY	
Data	Source Document Location(s) (i.e., CRIS, REDCap, REDCap survey, on a machine, paper, another department, outside lab/facility, other - please specify)	Where is data stored for analysis? (i.e., on the machine, REDCap, CRIS, spreadsheet, shared drive, other please specify).	Who maintains it?/ Point of contact person/s	Include note if data supports a primary or secondary objective	Notes
Screening Log	REDCap	REDCap	Jane		
Screening and Enrollment	REDCap	REDCap	Joe	Baseline A1C	
Informed Consent	CRIS	REDCap	Matt		
Demographics	CRIS	REDCap	Sai		
Eligibility criteria	CRIS	REDCap			
Inclusion/ Exclusion outside lab reports to meet Inclusion criteria	CRIS	CRIS			Mayo Clinic
Concomitant medication	CRIS	REDCap			
Pregnancy test (urine,s	CRIS	CRIS			

Pre collection Data Management

- Pre collection
 - EDC System selection
 - Access control and Access flexibility for collaborators
 - Validated system (FDA)
 - Regulatory compliance, QA features
 - Security and backup
 - Availability and cost



Collection phase Data Management

- Data collection
 - With proper planning requires the least consideration
 - Electronic Data Capture (EDC) – recommended, automatically captures audit trails and logs history of changes
 - Develop forms and logical structure i.e. Timepoints
 - Implement common data elements
 - Use standardized measures for data such as Adverse Events
 - Ensure project structure represents the SOA
 - Controlled access to the data
 - Implement integrations i.e. Electronic Health Record



Post Collection Data Management

- Post collection
 - Activities may happen while data collection is in progress
 - QA monitoring - site visits, data validation
 - Safety - deviations, adverse events, data safety monitoring
 - Data processing – getting what you need from everything collected
 - Interim analysis
 - Data lock
 - Data sharing



REDCap and Data Management



- REDCap is a web-based system used to create and manage study data sets.
- REDCap can enable improved data management and sharing
- REDCap does not cover all aspects of Data Management nor automatically equate to a data management framework
- Project teams need to choose how to use REDCap and actively use the tools available (i.e. data access groups, QA Queries)

REDCap and Data Management



- User Benefits of using REDCap
- Facilitates collaboration, metadata sharing, and data sharing
- Dynamic reporting outputs to multiple formats
- Consistent data output for analysis and replication
- Online participant survey feature
- Data validation can be automated

REDCap and Data Management

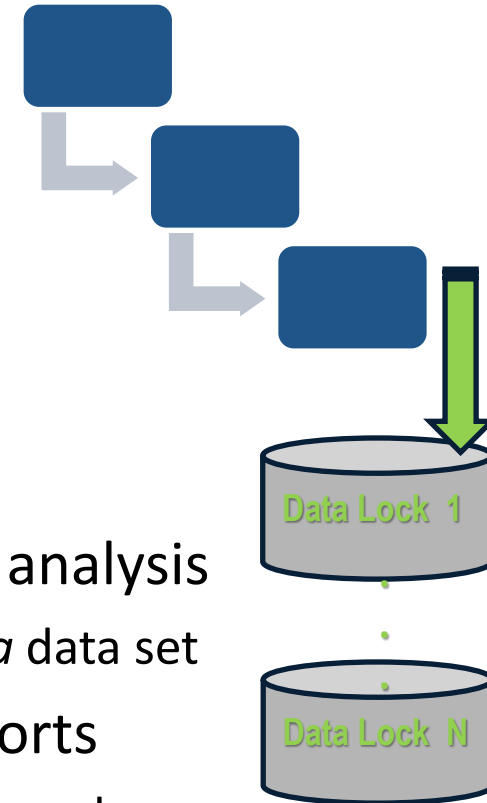


- Unseen Benefits of using REDCap
 - FISMA cleared and authorized, secure
 - Disaster recovery and backed up
 - Lower costs/efforts for monitoring and auditing
 - Features to promote regulatory compliance
 - Auditing and logging is done automatically

REDCap and Data Management



- Begin the development of your REDCap project as soon as practical
 - This will help focus on getting the pre collection elements in order
- Make use of the optional features in REDCap to build a solid data set
 - Develop and execute data quality rules
 - Enable e-signature and change tracking
- Upon each need to present data, 'lock' REDCap data set *then* generate analysis
 - Keep this data 'snapshot' so that analysis findings shared are reproducible from *a* data set
- Upon study completion, Lock the REDCap data set and standardize reports
 - The data lock leaves no question that the data sets shared are the data sets produced



REDCap and Data Management

Next
REDCap In Depth