Children's Hospital Boston

The Clinical Research Center

Life-changing care, world-changing research

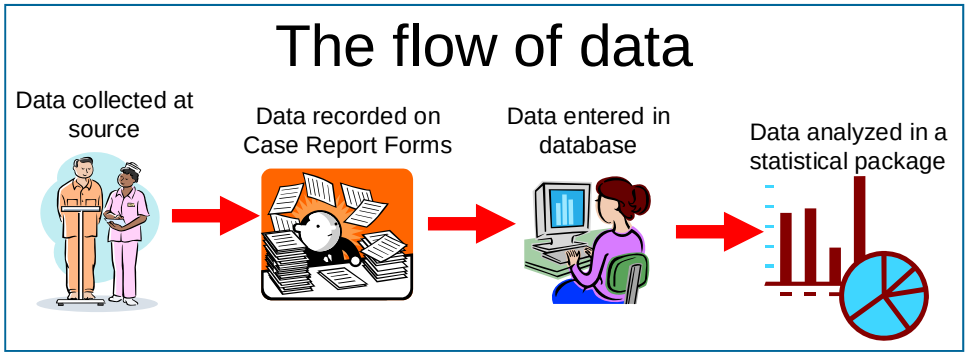
Clinical Research Database and Web Survey Technologies

An Overview of products available to Children's Hospital Boston Investigators

Data Management Technology Overview

What is a Clinical Research Database?

A Clinical Research Database is a tool used as part of the data collection process. A database allows you to store your research data collected in the field in an organized fashion so that it can be easily analyzed in statistical programs.



Databases offer advantages in data organization over spreadsheets like Microsoft Excel, in that you can organize how the data is stored. For example, if you want to store gender as a number where Male=1 and Female=2, you could program a database to only allow entries of Male and Female, and to store those entries as numbers in the database. Also, as opposed to a spreadsheet, databases allow you to enter data on one subject at a time in easy to enter forms rather than one large spreadsheet. Using a database can also help reduce the amount of error in your final dataset.

What is a Web Survey?

A web-survey is an instrument used to poll direct information from a population of interest. A web-survey is different than a database in that the participant fills out the web survey directly, rather than providing that information on paper to be entered by somebody on the study team. Because the participant must complete the survey via the internet they need to either have a link to the survey, or be emailed a specific link that identifies them to the investigators.

Web-surveys are ideal for research when the responses need to be anonymous. They can also offer advantage such as skip patterns which can make the survey questions condition on answers the respondent has already given. Also, because the respondent data goes directly into a dataset, there is need for another person to enter this data into a database.

How does a database differ from a statistical analysis package?

Databases are different programs than statistical analysis programs. Popular statistics packages like SPSS, SAS, STATA, R do not store data like databases do but can perform statistical tests, analysis and produce graphs and charts based on the data collected in your database. The database you choose does not impact the statistical package you use as databases can export data in a form read by most popular statistical packages.

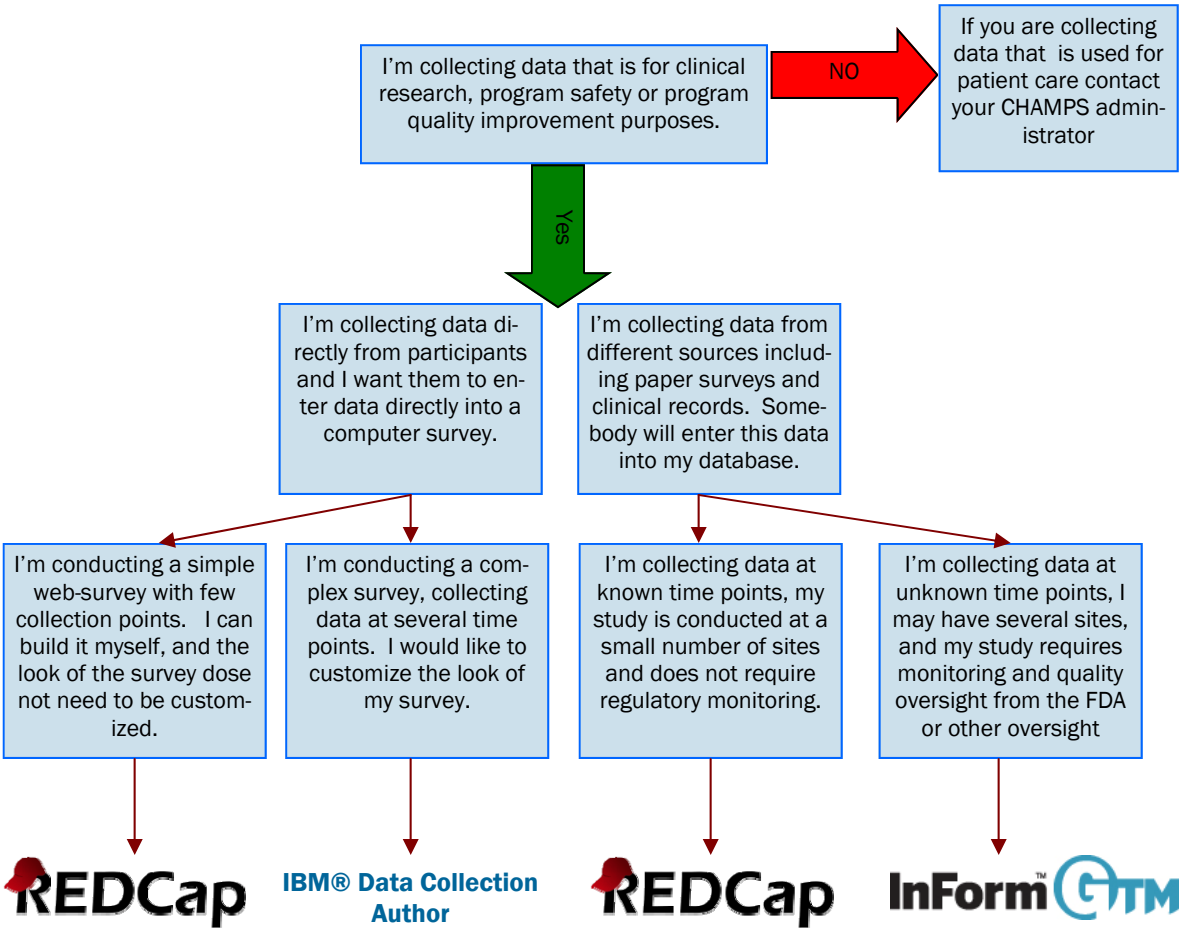
How do I choose the right database or web survey for my study?

Due to the wide range of clinical research conducted at Children's supports several different database technologies. Factors that can affect which data base is best include whether the study is single center or multicenter, whether the data are collected at one time point or multiple time points, and whether or not the research will be monitored by regulatory authorities such as the FDA. A database that may have worked for an investigator on pervious projects might not be the best fit for others. This brochure gives a summary of CRP database and web-survey technology, however it's best to meet with a CRC Specialist to discuss your data management needs early to make sure your using the correct product and have budgeted appropriately!

To request assistance with data management please complete an online assistance request form at

http://crp-apps.tch.harvard.edu/crp.intake/public/IntakeRequest.aspx

Decision tree for common application uses



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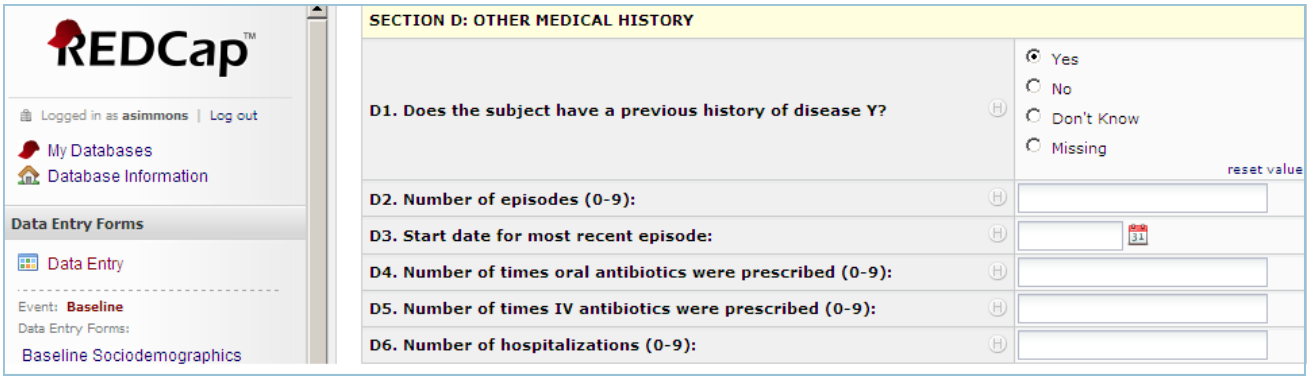
REDCap

Why Use REDCap?

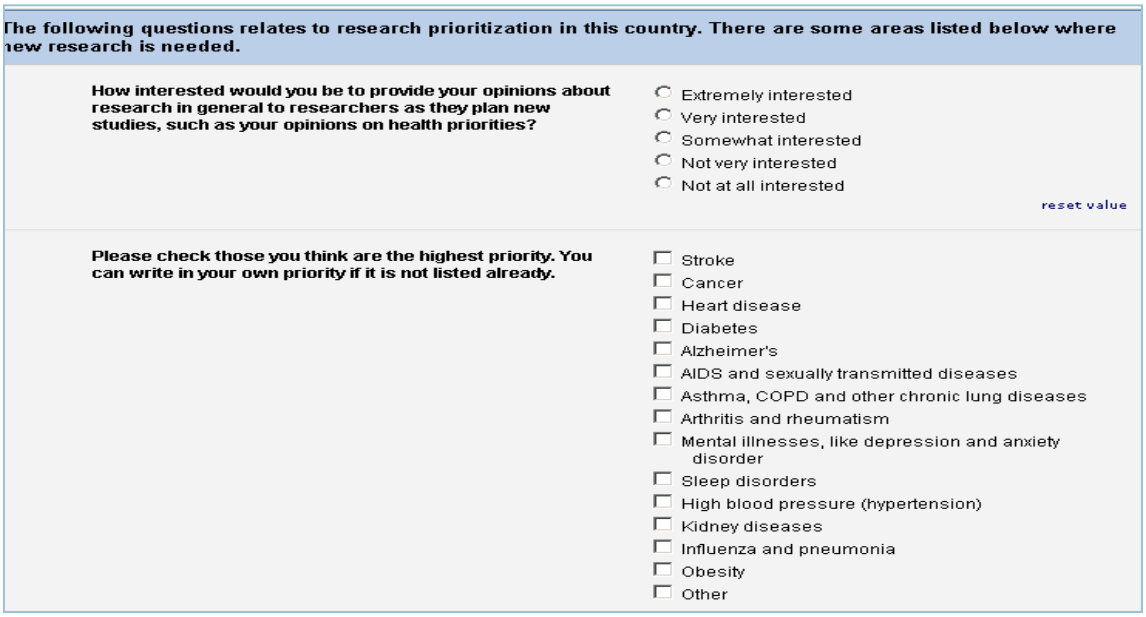
REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides:

- An intuitive interface for data entry (with data validation)
- The ability to create web-surveys
- Easy to build your own database.
- Automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R)

Sample form in REDCap

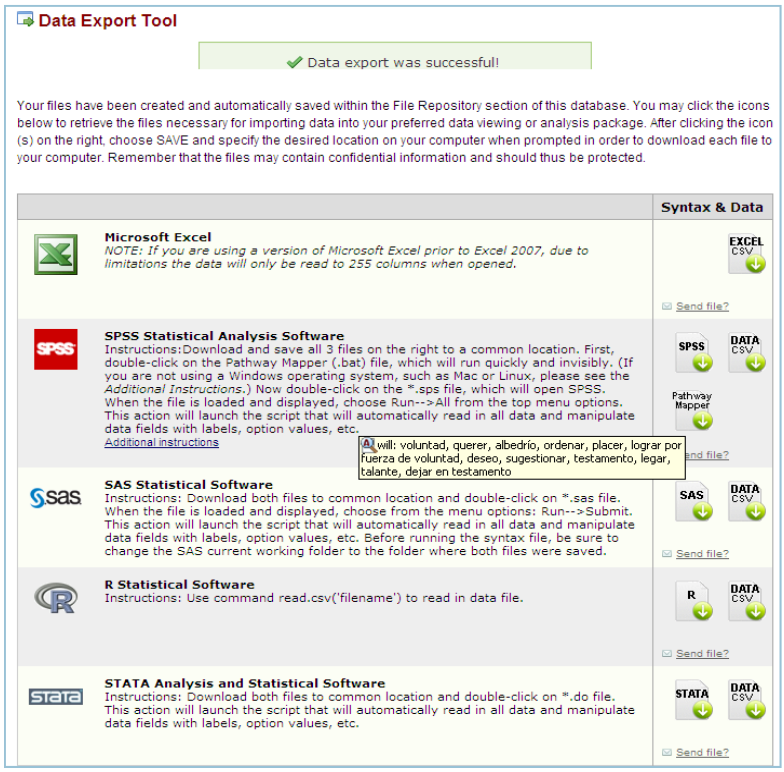


Sample web-survey in REDCap



Advantages of REDCap

- **Secure and web-based** - Input data from anywhere in the world with secure web authentication and data logging.
- **Fast and flexible** - Quick turnaround from conception to production-level database.
- **Multi-site access** - REDCap projects can be used by researchers from multiple sites and institutions.
- **Autonomous utilization** - Research groups have complete autonomy and control to add new users.
- **Export data to common data analysis packages** - Exports raw data and syntax files for SAS, Stata, R, and SPSS for analysis.
- **Fully customizable** - You are in total control of shaping your database.
- **Data import functions** - Data may be imported from an existing external database to begin a study or to provide mid-study data uploads.
- **Data comparison functions** - Double data entry / Blinded data entry



Fast and easy exports to common statistical packages or Excel

Budgeting and Recommendations for your REDCap project

- CRP staff will train and assist research teams in programming their own REDCap databases
- Data managers are available to program REDCap databases (for databases up to 100 variables there is no charge)
- It is recommended that you consult with a Data Manager and/or Project Manager to discuss database programming
- Database programming and quality control testing take approximately 1-2 weeks

Most common use: Non-regulated studies with defined data capture points

Additional resources:

- REDCap provides online instructional videos for database creation and use
- Harvard Catalyst EDC Support Specialist for REDCap **http://catalyst.harvard.edu/services/redcap/**

Database and Web Survey Applications Comparison Table

	Redcap (Research Electronic Data Capture) Both web-survey and EDC product	IBM® Data Collection Author	Phase Forward InForm™
System Use			
Web-based	Yes	Yes	Yes
Data validation (range check) Skip or conditional rules	Limited	Yes	Yes
Complex rules and skips	No	Yes	Yes
Repeating sections/forms (relational database functionality)	No (must pre-define events)	No	Yes
Control over layout	Minimal	Advanced	Minimal
Max number of variables (recommended number)	500 Total (less than 40 per form)	Unlimited (100 per form)	Unlimited (60 per form)
Export/ convertible data format	Excel, SPSS, SAS, STATA, and R	Excel, SAS, SPSS, and XML	Excel, SAS
EDC Features			
User rights control	Yes	No	Yes
Query management	No	No	Yes
Monitoring tools	Limited	No	Yes
Audit trail	Limited	Limited	Yes
Data safety protection	Moderate	Moderate	Best (closed-system)
FDA Part 11 Compliant as EDC System	No	No	Yes
Web Survey Features			
Invitation tracking	Yes	Yes	No
Sample Management (maintaining a respondent list with various features like ID assignments, groups)	No	Yes	No
Survey response reports (i.e: counts of complete and incomplete survey, invitations sent and failed attempts)	Minimal	Advanced	No
Randomization of question/response option ordering	Minimal	Advanced	No
Import of participant information in future questions	No	Yes	No
Alerts user of bounce			
*Access and Cost**			
Recommended use	Non-FDA regulated databases Simple web-surveys	Non-FDA regulated survey studies	FDA regulated, complicated multi-site trial
Building/end-user training	Yes for both	Training available soon	Yes, end-user training only
Estimated time from specifications to first end-user testing.**	1-2 weeks	2-4 weeks	1-2 months
License Fee	No cost through CHB	$500 license fee per project through CHB	$10,000 license fee per project per year through CHB

* Project cost should be discussed with The CRC during the study budgeting process.
**At the start of project The CRC will give the PI timelines for first deployment. Timelines depend on current project load, and size and complexity of the project. Once a database is turned over to the study team for testing, timeline is subject to the response of study team and number of requested changes.

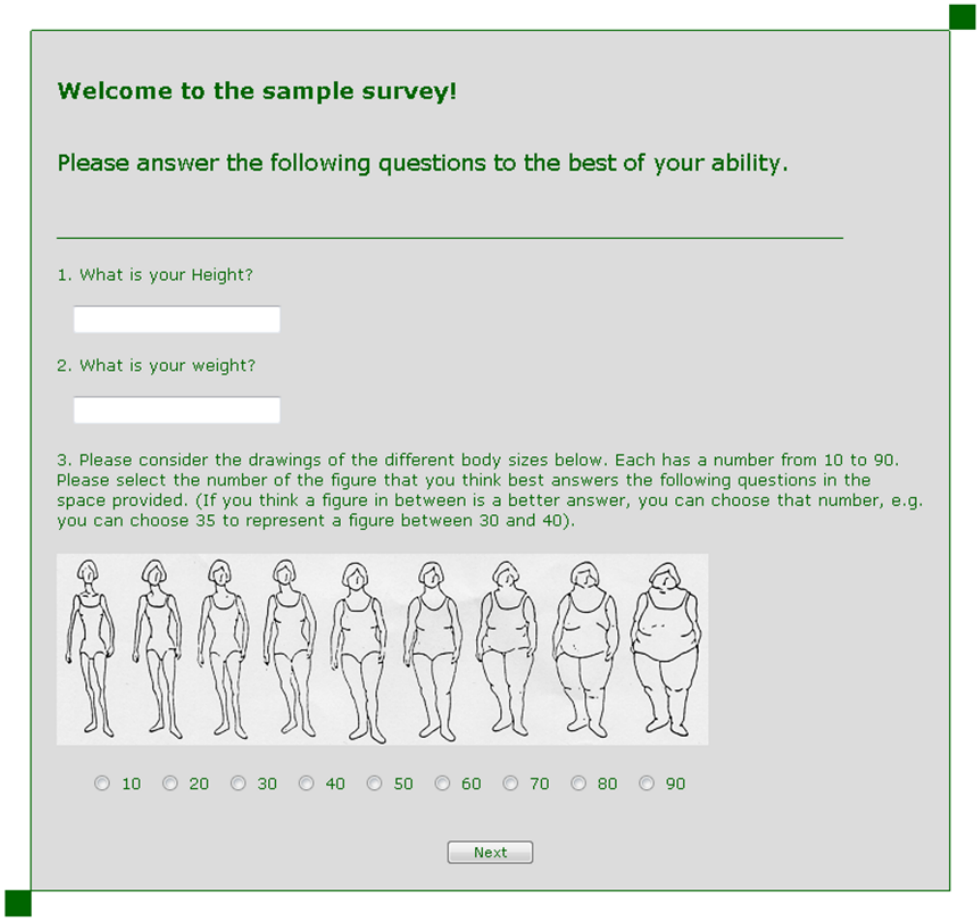
IBM® Data Collection Author

Why Use Data Collection Author?

IBM Data Collection Author offers powerful functionality for creating attractive and practical surveys.

- Create surveys with complex skip patterns and real time calculations
- Have advanced control over labeling, coding, response options, and formatting
- Export data to common statistical and basic software packages (SPSS, SAS, Excel, XML)
- May be used for single site or multiple sites

Sample survey question in Data Collection Author



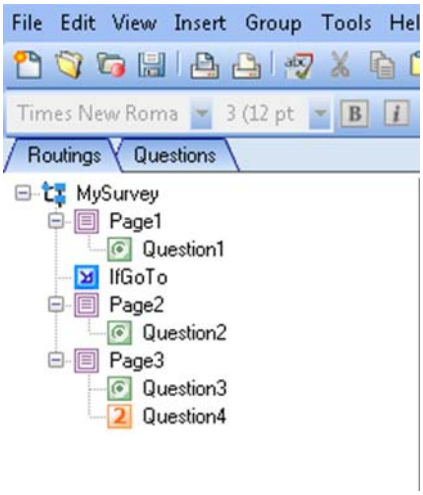
Advantages of Data Collection Author

- **Secure and web-based** - respondents or interviewers may enter data from any location with an internet connection
- **Deployment in multiple modes** (telephone interview or Web survey)
- **Complex routings** and skip patterns to different questions or sections
- **Advanced previewing and testing capabilities**, including the ability to generate test data
- **Sample management** - maintains lists of respondents with individual response status

Create complex skip patterns and branching logic.

Auto-insert information from previous responses into later questions.

Calculate information based on previous responses and insert into later questions or use as skip logic.



Budgeting for your Data Collection Author survey project

- Data managers and survey methodologists program surveys into Data Collection Author. There is a $500 license fee for using Data Collection Author in addition to time for programming and testing.
- It is recommended that you consult with a Survey Methodologist as you design and develop your survey to discuss programming cost
- Survey programming and quality control testing take approximately 2-4 weeks.

Most common use: Surveys with complex skip patterns or manipulations. Surveys with complex calculations needed in real time. Survey with specialized response options or other special formatting needed.

InForm™

What is InForm™?

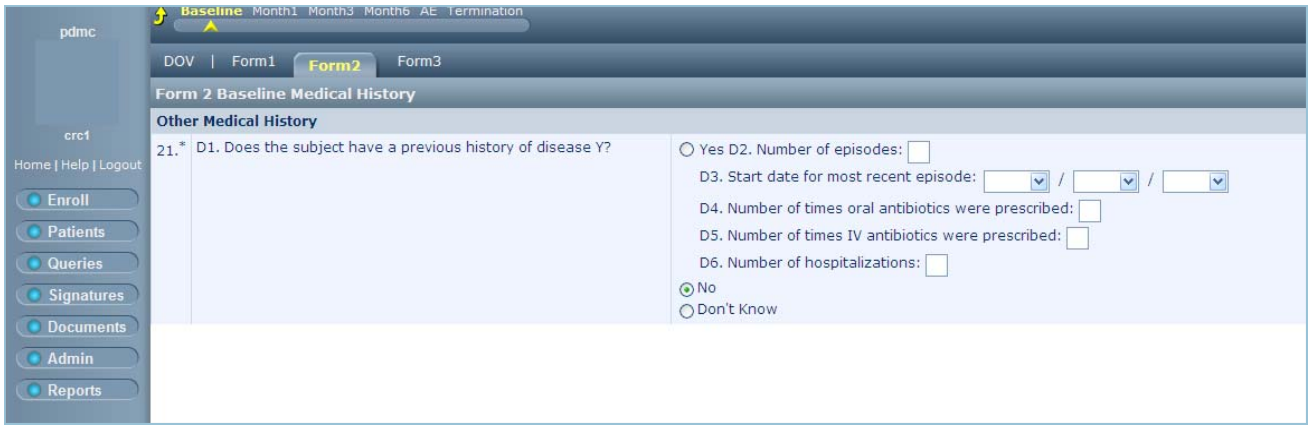
Phase Forward Inform offers powerful functionality for creating databases to capture complex data schemes.

- Data Management System (DMS) that allows for electronic data capture (EDC)
- Supports regulatory compliance with Good Clinical Practice (GCP)
- FDA-compliant (Section 21 CFR, Part 11)
- Tools for data management of multi-site trials
- Secure application accessible via Internet
- Role-appropriate access
- Audit Trails for: Data Entry, Exports, Reports, Monitoring, etc.
- Query management functionality
    - Validation of data entry through range checks built into the system
    - Complex & simple rules built in for certain types of questions with conditional logic

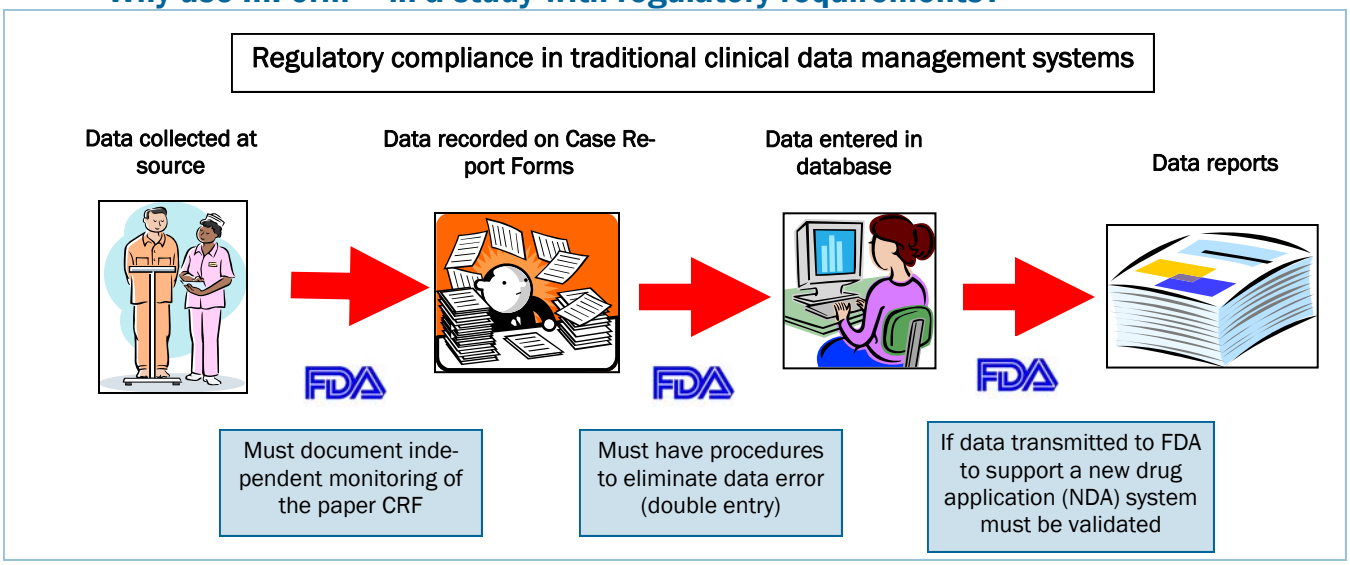
Advantages of Inform™

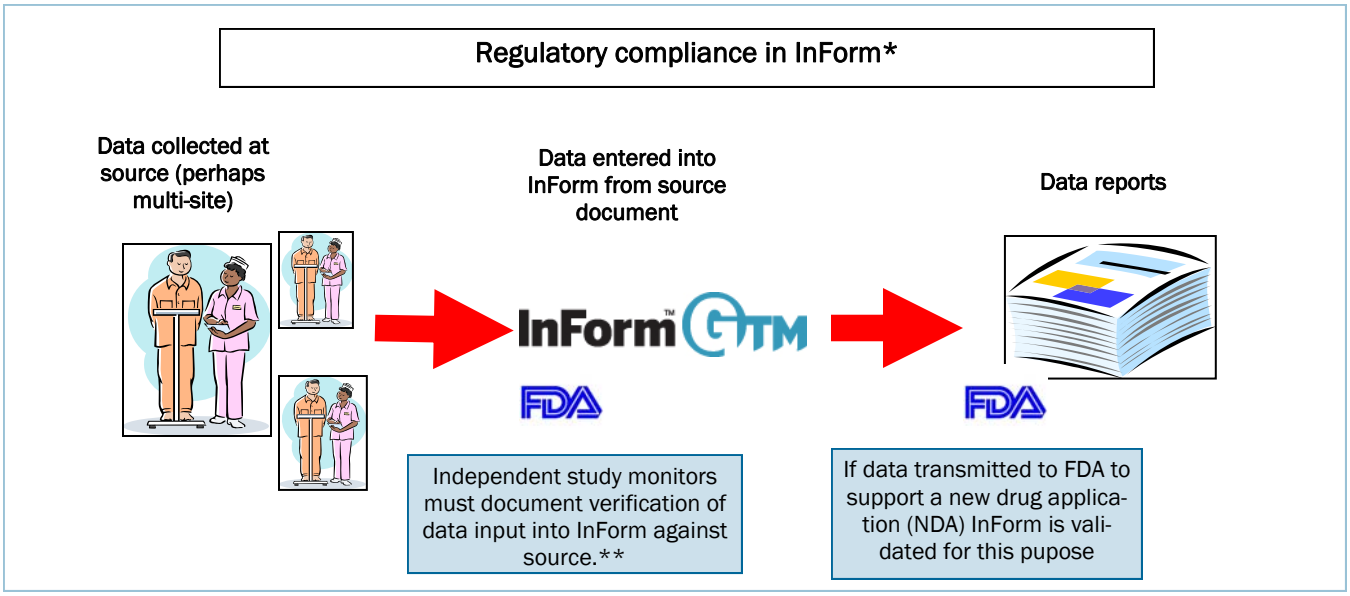
- Allows for sponsor data capture and monitoring electronically and eliminates the need for paper Case Reports Forms (CRFs) to be monitored or mailed in a multi-center trial.
- Reduce data entry workload (no need for double data entry when used in conjunction with a study monitor)
- Minimize data capture error through edit checks
- Validated system for data submissions to FDA to support a New Drug Application (NDA)*.
- Increase efficiency through monitoring and multiple reporting features
    - Reporting includes:
        - Reports by: subjects, form, query, date, time of enrollment, etc.,
        - Listings: snapshot of data
        - Customized reports
        - Routine SAS downloads: scheduled to run routinely & delivered via e-mail

Sample database in Inform™



Why use InForm™ in a study with regulatory requirements?





Budgeting for your Phase Forward Inform™ project

- Data managers and IT programmer must program databases into Phase Forward's Central Designer. Time for programming depends on size and complexity of your study. Additional statistical programming may be needed depending on the data needs of the client.
- There is $10,000 license fee per project, per year for programming and testing
- It is recommended that you consult with a Data Manager and/or Project Manager to discuss database programming cost for your study during the budgeting process.

Most common use:

- FDA regulated studies
- Multi-center trials
- Complex databases and registries with undefined time points (ie: # of visits)

** InForm is a tool that can assist with compliance. It does not make an investigator compliant by itself.*
***To utilize as an FDA complaint EDC system independent study monitoring must occur. Contact the EQuIP program for more details.*

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Other services offered by The Clinical Research Center

Activities	Consultative Services (Hospital Supported)	Direct Assistance (Investigator Supported)
Grants and Study Protocols	• Contributions to the writing of grant proposals and study protocols. • Survey research design • Study/Clinical Trial design • Qualitative research design methods • Power and sample size calculations • Data Analysis methods • Data management methods • Critique/review of grants or study protocols • cost impact/effectiveness research design	
Case Report Forms	• Guidance creating/review of case report forms	• Case Report Form development, formatting and coding
Survey Instruments	• Guidance creating/review of survey instrument	• Survey instrument development, formatting and coding • Administration of web-based surveys
Databases	• Assistance with creation of small, low complexity databases	• Development of complex, relational or customized databases • Database maintenance
Manuals of Operation	• Guidance/review of Study Manuals	• Writing and assembly of study manuals
Data Management	• Study ID assignment logs	• Data entry and management • Data conversion/extraction for analyses
Project Management	• Guidance/review of study timelines, management plans and priorities	• Project Director/Study Coordinator services
Randomization	• Randomization strategies • Randomization logs	• Randomization envelopes
Data Analyses	• Guidance on data analyses • Guidance on survey data analyses • Guidance on qualitative data analyses • Interpretation of results • Critique/review of manuscripts • Guidance on cost impact/effectiveness analyses/ Health Economics data analysis	• Data conversion/analysis file creation • Data set cleaning and verification • Data analyses • Survey data analyses • Qualitative data analyses • Manuscript writing • Cost impact/effectiveness analyses / Health Economics data analysis
Mentoring	• Mentoring	

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