Boston Children's Hospital
Until every child is well℠

The Clinical Research Center

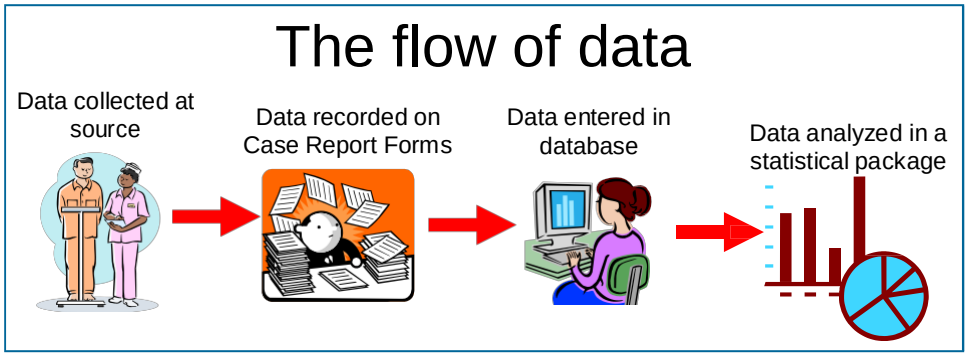
Clinical Research Database and Web Survey Technologies

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. A database that may have worked for an investigator on pervious projects might not be the best fit for others. This brochure gives a comparison of the two tools available at BCH to help you decide which may best meet your data management needs and you have budgeted appropriately. Consultation is also available from the Clinical Research Informatics Team and Clinical Research Center.

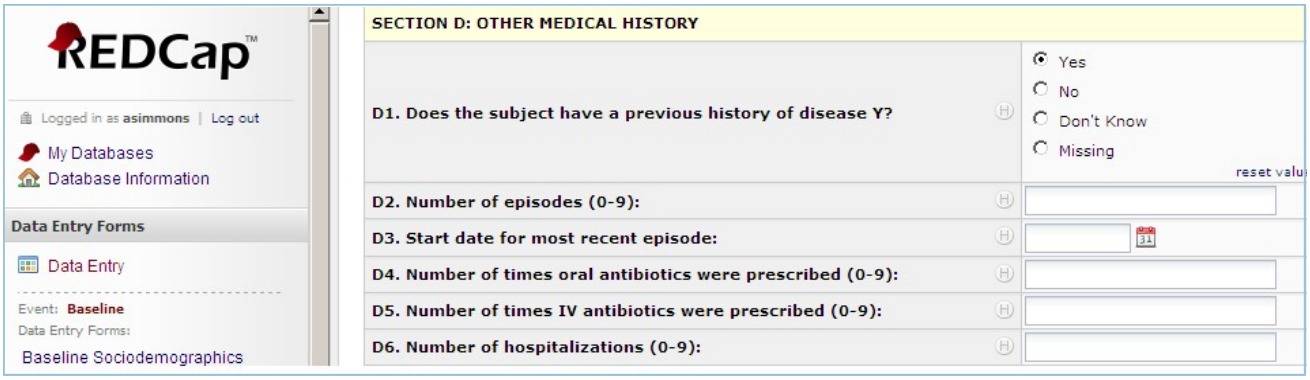
REDCap

Why Use REDCap?

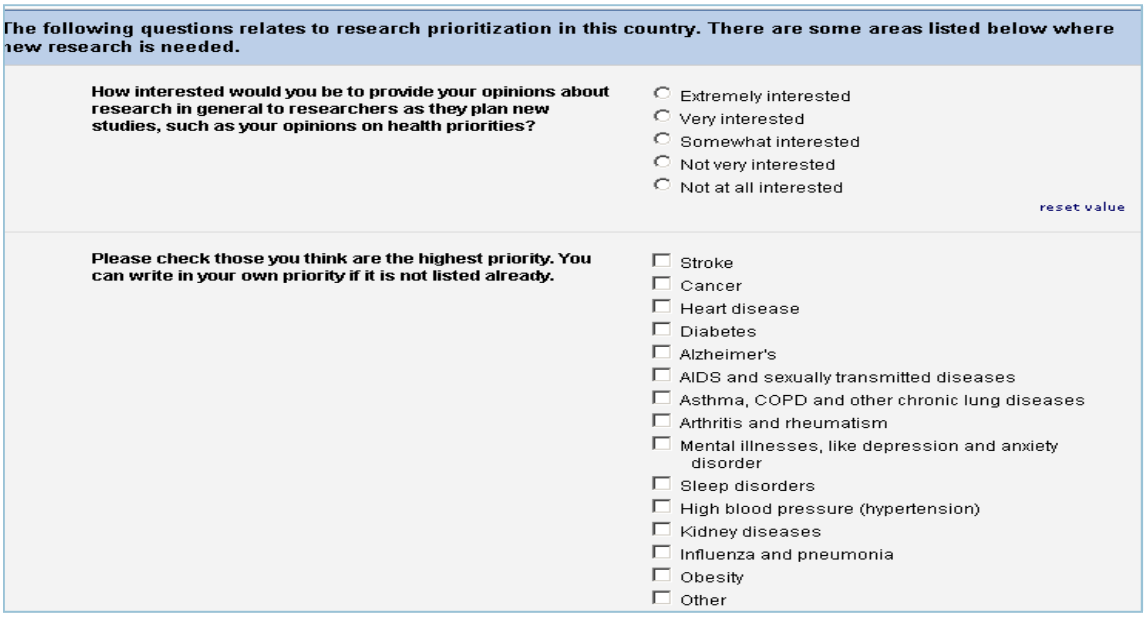
REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides:

- 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

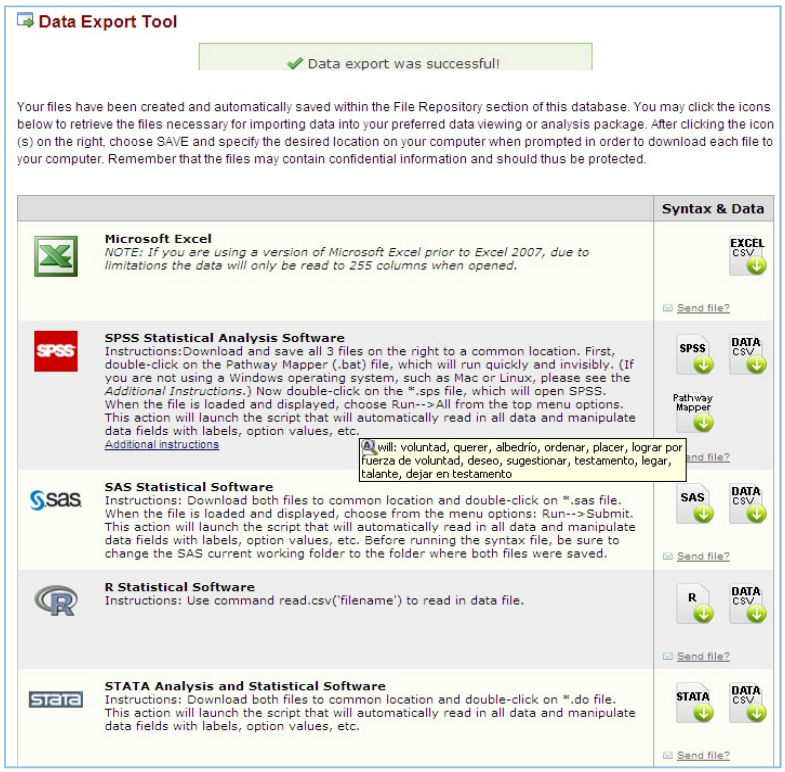


Sample web-survey in REDCap



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

- No cost for the software license
- User friendly-Your own staff can often be trained to use the tool so other programming staff may not be required
- Database programming and quality control testing take approximately 1-2 weeks

Most common use: Non-regulated studies, surveys or 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/**

InForm™

What is InForm™?

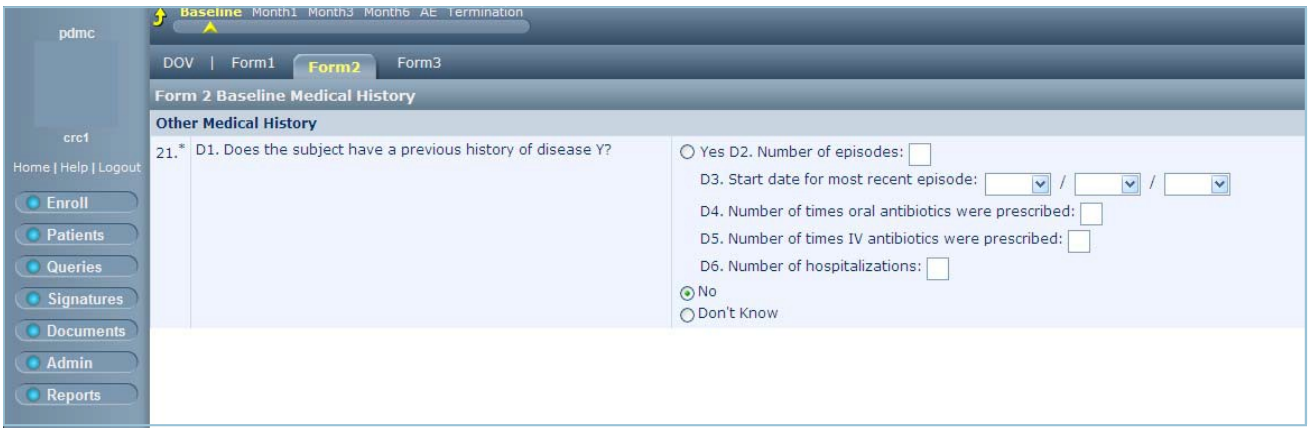
Phase Forward Inform offers powerful functionality for creating databases to capture complex data schemes.

- 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

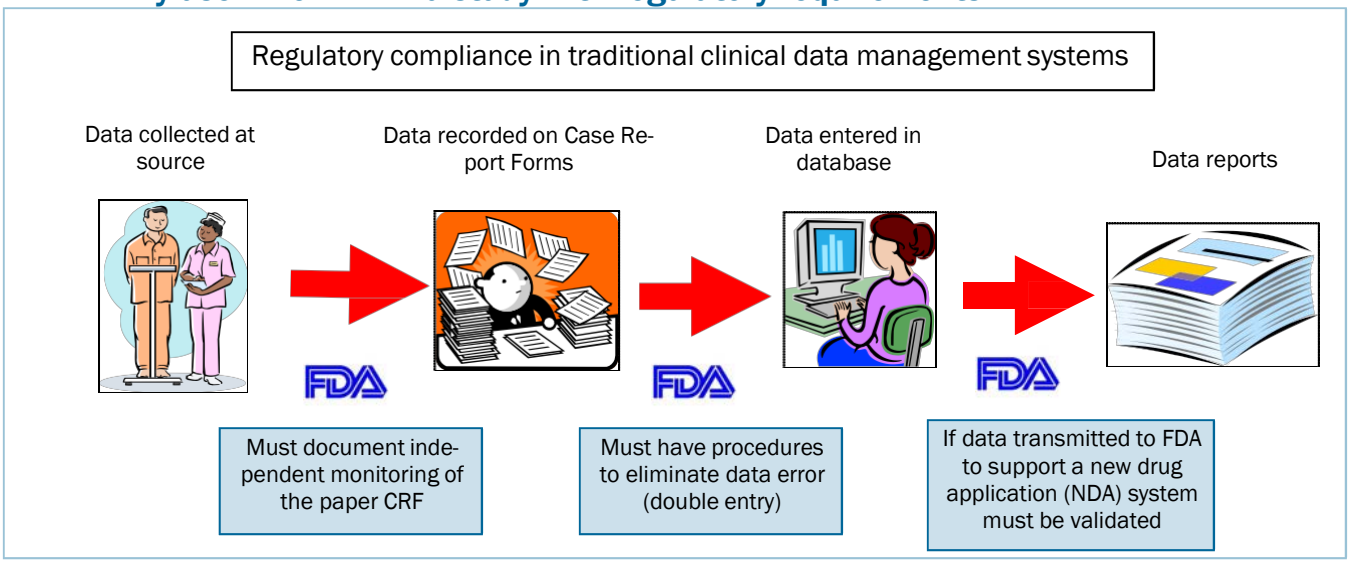
Advantages of Inform™

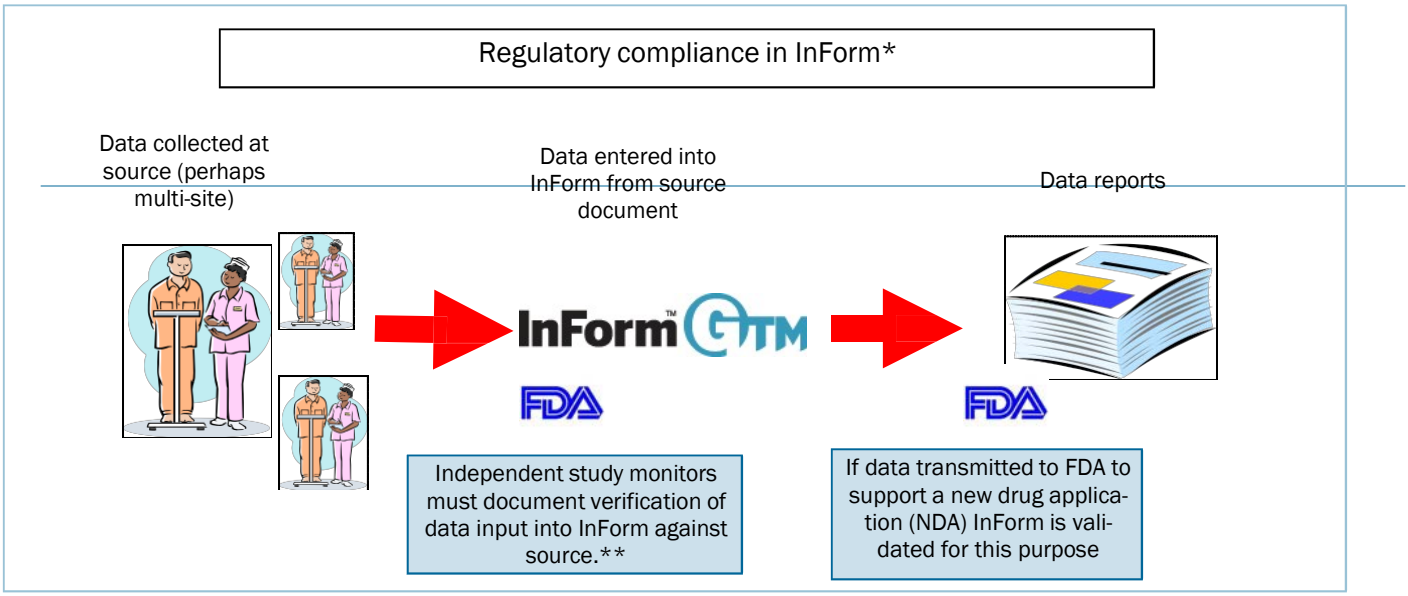
- Allows for sponsor data capture and monitoring electronically and eliminates the need for paper Case Reports Forms (CRFs) to be monitored or mailed in a multi-center trial.
- Reduce data entry workload (no need for double data entry when used in conjunction with a study monitor)
- Minimize data capture 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

- IT programmer must program databases into Phase Forward's Central Designer. Time for programming depends on size and complexity of your study.
- There is a license fee per project, per year for programming and testing
- It is recommended that you consult with CRIT to discuss database program ming cost for your study during the budgeting process.

Most common use:

- FDA regulated studies
- Multi-center trials

** 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.*

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

*Project cost should be discussed with the CRC during the studying 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.

For more information please contact:

REDCap:

Chris Botte: CBotte1@caregroup.org or 617-754-8828

CRIT (Clinical Research Information Technology):

Mohamad Daniar: mohamad.daniar@childrens.harvard.edu or 857-218-4249