

A Partnership Approach for Electronic Data Capture in Small-Scale Clinical Trials

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ITHS

Institute *of* Translational Health Sciences

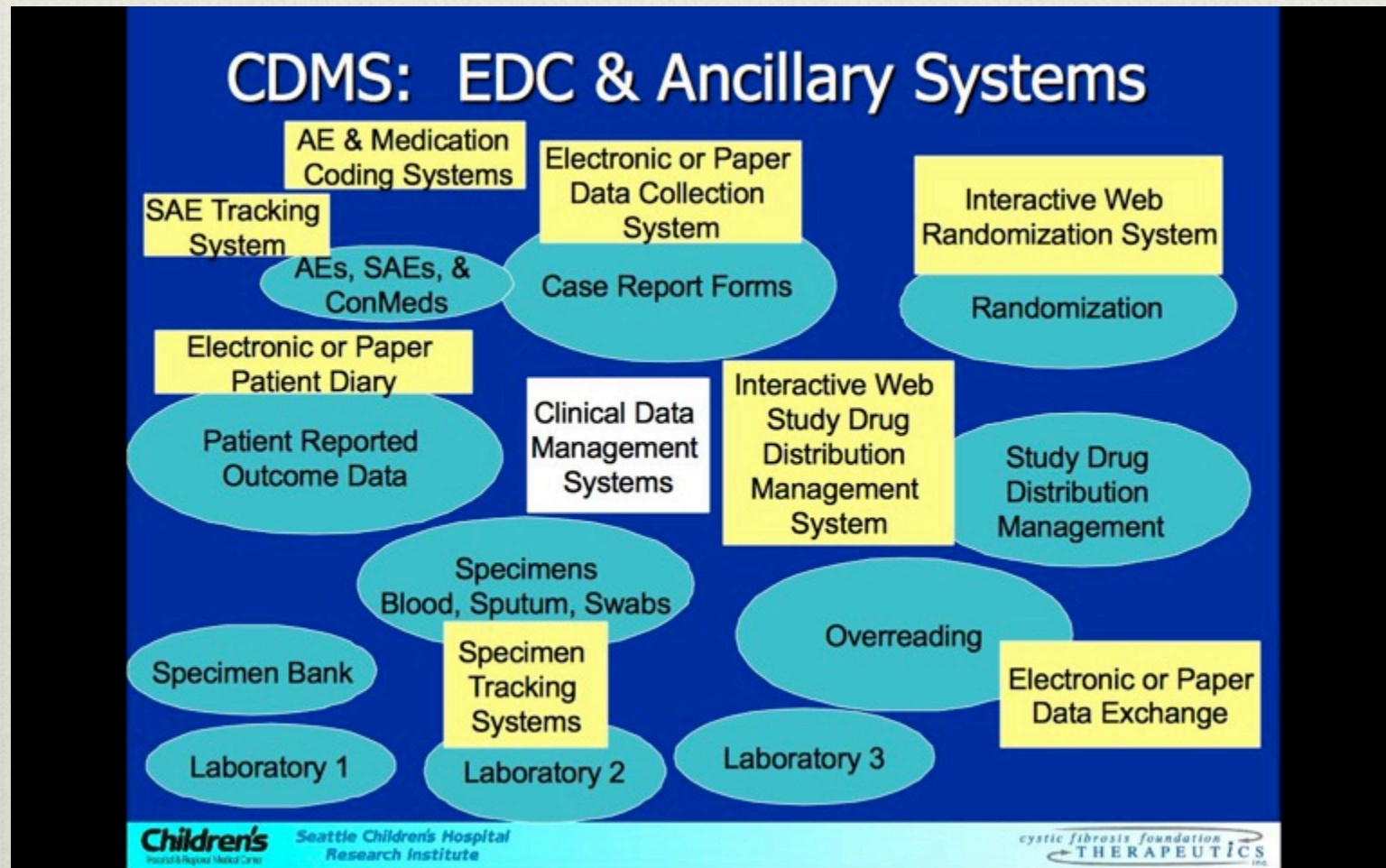
What I will talk about

- ❖ Part 1: Brief history of our EDC project journey
- ❖ Part 2: Summary of pilot partnership evaluations of three EDC systems from 2008-2010
- ❖ Some Terms:
 - ❖ CTSA: NIH Clinical and Translational Science Awards, or loosely the national consortium of institutes funded by CTSA
 - ❖ EDC: Electronic Data Capture, for managing semi-structured clinical trial data

Our EDC journey

- ❖ CTSA funded our Institute of Translational Health Sciences (ITHS) roughly 3 years ago
- ❖ We wanted a “Cadillac” Clinical Trials Management System (CTMS) infrastructure, but realistically needed to start small
- ❖ Many small-scale investigators lack funds for any EDC, so fall back on paper Case Report Forms (CRFs) transcribed to spreadsheets

Courtesy Dr. Nicole Mayer Hamblett



What small-scale investigators have

7-224.

TWELFTH CENSUS OF THE UNITED STATES.

SCHEDULE No. 1.—POPULATION.

State Ohio }
 County Delaware }

Township or other division of county Karlsruhe }
(Insert name of township, town, precinct, district, or other civil division, as the case may be. See instructions.) }
 Name of incorporated city, town, or village, within the above-named division, London Village }
 Enumerated by me on the 29 day of June, 1900, Frank S. Green }
 Name of Institution, X

LOCATION.			NAME of each person whose place of abode on June 1, 1900, was in this family. <small>Enter surname first, then the given name and middle initial, if any. Ignore every person living on June 1, 1900. Omit children born since June 1, 1900.</small>	RELATION. <small>Relationship of each person to the head of the family.</small>	PERSONAL DESCRIPTION.							NATIVITY.			CITIZENSHIP.			
IN CITY.	House Number.	Number of dwelling house, in the order of visitation.			Color or race.	Sex.	DATE OF BIRTH.		Age at last birthday.	Whether single, married, widowed, or divorced.	Number of years married.	Number of how many children.	Place of birth of this person.	Place of birth of Father of this person.	Place of birth of Mother of this person.	Year of immigration to the United States.	Number of years in the United States.	Naturalization.
Street.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
	73-74		Ignabrant, Ernest	Son	W	m	Aug 1879	20				Ohio	Ohio	Ohio				
	74-77		Book, Elizabeth	Head	W	f	Jan 1840	60				Ohio	Blairford Conn	Ohio				
			" Margaret B	Wife	W	f	Dec 1844	55				Ohio	Ohio	Ohio				
	75-76		Rice, Andrew	Head	W	m	May 1874	24	S			Ohio	Ohio	Ohio				
	76-77		Winton, Aaron	Head	W	m	Jan 1840	60				Ohio	Penn	Penn				
			" Jane	Wife	W	f	Mar 1840	60				Virginia	Virginia	Virginia				
			" John H	Son	W	m	Jan 1871	29				Ohio	Ohio	Virginia				
			" William	Wife	W	f	Aug 1874	25				Ohio	Ohio	Ohio				
			Opaschky, Jim	B. Law	W	m	Jan 1842	57	S			Virginia	Virginia	Virginia				
	76-79		Key, Willie L.	Servant	W	f	Dec 1871	28	S			Ohio	Ohio	Ohio				
			Blatt, Basil	Head	W	m	Dec 1860	39				Ohio	Ohio	Ohio				
			" Aaron	Wife	W	f	Jan 1870	30				Ohio	Ohio	Ohio				

Previous Work

- ❖ Foundation from interviews with investigators and survey of other informaticists
- ❖ “Concept Mapping to Develop a Framework for Characterizing Electronic Data Capture (EDC) Systems.” Guidry AF, Brinkley JF, Anderson N, Tarczy-Hornoch P. AMIA Annu Symp Proc. 2008 Nov 6:960.
- ❖ “None of the systems we evaluated provided all functionality”

Part 2: ITHS pilot projects

The screenshot shows a Google search interface with the query 'electronic data capture'. The results are categorized under 'Web' and include several links to websites and Wikipedia. The first three results are highlighted with a yellow background. Each result includes a title, a URL, and a brief description. Some results also include additional information like file size, cache status, and similar pages.

Google™ electronic data capture Search [Advanced Search](#) [Preferences](#)

Web

Electronic Data Capture
www.medicdatasolutions.com Easy-to-use **electronic data capture** for clinical trials.

electronic data capture
www.real-ediscovery.com/ Free eDiscovery webinars and whitepapers from Guidance Software.

Clinical Trials Software
www.ClinPlus.com ClinPlus - For Clinical **Data** Mgmt, Analysis, Reporting & Coding

Electronic data capture - Wikipedia, the free encyclopedia
An **Electronic Data Capture (EDC)** system is a computerized system designed for the collection of clinical **data** in **electronic** format for use mainly in human ...
en.wikipedia.org/wiki/Electronic_Data_Capture - 25k - [Cached](#) - [Similar pages](#) -

Electronic Data Capture - Phase Forward
Electronic Data Capture technology solutions in order to **capture data** electronically and store and refine **data** and ultimately being able to quickly report ...
<https://www.phaseforward.com/products/clinical/edc/> - 15k - [Cached](#) - [Similar pages](#) -

Clinical Trial Software for Electronic Data Capture | OpenClinica
Nov 12, 2007 ... OpenClinica is a free, open source clinical trial software platform for **Electronic Data Capture (EDC)** clinical **data** management in clinical ...
www.openclinica.org/section.php?sid=1 - 13k - [Cached](#) - [Similar pages](#) -

Narrowing Down

- ❖ Requirements:
 - ❖ Free, open source, or very low cost
 - ❖ Web based to prevent need to install software
 - ❖ API for data integration with other systems
- ❖ 7 systems met requirements
 - ❖ Discarded 2 systems with no recent activity
 - ❖ Found that 2 more systems did not include a way for the study team to create their own forms
 - ❖ Completed 3 pilot projects

Partnership Approach

- ❖ We provided the technical expertise:
 - ❖ secure server, including standard OS and database
 - ❖ install EDC system
 - ❖ SSL website security certificate
 - ❖ backups
- ❖ Study team configured their own project:
 - ❖ set up the system for data collection (with training)
 - ❖ performed all data entry
 - ❖ provided us with valuable user insights

Importance of Ease of Use

- ❖ Initially we assumed that functionality would be paramount (focus of a whitepaper we prepared)
- ❖ Study teams were willing to work around limitation since anything is a step up from paper and spreadsheets
- ❖ Our qualitative evaluation focused on **ease of use** of the functionality that was present

Qualitative evaluation

Criteria	Catalyst	OpenClinica	REDCap
Quality of training materials and documentation	Good	Fair	Good
Ease of designing CRFs including edit checks	Good	Poor	Good
Create a patient visit schedule for data entry	Poor	Good	Good
Flexibility of site and user roles and permissions	Fair	Good	Fair
Effort taken in exporting or importing data	Poor	Poor	Good

Pilot notes: UW Catalyst

- ❖ Open source suite including surveys, secure file management, and project workspaces
- ❖ General use, not specialized for clinical studies
- ❖ Setup requires a lot of manual customization
- ❖ Behavior on modification: if you edit wording in data export column is split:

2	Question	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c	Please fill c
3												
4	6:00 PM	Ringold, S	???	???	???	???	???	???	???	???	???	???
5	4:32 PM	???	Wennberg,	???	???	???	???	???	???	???	???	???
6	4:10 PM	???	???	Other - ple	???	???	???	???	???	???	???	???
7	4:53 PM	???	???	???	Wennberg,	???	???	???	???	???	???	???
8	11:58 AM	???	???	???	Baldwin, La	???	???	???	???	???	???	???

FAIL

Pilot notes: OpenClinica

- ❖ Open source, developed by Akaza Research
- ❖ Creating CRFs requires learning complex design with over 20 options per item (LEFT_ITEM_TEXT UNITS RIGHT_ITEM_TEXT SECTION_LABEL etc.)
- ❖ Potential good fit for centers with dedicated CRF design staff, but not for many small-scale studies

Pilot notes: REDCap

- ❖ Not Open Source, but free for “institutional partners”
- ❖ Extensive tutorials and online training materials
- ❖ Less functionality than OpenClinica in many areas such as complex CRFs and site management
- ❖ In the past few years, REDCap has added features including an online CRF editor, basic scheduling, API, and online surveys sent directly to subjects

Going Forward

- ❖ Early 2010 decided on REDCap as EDC system
- ❖ Current: local REDCap user group
 - ❖ “Power users” can assist others
 - ❖ CRF templates to augment REDCap Consortium’s Shared Library for common forms
 - ❖ Create website and other documentation with clear support options and steps for investigators to start using REDCap quickly
- ❖ Future: contribute to REDCap, for example value sets from OCRE (Ontology of Clinical Research)

Thanks!

❖ Questions?

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