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

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March 10, 2011

ITHS
Institute *of* Translational Health Sciences

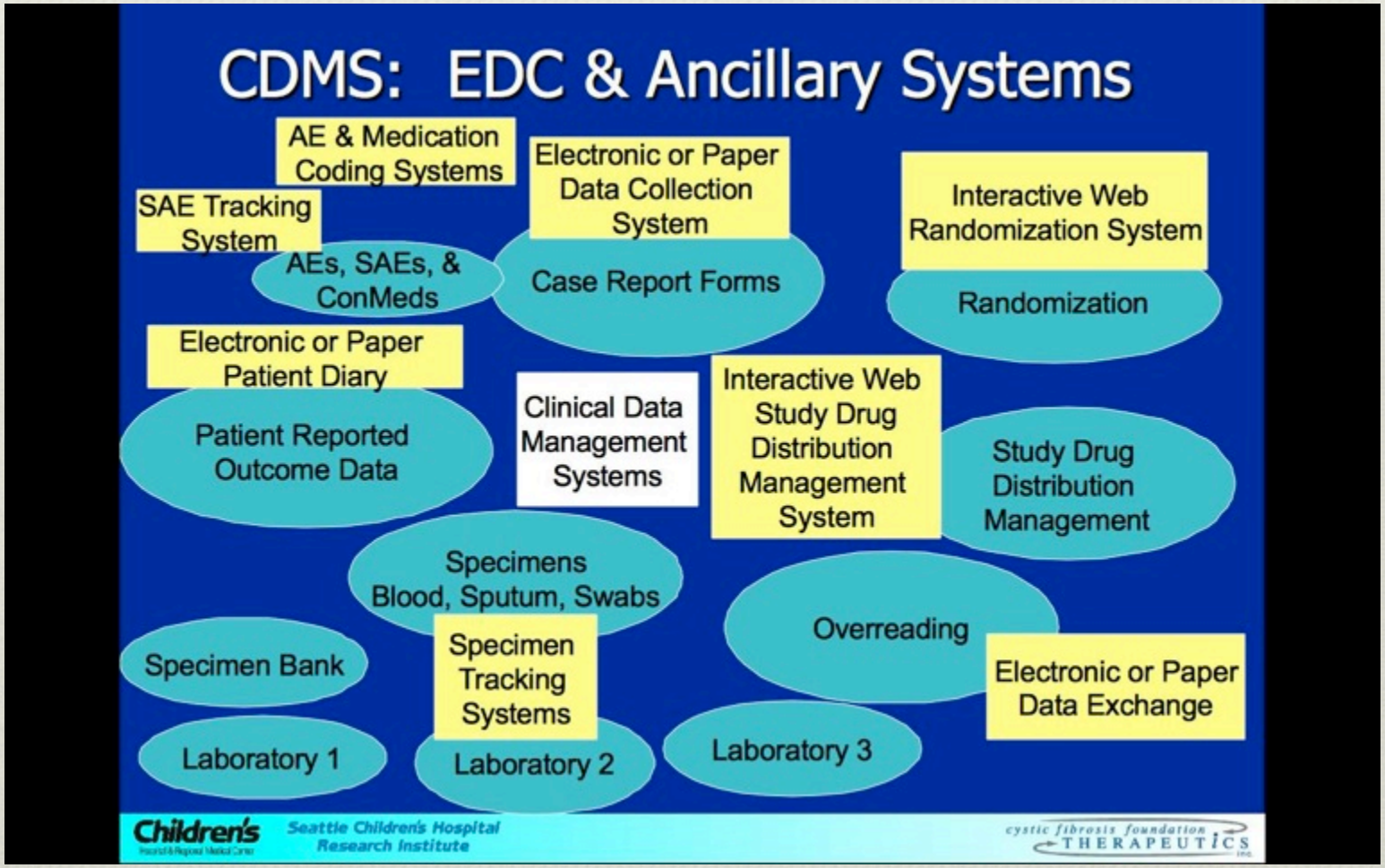
What I will talk about

- 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

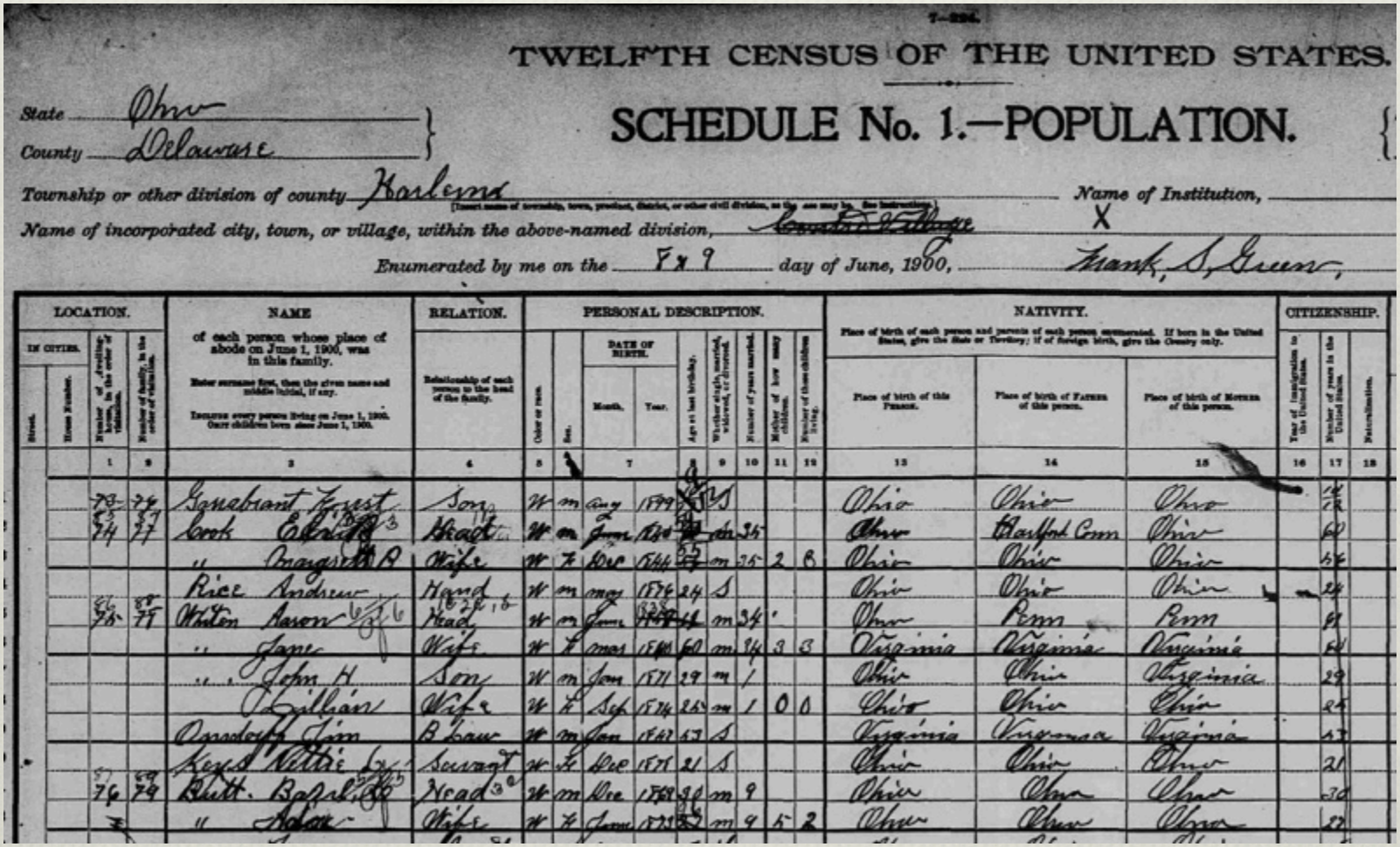
Our EDC journey

- 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



TWELFTH CENSUS OF THE UNITED STATES.

SCHEDULE No. 1.—POPULATION.

State Ohio
County Delaware
Township or other division of county Kirkland
Name of incorporated city, town, or village, within the above-named division, Sunbury Village
Name of Institution, X
Enumerated by me on the 7 & 9 day of June, 1900, Frank S. Green

LOCATION.		NAME	RELATION.	PERSONAL DESCRIPTION.							NATIVITY.			CITIZENSHIP.		
Street.	House Number.	of each person whose place of abode on June 1, 1900, was in this family.	Relationship of each person to the head of the family.	Color or race.	Sex.	Month.	Year.	Age at last birthday.	Whether single, married, widowed, or divorced.	Number of years married.	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.
1	2	3	4	5	6	7			9	10	11	12	13	14	15	16	17	18
	73	Genebrant Faust	Son	W	m	Aug	1879	20	S		Ohio	Ohio	Ohio			
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		" Margaretta A	Wife	W	F	Dec	1844	55	m	26	2	8	Ohio	Ohio	Ohio			
		Rice Andrew	Hand	W	m	may	1876	24	S				Ohio	Ohio	Ohio			
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		" Jane	Wife	W	F	mar	1846	60	m	34	3	3	Virginia	Virginia	Virginia			
		" John H	Son	W	m	Jan	1871	29	m	1			Ohio	Ohio	Virginia			
		Lillian	Wife	W	F	Sept	1874	25	m	1	0	0	Ohio	Ohio	Ohio			
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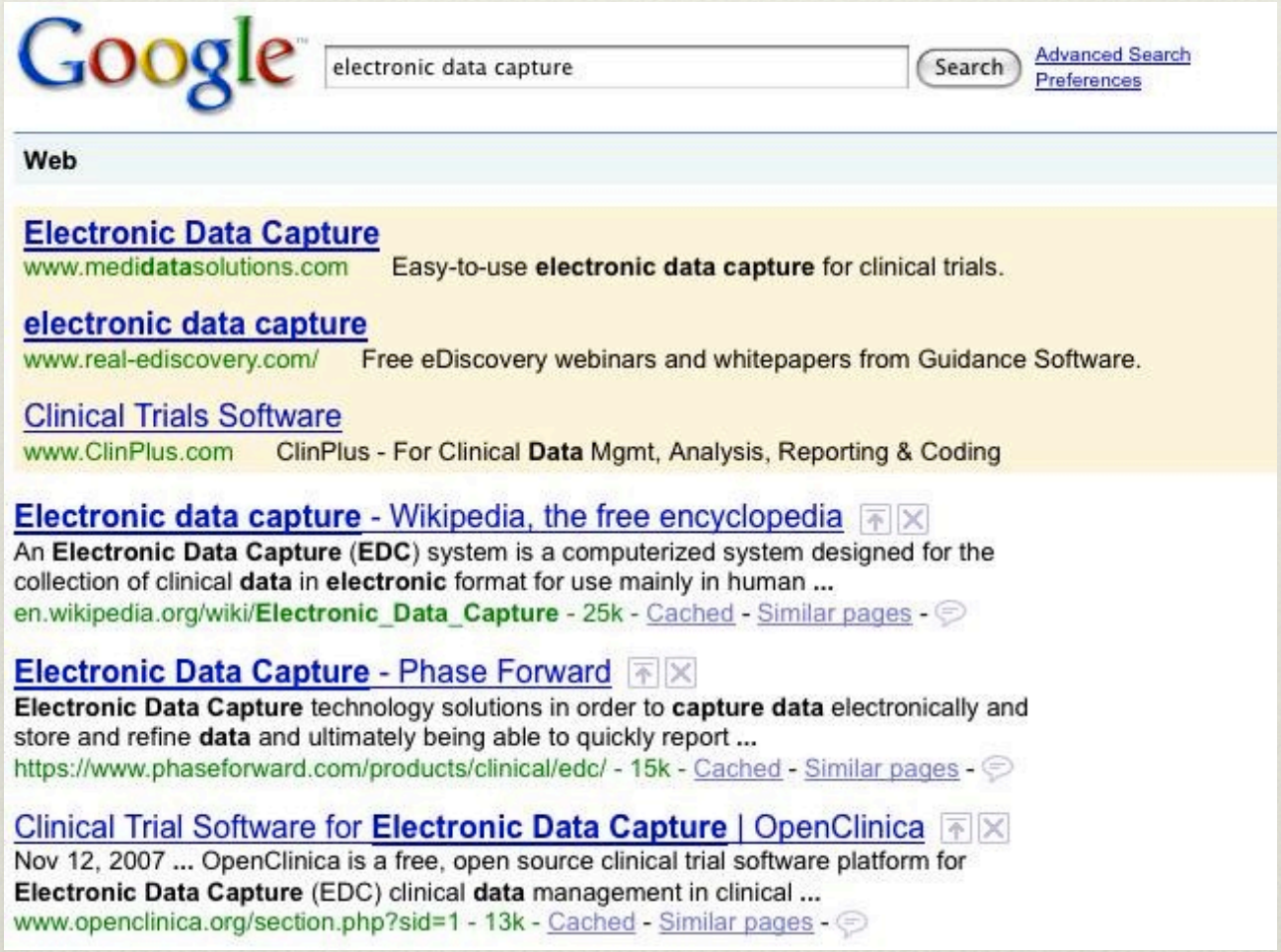
		" Adah	Wife	W	F	June	1873	26	m	9	5	2	Ohio	Ohio	Ohio			

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



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

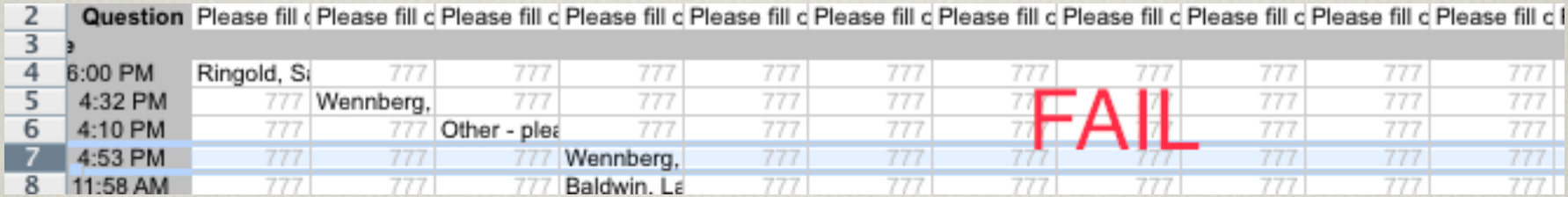
- Initially we assumed that functionality would be paramount (focus of a whitepaper we prepared)
- Study teams were willing to work around limitation since anything is a step up from paper and spreadsheets
- Our qualitative evaluation focused on **ease of use** of the functionality that was present

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:



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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