Concept Mapping to Develop a Framework for Characterizing Electronic Data Capture (EDC) Systems

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Introduction

Using paper or spreadsheets to keep records of data for translational research investigations can lead to difficulties keeping track of information and duplicated or missing data. Dealing with these difficulties could prove to be time consuming because of the possibility of duplication and missing data.

EDC systems are designed to do what paper based systems and spreadsheets are not able to do. Investigators are given the option of conducting trials at multiple sites and the ability to determine whether information is missing for a particular subject or not. This along with the idea of exporting and importing data from electronic medical records, tissue banks or other clinical trial data helps EDCs facilitate clinical/translational research.

The purpose of this work is to develop a framework for evaluating various EDC systems.

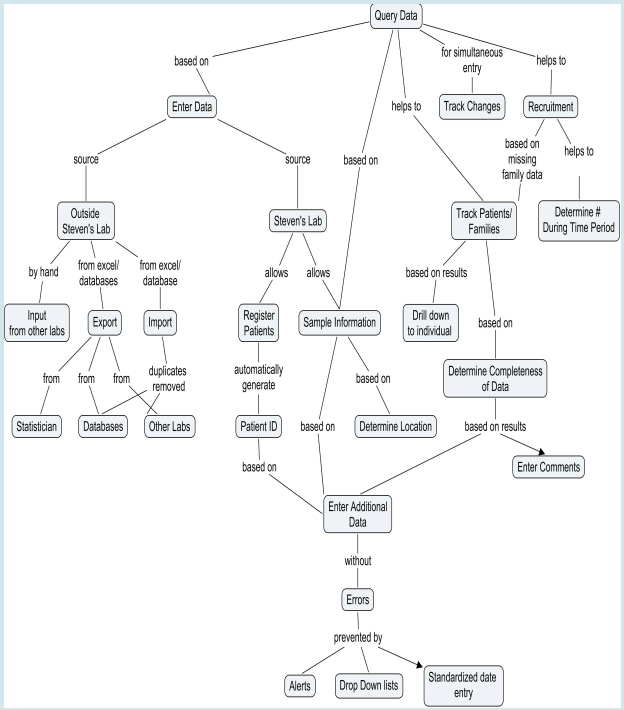

Figure 1

Methods

- Open-ended survey of EDC requirements given to members of a small clinical/translational research lab N=3
- Concept map created based on survey responses (See Figure 1)
- Major themes from concept map used to create an evaluation tool
- Changes made to tool with input from ITHS consultations and assistant directors of CTSA at Duke University, Oregon Health Sciences University and the University of Pittsburgh
- List of tools to evaluate obtained from National CTSA Inventory Working Group and and from UW ITHS lists of Informatics Tools
  - Non-proprietary systems – OpenClinica 2.2, RedCap (Vanderbilt University), WebTrial (University of Washington) and DADOS (Duke University)
  - Proprietary systems – Velos eClinical, Generic Spreadsheet
- Systems were evaluated based on three criteria (1 – Present, 2 – Present With Limitations, 3 – Not Present)
- Receiving a rating of 2 implies that there are too many button clicks, n > 2, to achieve the task or that the task is only partially available.

a.	Data can be exported easily.
b.	Data can be exported in correct form.
c.	Data can be imported easily.
d.	Data can be imported and duplicates are removed automatically
e.	The system accepts input from other labs.
f.	When registering patients, patient identification numbers are automatically generated
g.	Errors in data entry are noticed by the system
h.	Data entry can be done from a query screen
i.	It is easy to drill down for more information based on the results of a query
j.	Changes to data can be tracked when simultaneous data entry is taking place.
k.	The system indicates when data is missing
l.	Ability to insert comments based on query results
m.	Survey Tool for patients
n.	Ability to create data entry screens (institution specific)
o.	Application interface and workflow for clinicaltrials.gov submission
p.	Serious Adverse Event (SAE) reporting (has FDA form 3500) and generates ICSR HL7 message to FDA and Trial Sponsor
q.	Workflow for central SAE management and triage of FDA Safety Alerts
r.	Interface to eIRB systems for submission and progress tracking
s.	Ability to create a patient visit schedule
t.	Ability to store billing information for a protocol
u.	Ability to instiantiate billing information for individual patients and interface with institutional billing system
v.	Ability to aggregate milestones (enrollment, visits, etc. to accrue information for invoice to trial sponsor)
w.	Ability to interface with instiitutional Master Patient Index
x.	Ability to interface with Institutional Scheduling System

Table 1

Results

- Evaluation tool consists of 24 criteria (See Table 1)
- Six tools evaluated
- No system provided all functionality (See Table 2)
- Percentages in Table 2 represent the number of systems with rating, out of the total evaluated
- Spreadsheets do not allow for functionality beyond input, import, and export
- Velos e-Clinical provided 95.8% (23 of 24) tasks

Task	1 - Present	2 - Present w/ Limitations	3 - Not Present
A	66.67%	33.33%	0.00%
B	83.33%	16.67%	0.00%
C	50.00%	16.67%	33.33%
D	16.67%	33.33%	50.00%
E	83.33%	16.67%	0.00%
F	50.00%	0.00%	50.00%
G	33.33%	33.33%	33.33%
H	33.33%	0.00%	66.67%
I	50.00%	0.00%	50.00%
J	66.67%	33.33%	0.00%
K	33.33%	50.00%	16.67%
L	16.67%	33.33%	50.00%
M	33.33%	0.00%	66.67%
N	83.33%	0.00%	16.67%
O	16.67%	0.00%	83.33%
P	16.67%	16.67%	66.67%
Q	16.67%	16.67%	66.67%
R	16.67%	0.00%	83.33%
S	66.67%	0.00%	33.33%
T	16.67%	0.00%	83.33%
U	16.67%	0.00%	83.33%
V	16.67%	0.00%	83.33%
W	16.67%	0.00%	83.33%
X	16.67%	0.00%	83.33%

Table 2

Discussion

- The most widely provided functionality of EDCs surveyed is the ability to import and export data, patient tracking, and the ability to accept input from other locations.
- Tasks related to institutional and reporting interfaces, and billing are considered to be functionality of Clinical Trials Management Systems and not EDC systems.
- However, these tasks were considered to be important to the investigators surveyed and were therefore included in the framework.
- Future work will include an online survey sent to all currently funded CTSAs, 36 total, to determine the needs of their users related to EDC selection, development of a web-based tool to aid in system selection and a paper to discuss findings.

Works Cited

RedCap (Vanderbilt University) http://www.iwg-online.org/projects/redcap/index.php
WebTrial (University of Washington) No online link
DADOS (Duke University) No online link
OpenClinica http://www.openclinica.org
Velos http://www.velos.com/products_eres_overview.shtml

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