



Building a Trust Relationship with Your IRB

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Creating a Data Services Core

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Getting Started

Advertise

- Keep and publish your metrics (studies/researchers supported)
(useful for departmental website, talks, etc)
- Volunteer for every workshop and training seminar you can find
- Volunteer to present at lab meetings, departmental meetings, etc
- **Seek out the IRB and other regulatory groups**
(we're giving research teams an 'easy way to do the right thing')

Listen to Your Researchers

- Training sessions provide many bi-directional teachable moments
- Solve problems without overpromising
(95% for free and we can help you rethink 5% ... or \$80/hour)

Incorporate in Training Programs

- Best Practices + How to Implement
- First homework assignment: Build data management solution (your research)

Getting Started

Build a sustainable business model

- Using CTSA funding, Vanderbilt offers REDCap and REDCap Survey tool at no charge to investigators.
 1. Protects the Institution (centralized data capture, security)
 2. Protects the researcher (data quality and continuity)
 3. Protects the research participant (data security)
 4. Cost effective - Informatics investment is minimal
- We also run a fee-for-service core that is available to research teams when REDCap will simply not fit (4-Tier Model - Tier 1 is REDCap and used by 99% of projects)
- Grant deadlines are the best time to make new friends ...
(*let's create a REDCap database shell so you'll have a screenshot to go along with this boilerplate language*)





Implications of REDCap for HIPAA Compliance

Gaye Smith
Privacy & Health Record Official
Vanderbilt University Medical Center



REDCap to the Rescue!

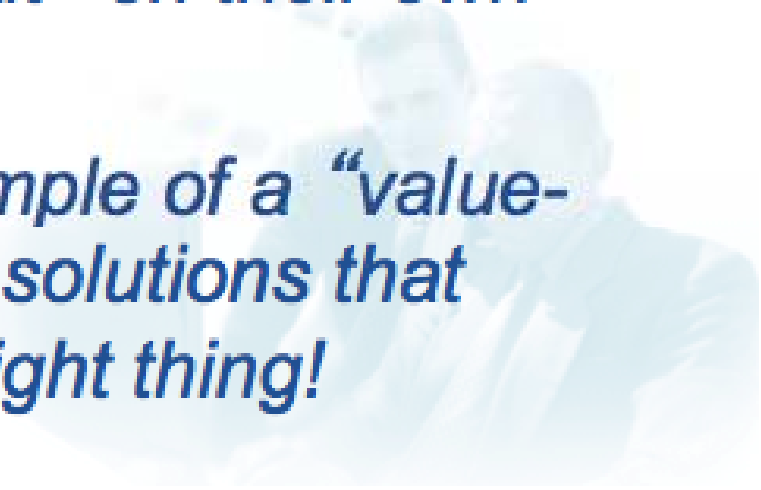
- Consistent approach & documented response to the requirements
 - Unique User ID
 - Audit Logs
 - Technical Safeguards
- Technical expertise
 - Ongoing Risk Assessments and Improvements
- Tools that make it easy to do the right thing!





Summary Thoughts:

- *Researchers and health care providers intend to do the right thing*
- *But, they may not be technically expert or motivated to “figure it out” on their own*
- *REDCap is a great example of a “value-added” set of tools and solutions that make it easy to do the right thing!*



Summary Thoughts:

- *Researchers and health care providers intend to do the right thing*
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IRB Chairs Presentation

Introducing REDCap DTS Functionality

*Recommended course of action after
proactively discussing with my favorite IRB +
Privacy contacts ...*

Researchers want/need
clinical data for conducting
research

‘At a place like Vanderbilt, ... ‘

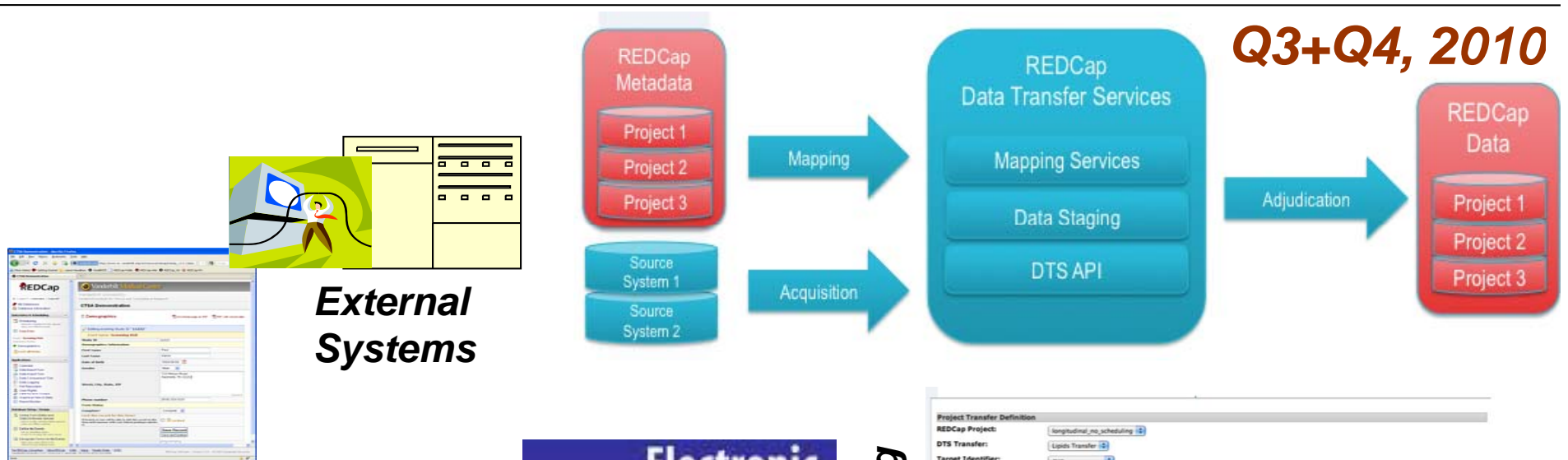
Researchers are right ...

We need a model that can support even junior
faculty

There are many complexities ...

- Data Access
- Costs
- **Regulatory**
- Expertise
- Time (one-off work always iterative)
- Infrastructure
- Process (Prioritization ...)

REDCap – External Systems Interoperability (DTS)



Mapping

Project Transfer Definition

REDCap Project: longitudinal_ms_scheduling

DTS Transfer: Lipids Transfer

Target Identifier: none

Use Scheduling: ☐

Project Transfer Status: Active

Project Transfer Mapping

Info Field	Screening	Baseline	Week 6	Week 12	Week 18	Week 24	Week 30
Redcap Temporal Variable	visit_date	visit_date	visit_date	visit_date	visit_date	visit_date	visit_date
LDL	Measurement Notes	ldl	ldl	ldl	ldl	ldl	ldl
Triglyceride	Measurement Notes	trig	trig	trig	trig	trig	trig
HDL	Measurement Notes	hdl	hdl	hdl	hdl	hdl	hdl
Measurement Notes	Measurement Notes	Measurement Notes	Measurement Notes	Measurement Notes	Measurement Notes	Measurement Notes	Measurement Notes

Production @ VU by 09/15/2010
Release to Consortium in Q4, 2010

Adjudication

Adjudication for REDCap Study ID: 1

Form	Event	REDCap Variable	REDCap Date	Source Date	REDCap Value	Source Value	Info	Status
Timepoints T0 enrollment	glucose		2009-09-27	2009-09-26	157	137		OK
				2009-09-27	157	157		OK
				2009-09-27	157	142		OK
				2009-09-27	157	165		OK
				2009-09-27	157	180		OK
				2009-09-27	157	146		OK
				2009-09-28	157	123		OK
Timepoints T0 enrollment	hct		2009-09-27	2009-09-26	46	46		OK
				2009-09-27	46	41		OK
				2009-09-27	46	44		OK
				2009-09-27	46	36		OK
				2009-09-28	46	41		OK
Timepoints T0 enrollment	hgb		2009-09-27	2009-09-27	32	32		OK
				2009-09-28	32	27		OK
Timepoints T0 enrollment	l_calcium		2009-09-27	2009-09-27		4.21		OK
				2009-09-27		4.25		OK
				2009-09-27		4.13		OK
				2009-09-27		4.05		OK
Timepoints T0 enrollment	lactate		2009-09-27	2009-09-27		1.4		OK
				2009-09-27		1.8		OK
				2009-09-27		1.3		OK

REDCap – External Systems Interoperability (DTS) - Regulatory

Condition #1

Addendum in a researcher's IRB proposal stating they will be pulling clinical data into REDCap via this new module.

- *Need Template*

Condition #2

For each user that will use the adjudication screen, we will verify that they have access to STAR before we grant access to use this module. We are going to add another option in the user rights section of REDCap for the adjudication screen and only super users (someone on our team) will be allowed to activate this right for a particular user.

Education

- Ask if IRB needs content speakers for research training (eg lunch/learns)
REDCap team presents at least once per year

Last Talk – What's New and What's Next

Next Talk – Data Security

Next Next Talk – What's New in RC4.0

- Volunteer for research education workshops --- Taylor/Wang volunteer ~ once per quarter

Summary

- Be proactive
 - Schedule time to talk with IRB
 - Offer boilerplate language to researchers
 - Look for education opportunities
- Don't be afraid to 'compare this with real-world today'
- Be honest - don't oversell and politely correct if they give you too much benefit of the doubt