Best practices for building interoperable systems for translational research

Melhores práticas para a construção de sistemas inter-operáveis em pesquisa translacional

September 27, 2010

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Take Home Message

Needs, technology, and designs will change

Process

Architect for change
Break down the problem
Chart the big picture
Design the modules
Engage the users
Follow advice
Iterate:
- Analysis
- Design
- Develop
- Test

Usability counts!

Technology

Use services as much as possible
Use automated testing
Use continuous integration
Version control!
Re-use

People

Find the best people
Listen
Communicate!

Outline

- Unifying Forces
- Best Practices
- Iterative analysis, iterative design, iterative development
- Testing
- Usability
- Vocabularies and Ontologies
- People, Technology, Process, Standards
- People roles
- Technology supports People and Processes
- Northwestern example projects

Unifying Forces

IT Best Practices
Data warehousing
Individual data
Deep phenotype
Deep sequencing
-omics : transcriptome, proteome, metabalome, 'phenome'
Regulatory Environment
Controlled Vocabularies and Ontologies
Quality Care and Outcomes of Care

Data mining

More data is better
Make it individualized/highly granular
Data reduction should be applied at the end, not during the acquisition process – you can never go back otherwise!
Rich collection of modeling methods
More data is better!!!!

Regulatory Environment

HIPAA in the US, as well as other legislation, has forced organizations to understand ethical and legal issues surrounding the patient/physician interaction, and how other members of the organization interact with patients.
Privacy, confidentiality, and associated liability has moved organizations to look at patient interactions through a single lens.

The role of clinical research associates, clinical researchers, and translational research in general must be examined from an enterprise perspective.

IT Best Practices

Sound project frameworks (Unified Process Framework, Agile Unified Process, etc)
Agile practices - embedded teams, testing, change
Iterative analysis, design, construction phases
We try to use two week sprints
Continuous integration (coupled versioning, automated testing, task management, bug/issue management)

Best Practices provide ability to adapt and reflect changes in healthcare practices and translational research needs and requirements

More Best Practices

- Define the project
  - We use Unified Process
  - Our hospital uses DMAIC (six sigma)
- Engage the community
- Engage the stakeholders
- Engage the sponsors
- Embed the users

Why iterative?

Brief History of Automobile Design

1890s to 2010

1890s Mercedes

~1900 electric car

Brief History of Automobile Design

1890s to 2010

1926 Model T

Rolls Royce Phantom

Brief History of Automobile Design

1890s to 2010

Rolls Royce Phantom

280SL (1970)

Brief History of Automobile Design

1890s to 2010

2010 Mazda

Iterate in small cycles because:

- Technology changes
- Requirements change
- Society changes
- Capabilities change

Architect for change!

Iterations should focus on the most critical

Testing

Critical for iterative software projects

Automate your tests
Use version control
Unit test
Functional test
Integration test
UI test
Regression test
Feature test
Limit test

Usability and Design

Engage a usability expert

Many different ways to approach design

Find a group willing to discuss iterative design and work with your iterative processes

Genius design is the exception, not the rule

Controlled Vocabularies and Ontologies

Getting coding right is critical for analysis and sharing!

HL7 has incorporated the CDISC SDTM clinical research model into the HL7 V3 RIM. BRIDG.
SNOMED may release ontological views of some of the knowledge represented
LOINC, Rxnorm, ICD-10 are useful too!
Open standards are being embraced - the caBIG™ caDSR as one example
Biological, experimental, and clinical trials ontologies have been or are being developed (GO, EXPO, CTO)

Open, computable, extensible and agile controlled vocabularies and ontologies that accurately reflect the realities of clinical care and clinical research are a cornerstone for interoperability and reasoning

People, Processes, Technology, Standards

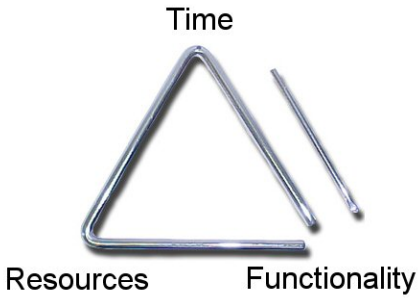
People Processes Technology

Lots of ways to put this classic management triangle

All are important
Failure to address any one can (and usually does!) result in project failure

Project resource/functionality/time

Fixed resources means only time and functionality can vary



You can reduce the time by cutting functionality or increasing resources. You cannot increase functionality without increasing time or resources

Data collection tools

Quality of life assessment, collection forms, adverse events all have existing recommended data structures. Find existing data collection tools that help your researchers! Don't forget vocabularies and ontologies!

Roles

You need people!

Executive sponsor – who is going to fight for the project?
Project lead – who will manage the communication?
Project manager - who will oversee the tasks?
Lead architect – who will make the technology design decisions
Lead analyst – who will map requirements onto design?
Usability analyst – who will evaluate the human interaction components?
Lead designer – who will assemble the 'visible architecture' for the project?
User – need the end user perspective on the team
Worker bees – someone has to build/integrate/test

Participatory Design

Engage the whole team
Employ design Charrettes
Charrette – an intense period of design activity (wikipedia)

Validate your progress

Evaluate satisfaction before the project
Evaluate as the project goes forward
Trace usage/usability

Anti-patterns

- Hero projects
- Genius design
- Separating the analysis, design, build and testing teams
- User proxies (acting as the real end users) are OK, but be aware of them

Take home point

- Results matter, but so does methodology, behavior and process. In science and medicine, reproducibility has value

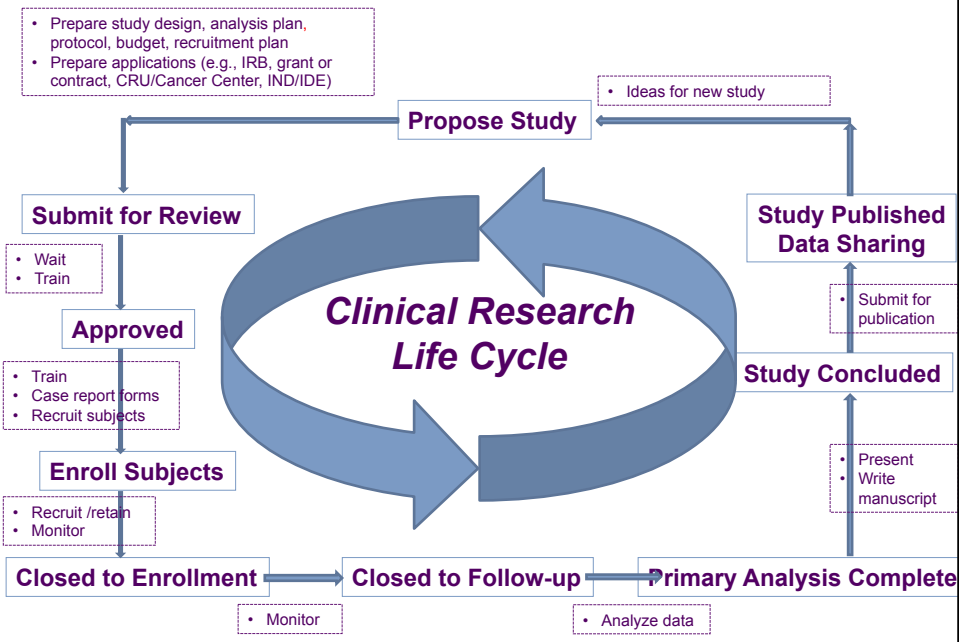
Too much abstract advice

- Some details of what we have done at Northwestern

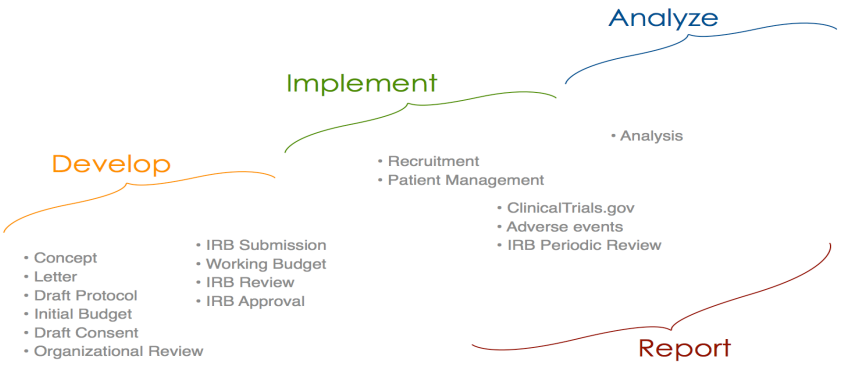
Supporting Translational Research

First the requirements

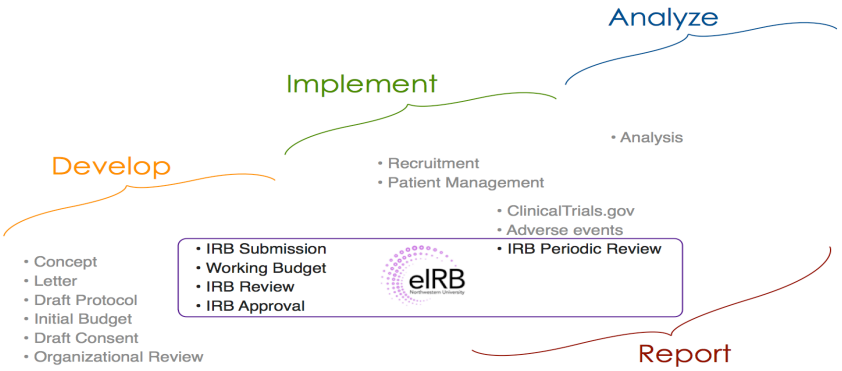
We need to support patient registries, recruitment, biobanking, clinical trials, data collection, retention, compliance with the protocol, completion, regulatory reporting, oversight and finally analysis



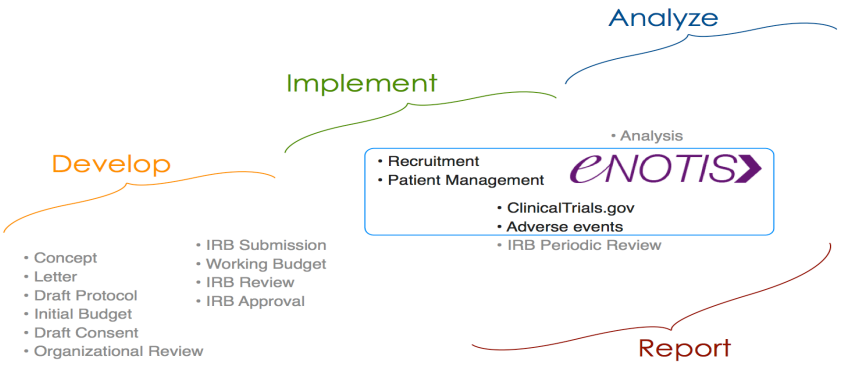
Clinical Research Workflow



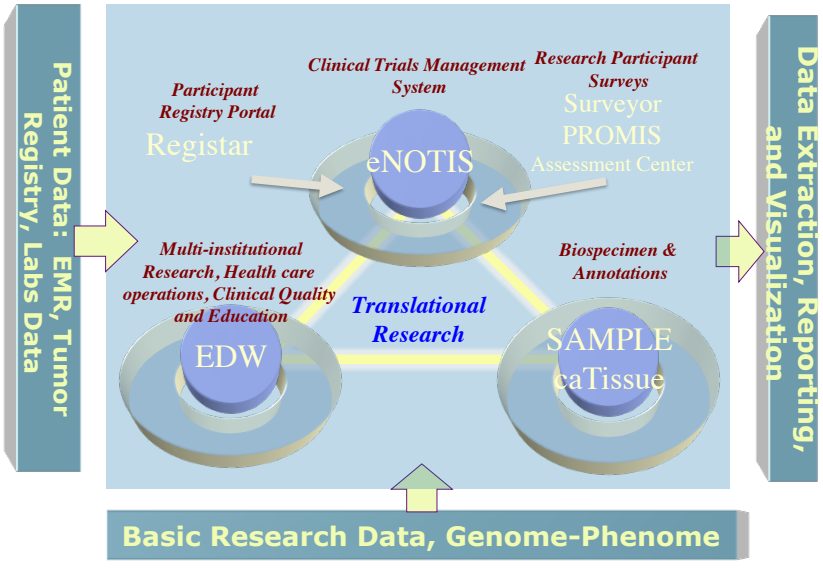
Clinical Research Workflow



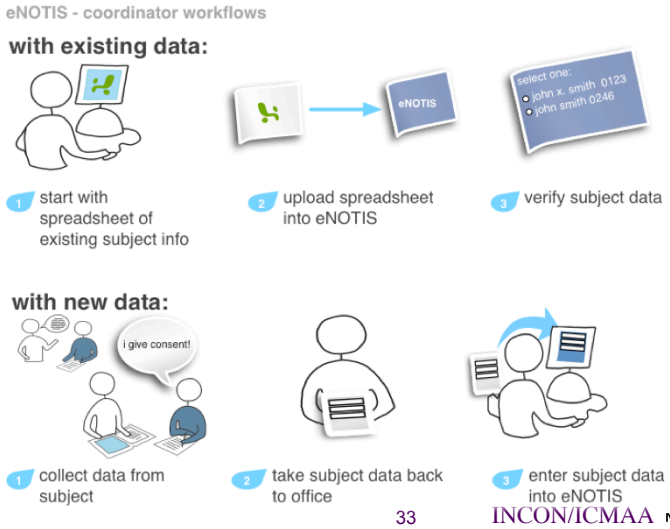
Clinical Research Workflow



Northwestern Translational Research Informatics



Workflow with eNOTIS



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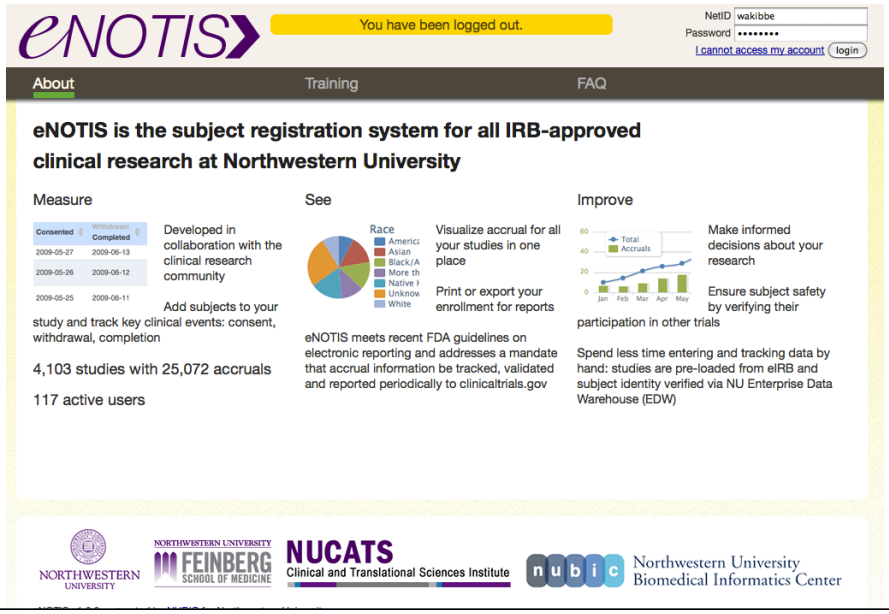
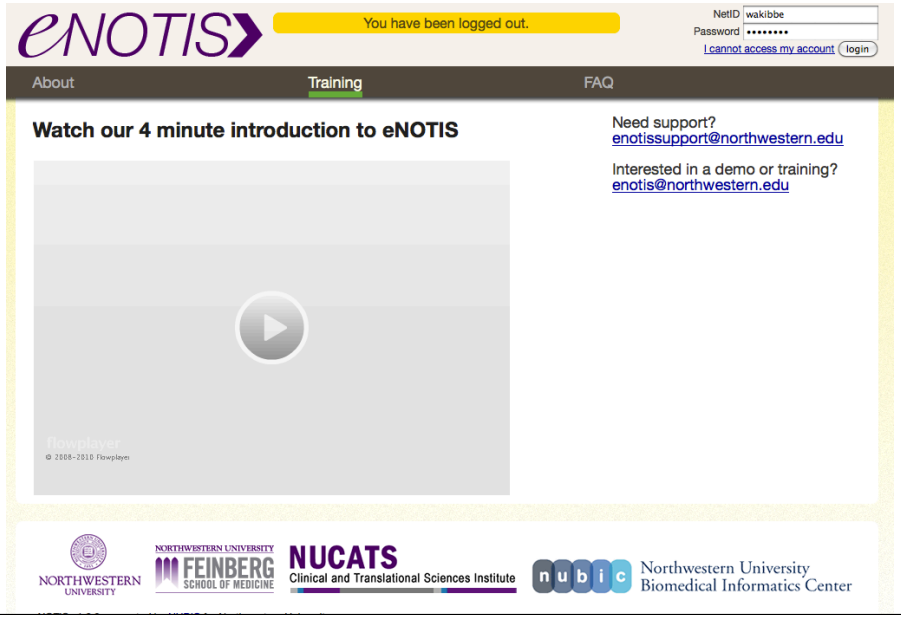
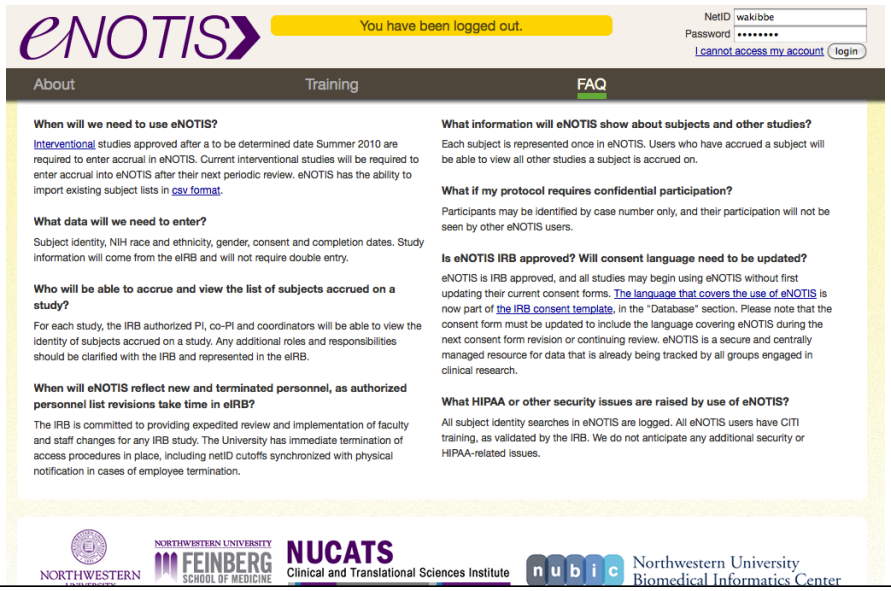
eNOTIS landing page



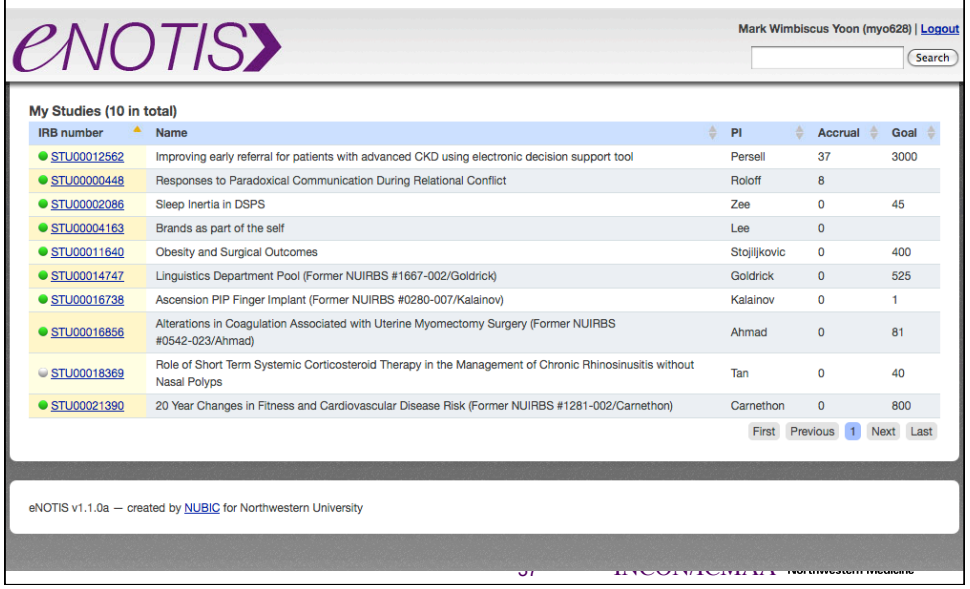
eNOTIS Training



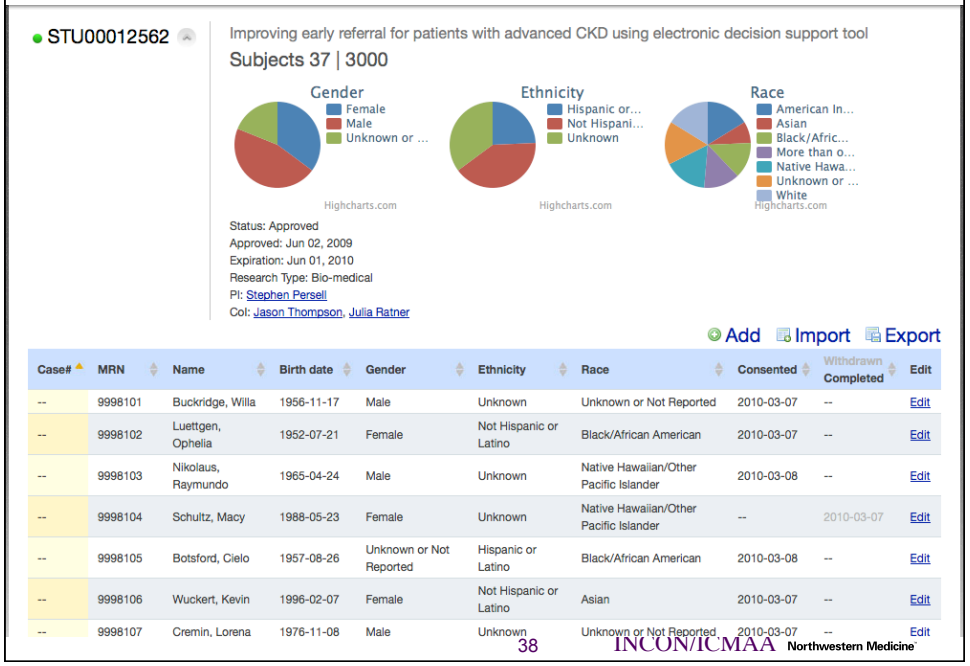
eNOTIS FAQ



Main eNOTIS screen



Simulated study data



Differing approach, shared goals

Clinical Research and Clinical Care share the same goals, and as you begin to apply the principles of continuous process improvement across the enterprise, these two approaches become more clearly synergistic and mutually reinforcing

Quality Care and Outcomes of Care

Quality care, quality assurance, quality data

Improved outcomes requires good analytics, understanding of existing practices, compliance metrics, and the ability to implement improved practices

The central theme for clinical research is understanding human disease and the practice of medicine with the goal of disease prevention and the improvement of outcomes

Unifying Forces

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Data warehousing
Regulatory Environment
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Thank You!

Questions?

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