

Best practices for building interoperable systems for translational research

Melhores práticas para a construção de sistemas interoperáveis em pesquisa translacional

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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

Technology

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

People

Find the best people
Listen
Communicate!

Usability counts!

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

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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



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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!!!!

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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.

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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?

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Brief History of Automobile Design

1890s to 2010



1890s Mercedes



~1900 electric car

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Brief History of Automobile Design

1890s to 2010



1926 Model T



Rolls Royce Phantom

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Brief History of Automobile Design

1890s to 2010



Rolls Royce Phantom



280SL (1970)

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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

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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

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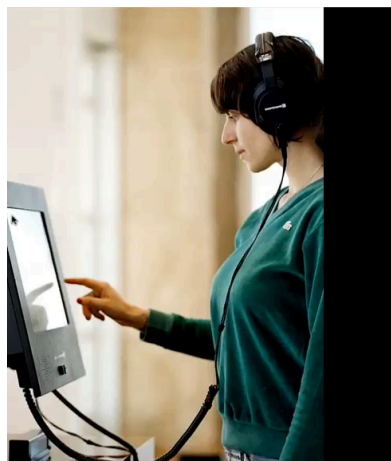
Usability and Design

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



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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

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People, Processes, Technology, Standards

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People Processes Technology

Lots of ways to put this classic management triangle



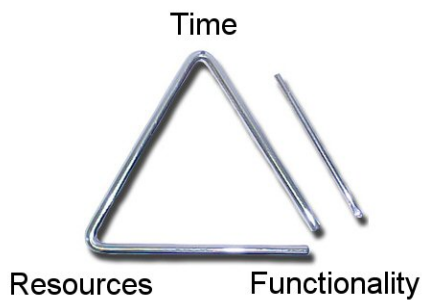
All are important
Failure to address any one can (and usually does!) result in
project failure

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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

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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!

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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

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Participatory Design

Engage the whole team

Employ design Charrettes

Charrette – an intense period of design activity (wikipedia)

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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

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Too much abstract advice

- Some details of what we have done at Northwestern

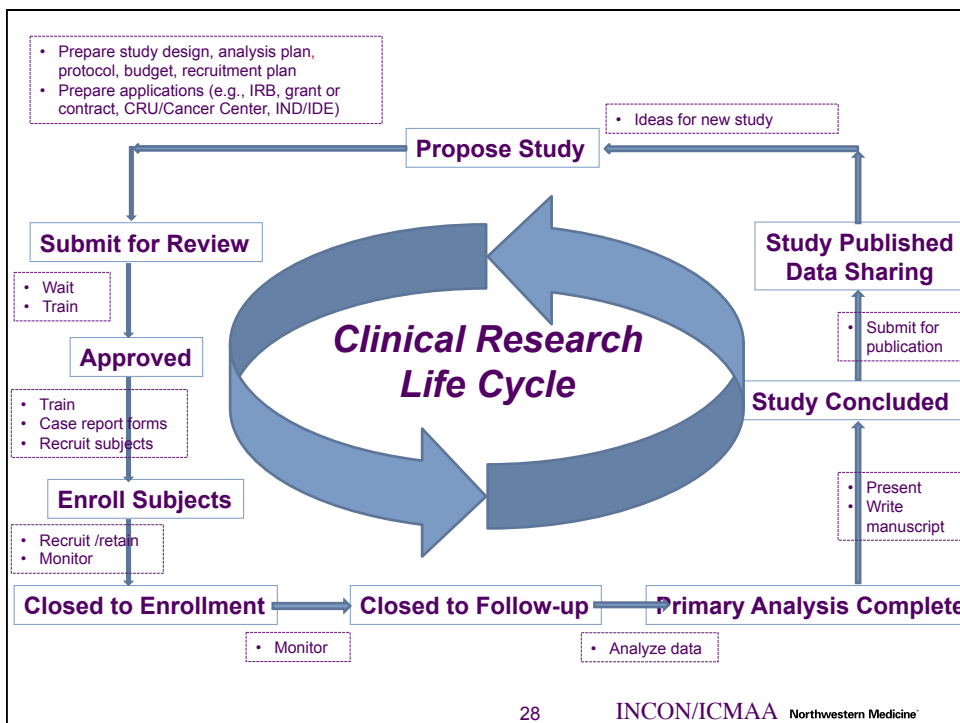
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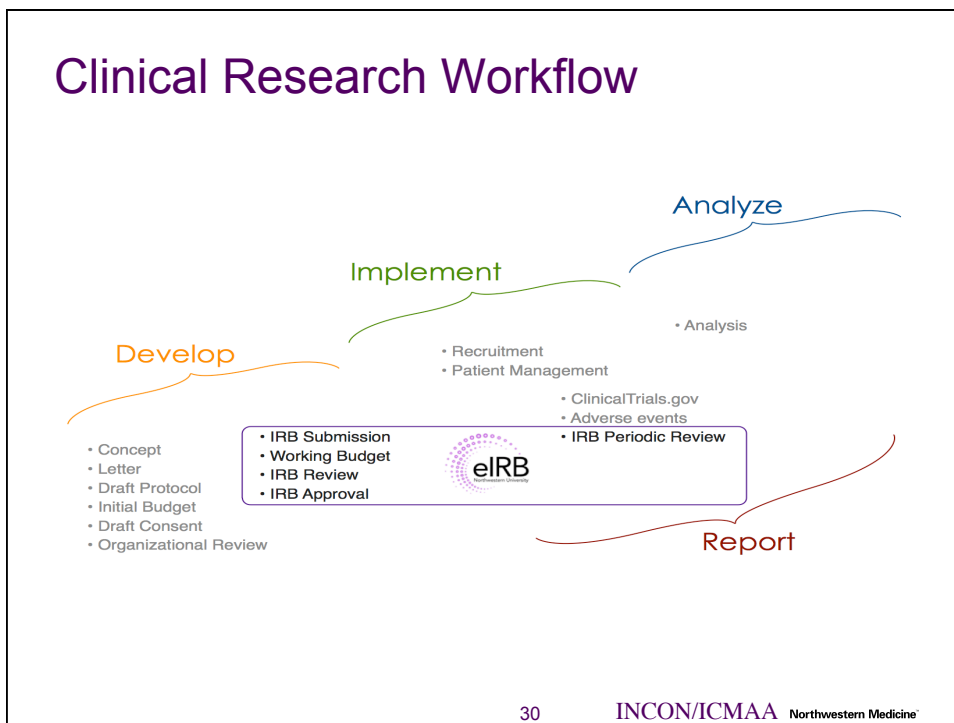
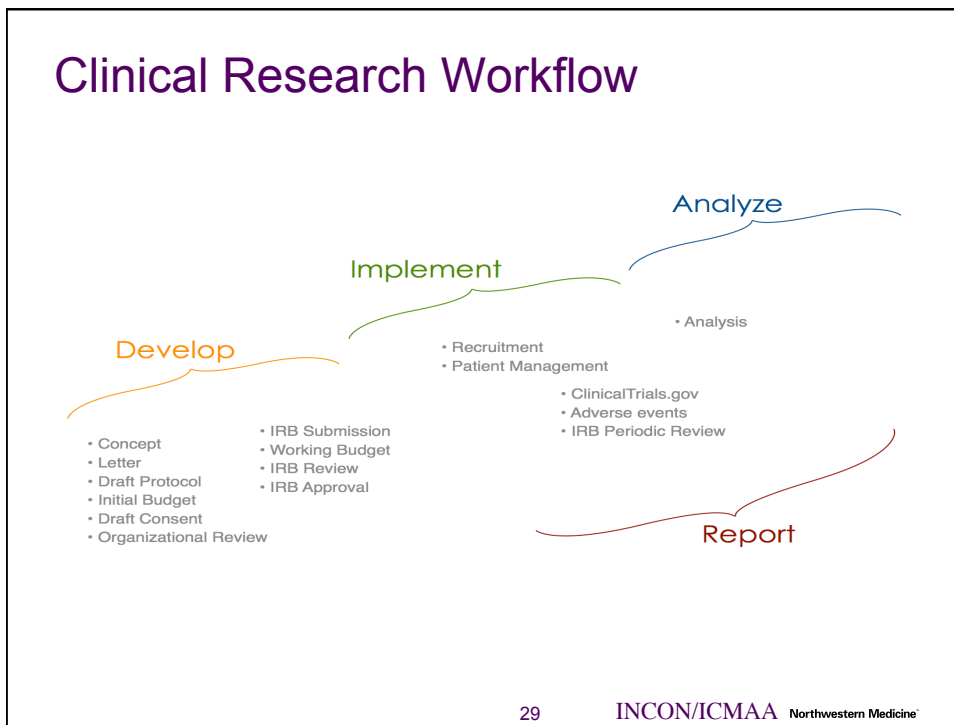
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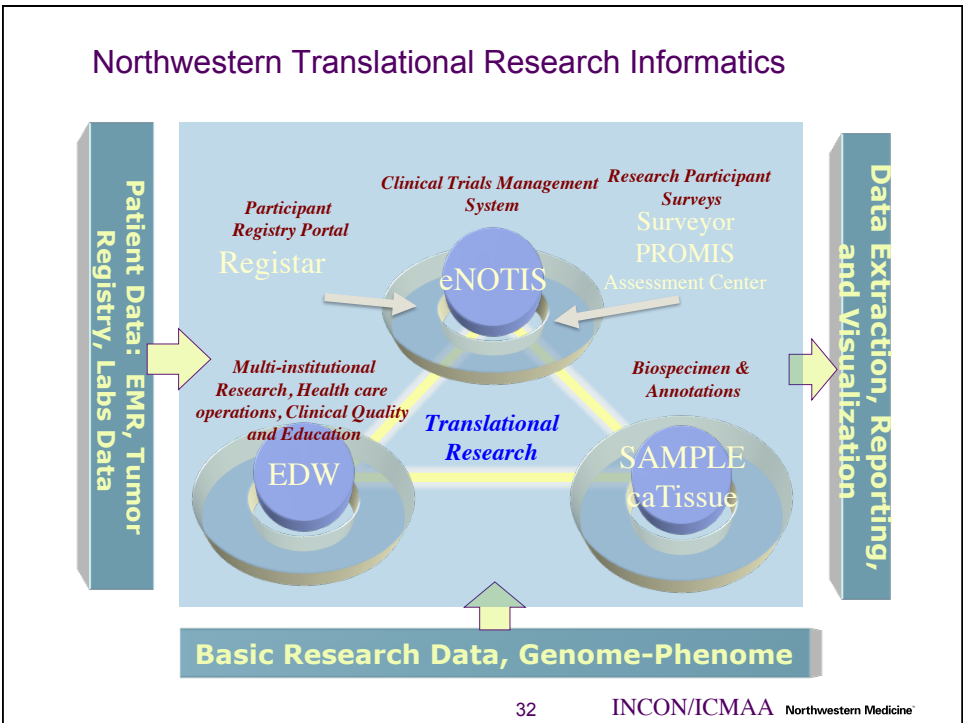
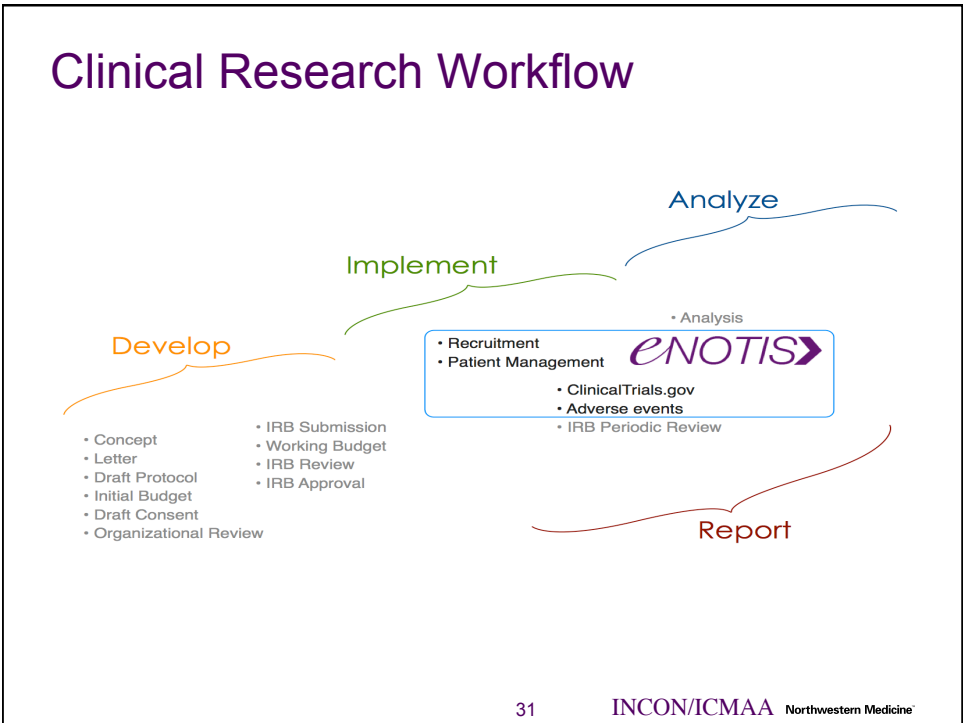
Supporting Translational Research

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







Workflow with eNOTIS

eNOTIS - coordinator workflows

with existing data:



1 start with spreadsheet of existing subject info



2 upload spreadsheet into eNOTIS



3 verify subject data

with new data:



1 collect data from subject



2 take subject data back to office



3 enter subject data into eNOTIS

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eNOTIS landing page

You have been logged out.

NetID wakibbe

Password

[I cannot access my account](#)

About
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FAQ

eNOTIS is the subject registration system for all IRB-approved clinical research at Northwestern University

Measure

Consented	Withdrawn	Completed
2009-05-27	2009-05-13	2009-05-13
2009-05-26	2009-05-12	2009-05-12
2009-05-25	2009-05-11	2009-05-11

Developed in collaboration with the clinical research community

Add subjects to your study and track key clinical events: consent, withdrawal, completion

4,103 studies with 25,072 accruals

117 active users

See

Race
■ American
■ Asian
■ Black/A
■ More th
■ Native I
■ Unknown
■ White

Visualize accrual for all your studies in one place

Print or export your enrollment for reports

eNOTIS meets recent FDA guidelines on electronic reporting and addresses a mandate that accrual information be tracked, validated and reported periodically to clinicaltrials.gov

Improve

Total Accruals

Make informed decisions about your research

Ensure subject safety by verifying their participation in other trials

Spend less time entering and tracking data by hand: studies are pre-loaded from eIRB and subject identity verified via NU Enterprise Data Warehouse (EDW)


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Watch our 4 minute introduction to eNOTIS




Flowplayer
© 2009-2010 Flowplayer

Need support?
enotissupport@northwestern.edu

Interested in a demo or training?
enotis@northwestern.edu


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eNOTIS FAQ





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About
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<p>When will we need to use eNOTIS?</p> <p>Interventional studies approved after a to be determined date Summer 2010 are required to enter accrual in eNOTIS. Current interventional studies will be required to enter accrual into eNOTIS after their next periodic review. eNOTIS has the ability to import existing subject lists in csv format.</p> <p>What data will we need to enter?</p> <p>Subject identity, NIH race and ethnicity, gender, consent and completion dates. Study information will come from the eIRB and will not require double entry.</p> <p>Who will be able to accrue and view the list of subjects accrued on a study?</p> <p>For each study, the IRB authorized PI, co-PI and coordinators will be able to view the identity of subjects accrued on a study. Any additional roles and responsibilities should be clarified with the IRB and represented in the eIRB.</p> <p>When will eNOTIS reflect new and terminated personnel, as authorized personnel list revisions take time in eIRB?</p> <p>The IRB is committed to providing expedited review and implementation of faculty and staff changes for any IRB study. The University has immediate termination of access procedures in place, including netID cutoffs synchronized with physical notification in cases of employee termination.</p>	<p>What information will eNOTIS show about subjects and other studies?</p> <p>Each subject is represented once in eNOTIS. Users who have accrued a subject will be able to view all other studies a subject is accrued on.</p> <p>What if my protocol requires confidential participation?</p> <p>Participants may be identified by case number only, and their participation will not be seen by other eNOTIS users.</p> <p>Is eNOTIS IRB approved? Will consent language need to be updated?</p> <p>eNOTIS is IRB approved, and all studies may begin using eNOTIS without first updating their current consent forms. The language that covers the use of eNOTIS is now part of the IRB consent template, in the "Database" section. Please note that the consent form must be updated to include the language covering eNOTIS during the next consent form revision or continuing review. eNOTIS is a secure and centrally managed resource for data that is already being tracked by all groups engaged in clinical research.</p> <p>What HIPAA or other security issues are raised by use of eNOTIS?</p> <p>All subject identity searches in eNOTIS are logged. All eNOTIS users have CITI training, as validated by the IRB. We do not anticipate any additional security or HIPAA-related issues.</p>
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Main eNOTIS screen


Mark Wimbiscus Yoon (myo628) | [Logout](#)

My Studies (10 in total)

IRB number	Name	PI	Accrual	Goal
● STU00012562	Improving early referral for patients with advanced CKD using electronic decision support tool	Persell	37	3000
● STU00000448	Responses to Paradoxical Communication During Relational Conflict	Roloff	8	
● STU00002086	Sleep Inertia in DGPS	Zee	0	45
● STU00004163	Brands as part of the self	Lee	0	
● STU00011640	Obesity and Surgical Outcomes	Stojilkovic	0	400
● STU00014747	Linguistics Department Pool (Former NUIRBS #1667-002/Goldrick)	Goldrick	0	525
● STU00016738	Ascension PIP Finger Implant (Former NUIRBS #0280-007/Kalainov)	Kalainov	0	1
● STU00016856	Alterations in Coagulation Associated with Uterine Myomectomy Surgery (Former NUIRBS #0542-023/Ahmad)	Ahmad	0	81
● STU00018369	Role of Short Term Systemic Corticosteroid Therapy in the Management of Chronic Rhinosinusitis without Nasal Polyps	Tan	0	40
● STU00021390	20 Year Changes in Fitness and Cardiovascular Disease Risk (Former NUIRBS #1281-002/Carnethon)	Carnethon	0	800

[First](#) | [Previous](#) | [1](#) | [Next](#) | [Last](#)

eNOTIS v1.1.0a -- created by [NUBIC](#) for Northwestern University

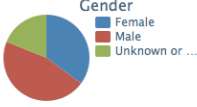
Simulated study data

● [STU00012562](#)

Improving early referral for patients with advanced CKD using electronic decision support tool

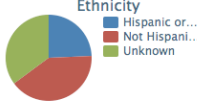
Subjects 37 | 3000

Gender



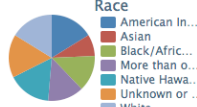
Highcharts.com

Ethnicity



Highcharts.com

Race



Highcharts.com

Status: Approved
 Approved: Jun 02, 2009
 Expiration: Jun 01, 2010
 Research Type: Bio-medical
 PI: [Stephen Persell](#)
 Col: [Jason Thompson](#), [Julia Ratner](#)

➕ Add 📄 Import 📄 Export

Case#	MRN	Name	Birth date	Gender	Ethnicity	Race	Consented	Withdrawn Completed	Edit
--	9998101	Buckridge, Willa	1956-11-17	Male	Unknown	Unknown or Not Reported	2010-03-07	--	Edit
--	9998102	Luetgten, Ophelia	1952-07-21	Female	Not Hispanic or Latino	Black/African American	2010-03-07	--	Edit
--	9998103	Nikolaus, Raymundo	1965-04-24	Male	Unknown	Native Hawaiian/Other Pacific Islander	2010-03-08	--	Edit
--	9998104	Schultz, Macy	1988-05-23	Female	Unknown	Native Hawaiian/Other Pacific Islander	--	2010-03-07	Edit
--	9998105	Botsford, Cielo	1957-08-26	Unknown or Not Reported	Hispanic or Latino	Black/African American	2010-03-08	--	Edit
--	9998106	Wuckert, Kevin	1996-02-07	Female	Not Hispanic or Latino	Asian	2010-03-07	--	Edit
--	9998107	Cremin, Lorena	1976-11-08	Male	Unknown	Unknown or Not Reported	2010-03-07	--	Edit

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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



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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

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Unifying Forces

IT Best Practices
Data warehousing
Regulatory Environment
Controlled Vocabularies and Ontologies
Quality Care and Outcomes of Care

Thank You!

Questions?

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