Rethinking Approaches to Research Integration at NYU Langone Medical Center

July 31, 2014
Presenters

**Gregg Fromell**  
M.D., Vice President of Science Operations and Transformation, NYU Langone Medical Center

![Gregg Fromell](image1)

**Nick Stier**  
Managing Director, Huron Education

![Nick Stier](image2)
Goals

• Emphasize the importance of an enterprise strategy/vision
• Discuss value of incorporating the study team perspective
• Evaluating readiness for implementing the enterprise vision
• Provide a high-level view of an approach to integration strategy
• Review human research as an example of operationalizing the strategy
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Click the Expand icon to reveal your webinar tools.

Enter a Question in this dialog area at any time.
Approaches to Integrating Research Administration:

- Developing an enterprise strategy
- Maintaining a research team focus

Gregg Fromell, MD
VP, Science Operations
NYU Langone Medical Center
<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Total Grant Funding</strong></td>
<td>$265M</td>
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<td><strong>Active Human Research Studies</strong></td>
<td>2,100</td>
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<tr>
<td><em>Active Clinical Research</em></td>
<td>700</td>
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</table>
Enterprise vision/strategy

• Why do we need one?
The view from the study team:
Select the statements that you agree with:

Poll Results (multiple answers allowed):

- Initiating research is a challenge for study team members: 56%
- Study team members spend too much time reentering data: 69%
- Reports to meet operational needs are not easy to come by: 77%
- Research business processes are smooth and effective: 19%
Rethinking the approach: Clinical Research Example

COI: Conflict of Interest
IBC: Institutional Biosafety Committee
IRB: Institutional Review Board
RSC: Radiation Safety
Rethinking the approach: Clinical Research Example

Study Regulatory Review

- COI Review
- RSC Review
- IRB Review
- IBC Review
- Cancer Ctr Review
- Study Management

Study

Grants

Agreements

COI: Conflict of Interest
IBC: Institutional Biosafety Committee
IRB: Institutional Review Board
RSC: Radiation Safety
Rethinking the approach: Clinical Research Example

COI: Conflict of Interest
IBC: Institutional Biosafety Committee
IRB: Institutional Review Board
PRMC: Protocol Review & Monitoring Committee
CRMS: Clinical Research Management System
Readiness for integration strategy

- True partnership between research administration and IT department
- “Integration” – making sure we’re all speaking the same language
- Leadership & collaboration
  - Communication between/among research administrative offices
- Common data elements
- Incorporating the study team perspective
- Project team logistics
Results of Poll #2

Our institution's IT organization understands our research administration operations:

Poll Results (single answer required):

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Well</td>
<td>33%</td>
</tr>
<tr>
<td>Somewhat</td>
<td>49%</td>
</tr>
<tr>
<td>Not at all</td>
<td>17%</td>
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</table>
“Integration”

- IT vs Operational definition
  - Copying data from one module into other(s)
  - Publishing data from one module to other(s)
  - Viewing data from one module in a different module
  - Linking data between modules
Leadership & collaboration

• Identifying project owner
  – Responsible for eliciting cross-dept vision
  – Responsible for implementing the vision

• Defining common needs
  – Understanding each other’s business processes enough to “row together”

• Structuring project teams
  – Module specific teams
  – Inter-module working groups
Common Data Elements

- Common data dictionaries; e.g. gold standard source of common information:
  - Persons
  - Organizations
  - Study interventions (drugs, devices, etc.)
Results of Poll #3

**QUICKPOLL**

**To what degree has your institution established the use of common data elements across administrative departments?**

Poll Results (single answer required):

- No 2 departments are using common data elements: 20%
- 2 or more departments are using common data elements: 49%
- We have a global initiative to standardize data elements: 31%
The study team perspective

• Direct:
  – Focus groups
  – Feedback groups
  – Involvement in system testing

• Indirect:
  – Members of central administrative team with research experience
Many different approaches

Important to design an approach that fits with your organizational structure/culture
Rethinking the approach: Clinical Research Example

COI: Conflict of Interest
IBC: Institutional Biosafety Committee
IRB: Institutional Review Board
PRMC: Protocol Review & Monitoring Committee
CRMS: Clinical Research Management System

Study Regulatory Review

COI module → RSC module → IRB module → IBC module → Cancer Ctr Review → CRMS module

Study Module

Grants Module

Agreements Module
The Regulatory Review Process

Prior to Regulatory Review

Queries to PI & Study Team

Conduct Pre-Review

Type IIa
Type IIb
Type IIIc

Review Type?

Schedule board meeting

Conduct meeting

Initial Review Decision

Communication with PI & Study Team

Exempt from IRB review

Designated Reviewer Review

Initial full board/committee review

Period from initial approval to continuing review

Study Team Post-Approval Actions

- Modifications (Amendments)
- Reportable New Event (RNI)

Continuing Review

Respond to Mods & RNIs

Finalize Review

Study Closure

Continuing Review

Respond to Mods & RNIs

Study Team Post-Approval Actions

- Modifications (Amendments)
- Reportable New Event (RNI)
COI: Conflict of Interest
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NYU Web posting
Clinicaltrials.gov Registration
CRMS
NYULMC Metrics Reporting
FDA IND/IDE Requirements

Grants
Contracts

COI
IBC
RSC
IRB
PRMC

NYU Review Bodies

Human Study

NYU Web posting
Clinicaltrials.gov Registration
CRMS
NYULMC Metrics Reporting
FDA IND/IDE Requirements

Grants
Contracts

COI
IBC
RSC
IRB
PRMC

NYU Review Bodies

Human Study
Summary

- **Enterprise strategy/vision** – the overarching roadmap
- **Importance of study team perspective** as a driver to user interface
- **Evaluate readiness** for implementing the enterprise vision
  - Sr. Leadership support
  - Shared ownership - operational and IT owners
  - Common language about “integration”
  - Standardizing common data sets (persons, organizations, drugs, etc.)
- **Project team organization**
  - Key “command and control” structure for implementation
  - Supports co-ownership model (operations + IT)
  - Relies on and supports cross-department collaboration
<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Status</th>
<th>Related IRB Study</th>
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### My Studies

Studies you have created or with which you are associated.

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<th>Related CRMS Study</th>
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</table>
Study: Example Study (s14-00429)

Principal Investigator: Gregg Fromell
Study Purpose: Treatment
Responsible IRB: NYU School of Medicine
Version: 0.0
Update Explanation: view
Brief Description: view

Related Submission Link
IRB: N/A
CRMS: N/A
Ancillary Review
PRMC: N/A
RSC: Required
IBC: N/A
ESCR: N/A
COI: Required

Study Submissions
Study Documents Related Agreements Study Contacts/Personnel History Log Data for IRB

Related submissions
No data to display.
Study: Example Study (s14-00429)

Principal Investigator: Gregg Fromell
Study Purpose: Treatment
Responsible IRB: NYU School of Medicine
Version: 0.0
Update Explanation: view

Associated Agreements:

IRB Documents:
Protocol: Protocol_Demo_2013-10-10.docx(0.01)

Consent Forms:
name: Consent_Demo_2013-10-10.docx

Assent Forms:
There are no items to display
Study: Example Study (s14-00429)

Principal Investigator: Gregg Fromell
Study Purpose: Treatment
Responsible IRB: NYU School of Medicine
Version: 0.0
Update Explanation: view
Brief Description: view

Related Submissions Link
IRB:
CRMS:
Ancillary Review
PRMC:
RSC:
IBC:
ESCRD:
COI:

Status Current?
N/A
Required
N/A
Required

Related Agreements:

ID Name Created By Document Status Selectica Status
a00001778 Inbound project funding/support - SANOFI-AVENTIS US INC Gregg CTA_Demo_2013-10-10.docx(0.01) Prepare Submission
- Fromell
### Principal Investigator:
Gregg Fromell

### Study Departmental Administrator:
Anny Fernandez

### Study Team Contacts:
There are no items to display

### Team Sub Investigators:

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<th>Last Name</th>
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<td>Czeisler</td>
<td>Science Operations &amp; Transform</td>
<td>Dir-Institutional Review Board</td>
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<tr>
<td>Jean</td>
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<td>Dir-Clinical Trials</td>
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### Research Coordinators:

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<tbody>
<tr>
<td>Lenide Geффrad</td>
<td>Office of Science &amp; Research</td>
<td></td>
<td><a href="mailto:geffr01@nyumc.org">geffr01@nyumc.org</a></td>
</tr>
<tr>
<td>Ronnie Landis</td>
<td>Office of Science &amp; Research</td>
<td></td>
<td><a href="mailto:landr01@nyumc.org">landr01@nyumc.org</a></td>
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- **Study Purpose:** Treatment
- **Responsible IRB:** NYU School of Medicine
- **Version:** 0.0
- **Update Explanation:**
- **Brief Description:** view

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<table>
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<td>ESCRO:</td>
<td>N/A</td>
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<tr>
<td>COI:</td>
<td>Required</td>
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**Study Submissions**

- **Filter by**

**Related submissions**

No data to display.
General Information

* Principal Investigator: Gregg Fromell

Administrative Department: Office of Science & Research

* Official Study Title:

Example study

* Brief Title: Example Study

Acronym Title:

* Primary Focus of Study: Intervventional research
  
  Drug, device, behavioral, surgical or other medical intervention.
**Primary Focus of Study:**

*Interventional research*
- Drug, device, behavioral, surgical or other medical intervention.
- Mechanistic or physiologic study in humans.
- Expanded access.

*Non-interventional research*
- Biospecimen research.
- Research on human data sets.
- Survey research.
- Observational research.
- Enrollment screening protocol.

*Special Cases*
- Research evaluating educational practices or educational tests.
- Taste/food quality evaluation.
- Evaluation of public benefit or service programs.

**Study Purpose:**

- Treatment
- Prevention
- Diagnostic
- Supportive Care
<table>
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<tr>
<th>Section</th>
<th>Question</th>
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<th>No</th>
<th>Clear</th>
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<td>8.1</td>
<td>NYU Investigator is the Protocol Author or contributed in a significant way to the Study Design or Study Plan:</td>
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<td>Ancillary Study:</td>
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<td>* Cancer-related Research:</td>
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<td>* Genetic Testing:</td>
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<td>CTSI resources will be used in this study:</td>
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<td>13.0</td>
<td>* Multi-site Study?</td>
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<td></td>
<td>Is NYU Investigator the Study Chair?</td>
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<td>NYU is the clinical coordinating center:</td>
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<td>NYU is the data coordinating center:</td>
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<td>External DSMC Used:</td>
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<td>NYU School of Medicine</td>
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<td>Other (Specify)</td>
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</table>
**General Information**

1.0
*Principal Investigator:* Gregg Fromell

1.1
**Administrative Department:** Office of Science & Research

2.0
*Official Study Title:* Example study

3.0
*Brief Title:* Example Study

4.0
**Acronym Title:**

5.0
*Primary Focus of Study:*
- Interventional: Drug, device, behavioral, surgical or other medical intervention.
- Interventional: Mechanistic or physiologic study in humans.
## General Information

### 1.0 Principal Investigator

### 1.1 Administrative Department

### 2.0 Official Study Title:

Example study

### 3.0 Brief Title:

Example Study

### 4.0 Acronym Title:

### 5.0 Primary Focus of Study:

- Interventionsal
  - Drug, device, behavioral, surgical or other medical intervention.
- Interventional
  - Mechanistic or physiologic study in humans.

## Funding Sponsorship Information

### 2.1 Sponsor

## Study Design

### 3.1 Interventional Research

### 3.1.1 Interventional Research Continued

## Subject & Analysis Information

### 4.0 Subject & Analysis Information

## Locations

### 5.0 Locations
General Information

1.0
* Principal Investigator

1.1
Administrative Department

2.0
* Official Study Title: Example study

3.0
* Brief Title: Example Study

4.0
Acronym Title:

5.0
* Primary Focus of Study:
  - Interventional
  - Interventional
  - Interventional
  - Non-Interventional
  - Non-Interventional
  - Non-Interventional

6.0
Cancer Institute: PRMC Information

7.0
Uploads

3.0
Subject & Analysis Information
- 4) Subject & Analysis Information

5.0
Locations
- 5) Locations

03 - Study Design
- 3.1) Interventional Research
- 3.1.1) Interventional Research Continued

04 - Subject & Analysis Information
- 4) Subject & Analysis Information

05 - Locations
- 5) Locations

06 - Cancer Institute: PRMC Information
- 6) Cancer Institute: PRMC Information

07 - Uploads
- 7) Uploads
## Study Design - Interventions

<table>
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<tr>
<th></th>
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Results of Poll #4

Which statement best describes your research IT development resources?

Poll Results (single answer required):

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<tr>
<th>Statement</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Research application development reports to Research</td>
<td>23%</td>
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<tr>
<td>Research application development reports to central IT</td>
<td>39%</td>
</tr>
<tr>
<td>Application development reports to both Research and IT</td>
<td>30%</td>
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<tr>
<td>We don’t have any research application development resources</td>
<td>2%</td>
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<tr>
<td>Don’t know</td>
<td>7%</td>
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Webinar Next Steps

- A copy of the webinar recording will be available next week (you will receive an automatic email)

- All questions will be answered in the summary Q&A available next week

- Results of the polling questions will be included
Nick Stier
Managing Director, Huron Education
503.748.3911
nstier@huronconsultinggroup.com