Critical Success Factor for Clinical Trials: A Protocol Feasibility Process

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Speaker Information

- Jenna Stump, MS, CCRC
  - Director, FDA Guidance Core: University Hospitals Cleveland Medical Center
  - Research administration for over 10 years
  - Oversight of Research Support Services at University Hospitals Cleveland Medical Center which includes Research Support Specialist Staff, FDA Guidance Core Staff
Learning Objectives

• Identify issues facing investigators when evaluating sponsored research at University Hospitals Cleveland Medical Center

• Discussion of process set-up, implementation, and outcomes evaluation of Feasibility Pilot

• Evaluation of metrics data on the use of a comprehensive Feasibility process and its potential for expanded use
Research Landscape: Current Challenges

Challenges that impact Investigators in Research:

- Regulatory and compliance requirement burden
  - Sponsor requirements/CRO requirements/FDA Regulations
- Recruitment and retention standards
  - Stringent timelines/timeframes; unrealistic start-up goals
- Economic pressures
  - Inadequate clinical research personnel allocation in budget
  - Budget negotiation barriers
Feasibility Matters..... For Everyone

When we think of Feasibility, what and who do we think of???

• **Sponsor**
  • Trial specific questionnaire

• **CRO**
  • Site evaluation visit

• **Cooperative Group Programs**
  • Balancing group similarities and differences
Feasibility Matters..... For Everyone

Site Importance = Highest Importance
Why is a Feasibility Review so Important for Sites?

- **Quality Vs. Quantity**
  - Resource allocation

- **Consistency in Review and Outcomes**
  - Emphasis on site standards

- **Focused effort by all involved**
  - Department/System-wide metrics
Finding the Missing Link
Development of a Pilot Feasibility Process
Feasibility Pilot: Potential Solution

- Formation of centralized process through the Center for Clinical Research and Technology
  - Central implementation point:
    - Consistency in training and support
    - Experience from director/manager level for process rollout
Feasibility Review Pilot

• Development of a standardized, feasibility review process began in January 2016 at University Hospitals Cleveland Medical Center
  – Directors from Center for Clinical Research and Technology in collaboration with Department liaisons

• Pilot departments vetted and chosen in March 2016
  – Site survey
  – Department Chairman interest
Feasibility Review Pilot

- Training on Feasibility tools and materials conducted in May 2016
  - Department “Feasibility Champions” chosen and trained
  - 3 Part electronic tool

- Rollout of Feasibility pilot in June 2016
  - 10 Pilot departments
Feasibility Review Pilot Departments

• Dermatology
• Emergency Department
• Neurological Institute
• Ophthalmology
• Orthopedics/Sports Medicine

• Pediatric
• Pediatric Ophthalmology
• Pediatric Pulmonary
• Pediatric Surgery
• Psychiatry
• Urology
Feasibility Review Pilot

ULTIMATE GOALS

1) Minimize costs by eliminating financially unfavorable trials earlier

2) Identify contractual/financial issues earlier in the process for leverage in negotiation

3) Ensure department personnel resources are dedicated to vetted trials

4) Research growth at the department level through an expand portfolio of research trials
Reviewing the Model

Feasibility Review Process
Reviewing the Model Process Workflow

- 3 part parallel review
  - Finance
  - Contracts
  - Site Logistics/Site Implementation
Reviewing the Model Process Workflow Metric

- Established Metric for Workflow
  - 5 days for completion of review for all parties
  - Unless full coverage analysis needed
    - 25 days
## Reviewing the Model: Department Collaboration

<table>
<thead>
<tr>
<th>TYPE OF ROLE OR POSITION</th>
<th>LEVELS/JOB DESCRIPTIONS</th>
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<tbody>
<tr>
<td>Clinical Research Nurse Specialists</td>
<td>(Levels I to IV)</td>
</tr>
<tr>
<td>Clinical Research Specialists</td>
<td>(Levels I to III)</td>
</tr>
<tr>
<td>Clinical Research Regulatory Specialists</td>
<td>(Levels I to III)</td>
</tr>
<tr>
<td>Research Finance Specialists</td>
<td>(Levels I to III)</td>
</tr>
<tr>
<td>Grant Support Specialists</td>
<td>(Levels I and II)</td>
</tr>
<tr>
<td>Clinical Research Data Specialists</td>
<td>(Levels I to III)</td>
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</table>
Reviewing the Model: Who are the Players

- **Research Specialist/Research Nurse Specialist**
  - Coordinate and manage trial logistics for department

- **Research Finance Specialist**:
  - Build Budgets
  - Create Coverage Analysis
  - Complete research billing claims

- **Feasibility Champion**
  - Implement and oversee feasibility process for department
  - Liaison with central research office

- **Pre-Award Contracts Specialist**:
  - Negotiate contracts
  - Finalize budget negotiations
  - Interact with legal department on contract terms
Reviewing the Model: Process Workflow

1. Completion of Site Confidentiality Agreement
2. Feasibility Champion Starts Process within Department
3. Finance, Contracts, Site Logistics Review Begin
4. Cumulative Summary provided for Scientific Review
5. Decision to proceed or discard trial
Reviewing the Model: Process Workflow

Completion of Confidentiality Agreement

Principal Investigator

Feasibility Champion

Electronic Feasibility Tool

Research Finance

Pre-Award Contracts

Research Team
Reviewing the Model: Financial Breakdown

- Initiated through Research Finance Department
  - Key Elements of the review include:
    - Investigational drug and device coverage
      - Donated/covered/billed
    - Full coverage of personnel costs
    - Full coverage of procedural costs
      - Caution: Costs related to radiology Scans/hidden pharmacy costs
Reviewing the Model: Financial Breakdown

More NO’s than YES’s??????
Reviewing the Model: Financial Breakdown

• If the Research Finance Specialist concludes that cost coverage circumstances are not favorable after an initial review, than a full coverage analysis will be conducted

***** Current Metric is 25 days*****
Reviewing the Model: Process Workflow

Completion of Confidentiality Agreement

Principal Investigator

Feasibility Champion

Electronic Feasibility Tool

Research Finance

Pre-Award Contracts

Research Team

Research Finance
Reviewing the Model: Contracts Breakdown

• Initiated through the Pre-Award Contracts team
  – Key Elements of the Review Include:
    • Full coverage of institutional overhead
    • CRO involvement for negotiations
    • Sponsor history of slim budgets
    • Sponsor history of early trial Termination
Reviewing the Model: Contracts Breakdown

Key combination of YES’s and NOs???????
Reviewing the Model: Contracts Breakdown

- Institutional overhead coverage
  - This should be a YES!
    - CAUTION: If you see a NO....

- Sponsor Related Questions
  - These should be a NO!
    - CAUTION: If you see a NO....
Reviewing the Model: Contracts Breakdown

Always Remember

**Feasibility Review for Contracts is NOT Final Negotiation**

Don’t Walk away from the Table just yet.....
Reviewing the Model: Process Workflow

Completion of Confidentiality Agreement

Principal Investigator
Feasibility Champion

Electronic Feasibility Tool

Research Finance
Pre-Award Contracts

Research Team
Reviewing the Model: Site Logistics Breakdown

- Initiated through Research team and PI
  - Key Elements of the Review Include:
    - **Recruitment Requirements**
      - Number of patients
      - Timelines
      - Visit schedule
    - **Procedure/Radiology Schedule**
      - Scanner requirements
      - Equipment requirements
    - **Placement of entry into trial design**
      - Will trial be ending soon
      - First or last site to start study
Reviewing the Model:
Site Logistics Breakdown

• Key Elements of the Review Include (contd.):
  • *Space Logistics*
    – Longevity of visits
    – Frequency of visits
  • *IT Considerations*
    – Software installations
    – Firewall considerations
    – Access to electronic medical record
    – Electronic data capture considerations
Reviewing the Model:
Site Logistics Breakdown

Key combination of YES’s and NOs??????
Reviewing the Model: Site Logistics Breakdown

Recruitment, Recruitment, Recruitment!!!

**Keys for Success:**

1) Mine information from EMR
2) Confirm recruitment numbers with 2\textsuperscript{nd} physician other than PI
During feasibility process, if an unfavorable review occurs for the Pre-Award Grants, Research Finance, or Research logistics sections of the vetting ticket, the Feasibility champion is contacted and a meeting occurs with the PI to discuss the issues.

PI will need to determine intent to move forward with trial or exit their involvement.
Reviewing the Model: Process Workflow Wrap-up

1. Completion of Site Confidentiality Agreement
2. Feasibility Champion Starts Process within Department
3. Finance, Contracts, Site Logistics Review Begin
4. Cumulative Summary provided for Scientific Review
5. Decision to proceed or discard trial
Reviewing the Model: Process Workflow Wrap-up

- Completed vetting ticket is presented for scientific review to department chairman prior to IRB submission for approval
Conception to Implementation
Results of Pilot Feasibility Process

To date, the Pilot Feasibility Process has:

- Conducted a review on 27 industry sponsored clinical trials in 8 departments over a 5 month period

- Identified and eliminated 6 unfavorable clinical trials prior to conducting regulatory work which minimized study start up hours
  - Lack of patients: 2 studies
  - Site Entry: 1 study
  - Sponsor Issues: 2 studies
  - Visit schedule issues: 1 study

- Discovered incorrect patient population assessments for 3 trials
What We Confirmed

• Our focus of “financial emphasis” has not interfered with scientific merit or novelty in clinical trials chosen

• Management of process from department level by means of “feasibility champion” has aided in engagement by department
What We Learned

• Department Chairmen are open to concept of change
  – Acknowledge issues with choosing trials
  – Acknowledge desire to adopt standardized process

• 5 day metric is difficult for all parties to meet
  – Research Finance is running between 8-12 working days
What We Need to Overcome

• Expansion of IT section may be necessary
  – Development of 4 parallel reviews

• Department Perception “duplication of effort”
  – Site feasibility questionnaire and Sponsor feasibility questionnaire
  – Research staff not comfortable “pushing” back on sponsors
Future Opportunities

- Conclude pilot in December 2016 and review overall results
- Development of finalized master vetting ticket for system-wide rollout
- Collaborate with Research Finance on post-Coverage analysis cross-check for strength in feasibility assessment
Questions?