What to Measure and How to Measure it – Let’s Talk Metrics!

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You see a lot.

What is important to share?
Outline

• Considerations when communicating
• Establishing Standards
• Strategies for communicating
• Metrics report and sample metrics
Partners Healthcare:

• Founded by Massachusetts General Hospital and Brigham & Women’s Hospital in 1994
• Network of 11 hospitals in Massachusetts
• *Partners Human Research Affairs* overseas IRB and other systems that support regulatory oversight at MGH, BWH, McLean Hospital, North Shore Medical Center
• Over 8000 ongoing protocols
Partners Human Research Quality Improvement Program

- Provides education and support to Partners research community
- Established in 1999
- QI Team: Director, 4 Specialists, 1 Analyst
- Reports to Director of Research Affairs
  - Information reported to: VP/IO at institutions, CAO at Partners
Partners QI Program

- QI activities include:
  - Not-for-cause onsite reviews
  - For-cause onsite reviews
  - Assistance in study start-up
  - Educational in-services
  - Assistance to FDA Sponsor-Investigators
  - Assistance with ClinicalTrials.gov

- Summary of service FY2015:
  - 112 on-site reviews (101 protocols)
  - 53 education & support activities
  - 37 presentations
Considerations when communicating your data
Considerations when communicating your data

- Audience
- Purpose
- Content
- Forum
Considerations when communicating your data

Audience
- Investigator/study team
- IRB committee/leadership
- Institutional leadership
- Internally within own QI Program

Purpose

Content

Forum
Considerations when communicating your data

Detailed Observations

Investigator / staff

QI Program & IRB committees/ leadership

Aggregate Information

Institutional leadership

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Considerations when communicating your data

**Audience**

**Purpose**
- Want investigator/study team to take action
- Collaborate for systematic improvements
- Alert leadership
- Want leadership to take action
- Guide program activities

**Content**

**Forum**
Considerations when communicating your data

- Audience
- Purpose
- Content
  - Program Activities
  - Observations of noncompliance
  - Suggested corrective actions
  - What you’ve done to obtain compliance
  - Systematic improvements
- Forum
Considerations when communicating your data

<table>
<thead>
<tr>
<th>Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
</tr>
<tr>
<td>Content</td>
</tr>
<tr>
<td>Forum</td>
</tr>
</tbody>
</table>

- Verbal
  - One-on-one with Investigators/study team
  - Meetings
  - Presentation
- Written
  - Onsite review/audit report
  - Metrics report
Establishing standards for collecting metrics

(1) Standard observations
(2) Categories of noncompliance
(3) A database to store, track, and analyze observations
(1) Standard Observations

- Create a standard observation index
  - Allows program to be consistent
  - Categorized by Topic (e.g. Regulatory documentation, Subject documentation, Informed consent process)
- Regulatory citations and recommended corrective actions linked to specific observations
  - Use federal regulations, institutional policies, GCP
  - Accommodate drug/device verses non drug/device studies
- Allow flexibility
  - New observations/corrective actions can be approved by manager or by team consensus
# Example Observation Index

<table>
<thead>
<tr>
<th>Short Topic</th>
<th>Observation</th>
<th>Applicable Reg/Policy/GCP</th>
<th>Corrective Action</th>
<th>Scale</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory Documentation</td>
<td>Training: There is no documentation that study staff have been trained on the protocol.</td>
<td>The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational products, and their trial related duties and functions. [Partners Guidance: Principal Investigator’s Responsibilities; GCP 4.2.4]</td>
<td>Document study staff training.</td>
<td>1</td>
<td>Approved</td>
</tr>
<tr>
<td>Subject Documentation</td>
<td>Adverse Event: Tracking, assessment, and/or reporting of adverse events to the IRB and/or Sponsor is not adequate/document ed.</td>
<td>The principal investigator is responsible for documenting and reporting adverse events in accordance with institutional policies, federal regulations and good clinical practice guidelines. [Partners Policy: Adverse Event Reporting; GCP 4.11.1]</td>
<td>Obtain documentation and/or report adverse events as applicable. A log can be used to ensure adverse events are reported in a timely manner. A template can be found at: <a href="http://www.partners.org/phsql/OM/Web/Logs/AETrackingLog.xls">http://www.partners.org/phsql/OM/Web/Logs/AETrackingLog.xls</a></td>
<td>3</td>
<td>Approved</td>
</tr>
<tr>
<td></td>
<td>CRF: CRFs are not consistently completed.</td>
<td>The investigator should ensure the accuracy, completeness, legibility, and</td>
<td>Complete CRFs.</td>
<td>1</td>
<td>Approved</td>
</tr>
</tbody>
</table>

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Observation Index vs. Report

Provide details regarding the observation in the report

**Index**

Study procedures were performed by individuals who are not IRB-approved study staff.

Changes were made to study procedures without IRB approval.

**Report**

“Study procedures were performed by individuals who are not IRB-approved study staff. Subjects A1, B2, and C3 were consented by the attending.”

“Changes were made to study procedures without IRB approval. Surrogate consent was obtained for some subjects. The IRB has not approved a surrogate consent process for this study. Surrogate consent was obtained for the following subjects...”
(2) Categories of Noncompliance

- Noncompliance is not all the same!
- Establish and define categories
  - Major noncompliance
  - Minor noncompliance
  - Noncompliance with GCP or Recordkeeping guidelines
- Seek input/agreement from groups receiving this information (e.g. IRB)
- Scale each observation according to internal categories
(2) Categories of Noncompliance, con’t

• Allow for changes given context
  – Isolated incident vs. pattern vs. systemic
  – Does the observation effect safety or data integrity?

• Standard observation index and categories of noncompliance allow for aggregate data analysis

Q: Do you communicate your scale of noncompliance with Investigators?

Recommend using categories as an internal communication tool with IRB, Institutional officials, other leadership
(3) A Database

Purpose:
• Track program activities
• Store observations collected during audits
• Generate standardized reports
• Generate metrics

Goal:
Maximize the use of your data to drive program efforts
QA/QI Database

Who

Why

When

Sponsor

Observations of Noncompliance

Type of Study

Program Output

- Metrics
- Data Analysis
- Reports

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Logistics of the database

Technical standpoint:
• 1 database – linear management of QI Activities
• Web-based system (remote access)
• Use institution application framework and security models
• Secure back-end; ideally on a network server (you are collecting information and issues of noncompliance with names attached)
• Built-in feature for managing user rights (administrative vs. staff access)
Logistics of the database

User Standpoint:
- Ensure multiple people can use it at once
- Online forms for submitting and processing service requests
- Console for adding, scheduling and managing visits
- Observation index
  - Linked forms for adding/editing site observations
  - Stores observations from reviews
- Data analysis queries
- Generate Report (Standard templates)

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Strategies for Communicating
Strategies for Communicating

• Protocol Specific Data
  – Investigator/study teams
  – IRB Committees

• Aggregate data
  – QI Program
  – IRB leadership
  – Institutional leadership
  – Investigator/Study team
Strategies for Communicating

• Protocol Specific Data
  – Investigator/study teams
  – IRB Committees

• Aggregate data
  – QI Program
  – IRB leadership
  – Institutional leadership
  – Investigator/Study team
Protocol Specific Data: *Investigators/Study Teams*

- **Purpose:**
  - Communicate details of recent audit
  - You want them to take action

- **How:**
  - One-on-one: in person, via telephone
  - Specific observations, references, corrective actions
  - Written, detailed report

- **When:**
  - Verbal notification - immediately
  - Written report (ideally w/i 2 week)
Protocol Specific Data: *IRB committees/leadership*

- **Purpose**
  - Communicate details of IRB requested audit
  - Communicate noncompliance
  - Collaborate on corrective action plan

- **How**
  - Detailed information – written report
  - Summary of findings

- **When**
  - Within 2 weeks
Strategies for Communicating

• Protocol Specific Data
  – Investigator
  – IRB Committees

• Aggregate data
  – QI Program
  – IRB leadership
  – Institutional leadership
  – Investigator/Study team
Aggregate Data:

*The QI Program*

- **Purpose**
  - Guide program activities
  - Identify gaps in institutional policies & forms
  - Generate/develop systemic improvements
- **How**
  - Program activities
  - Frequency/trending noncompliance
  - Hot spots of noncompliance
  - Best practices
- **What/When**
  - Detailed metric report; Quarterly
Aggregate Data:

IRB leadership

• Purpose
  – Communicate trends of noncompliance
  – Identify gaps in institutional policies & forms
  – Collaborate on systemic improvements

• How
  – Frequency/trends of noncompliance
  – Specific major noncompliance
  – Best practices

• What/When
  – PPT presentation; twice per year or as requested
Aggregate Data:

*IRB Leadership*

Keep in mind...

- Have a discussion
- People at table may have other *knowledge* or see noncompliance from a different angle
- Confidential attorney client privilege
Aggregate Data:

Institutional leadership

• Purpose
  – Provide pulse on noncompliance activity
    • Major and ‘under their radar’
  – Inform about follow-up (short & long term)
  – Inform about systemic improvements
  – Program activities
    • Gain support for program activities

• How
  – Demand for services
  – Detailed information about ‘Investigators of concern’
  – Comparative analyses and historical trending
  – Use quantitative and qualitative information

• What/When
  – PPT presentation; Routinely (twice per year) or as requested
Aggregate Data:  
*Institutional leadership*

Keep in mind...

- Leadership relies on you to know all details within the aggregate dataset
- People at table may not be experts in this area
- You may have a very short amount of time during a meeting with a packed agenda. Get to the point quickly.
Aggregate Data:

*Investigators/Study Teams*

**Q: What about aggregate data for investigators?**
QI Program Observations of noncompliance – when do you alert others?

- Do you have an obligation to inform ‘higher ups’ of observations of noncompliance?
- All or some noncompliance?
- Do you have a process?
- Do external inspectors/auditors or federal agencies see your written reports?
Sample Metrics
Metric reports

• Aggregate data:
  – Effective at giving big picture
  – Identify problem areas
  – Are you consistently providing follow up when needed?
  – Leads to development of systematic improvements

• What it doesn’t give you:
  – Necessary details – you will always need individual reports
  – Root causes – need QI staff and discussion

Don’t lose site of the qualitative data!

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Metric reports

• Examples
  – Service demands
  – Grouping of site observations by: areas of deficiencies, departments, sponsor, review type
  – Areas or investigators of concern
  – Comparing most frequent observations from year to year
  – How did a systemic improvement affect observations of noncompliance?
  – Best practices
Considerations when communicating

Detailed Observations

Aggregate Information

Investigator / staff

QI Program & IRB committees/ leadership

Institutional leadership
Activity trending (details)

![Graph showing activity trending over quarters for FY 2011, FY 2012, and FY 2013. The graph compares reviews and education categories.]

- Q2: FY 2011: 22, FY 2012: 15, FY 2013: 15
- Reviews: Blue line
- Education: Red line
Activity trending (details)
## Activity trending (aggregate)

<table>
<thead>
<tr>
<th>Risk</th>
<th># IRB approved protocols</th>
<th># audited by QI Program</th>
<th>% oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Initiated</td>
<td>#</td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td>Sponsor Initiated</td>
<td>#</td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td>Sponsor-Investigator</td>
<td>#</td>
<td>#</td>
<td>%</td>
</tr>
</tbody>
</table>
Onsite Reviews - Characteristics

**Institutions**
- Inst A, 21, 58%
- Inst B, 14, 39%
- Inst C, 1, 3%

**Investigators**
- No previous contact with QI: X%
- New PI: X%

**Protocols**
- Full Board: X%
- Non-industry sponsored: X%
- FDA Regulated: X%
Onsite Reviews - Characteristics

Activities by Review Category and x (N = #)

Investigators (N = #)
- No previous contact with QI: x%
- < 4 protocols: x%

Protocols (N = #)
- Full Board: x%
- Non-industry sponsored: x%
- FDA Regulated: x%

Colored categories could be: department, source of funding, type of review
Observations of Noncompliance

• Total Observations: 461
• Range: 4 to 18 observations (M =12, SD 4)
• Scale:
  – Level 1 = 84%
  – Level 2 = 14%
  – Level 3 = 2%
Example – Onsite review/audit conclusions

- Serious/Continuing Noncompliance: 1,20%
- Reportable Regulatory issues: 3,60%
- Non-adherence w/ Recordkeeping guidelines: 1,20%
Example – Most Frequent Observations (for QI team/IRB)

<table>
<thead>
<tr>
<th>Level</th>
<th>Observation</th>
<th>Count (%)</th>
<th>Rank 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncompliance with Recordkeeping Guidelines</td>
<td>Top 5 Observations (e.g. Blank and incomplete data entries were observed throughout subject’s files.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor Noncompliance</td>
<td>Top 5 Observations (e.g. Changes made to study procedures without IRB approval)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Noncompliance</td>
<td>Top 5 Observations (e.g. Subjects completed study procedures before the consent form was signed)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example – Most Frequent Observations (for institutional leadership)

<table>
<thead>
<tr>
<th>Frequent Observation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copies of IRB correspondences not on file</td>
<td>• Collaborate with IRB office to insert language on approval letter to remind investigators to print or save for internal records.</td>
</tr>
<tr>
<td>Changes made to study procedures without IRB approval</td>
<td>• Email bulletins to research community</td>
</tr>
<tr>
<td></td>
<td>• More emphasis during IRB review on protocol monitoring plans</td>
</tr>
</tbody>
</table>

* Be prepared to track systematic improvements
Example Tracking Noncompliance

<table>
<thead>
<tr>
<th>Status</th>
<th>Protocol #</th>
<th>PI</th>
<th>Observation</th>
<th>Comment/Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Followup Complete</td>
<td></td>
<td></td>
<td>English consent form was used to consent non-English speaking subject(s).</td>
<td></td>
</tr>
<tr>
<td>Followup Needed</td>
<td></td>
<td></td>
<td>Tracking, assessment, and/or reporting of adverse events to the IRB and/or Sponsor is not adequate документирован.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subjects were not re-consented when major changes were made to the consent form.</td>
<td></td>
</tr>
</tbody>
</table>
### Example – Investigators of concern

<table>
<thead>
<tr>
<th>Investigators of concern (reason why)</th>
<th>Follow up</th>
</tr>
</thead>
</table>
| E.g. Non-English speaking subjects consented with English consent form (n = x) | • Onsite education of informed consent  
• Directed audit of 2\textsuperscript{nd} study |
| ... | • ... |
QI Education – Characteristics

Institutions

Investigators

• No previous contact with QI: X%
• New PI: X%

Services

• IND/IDE Assistance: X%
• General Consultations: X%
• Regulatory Binder Consult: X%
• QI In-service: X%
Thank you!

&

Questions?

Thanks & Acknowledgement to Michele Gomez, Sr. QI Program Analyst