The Impact of Quality on Research

Research Compliance and Quality Assurance

Johanna Stamates
Executive Director

Yolanda P. Davis
Clinical Trial Disclosure Manager
Within the Office of the Vice Provost for Research

Close working relationship with the Human Subject Research Office (HSRO), the Institutional Review Board (IRB) and other operational departments, but independent from those functions

Provides the following university-wide functions: Good Clinical Practice (GCP) auditing; assistance with federal audits before, during and after the inspection; Research Compliance related education; Clinical Trial Disclosure (CTD) support and oversight; Corrective and Preventive Action (CAPA) plan support and oversight
Quality is everyone’s responsibility
What does it mean?

- protection of subject safety and rights
- data integrity
- reproducibility
- consistency
- and so much more . . .
CUSTOMERS and RESPONSIBLE PARTIES

- Investigator and research team
- Sponsor/CRO
- FDA and other regulatory agencies
- Study participant
- Is Quality defined by customers?
- The Public

Is Quality defined by customers?
What are the quality indicators?

Although everybody agrees that quality in clinical research is important: “There are no scientifically valid measures of the quality of clinical trials”*

What about subject satisfaction, data integrity, meeting the defined objective ...

---

*http://www.appliedclinicaltrialsonline.com/quality-clinical-trials
IMPACT of QUALITY

- Protocol writing
- Document submission to IRB and agencies
- Feasibility and Study Start-Up
- Ongoing QC and QA
- Quality Systems – CAPA, CTD, Quality Reviews
Can you find the six words/topics hidden in this picture that facilitate quality in research?
STUDY START-UP REVIEW

Study Start-Up Review:

for complex, inter-departmental or translational research studies
for new investigators/research teams

Process:

review of the study teams' processes, forms, etc. prior to enrollment of the first subject
a report with recommendations will be issued to the investigator and their teams only
Investigator may request a Mock FDA Audit

RCQA will conduct the audit to mimic an FDA inspection

A report with recommendations will be issued to the investigator and their teams only
CORRECTIVE ACTIONS PREVENTIVE ACTIONS

When?

- After internal Quality Reviews/audits
- After external federal audits (FDA, NIH, EMA)
- After problem detection by research teams

CAPA Plans vs Full CAPA

Why?

- To continuously improve quality

Creating Internal CAPA Plan Flowchart
Policy HSR-P-004
Set of actions required to rectify and eliminate the occurrence/recurrence of nonconformance

To resolve the quality issue in a timely, effective and compliant manner

To document activities and provide information for management review/resolution of quality issues
CORRECTIVE ACTION (CA)

Reaction to a problem that has already occurred and has been identified by either external or internal sources.

Action(s) taken to eliminate identified non-compliance and/or actions(s) taken to address and correct a problem.
PREVENTIVE ACTION (PA)

Action(s) taken to eliminate the root cause(s) of the problem

Actions taken to prevent the issue from occurring in the future
At UM we should move from CAPA to PACA.
**Effectiveness:**

- Internal Quality Review observations classified as Immediate Action Required
- Federal Audits where a Form FDA 483 or equivalent was issued
- Full CAPA Plans

**Purpose:**

- Verification that the observations or non-compliance have not recurred
- If the observations have not recurred, the CAPA Plan was successful
- If observations have reoccurred, this indicates the CAPA Plan did not resolve the issues and should be revised

**CAPA Plan Effectiveness Check Flowchart**
Quality Control of your record involves a detailed review that compares the ClinicalTrials.gov record to the latest IRB approved study protocol, ICF, and/or published articles for data integrity, accuracy, and consistency.

https://www.ctd.uresearch.miami.edu/contact-us/request-for-qc/index.html
The CTD group can assist you with a variety of needs as it pertains to reporting results on ClinicalTrials.gov. We are able to assist with:

- Organization of data to facilitate entry
- Step by step instructions for entering results
- Redacting and uploading of protocol

https://www.ctd.uresearch.miami.edu/contact-us/request-assistance/index.html
I didn’t realize how much RCQA could help.
At the U, we transform lives through teaching, research, and service.
Johanna Stamates
(305) 243-4538
Email: jstamates@med.Miami.edu
Web – http://rcqa.uresearch.Miami.edu

Yolanda P. Davis
(305) 243-0494
E-mail: y.p.davis@med.Miami.edu
Web – http://ctd.uresearch.Miami.edu