

Clinical Trials Compliance: Collaboration Builds Effectiveness

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Emory University: About Us

1. Large academic medical center
2. CTSA, NCI Comprehensive Cancer Center, AAHRPP accredited
3. 9 Hospitals
4. \$628 million in research funding last year
5. 4,000 active protocols (2/3 biomedical)



“Anne, I want you to go and meet with investigators and tell them that you are there to help them.”

Chairman, Woodruff Health Sciences Center Board

Emory University Trustees want assurance that Emory has excellence in its clinical trials. They want to ensure that there is safety to patients and those who are willing to participate in clinical trials.

- Oversight and Corporate Accountability Expectations
- Interested Board Members
- Governmental Expectations
- Increased FDA scrutiny
- Improved Relationships and Trust with Community, Sponsors and Regulators
- Minimize Risk - Health, Financial, Operational, and Reputational, Fine & Penalties



Mission

To contribute to the advancement of research excellence by undertaking activities aimed at:

- Protecting the human subjects, the institution, its faculty, staff and students, as well as our research partners and collaborators, and the members of our local and global communities who benefit from and are affected by our research activities
- Working to ensure compliance with applicable governmental and institutional requirements, and the implementation of appropriate best practices related to the conduct, administration and reporting of research
- Fostering a culture of responsibility and stewardship

New Kids on the Block Our Program

- Design is similar to a healthcare compliance program
- Education & Quality Assurance Reviews
- Collaboration with Institutional Review Board and Office for Research Compliance
- Acceptance and Trust



Achieving our Mission

- Collaborate with Administrative and Clinical Leadership
- Input into program from Chairs, PIs, nurses and coordinators
- Proactive value based program
- Transparency/Transparent communication
- Accountability
- Fair and Just Culture
- Consistent message – no room for off message



Achieving our Mission

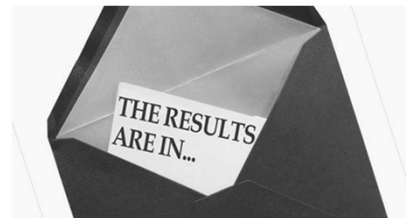
- Identifying compliance risks and effective methods to mitigate those risks
- Compliance staff/resources (including technical resources)
- Promoting awareness of clinical trials standards and legal requirements
- Coordinating education between clinical trials departments (IRB, Office for Clinical Research, Office for Research Compliance)
- Partnering with designated representatives to monitor compliance and to ensure that appropriate and effective corrective actions are taken when issues found



Results

Education and Protocol Reviews:

- Safer trials
- Identifying and addressing problems early
- Improved protocol compliance
- Better trained workforce, improve morale
- Assist in defining roles and responsibilities
- Better quality research operations
- Minimize likelihood of government audits & investigations



QA/QI at Emory

- Clinical Trials Audit and Compliance
- Emory IRB QA Team
- Office of Compliance
- Winship Cancer Monitoring Team
- QA functions in Office of Research Administration Units (e.g., Research Billing, Conflict of Interest)



QA Reviews

- Paper 2010
- Vendor out-of-the box electronic audit tool 2011-2013
- REDCap 2013-present
- QA Review Reports
 - Summary of Significant Deficiencies and CAPA
 - Detailed Review Checklist
 - Confidential between audit and study teams



QA Reviews: regulatory

- IRB history
- Regulatory documentation
- Study staff: training and delegation of authority
- Adverse events: internal and external recording and reporting
- Protocol deviations: recording and reporting
- Data and safety monitoring
- Investigational product accountability: receipt, storage, dispensation, and return



QA Reviews: subjects

- Informed consent
- Eligibility
- Study procedures
- Study treatment
- Adverse events
- Investigational product accountability



Choosing studies for review

- Priority list
 - Sponsor-Investigator, investigator-initiated, DHHS-funded, no monitoring
 - Sponsored research with unfavorable monitoring reports
 - PI-requested reviews
- Investigator-initiated studies
 - Get to them early
 - Train team how to manage the study and self-monitor—send reports to us
- CAPA



After the review

- Preliminary report
- Close-out discussion with PI and study team
- Final report
- Studies with significant deficiencies
 - PI reports events to sponsor and/or IRB, per policies
 - CAPA plan implementation
 - Training by CTAC
 - CAPA implementation QA review
 - Additional QA reviews, site visits, keep in close communication



REDCap QA review checklist

- Group questions by categories
- Question answers
 - Yes, No, Not assessed, Not applicable
- Compliance assessment
 - In compliance, Noncompliance
- Comments
 - List your review findings, both positive and negative



Study page

Study Title **S1007**
(Arm 1: Audit Checklists)

Data Collection Instrument	Study Information	Audit 1	Audit 2	Audit 3	Audit 4	Audit 5	Audit 6	Audit 7
Study Information	<input checked="" type="radio"/>							
Audit Information		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Emory Investigator as Sponsor		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Regulatory Documentation		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Winship Audit		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subject Checklist		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
CAPA Audit		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Audit Summary Information		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



REDCap reporting

- Summary information form
- Group significant deficiencies by category
- Add flags for IRB reporting and other follow-up (e.g., training)
- Add flags for studies needing a CAPA implementation review



REDCap reports

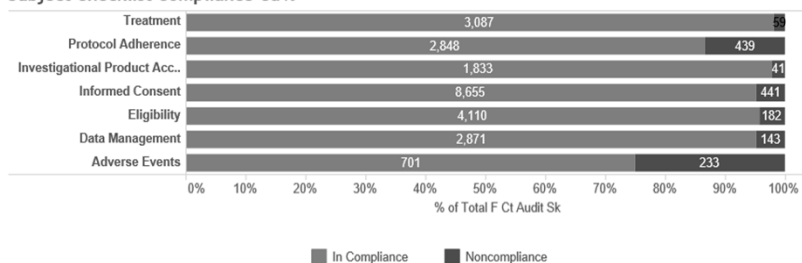


Trend reporting: Tableau

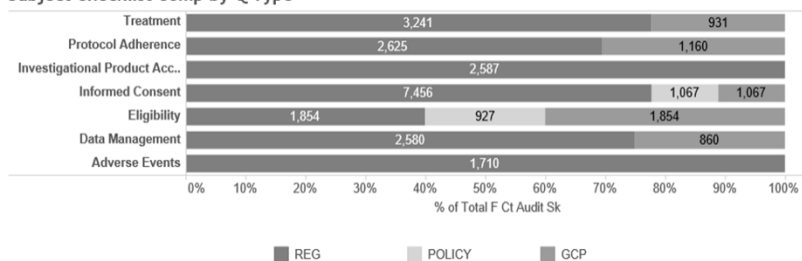
- External, customizable tool for reporting data and trends
- Emory REDCap administrator copies data into Tableau monthly



Subject Checklist Compliance Ct/%



Subject Checklist Comp by Q Type



Audit Quarter
(All) ▼

Event Type
Total Audits ▼

Study Department
(All) ▼

Audit PI
(All) ▼

Significant Deficiencies
No ▼

Sponsor Investigator
(All) ▼

Investigator Initiated
(All) ▼

Federal Supporter
(All) ▼

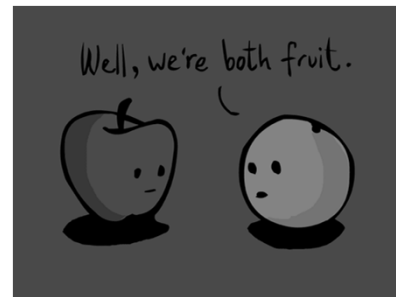
Industry Supporter
(All) ▼

Cancer Study
(All) ▼

Abbrev Checklist
(All) ▼

Trend reporting: variables

- Study duration
- Study complexity
- Study funding/resources
- Study team
- Investigator-initiated
- Sponsor-investigator



Thank you!

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