Update on the Quality Improvement Assessment (QIA)

Gini Guptill, PhD and Alissa Mun, MS

Office of Research Support and Compliance

History of the Quality Improvement Assessment aka The QIA

- Fall 2016 FDA inspection
- Data call for reporting of events to the IRB, FDA and Office of Human Research Protections (OHRP)
- Heightened awareness and training initiative in late 2016 and early 2017
- How do we:
  - Measure the success of the training?
  - Assess protocol compliance globally?

Quality Improvement Assessment (QIA) - Phase I aka The Pilot

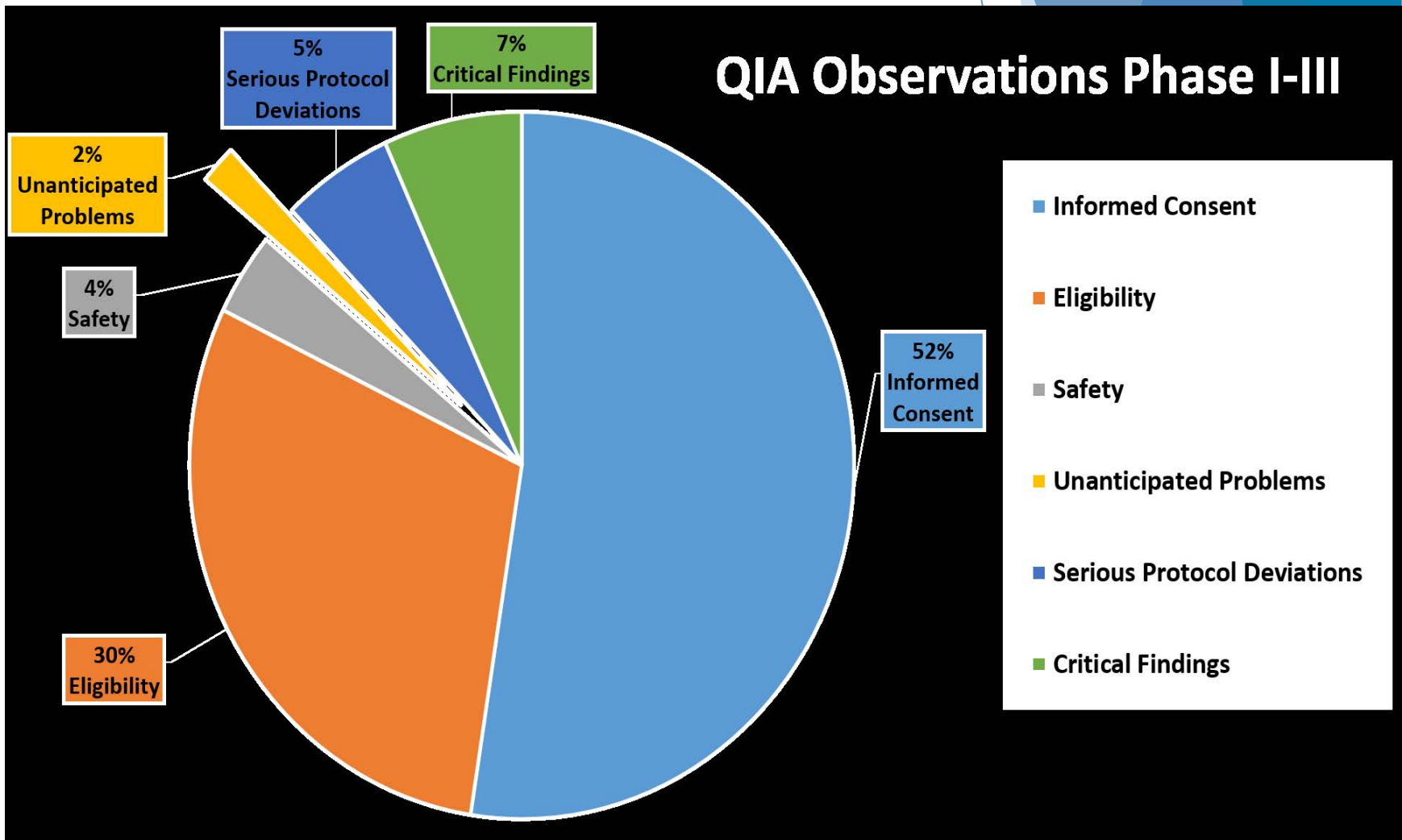
- Establish the QIA Working Group
- Baseline measurement
  - Informed Consent process
  - Documentation of Eligibility
  - Unanticipated Problem Reports
- Identify independent third party reviewer

Quality Improvement Assessment (QIA) - Phase I-III

- NIH Intramural Research Program wide assessment of 105 protocols across 18 Institutes and Centers
- QIA Working Group Initiative:
  - Collect and analyze global NIH trends for process improvement

Quality Improvement Assessment (QIA) – NIH Global Observations

- Minimal Observations in Unanticipated Problem Reporting
- Assess where improvements could be implemented
  - Documentation of Informed Consent and Eligibility
  - Develop Training Opportunities



Clinical Research Quality Management Initiatives – Documentation of Informed Consent

- Observations of Documentation of Informed Consent
  - Limited in capturing the ways consents occur
  - The Progress Note in Electronic Health Record system (CRIS) was not being utilized
    - Some investigators were not aware there was a note in CRIS to document this process
    - There is no requirement to use the current note
- Revise “Documentation of Consent” Note in (CRIS)
- Update policies requiring documentation of the consent process in the medical record or research records
- Ready to go live in January 2020

Clinical Research Quality Management Initiatives – Training Programs

- Good Clinical Practice (GCP) Training for NIH Principal Investigators
  - 3 day in-person course
- Online Refresher Training for Sponsors
- Corrective Action and Preventative Action (CAPA) training
  - Introduction, Case Studies, Toolkit Seminar

- NIH-wide Audit 2020
- Informed consent, Eligibility, Problem Reporting, Protocol Compliance, and Corrective Actions and Preventative Actions (CAPA's)
  - Measure for success of Documentation of Informed Consent
  - Measure for success of previous trainings
  - Updates in Policies

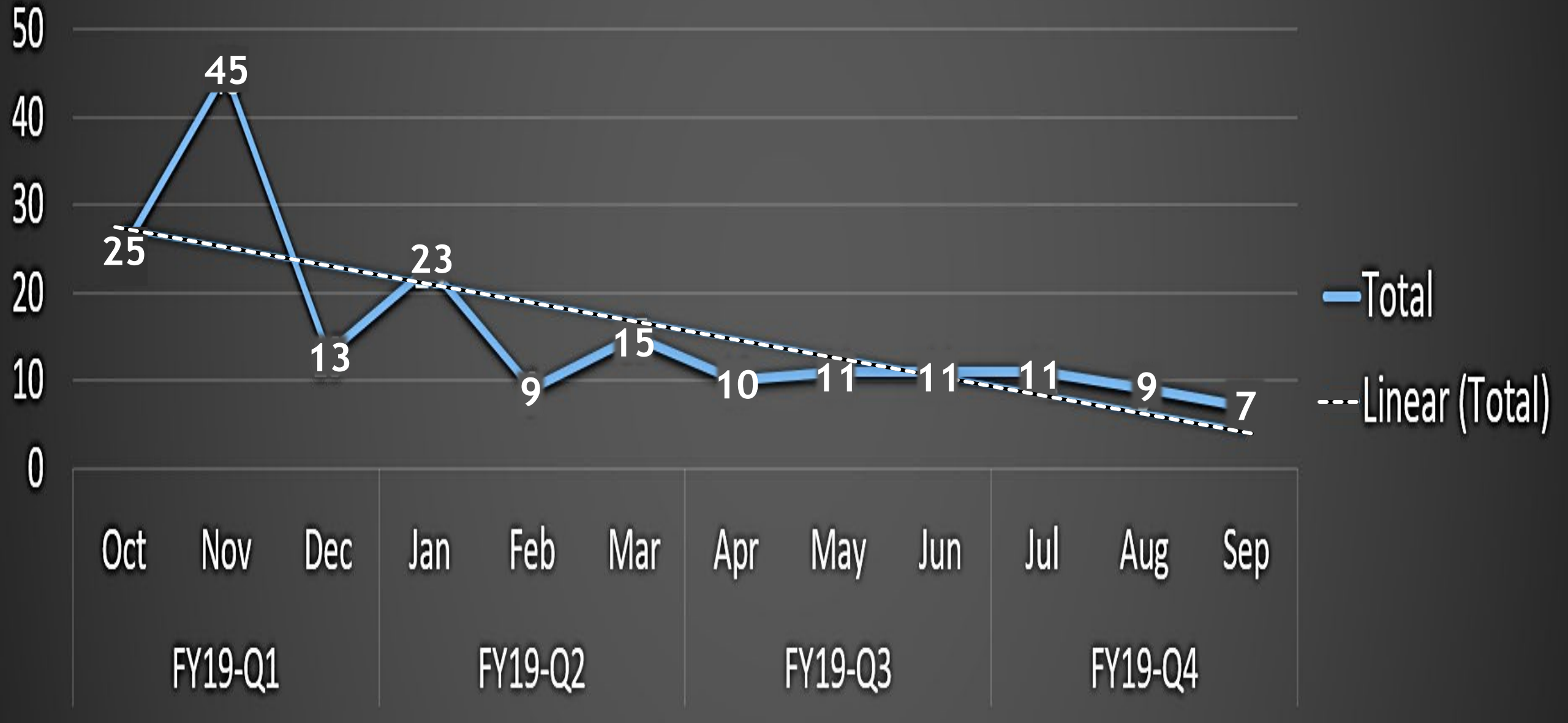
Clinical Research Quality Management Initiatives – Collaborative Assessment

- NIH Clinical Center Investigational Drug Control Unit (IDCU)
  - Define consistent roles/responsibilities
  - Identify expectations of Investigator and Sponsor communication per regulations
  - Develop a Memorandum Of Understanding
- Office of Human Subjects Research Protections (OHSRP)
  - 12 Institutional Review Boards (IRBs) within NIH
  - Identify trends and processes in transition

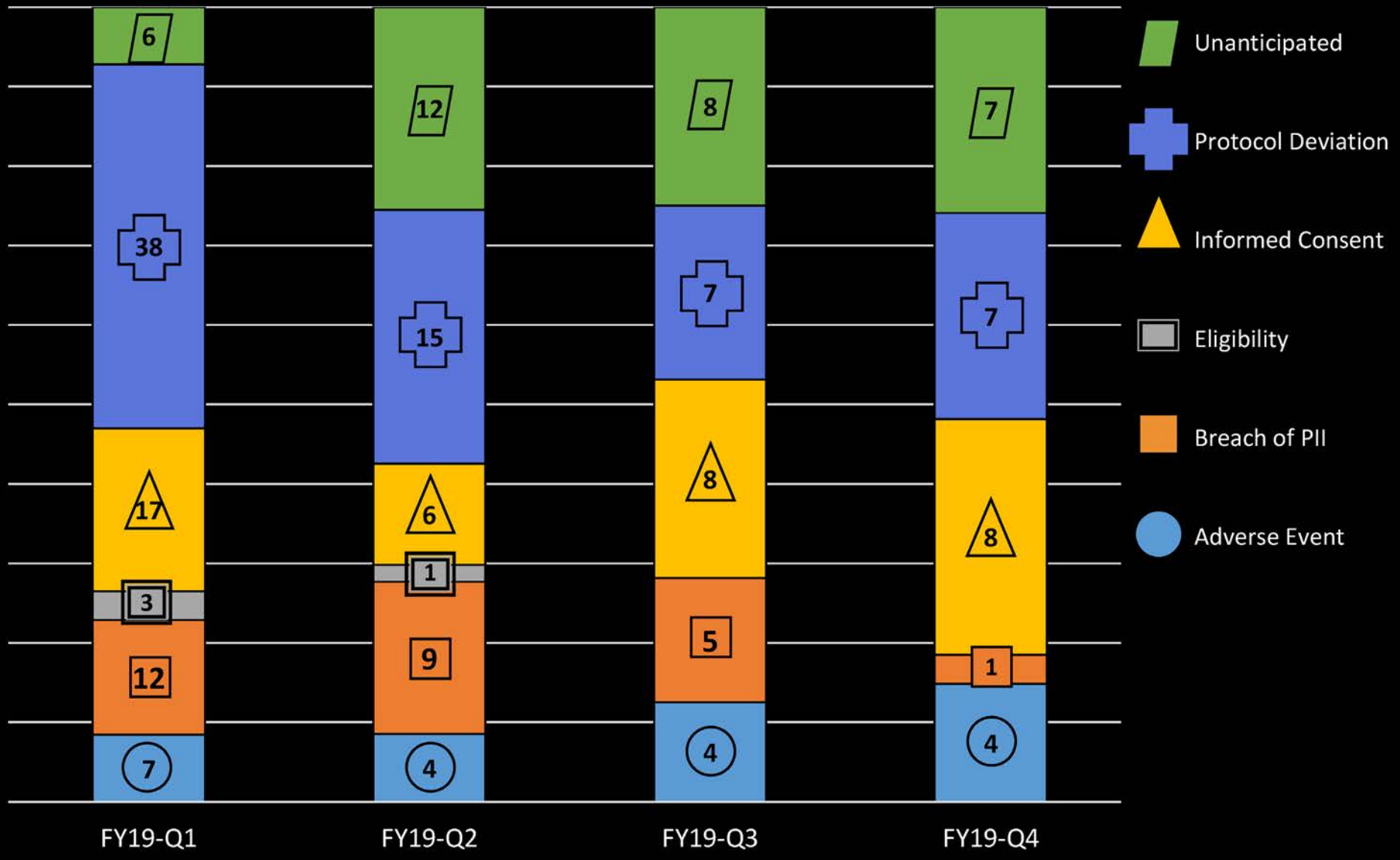
NIH Event Reporting Dashboard

- Event Reports submitted to the FDA and/or the Office of Human Research Protection (HHS)
- Interactive dashboard to identify global NIH trends
  - Where NIH ***can*** improve
  - Where NIH ***has*** improved
- Quarter and Annual Fiscal Year Reports are sent to Drs. Gilman, Gottesman, and Green
  - Identify Key Trends
  - Response to noted trends
  - Recommendations for further action

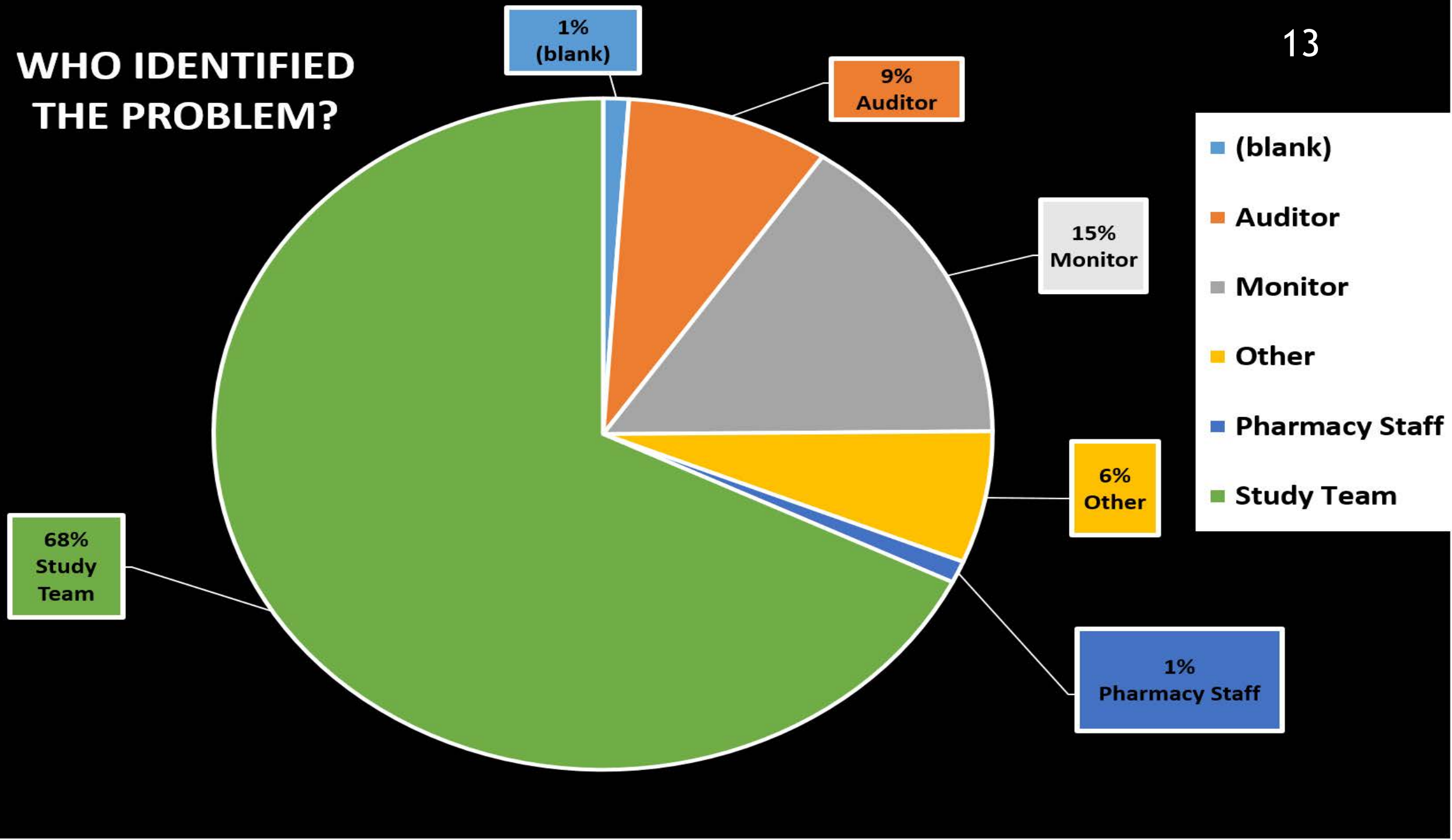
Monthly Trend of Event Reports



TYPES OF EVENTS



WHO IDENTIFIED THE PROBLEM?



Quality Improvement and Quality Assurance Data Call

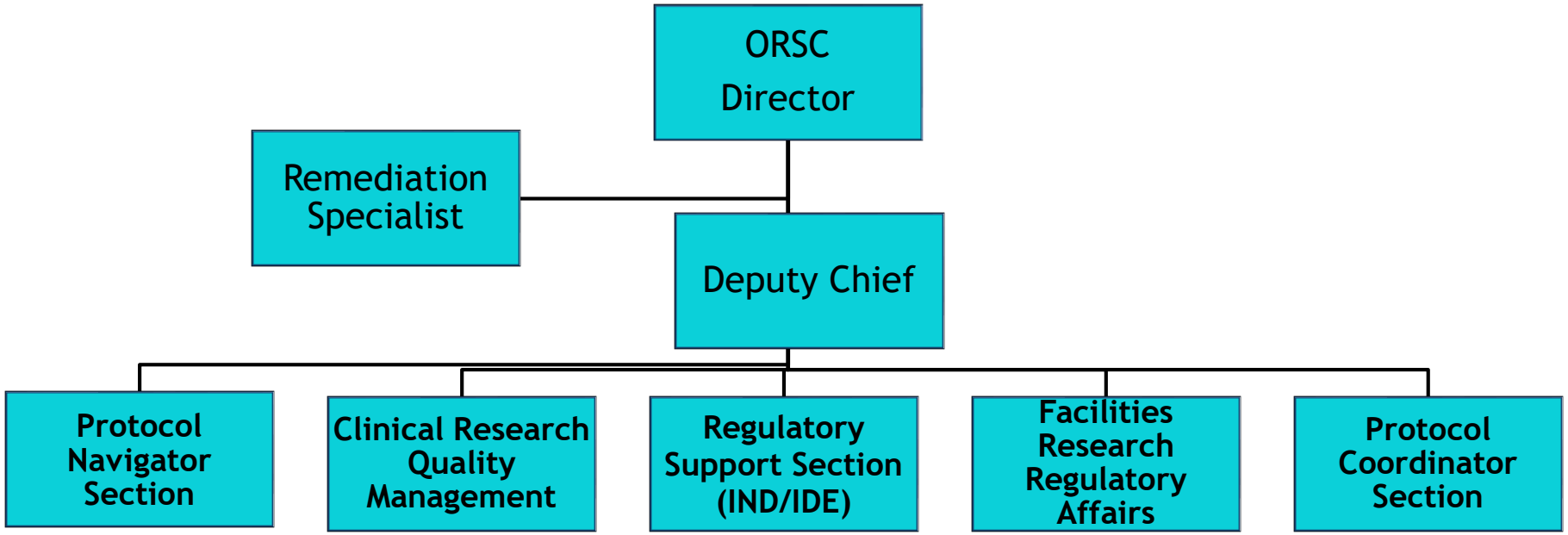
- **Association for the Accreditation of Human Research Protection Programs**
  - **Standard I-5: The organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.**
- **Improve process and standardize data elements**
  - **Workflow process**
  - **Smart Form**
  - **Branching Logic**

Future Plans

- Auditing and Monitoring Program
- Documentation of Eligibility
- Developing a data warehouse to track and trend the Reportable Events Form (REF)
- Electronic Records and Signature Compliance for Sponsors, Principal Investigators and Data Managers
- Developing a Quality Management System

Office of Research Support and Compliance 2019

Office of Research Support and Compliance



Protocol Navigator Section

Support to clinical investigators from the initial phase of protocol development until the protocol is completed and closed by the IRB. Protocol navigators identify whether protocols need additional review or regulatory support and direct PIs to those sections in the office.

- **Support includes:**
  - **Providing protocol templates**
  - **Routing protocols through ancillary reviews (pre-IRB)**
  - **Submissions to the IRB**

Regulatory Support Section (IND/IDE)

Provides guidance and support to sponsors and investigators conducting FDA regulated research.

Support includes:

- **Initial and continuing applications to the FDA**
- **Consultation to determine if an IND or an IDE is needed**
- **Support FDA meetings (Type A, B, and C)**
- **Support during FDA Inspections of Clinical Investigators and IRBs**

Research Regulatory Affairs-Aseptic Processing Facilities (APFs)

Provides regulatory support for the Aseptic Processing Facilities on campus.

- Developing SOPs and guidance - corporate quality management system
- GMP training
- Provides support and assistance with FDA inspections of facilities
- MasterControl implementation
- Management of specialized support contracts for facilities

Protocol Coordinator Section

Provides a wide variety of functions and is primarily focused on providing operational support for the conduct and implementation of protocols.

Support includes:

- Developing SOPs, Manual of Operating Procedures, and study forms for protocols,
- Conduct Site Initiation Visits
- Clinical Trial Implementation
- Respond to monitoring and audit findings

Office of Research Support and Compliance 2019

- Continued growth both in personnel and operations
- Vision continues to be to develop a trans NIH approach to support which will make compliance easier to achieve
- Thank you to the NIH leadership, CC leadership and the NIH Community