Inspections Across Sponsors, Contract Research Organizations and Investigator Sites

2024 CDISC + TMF US Interchange Program

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Office of Bioresearch Monitoring Inspectorate

Topics Covered

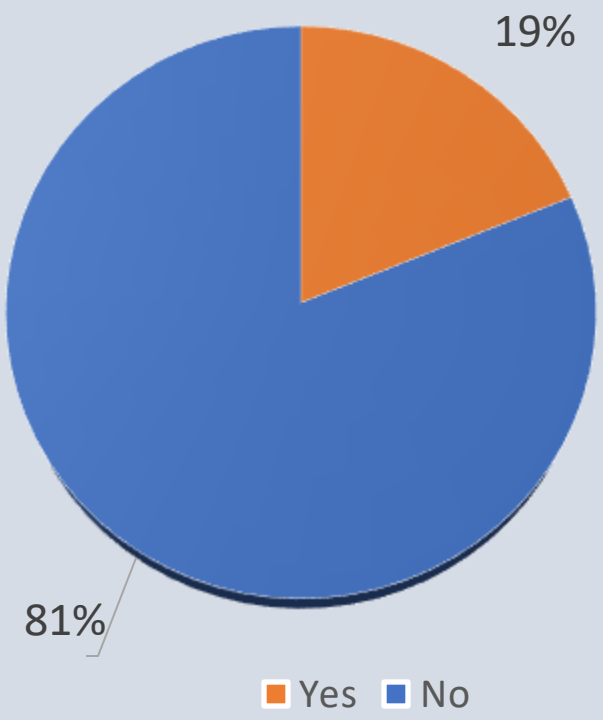
- Recent Inspection findings
  - Sponsors/Contract Research Organizations
  - Sponsor-Investigators
  - Clinical Investigators
- Relationships Between Findings at Sites
- Corrective Actions Suggested by Findings
- Benefits of Standardized Trial Master Files and Investigator Site Files from an Inspection Perspective

Sponsor Inspections FY 2018-2024

418 Inspections

No FDA 483 - 339
FDA 483 Issued - 79

*includes CROs

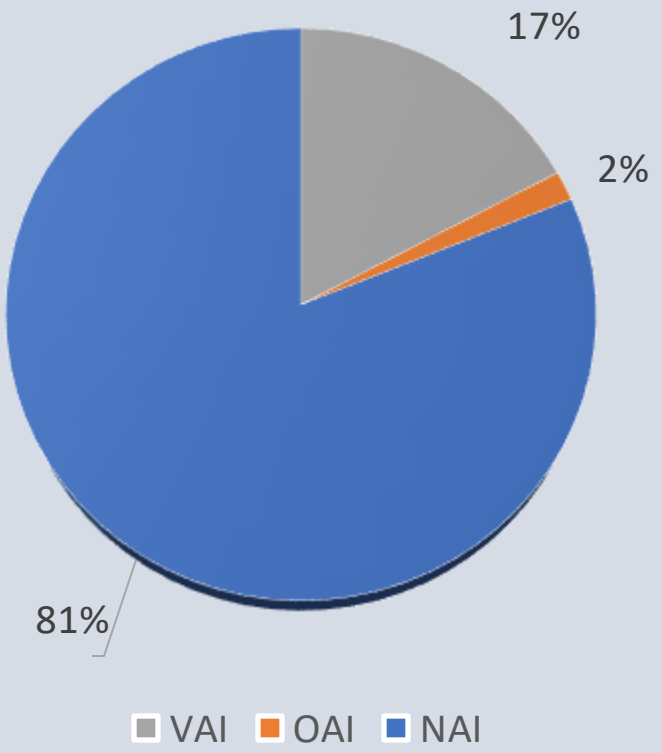


Sponsor Inspections FY 2018-2024

418 Inspections

NAI - 339
VAI - 72
OAI - 7

*includes CROs

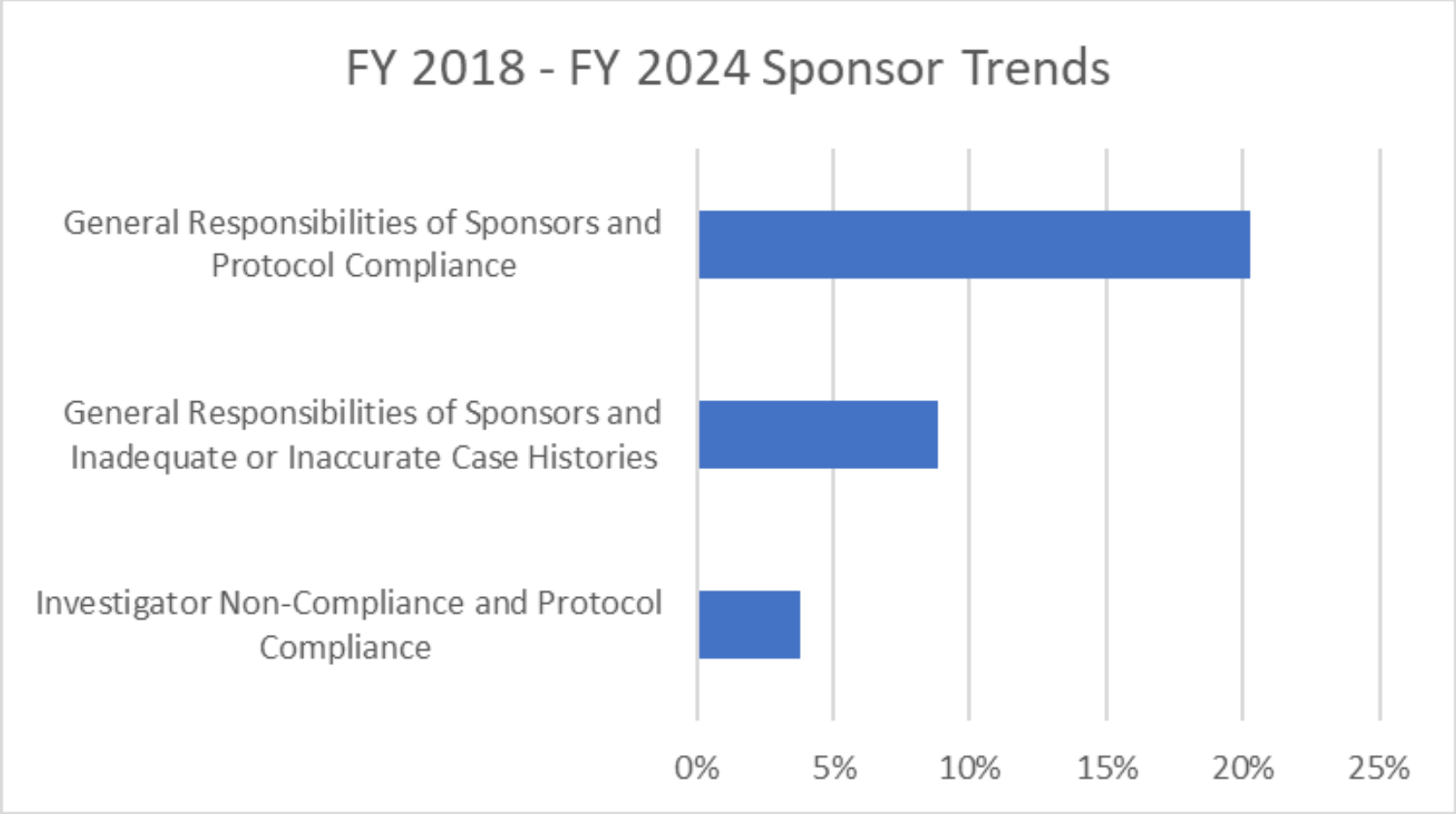


Sponsor and Investigator Inspections Same Application FY 2018-2024

During inspections of sponsors and investigators where we covered the same application, these trends were noted

Where deficiencies are observed at sponsor, there are related deficiencies at investigator site

Protocol compliance and inadequate case histories



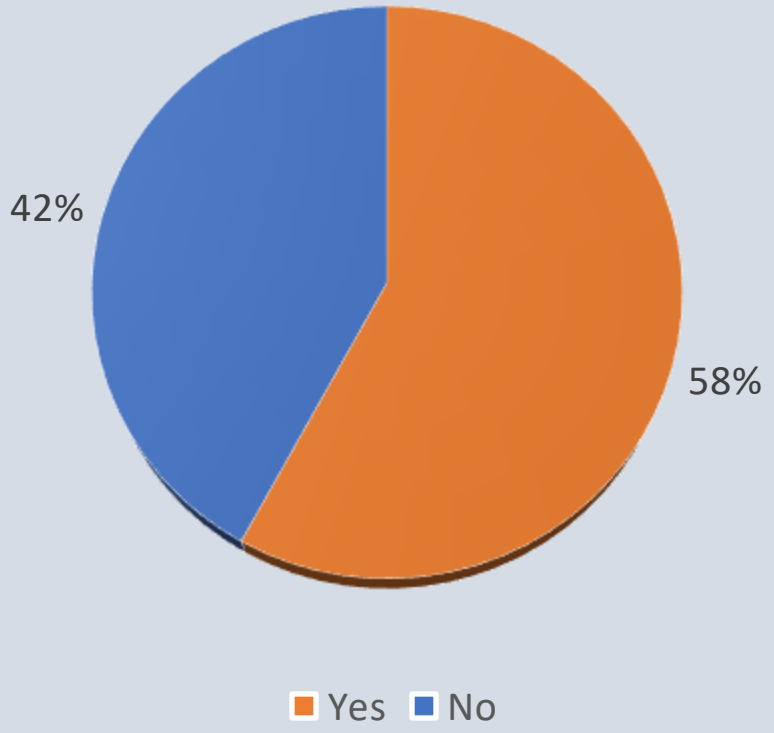
A Note on Data for Sponsors and Sponsor-Investigators

- We use Program Assignment Codes (PAC) to track the different types of inspections we conduct
- Sponsors and Sponsor-Investigators were previously reported against the same PAC for sponsor responsibilities
- In 2018, we implemented a separate PAC specific to Sponsor-Investigators
- CROs are reported under Sponsor PAC
- I expect some of the data from 2018 and 2019, may still be mixed as we transitioned to new PAC

Sponsor-Investigator Inspections FY 2018-2024

88 Inspections

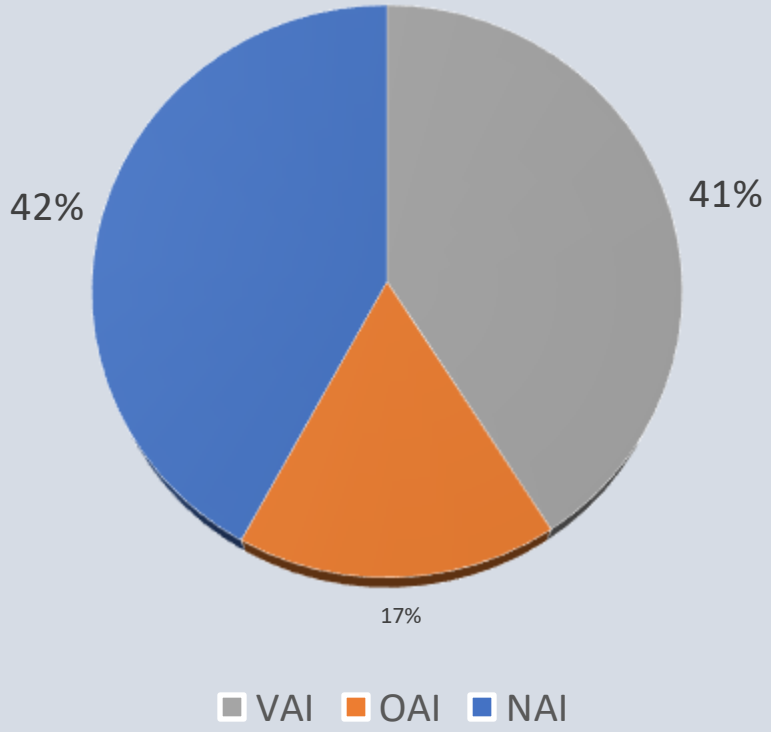
No FDA 483 - 37
FDA 483 Issued - 51



Sponsor-Investigator Inspections FY 2018-2024

88 Inspections

NAI - 37
VAI - 36
OAI - 15

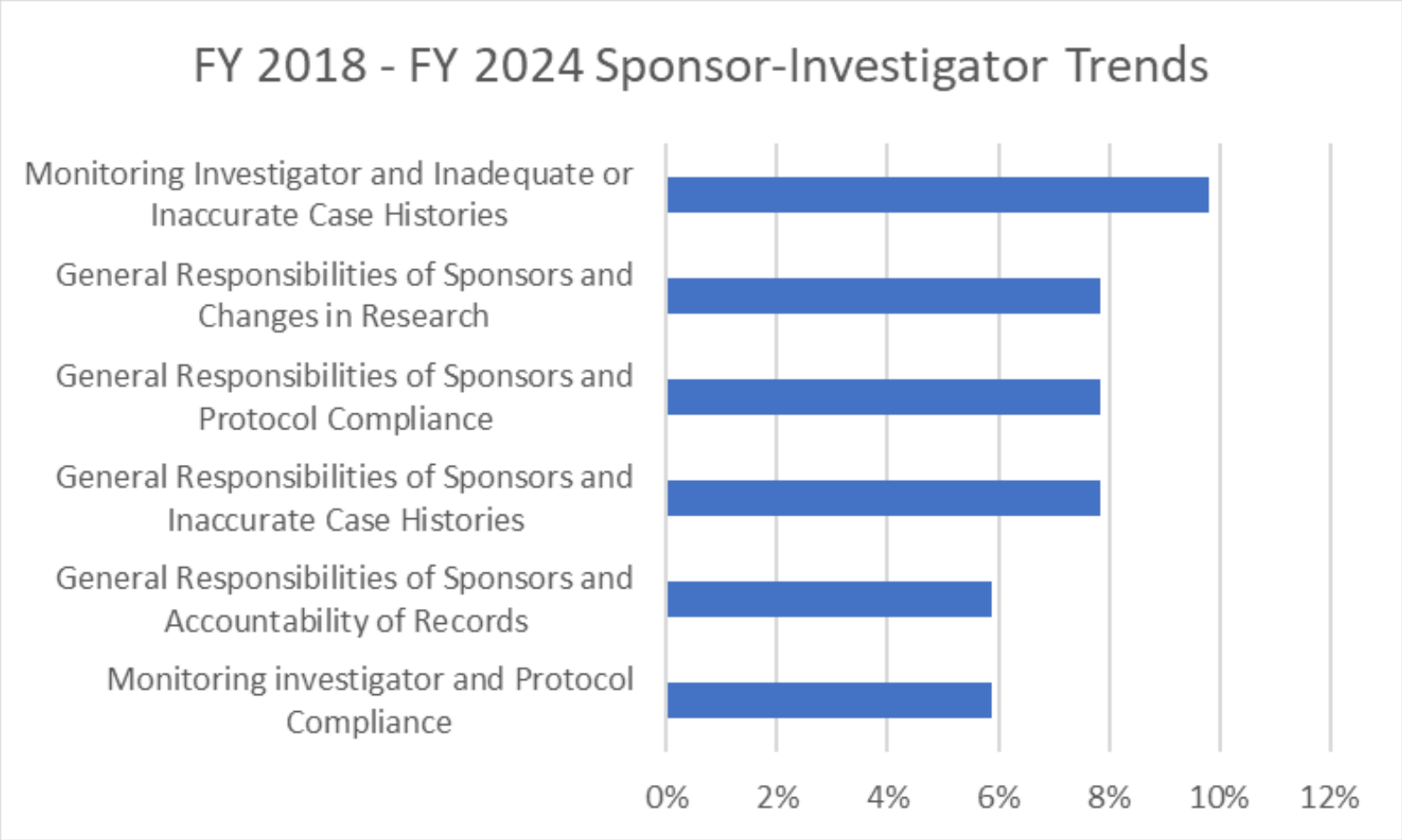


Sponsor-Investigator Inspections – S-I and Investigator Cites FY 2018-2024

Most of these are same site with both Sponsor and Investigator responsibilities assessed

- Inadequate case histories
- Protocol compliance
- Records accountability
- Monitoring

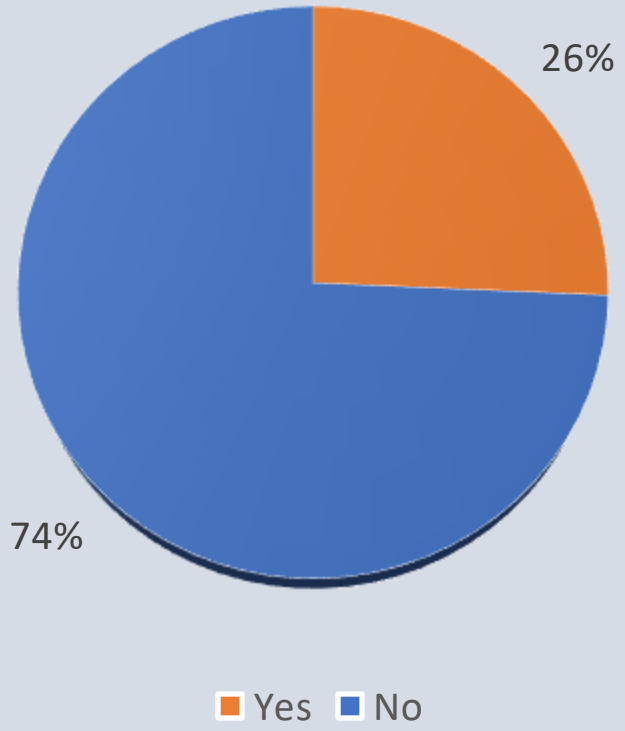
Usually, physician trying to run own study



Combined Sponsor and Sponsor-Investigator Inspections FY 2018-2024

506 Inspections

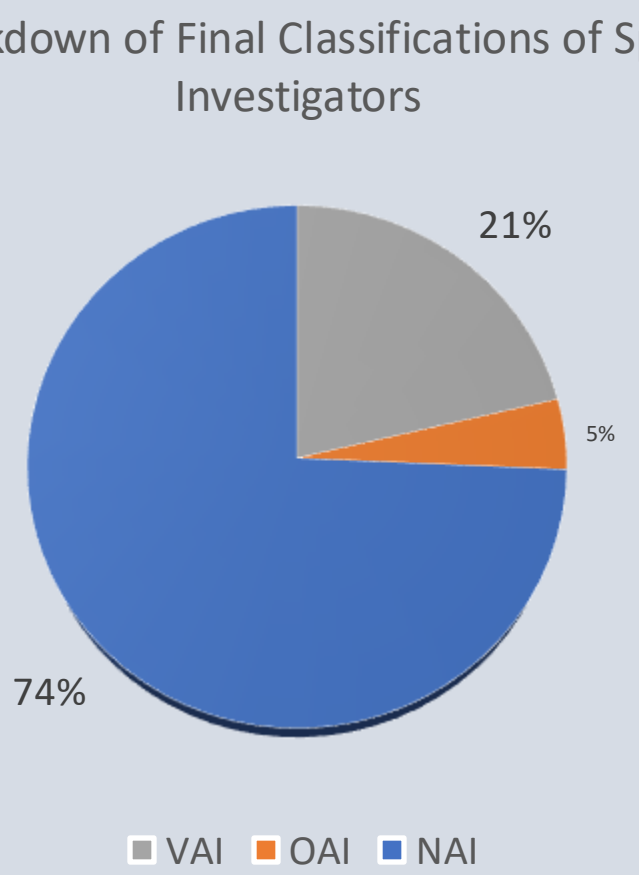
No FDA 483 - 376
FDA 483 Issued - 130



Combined Sponsor and Sponsor-Investigator Inspections FY 2018-2024

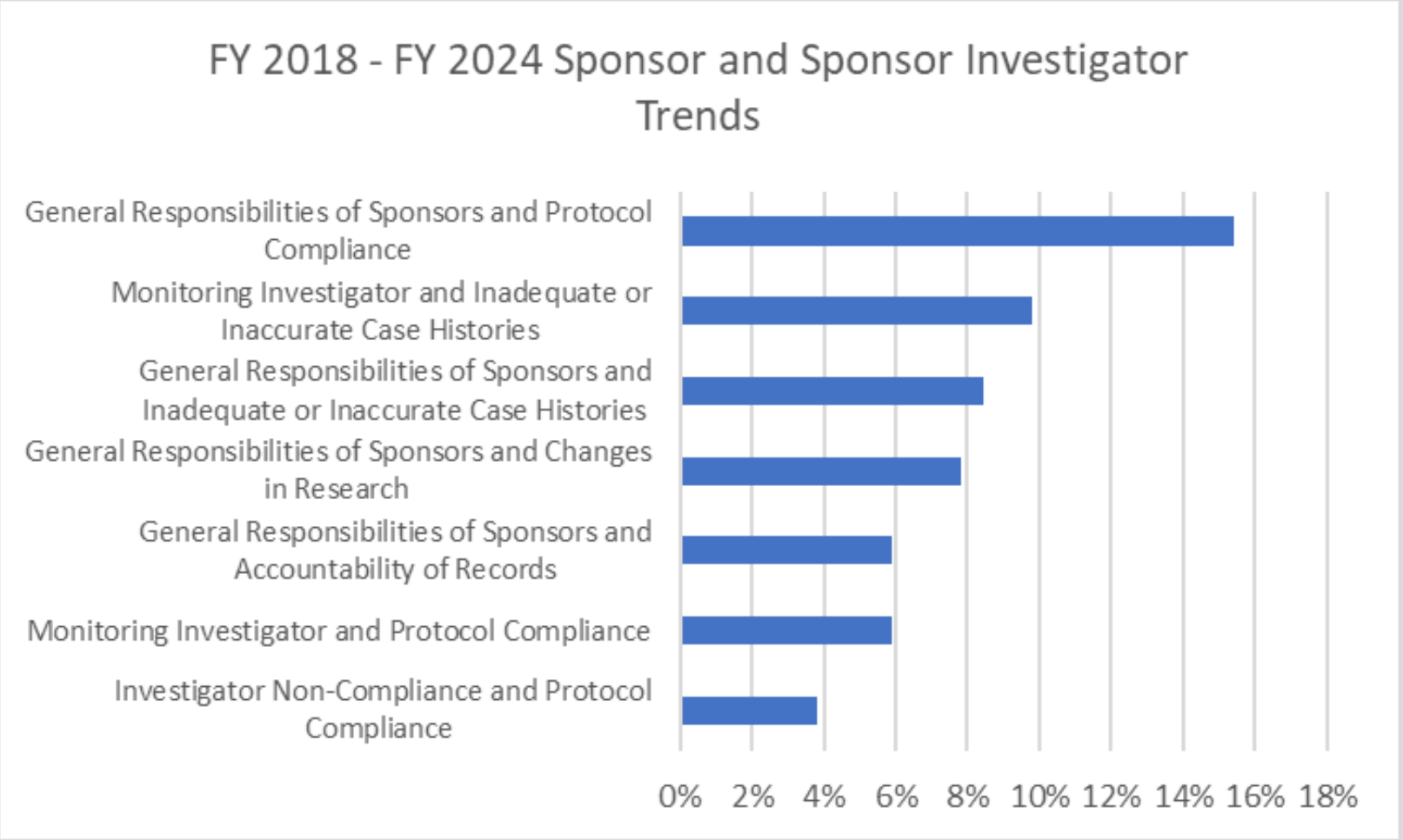
506 Inspections

376 – NAI
108 – VAI
22 - OAI



Sponsor, Sponsor-Investigator, and Investigator Inspections Same Application FY 2018-2024

Many of the same themes, with protocol compliance top citation



Corrective Actions Suggested by Data

Sponsor-Invest… more likely to … than tradit…	When sponsors are not compliant, the likelihood of investigators being non-compliant rises
• Sponsor … ng … • When add… are recruited by … investigators, re… eed … site initiation, tra… and … monitoring	• Ensure training of sponsor staff or CROs • CROs need oversight by Sponsors • Site initiation, training, and monitoring of sites important for investigator compliance

Benefits of Standardized TMF/ISF from Inspection Perspective

Consistency

- Across investigator sites for same application
- Across studies at sponsors

Organization

- Standardization results in logical organization of records and information

Efficiency

- The increased consistency and organization provides for more efficient inspections as the learning curve at each site is reduced

FDA Reorganization

As of 10/1/2024, the Office of Regulatory Affairs (ORA) is now the Office of Inspections and Investigations (OII)

OII is the lead office for conducting inspections and investigations for the agency

All compliance functions have been moved to the respective center organizations

Questions?

Contact Information

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