



FY 2024 CI 483 OBSERVATION TRENDS

Purpose

Broadly written regulations do not always convey the specific details of the observed violation(s).

FDA 483 citations issued during this fiscal year were reviewed and sub-categorized into more granular themes in order to identify trends.

These data slides are the result of the sub-categorization efforts.

Acronyms

AE (Adverse Event)

CI (Clinical Investigator)

FDA (Food and Drug Administration)

ICF (Informed Consent Form)

IP (Investigational Product)

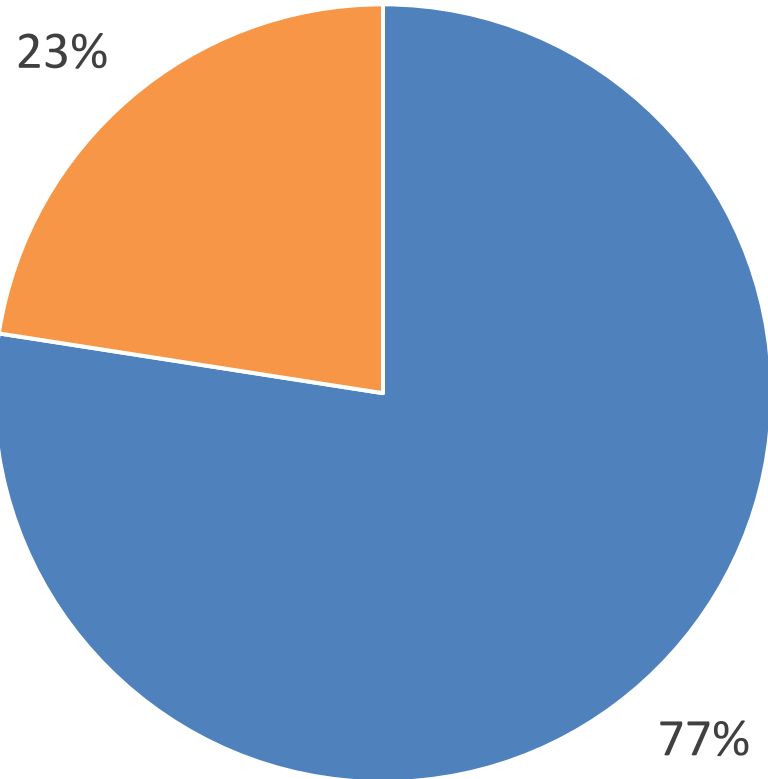
IRB (Institutional Review Board)

OOW (Out of Window)

SAE (Serious Adverse Event)

FY 2024 CI Firms Issued a 483

483 Issued



692 Inspections

No FDA 483 Issued – 536
FDA 483 Issued - 156

■ No ■ Yes

Themes Identified in FY 2024

Protocol Compliance (312.60 / 812.100 & 812.110)

Accurate/Adequate Case Histories (312.62(b)/812.140(a)(3))

Failure to Report Adverse Events to Sponsor Promptly (312.64(b))

IP Accountability Records (312.62(a) / 812.140(a)(2))

Institutional Review Board (312.66) (812.150(a)(3))

Protocol Compliance Themes

(312.60/812.100 & 812.110)



ICF Not Per Investigational Plan

- ICF Not Per Investigational Plan
- Revised Consent Not Obtained/Timely
- ICF Not Obtained Prior to Screening/Reconsent/IP Administration
- ICF Not Obtained at Rescreening
- ICF Not obtained
- ICF Not obtained for Sub-Study

Eligibility

- Inclusion Criteria Not Met
- Exclusion Criteria Met
- Randomized prior to meeting eligibility

Drugs

- Prohibited Medication
- Missed Concomitant Medication

Adverse Events

- Missed AE/SAE
- Late Report AE/SAE

Protocol visits/assessments/procedures

- Study Procedures Performed Incorrectly/Missed
- Missed Visit
- Missed Assessment
- Missed Lab
- OOW Visit/Assessment/Lab

Protocol Compliance Themes, contd.

(312.60/812.100 & 812.110)



Investigational Product

- Randomization Error
- Treatment Compliance
- IP Kit Selection Error
 - Overdosing
 - Underdosing
 - Missed Dose
- Inadequate IP Storage/
Preparation

Other Protocol Requirements

- Unblinding
- Missing Protocol Required
Documentation
 - Study Procedures Performed Incorrectly
 - Not Personally Supervised/
Unidentified
Sub- investigator/
Unqualified Personnel
 - Failure to Discontinue from Study

Records and Documentation Themes

Accurate/Adequate Case Histories (312.62(b)/812.140(a)(3))

- Record not maintained - missing or inadequate record
- Missing data or inadequate data
- Data discrepancy or inaccurate Records/Data (not contemporaneous)
- ICF not maintained/signed/dated

IP Accountability Records (312.62(a) / 812.140(a)(2))

- Missing IP records
- Missing IP use/exposure by subject
- Missing IP date
- Inadequate/inaccurate/missing IP quantity
- Missing IP batch/code
- Missing IP return/ repair/ disposition

IRB and Adverse Events Reporting

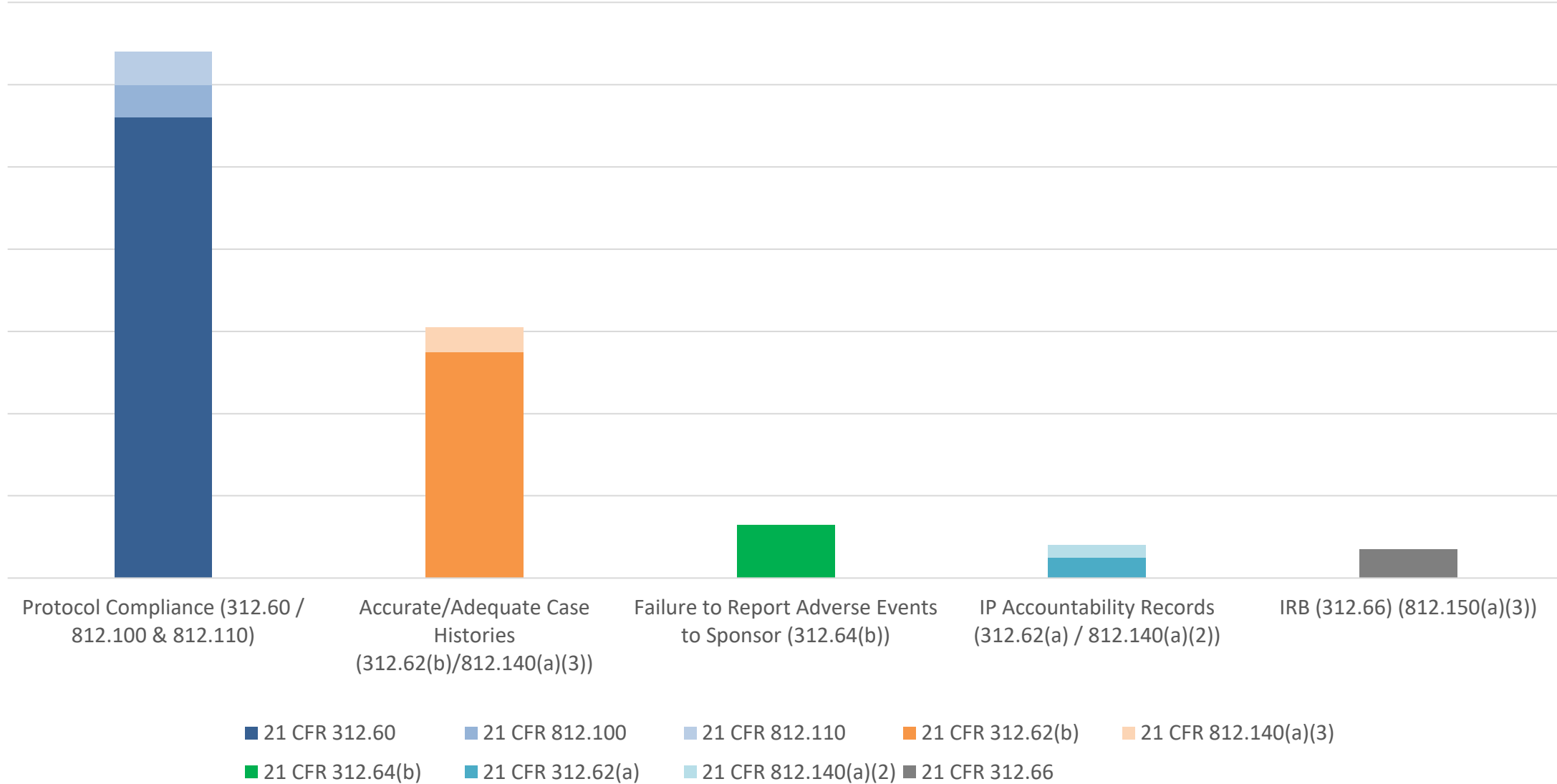
Assurance of IRB review (312.66 & 812.150(a)(3))

- Not All Changes Approved by IRB Prior to Implementation
- Unanticipated Problems Report to IRB
- IRB Initial/ Continuing Review
- Prompt Reporting of changes in research to IRB
- Progress Reports Not Submitted to IRB/IRB Lapse

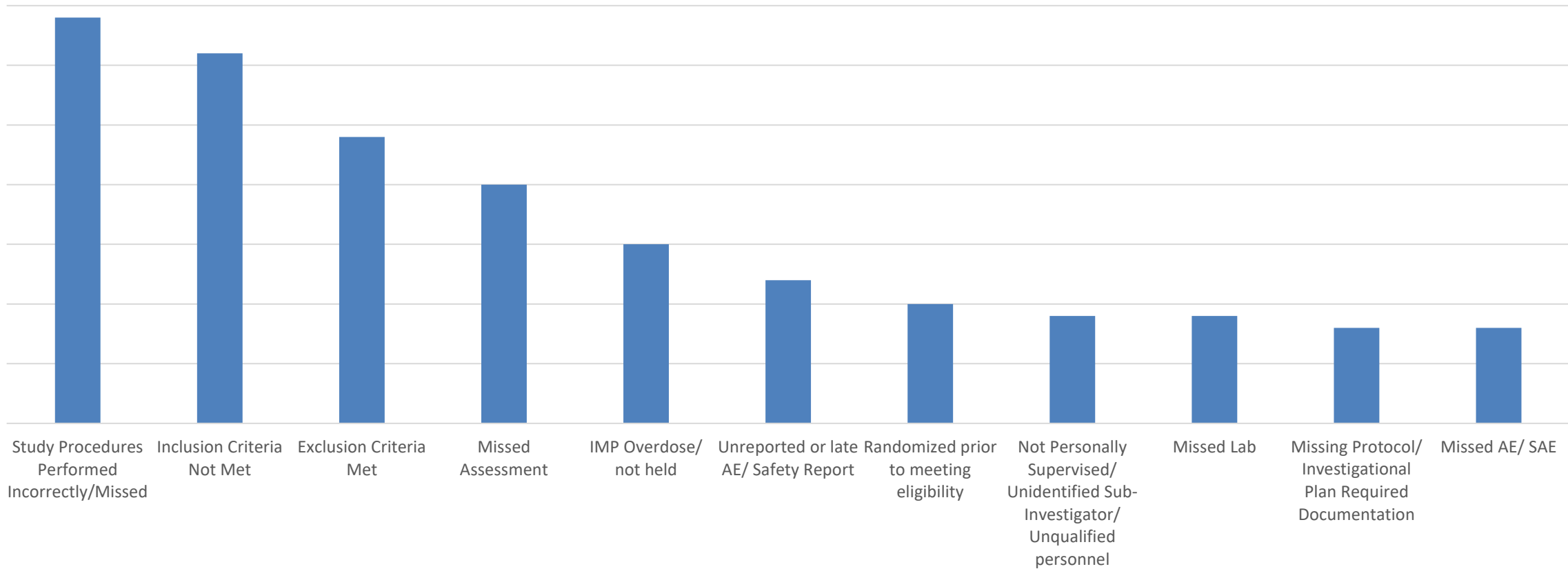
Failure to Report Adverse Events to Sponsor Promptly (312.64(b))

- Unreported or late AE/ Safety Report

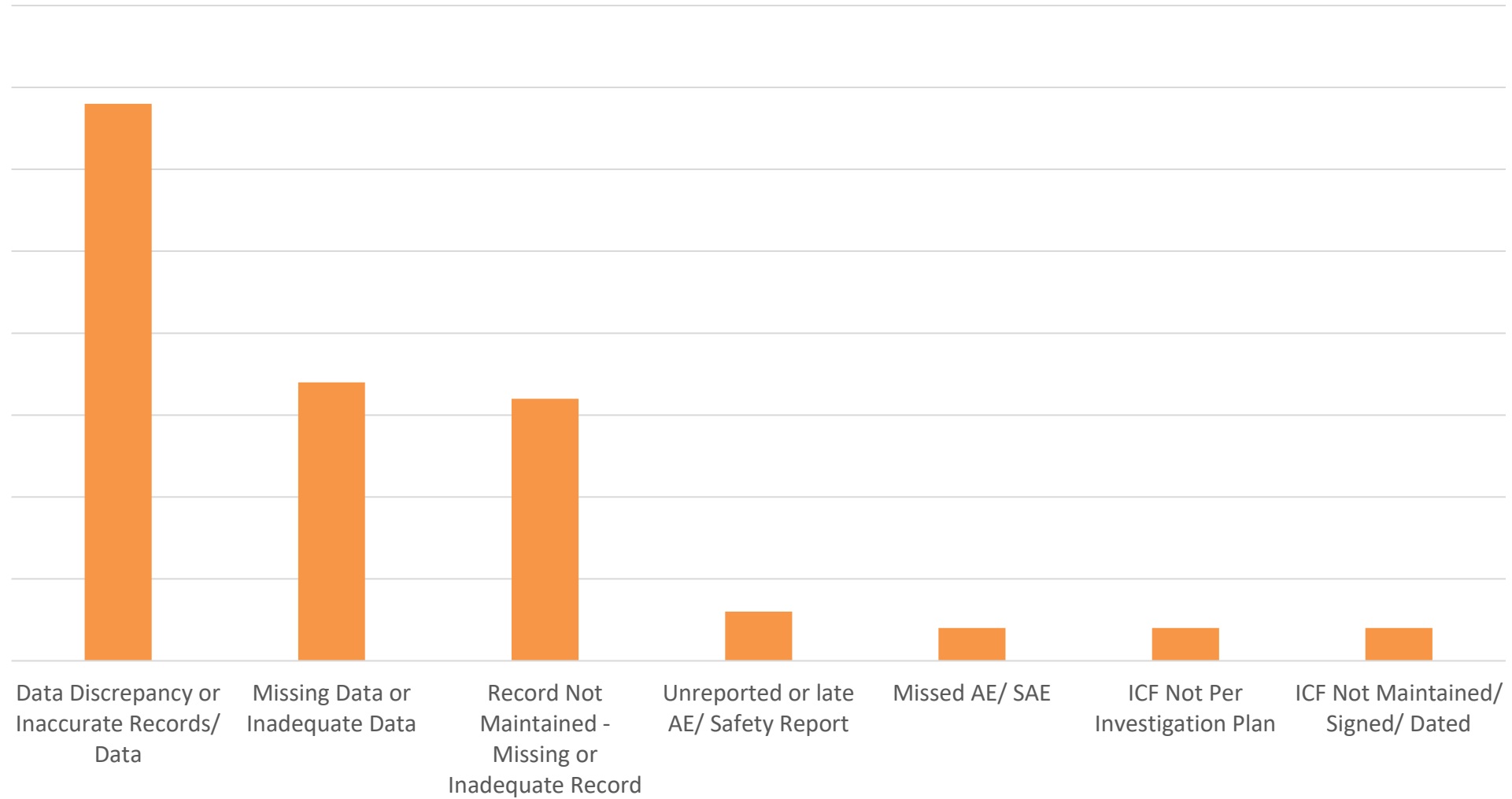
FY 2024 CI 483 Themes by Reference Number



1572 Protocol Compliance Details



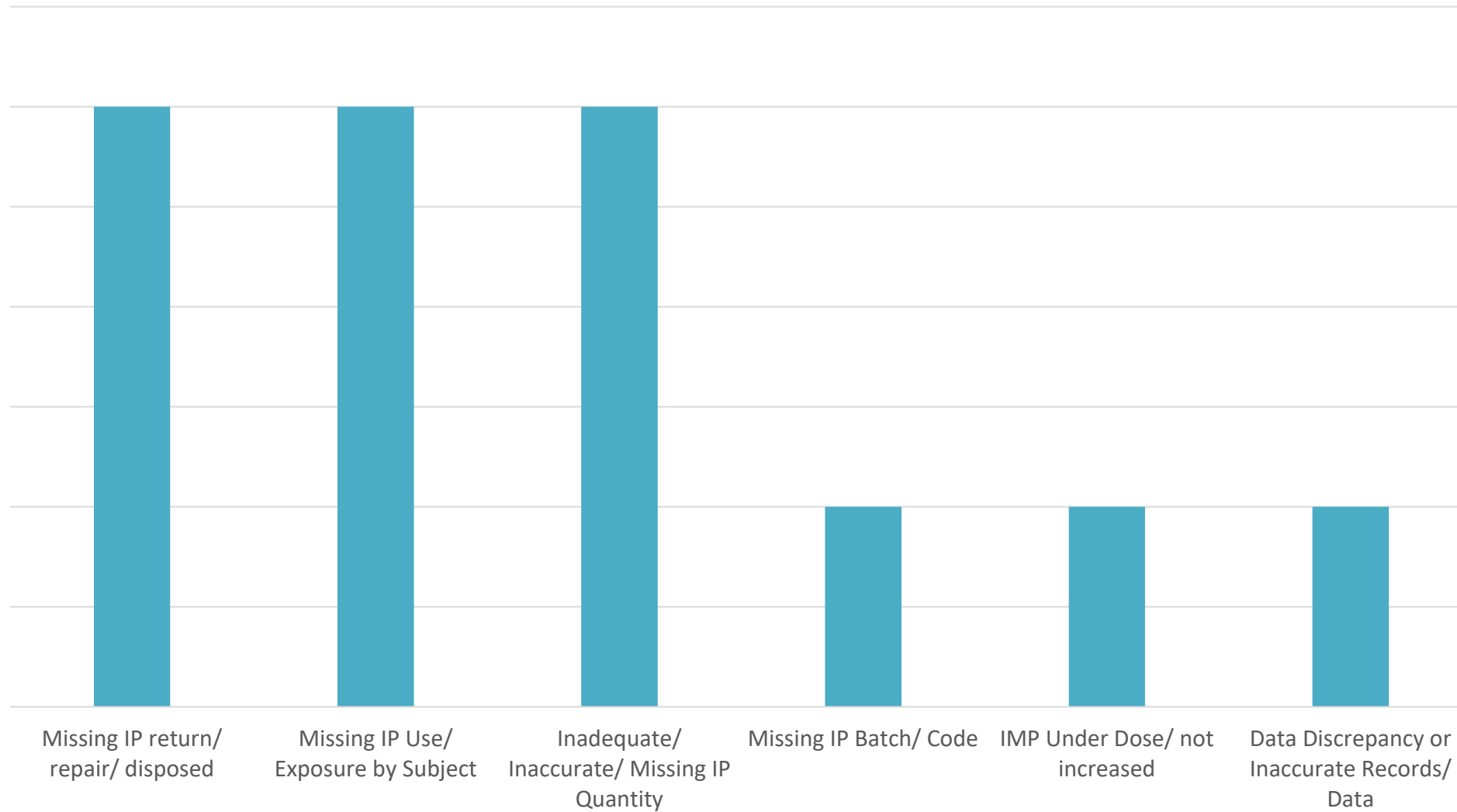
Accurate/Adequate Case Histories (312.62(b)/812.140(a)(3)) Theme Details



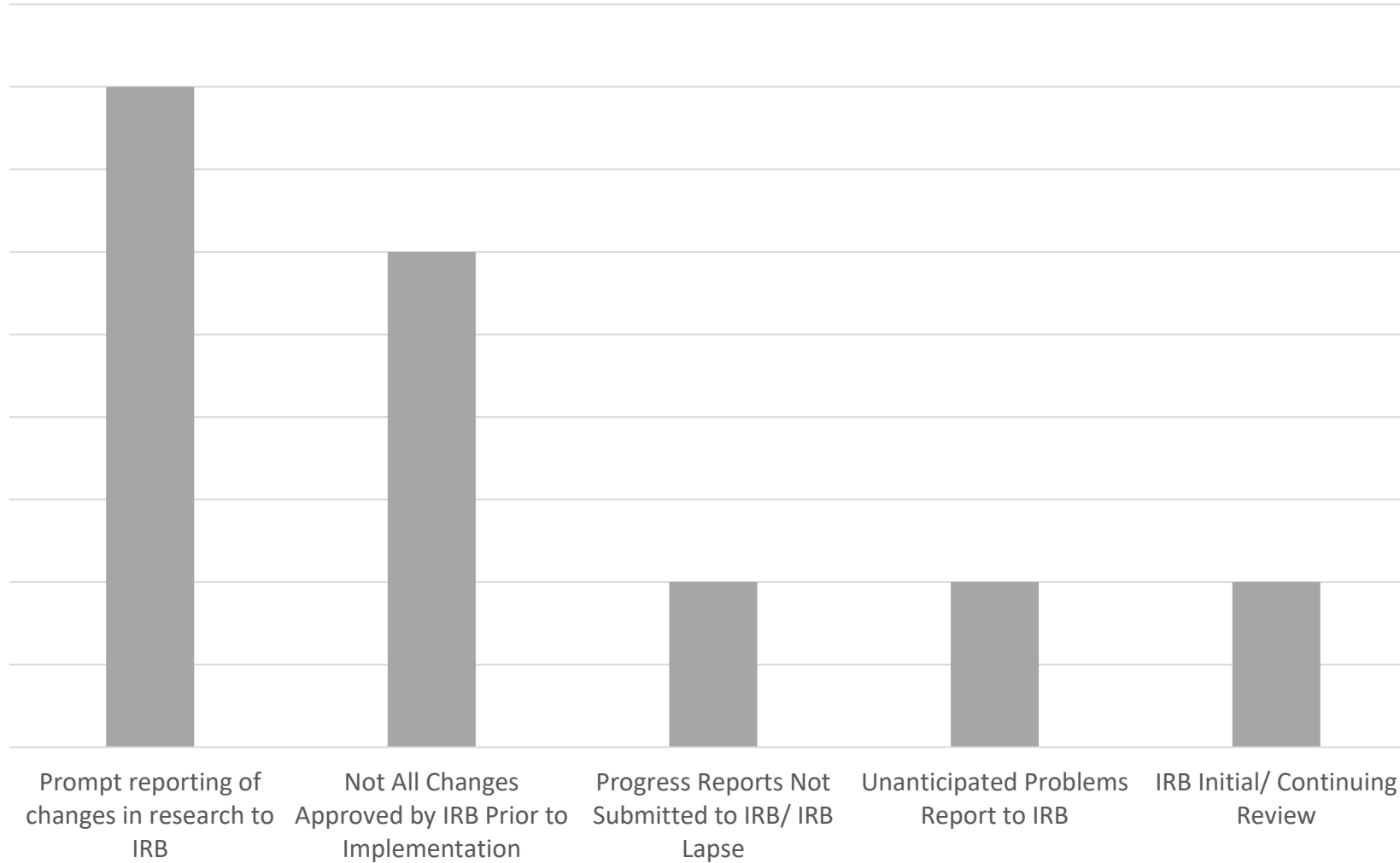
Failure to Report Adverse Events to Sponsor (312.64(b)) Theme Details



IP Accountability Records (312.62(a) / 812.140(a)(2)) Detail Themes



IRB (312.66) (812.150(a)(3)) Theme Details





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