



FY 2023 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)

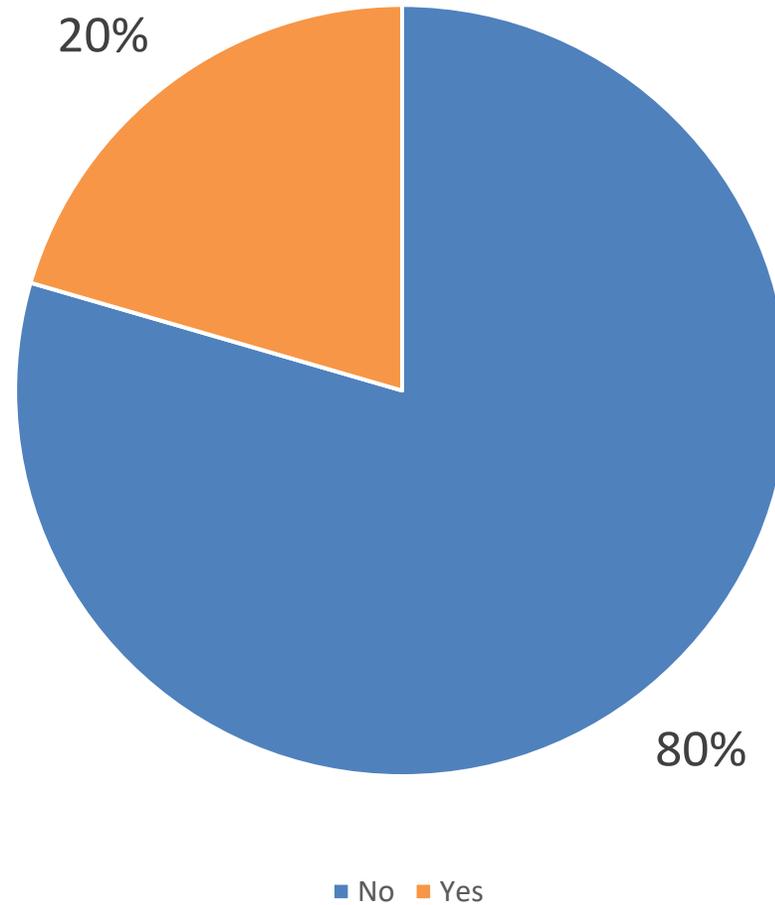
IRB (Institutional Review Board)

OOW (Out of Window)

SAE (Serious Adverse Event)

FY 2023 CI Firms Issued a 483

483 Issued



693 Inspections

No FDA 483 Issued – 551
FDA 483 Issued - 142

Themes Identified in FY 2023

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(d))

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

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

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

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

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

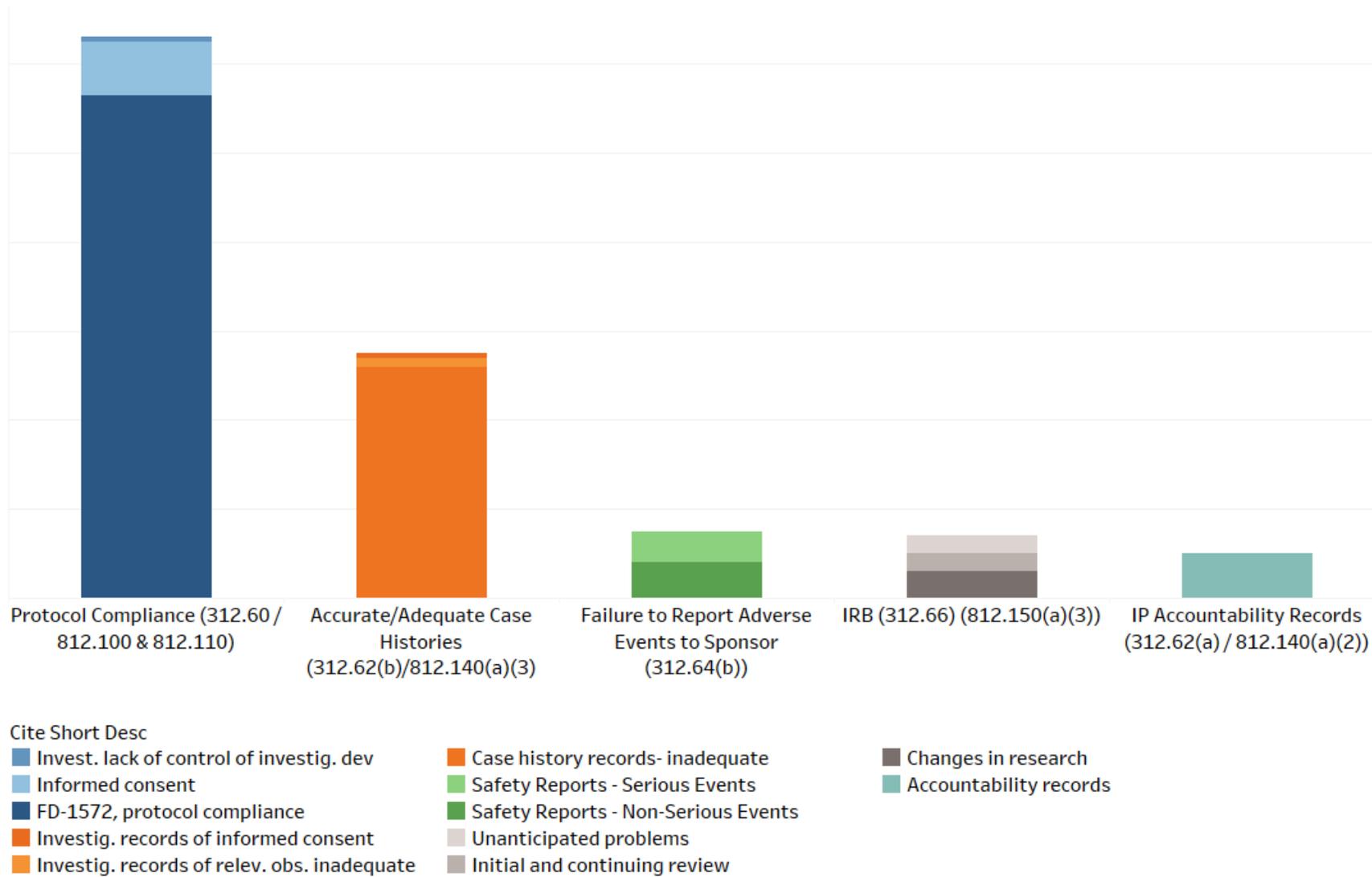
Assurance of IRB review (312.66 & 812.150(a)(3))

- Not All Changes Approved by IRB Prior to Implementation
- Unanticipated Problems Report to IRB
- IRB Initial/ Continuing Review

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

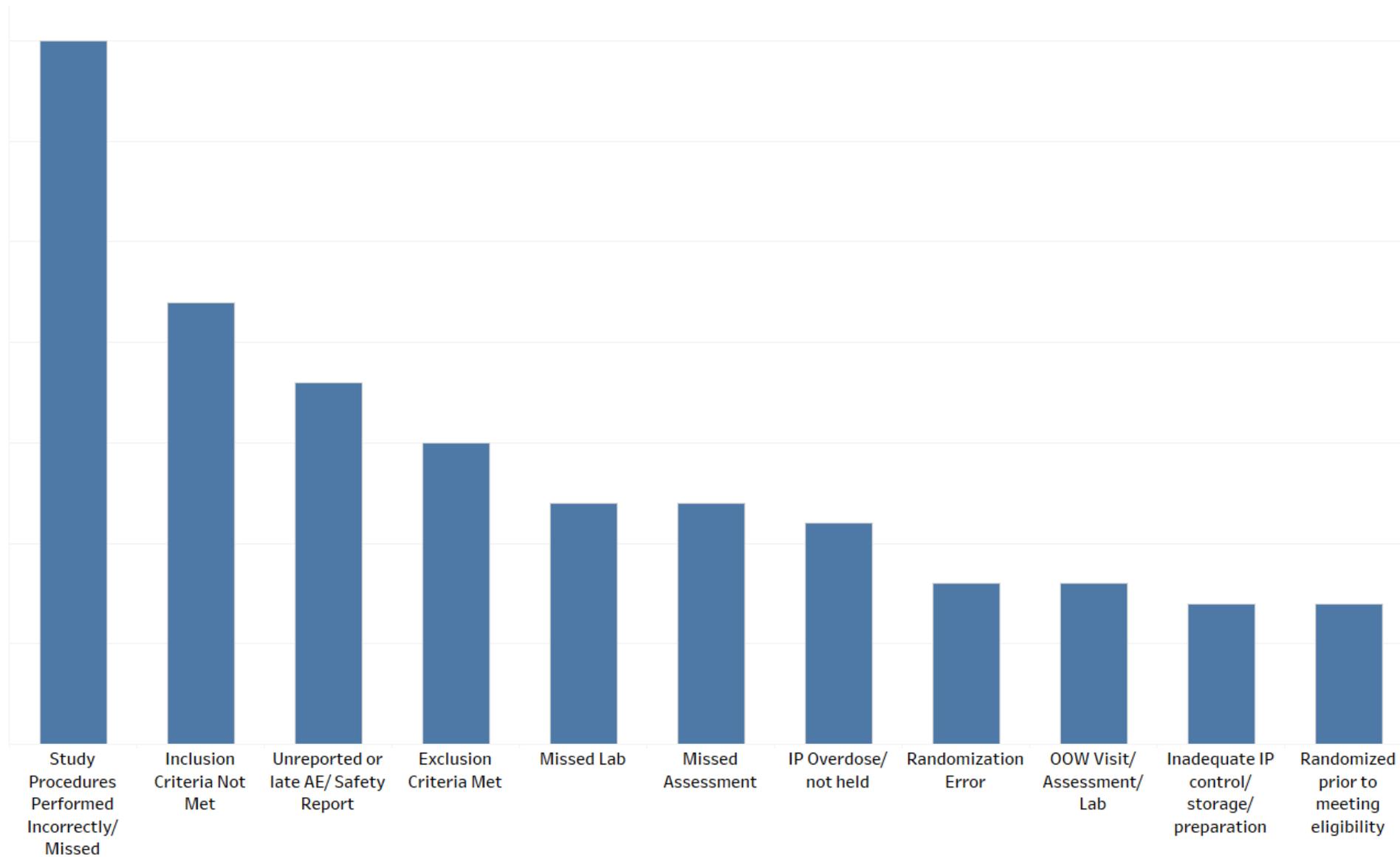
- Unreported or late AE/ Safety Report

FY 2023 Most Common Clinical Investigators 483 Short Cites by Theme

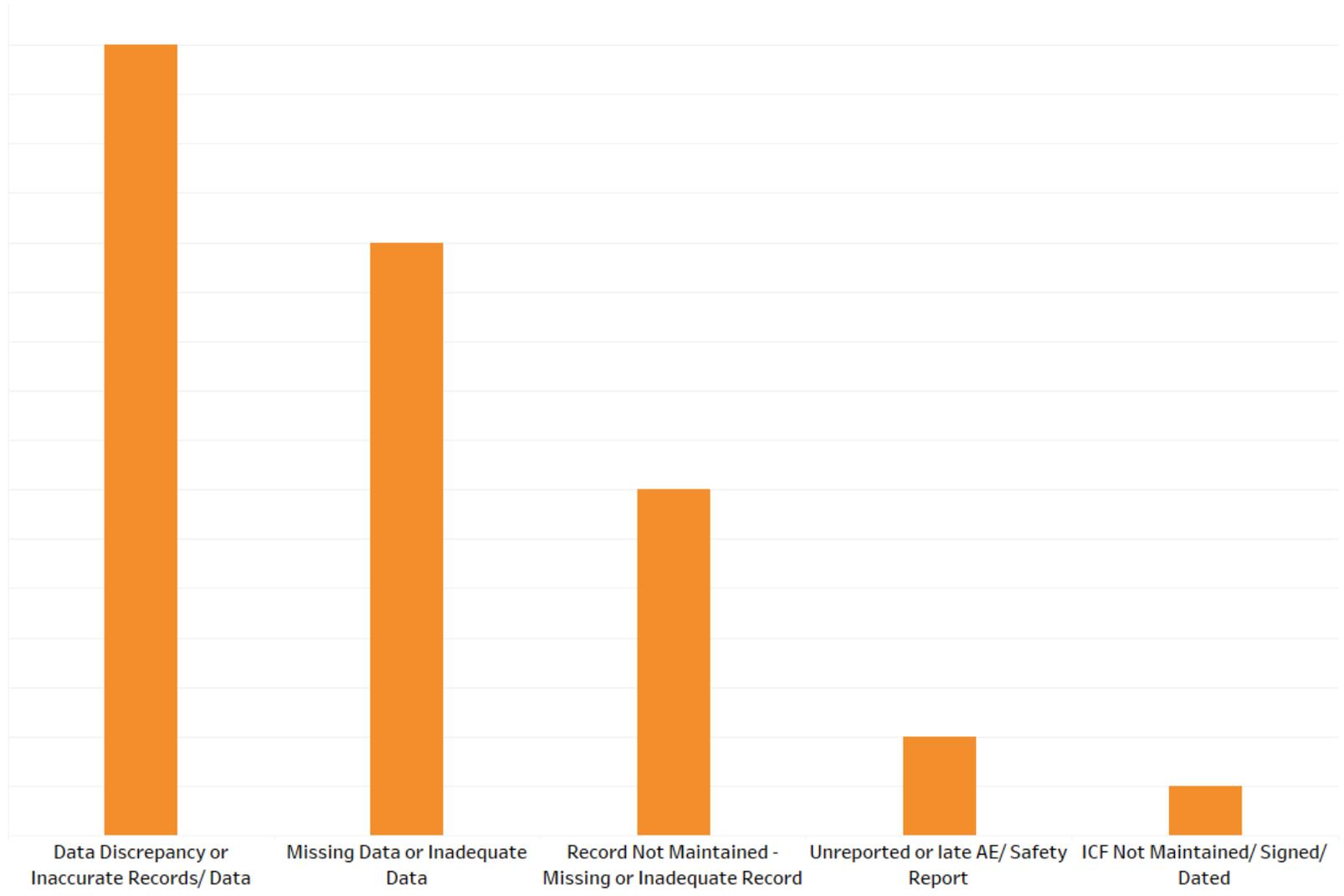


The chart above highlights only the top themes, it is not all inclusive

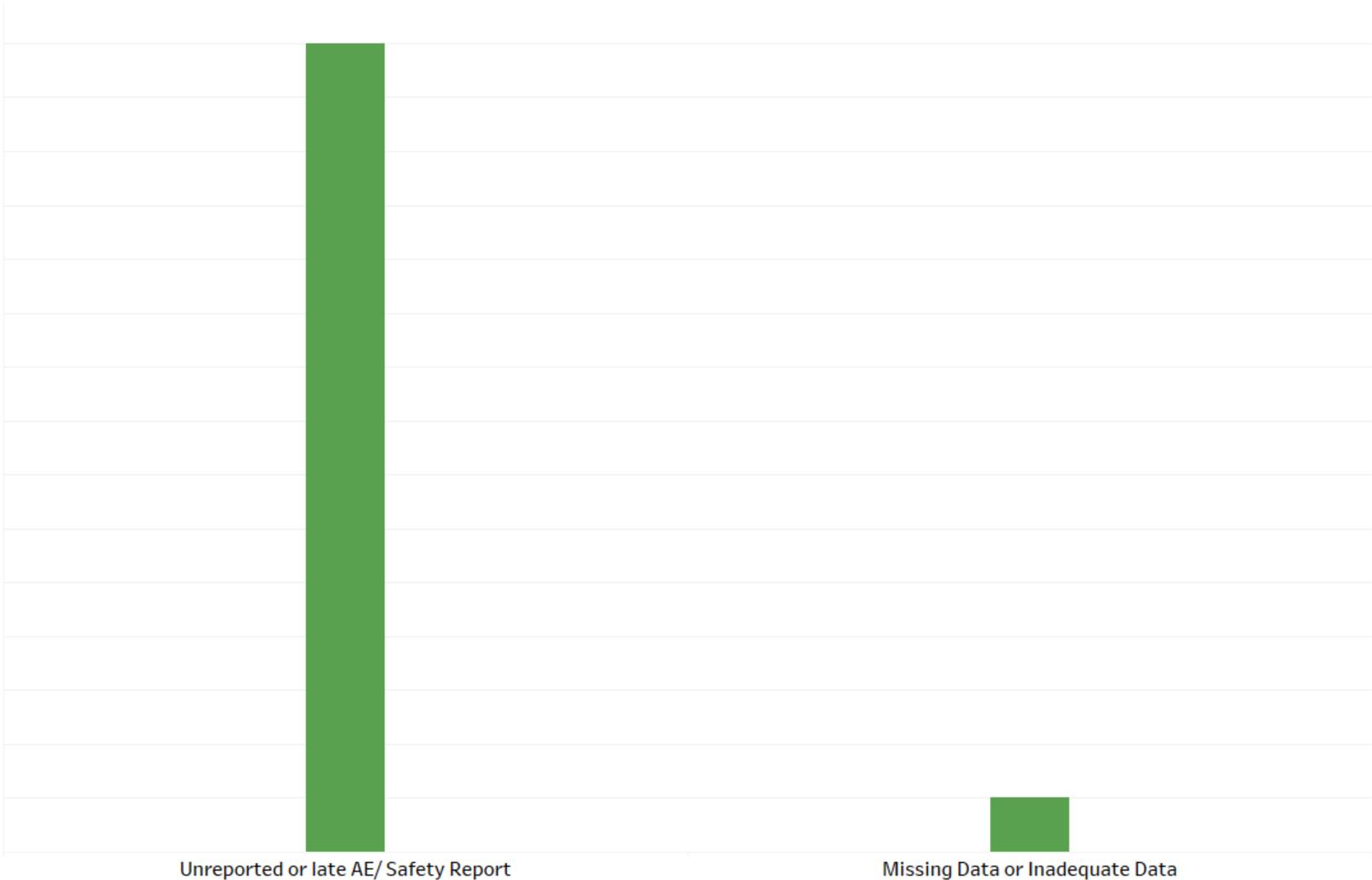
1572 - Protocol Compliance Theme Details



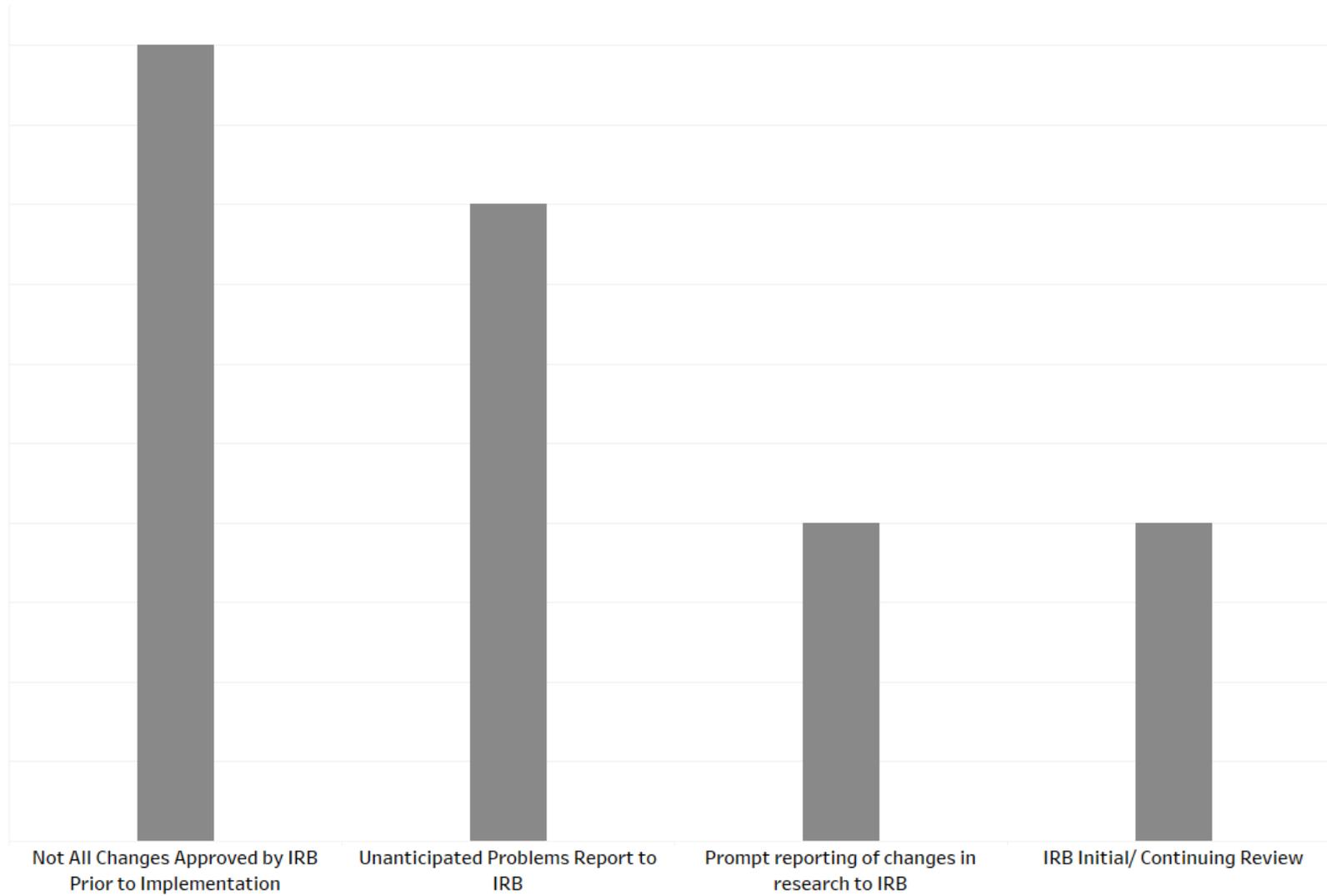
Accurate/ Adequate Case Histories (312.62(b)/812.140(a)(3) Theme Details



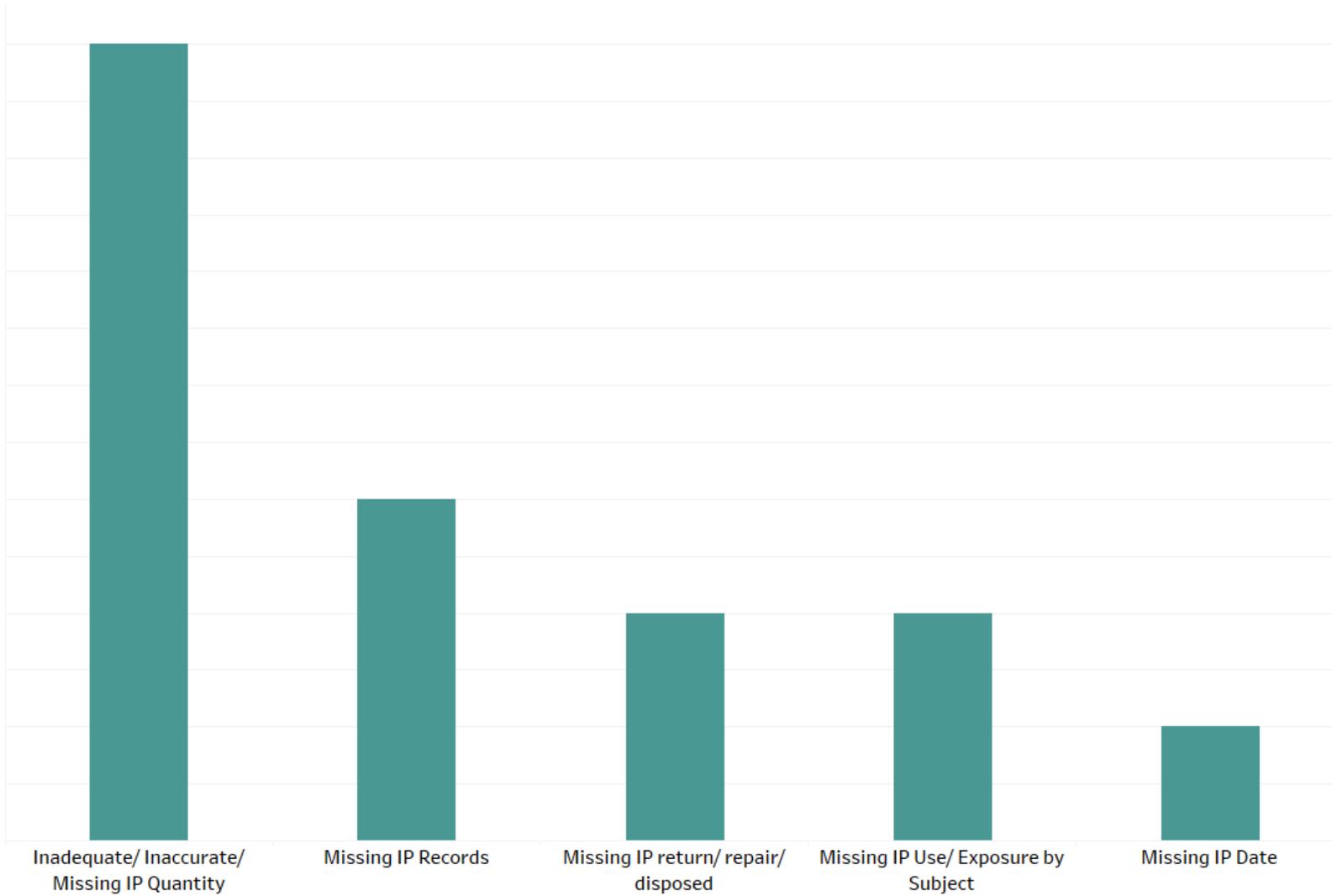
Failure to Report Adverse Events to Sponsor (312.64(b)) Theme Details



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



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





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