FY 2020 CI 483 OBSERVATION TRENDS

Acronyms

AE (Adverse Event)

CI (Clinical Investigator)

FDA (Food and Drug Administration)

ICF (Informed Consent Form)

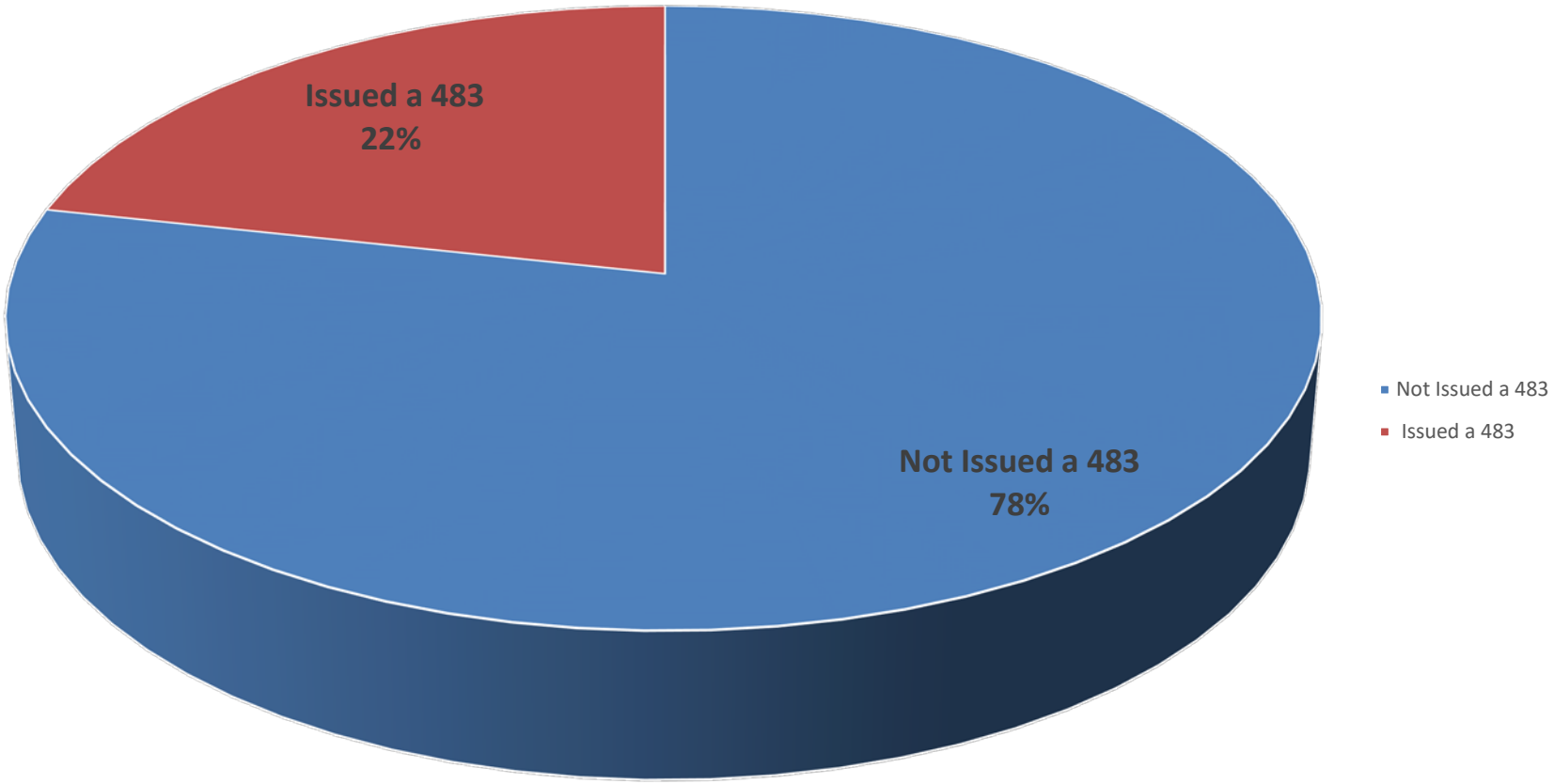
IP (Investigational Product)

IRB (Institutional Review Board)

OOW (Out of Window)

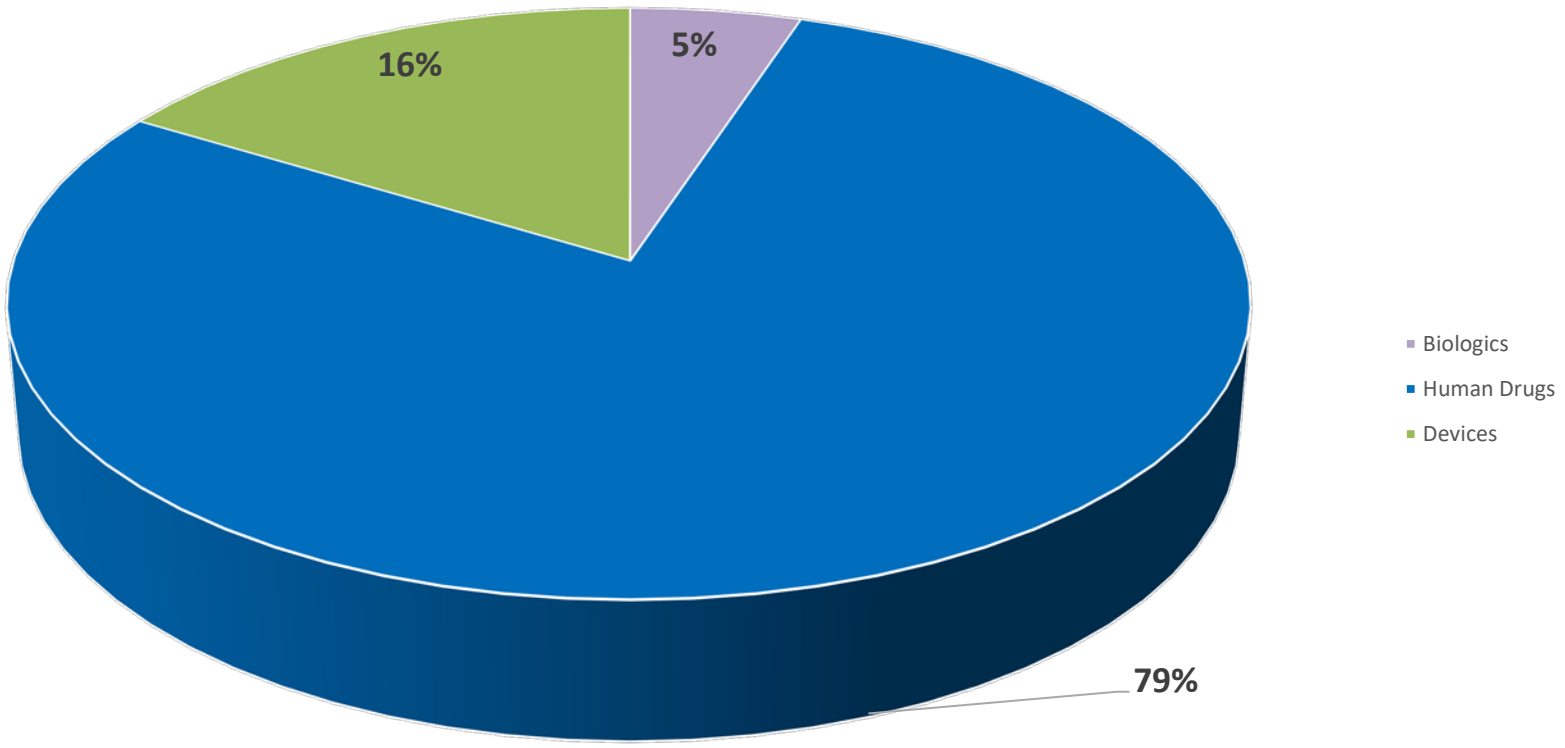
SAE (Serious Adverse Event)

FY 2020 Percentage of CIs Issued a 483



FY 20 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 10/19/2020

FY 2020 Percent of CIs Issued a 483 by Product Area

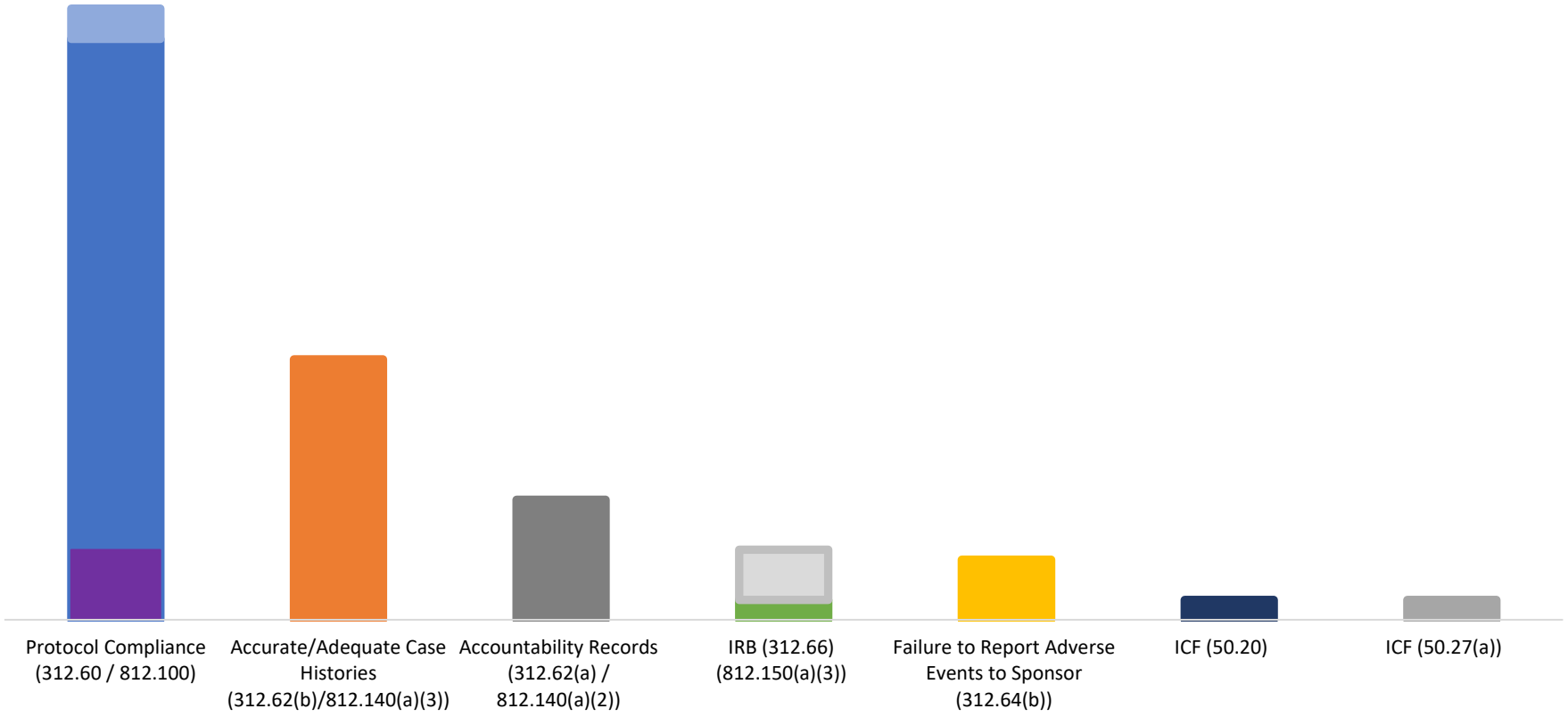


FY 20 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 10/19/2020

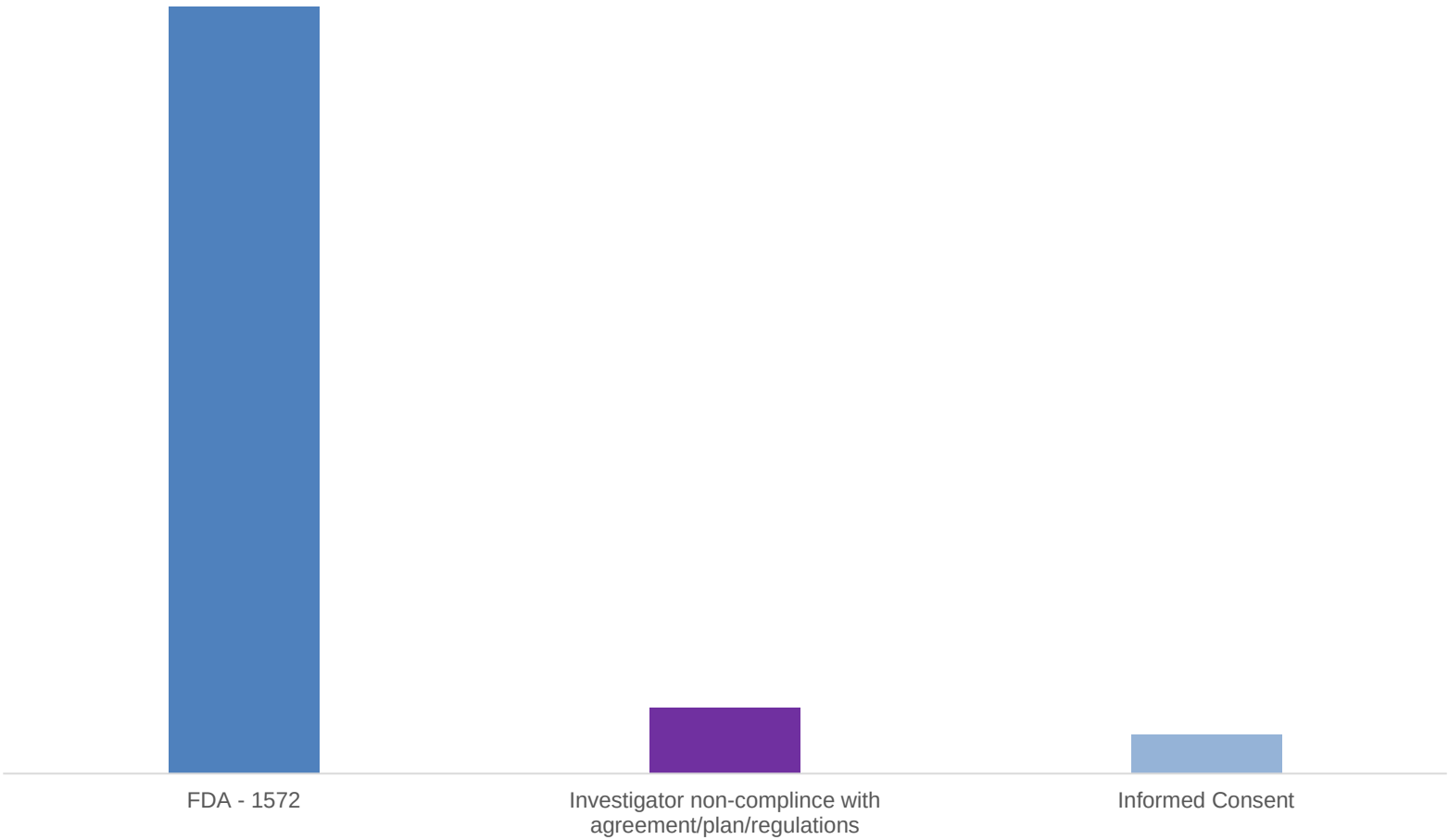
Themes

Themes Identified in FY 2020
Protocol Compliance (312.60 / 812.100)
Accurate/Adequate Case Histories (312.62(b)/812.140(a)(3))
Accountability Records (312.62(a) / 812.140(a)(2))
Institutional Review Board (312.66) (812.150(a)(3))
Failure to Report Adverse Events to Sponsor (312.64(b))
Informed Consent Form (50.20)
Informed Consent Form (50.27(a))

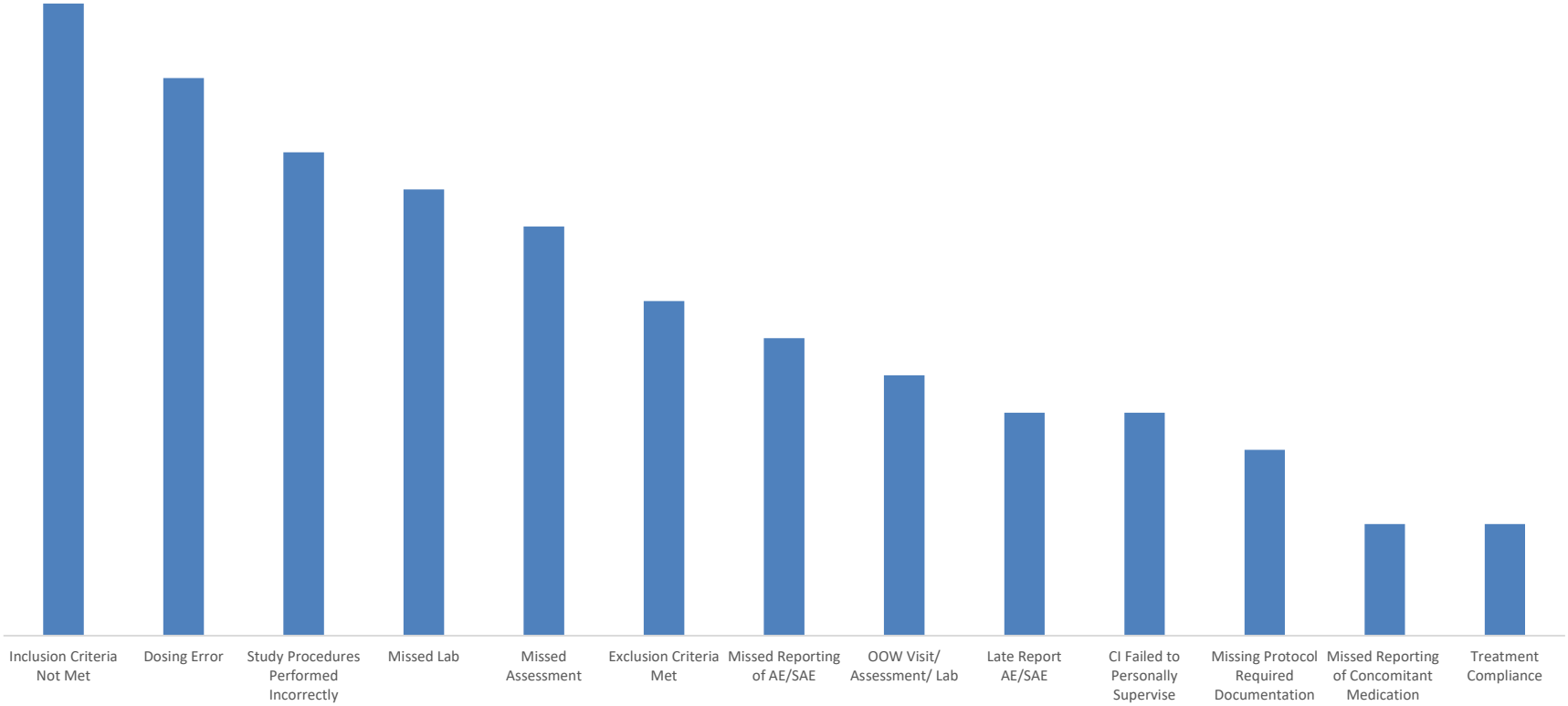
FY 2020 Clinical Investigator Short Cites by Reference Number and Theme



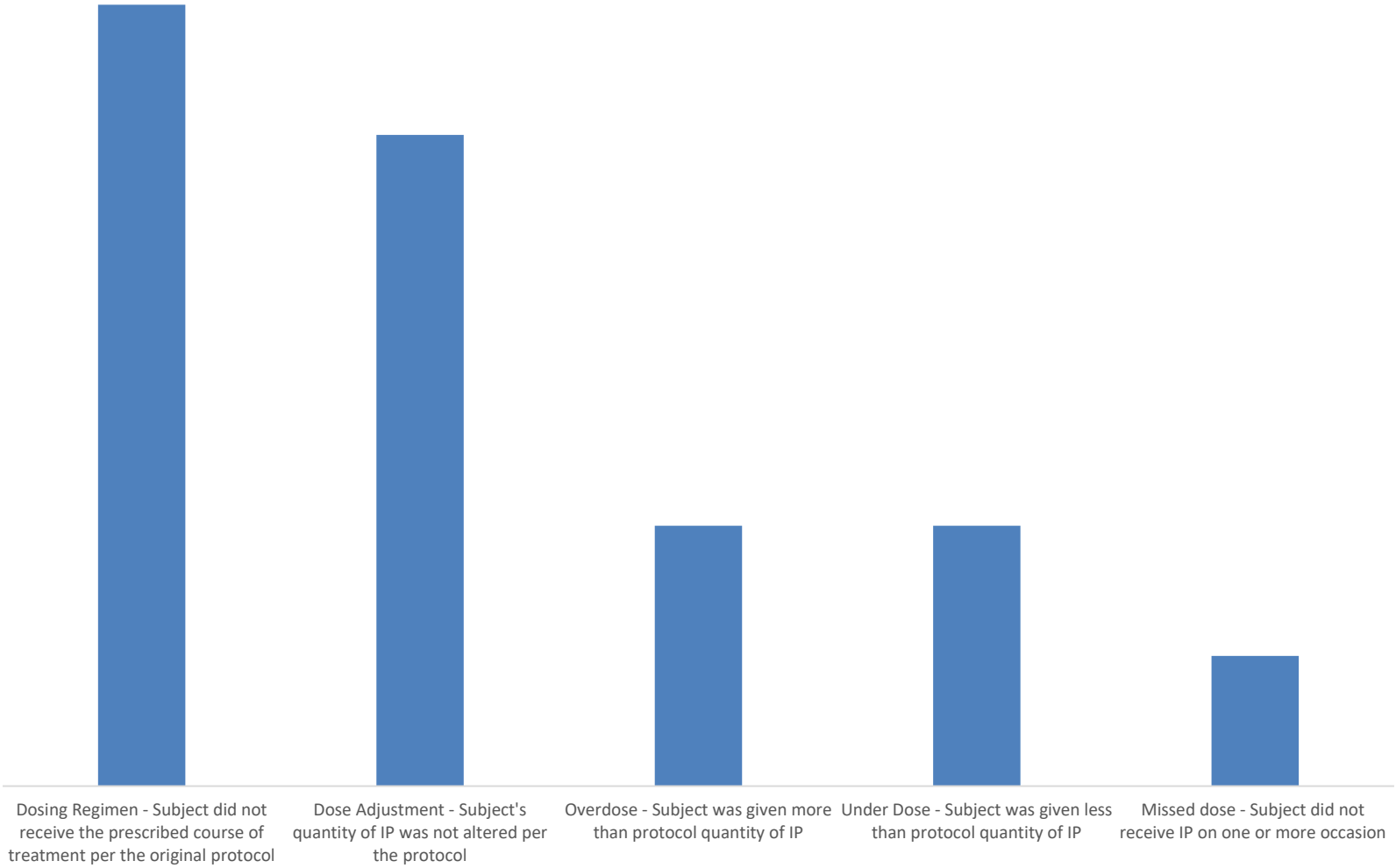
FY 2020 Protocol Compliance (312.60 / 812.100)



FY 2020 FDA 1572 (312.60)

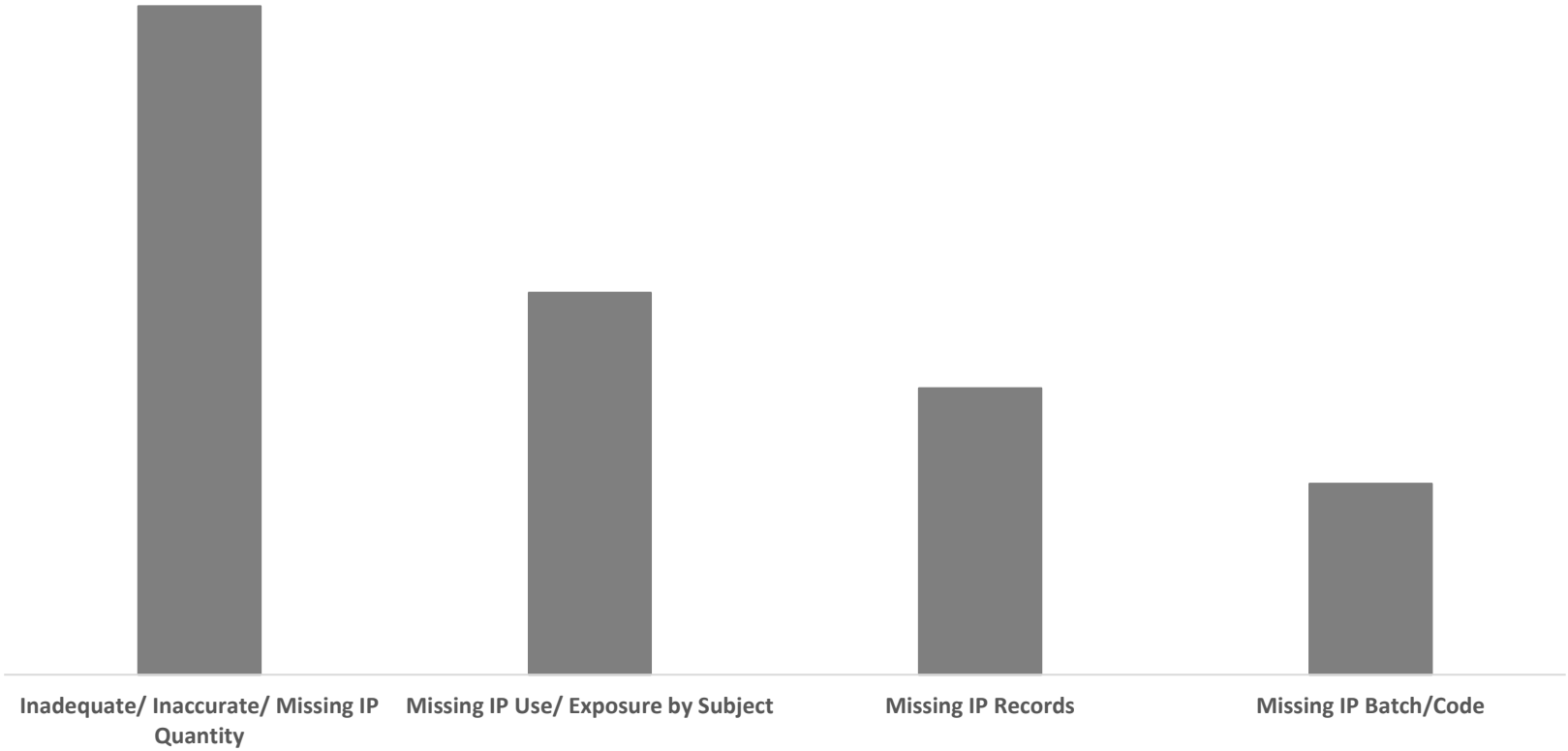


FY 2020 Breakdown of Dosing Error Type (312.60 / 812.100)

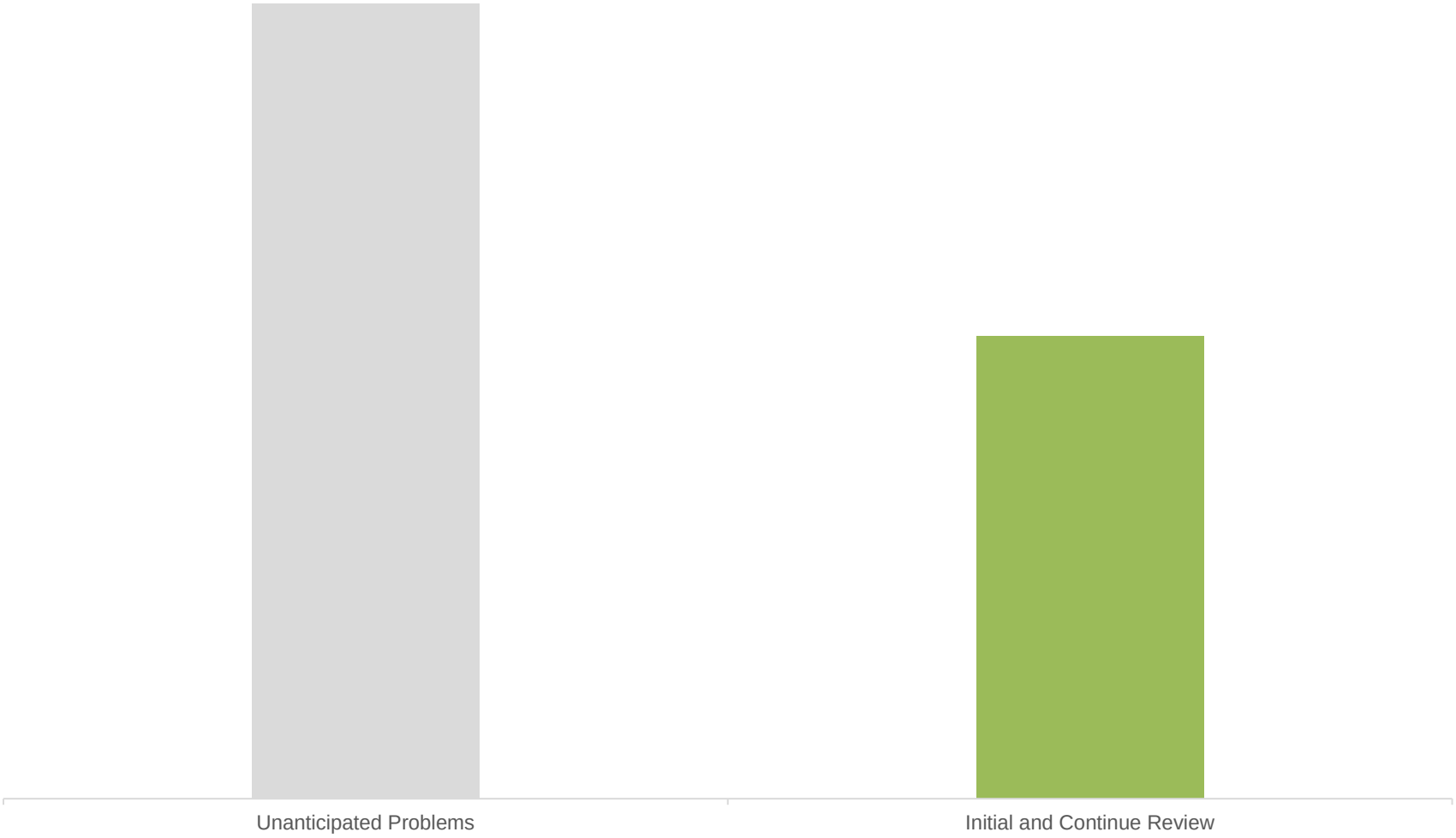


FY 2020 Breakdown of Accurate/Adequate Case Histories Under (312.62(b)/812.140(a)(3))

FY 2020 Breakdown of IP Accountability Records Under (312.62(a)/812.140(a)(2))



FY 2020 Cite Trends Under IRB (312.66) (812.150(a)(3))

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