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

- Issued a 483: 22%
- Not Issued a 483: 78%

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

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FY 2020 Percent of CIs Issued a 483 by Product Area

- Biologics: 79%
- Human Drugs: 5%
- Devices: 16%

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

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## 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

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))

IRB (312.66) (812.150(a)(3))

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

ICF (50.20)

ICF (50.27(a))
FY 2020 Protocol Compliance (312.60 / 812.100)

- FDA - 1572
- Investigator non-compliance with agreement/plan/regulations
- Informed Consent

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Inclusion Criteria Not Met
Dosing Error
Study Procedures Performed Incorrectly
Missed Lab
Missed Assessment
Exclusion Criteria Met
Missed Reporting of AE/SAE
OOW Visit/Assessment/Lab
Late Report AE/SAE
CI Failed to Personally Supervise
Missing Protocol Required Documentation
Missed Reporting of Concomitant Medication
Treatment Compliance
FY 2020 Breakdown of Dosing Error Type (312.60 / 812.100)

- Dosing Regimen - Subject did not receive the prescribed course of treatment per the original protocol
- Dose Adjustment - Subject’s quantity of IP was not altered per the protocol
- Overdose - Subject was given more than protocol quantity of IP
- Under Dose - Subject was given less than protocol quantity of IP
- Missed dose - Subject did not receive IP on one or more occasion
FY 2020 Breakdown of Accurate/Adequate Case Histories Under (312.62(b)/812.140(a)(3))

- Data Discrepancy or Inaccurate Records/Data
- Record Not Maintained - Missing Record or Inadequate Record
- Missing Data or Inadequate Data
- ICF Not Maintained/ Signed/ Dated
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))

Unanticipated Problems

Initial and Continue Review