FY 2022 SPONSOR FDA 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

FDA (Food and Drug Administration)

ICF (Informed Consent Form)

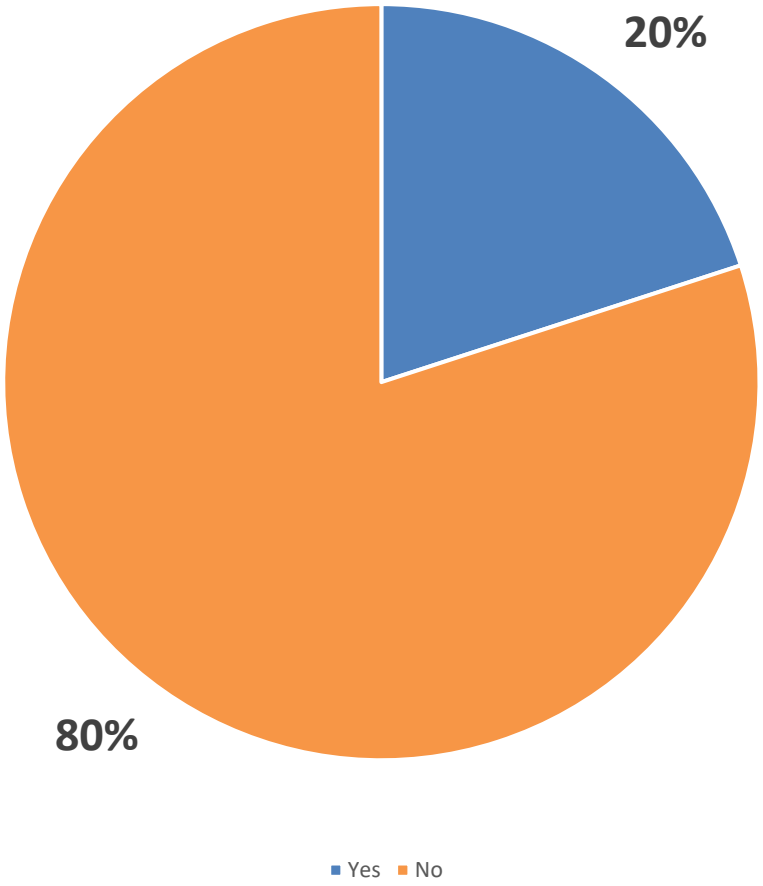
IND (Investigational New Drug)

IRB (Institutional Review Board)

PD (Protocol Deviation)

IDE (Investigational Device Exemption)

FY 2022 Sponsor Firms Issued a 483



Trends and Themes Identified in FY 2022 Sponsor Data

- Inadequate Case Histories
- Inadequate Monitoring
- Annual Report (IDE/IND) not Submitted
- Failure to Secure Compliance
- Failure to Submit an IND to FDA
- Inadequate IP Accountability

Details for Themes

Inadequate Case Histories

- No audit trails on electronic records
- Raw data not verified with electronic record submissions
- Eligibility cannot be verified
- Subject disposition could not be verified

Inadequate Monitoring

- No monitoring of safety or protocol compliance
- Monitoring plans not followed

Details for Themes

Annual Report (IDE/IND) not Submitted

- IND/IDE annual reporting requirements were not followed
- annual progress report to the FDA within 60 days of anniversary of IND timeframe not met

Failure to Secure Compliance

- Investigator sites used unapproved ICFs
- Subjects remained on study after meeting exclusion criteria
- Study visit timeframes not met

Details for Themes

Failure to Submit an IND to FDA

- Clinical investigations subject to IND requirements were conducted prior to FDA submission
- Sponsor-Investigators were the only firms cited
- Subjects were enrolled at CI sites prior to submitting an IND to the FDA

Inadequate IP Accountability

- Detailed records documenting shipment, receipt, and disposition of investigational product were not maintained
- Dosing amount and date were not documented

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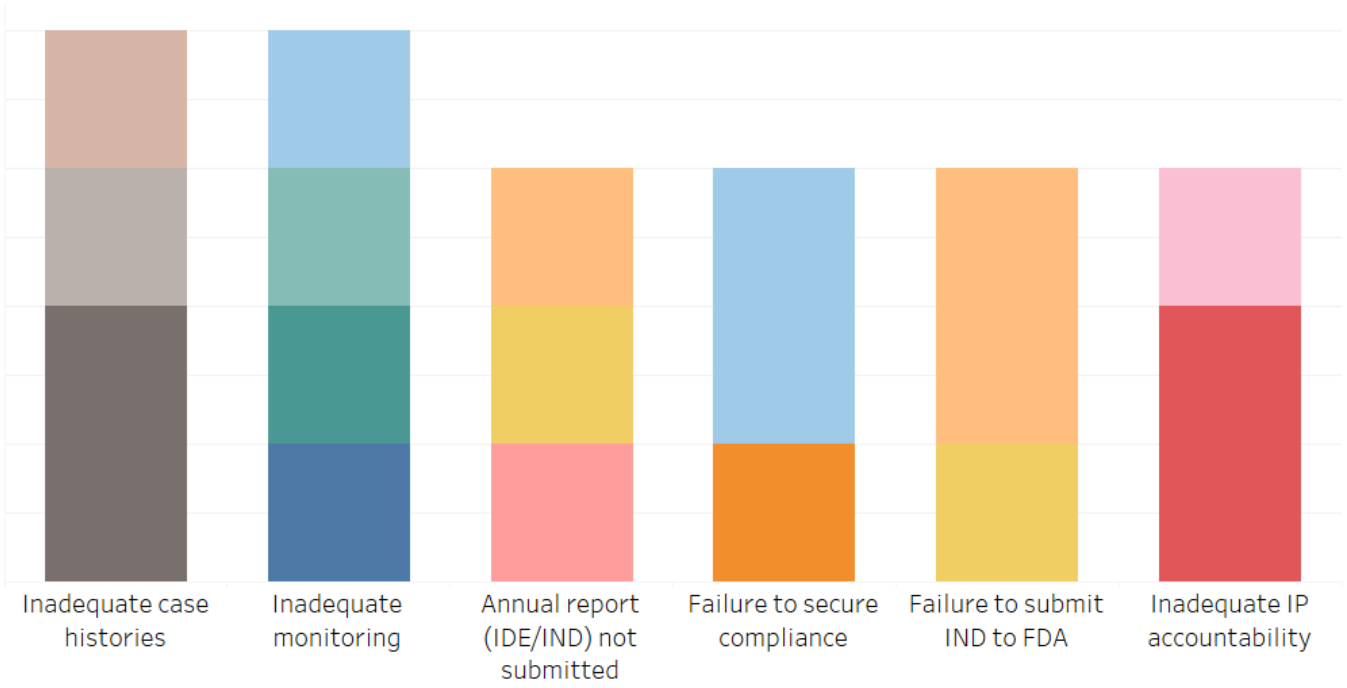
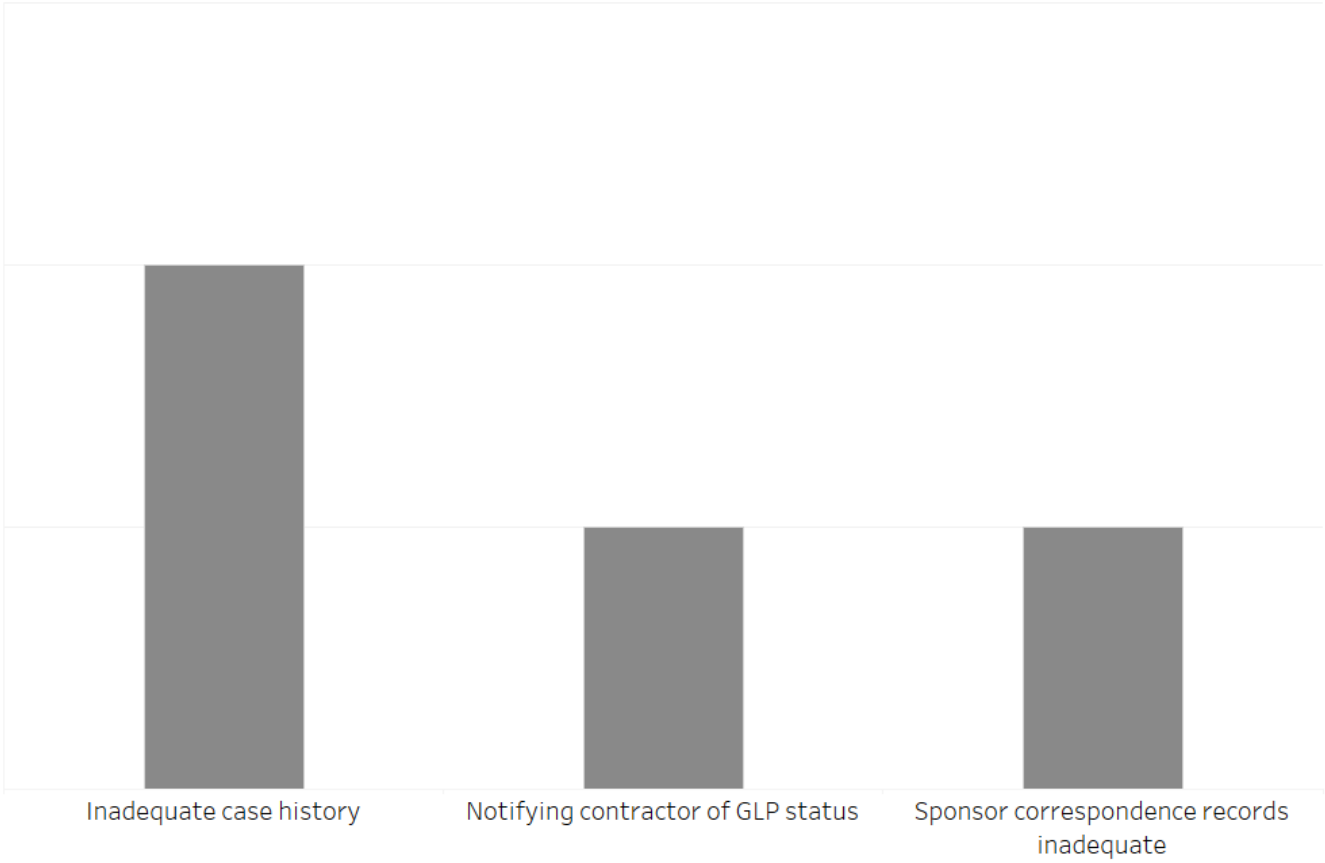
FY 2022 Sponsor 483 Cite Trends by Reference Number



Ref Num

- 22 CFR 58.10
- 21 CFR 812.40 (b) (1)
- 21 CFR 312.62(b)
- 21 CFR 312.50
- 21 CFR 812.40
- 21 CFR 812.140(b)(2)
- 21 CFR 312.56(a)
- 21 CFR 312.20(a)
- 21 CFR 812.2(b)
- 21 CFR 312.20(b)
- 21 CFR 312.56(c)
- 21 CFR 312.59
- 21 CFR 312.62(a)

Inadequate Case History Details



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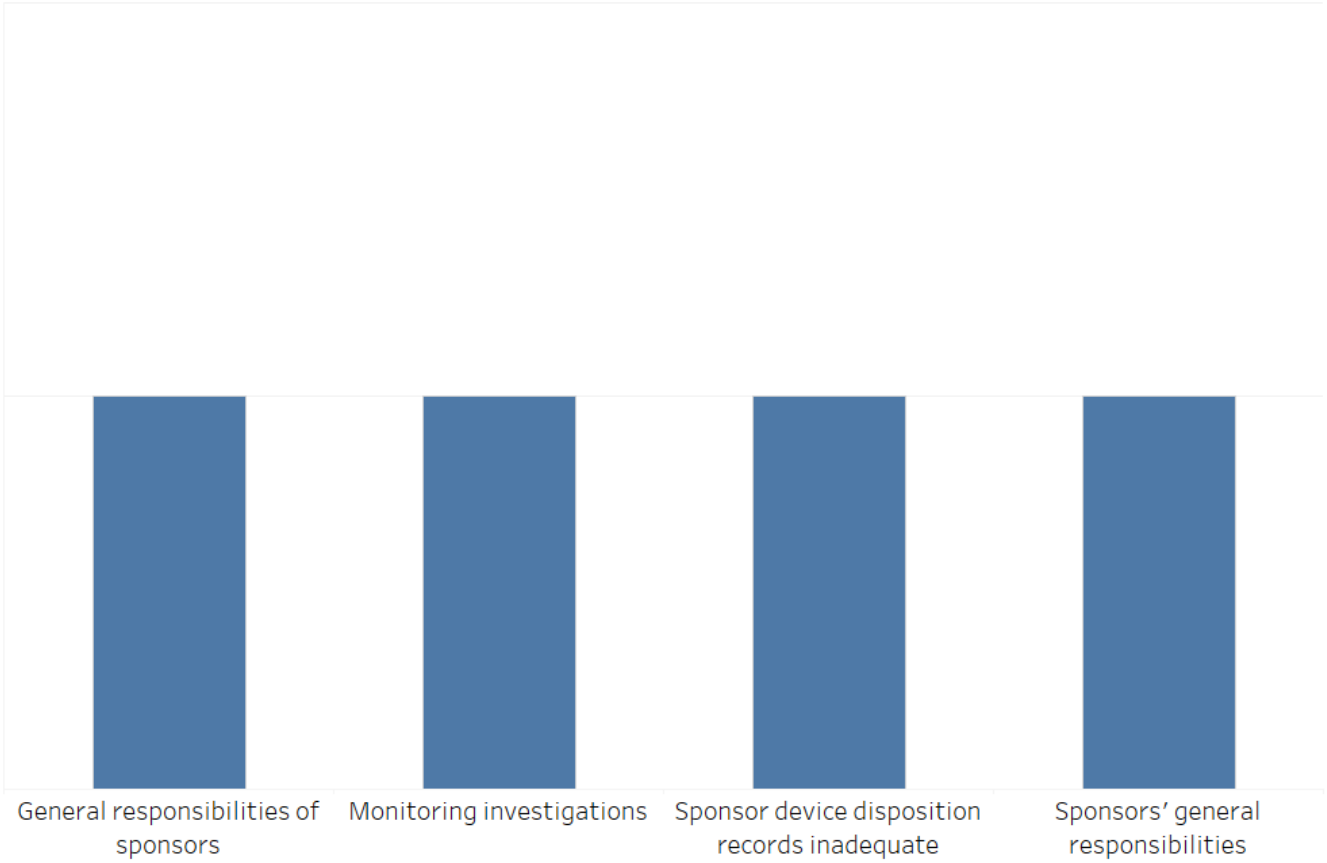
Inadequate Monitoring Details



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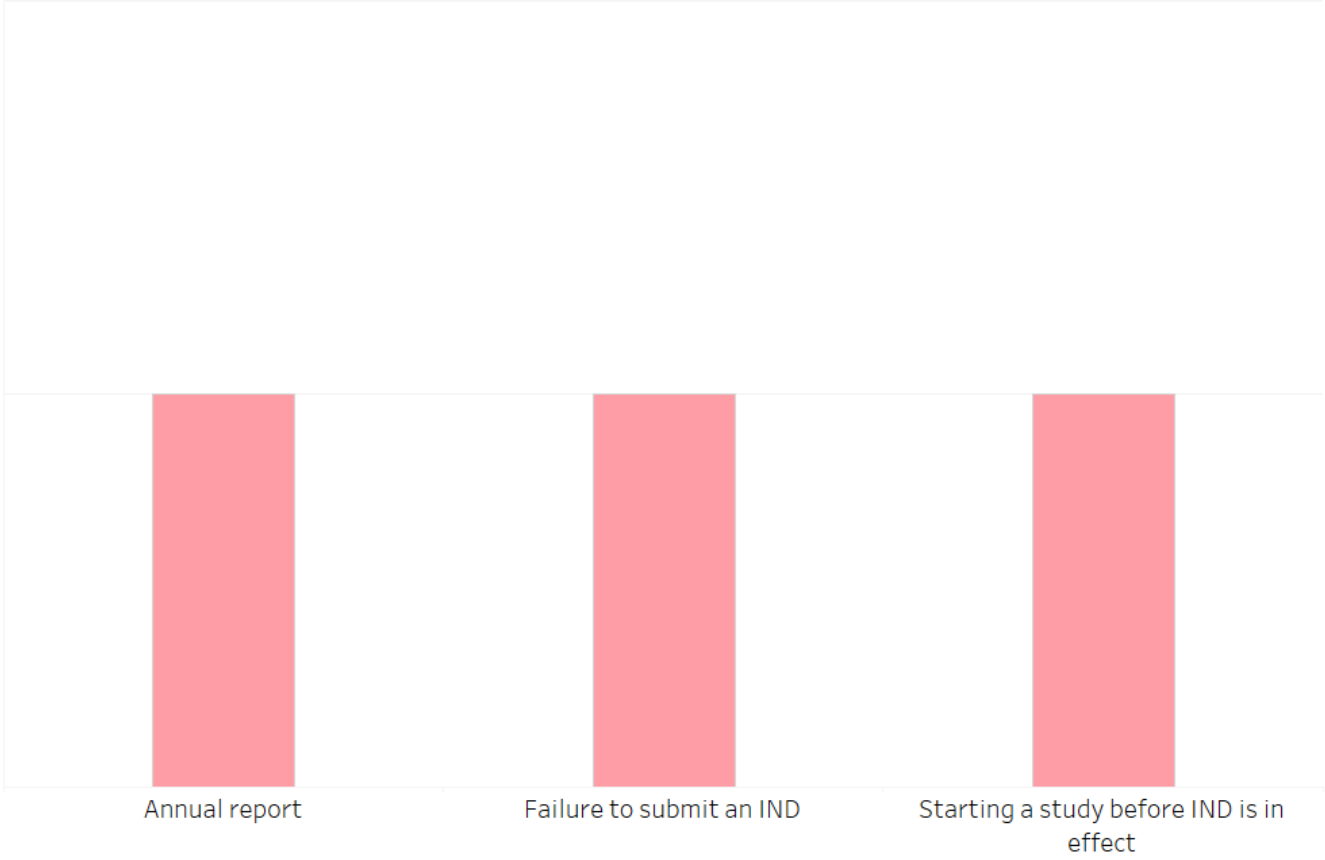
Annual Report (IDE/IND) not Submitted Details



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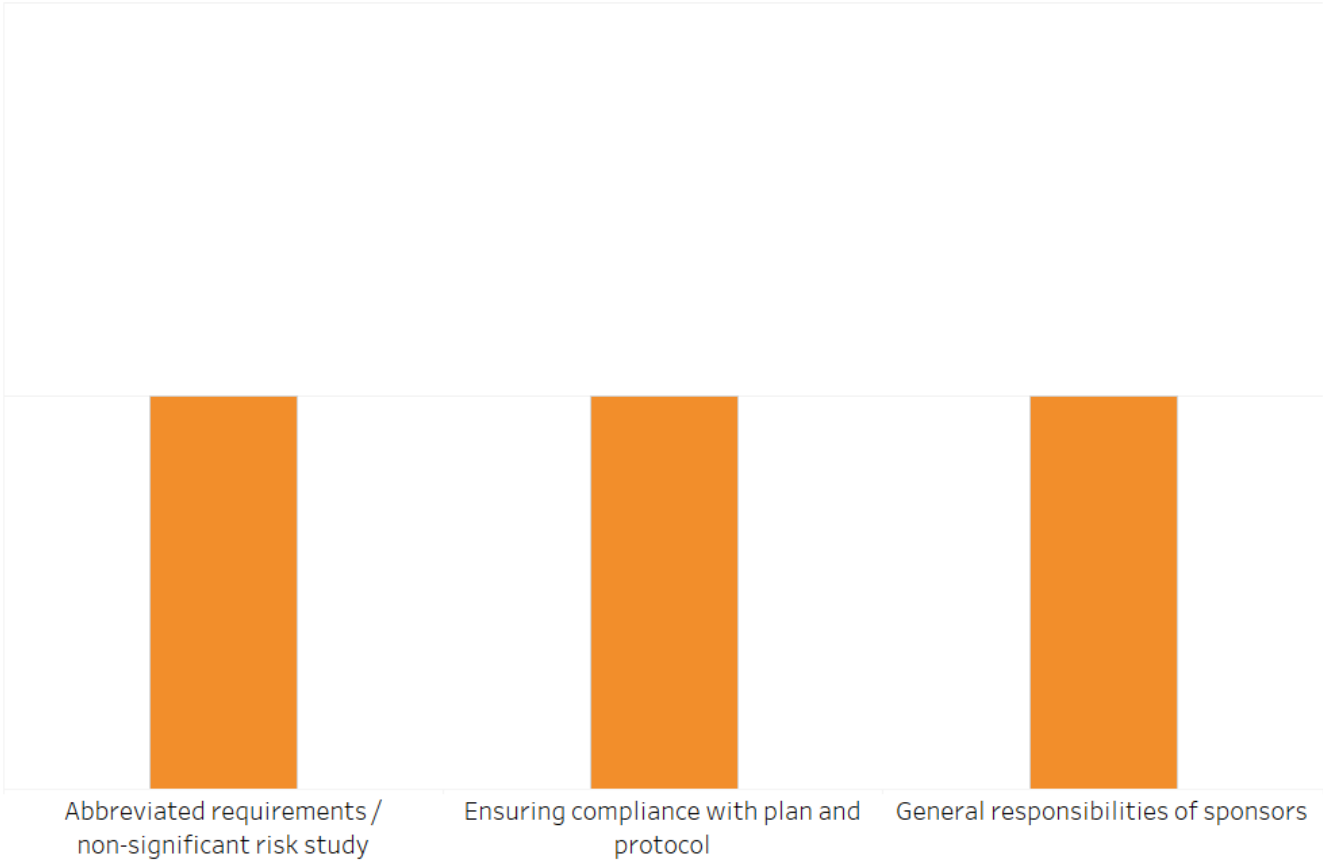
Failure to Secure Compliance Details



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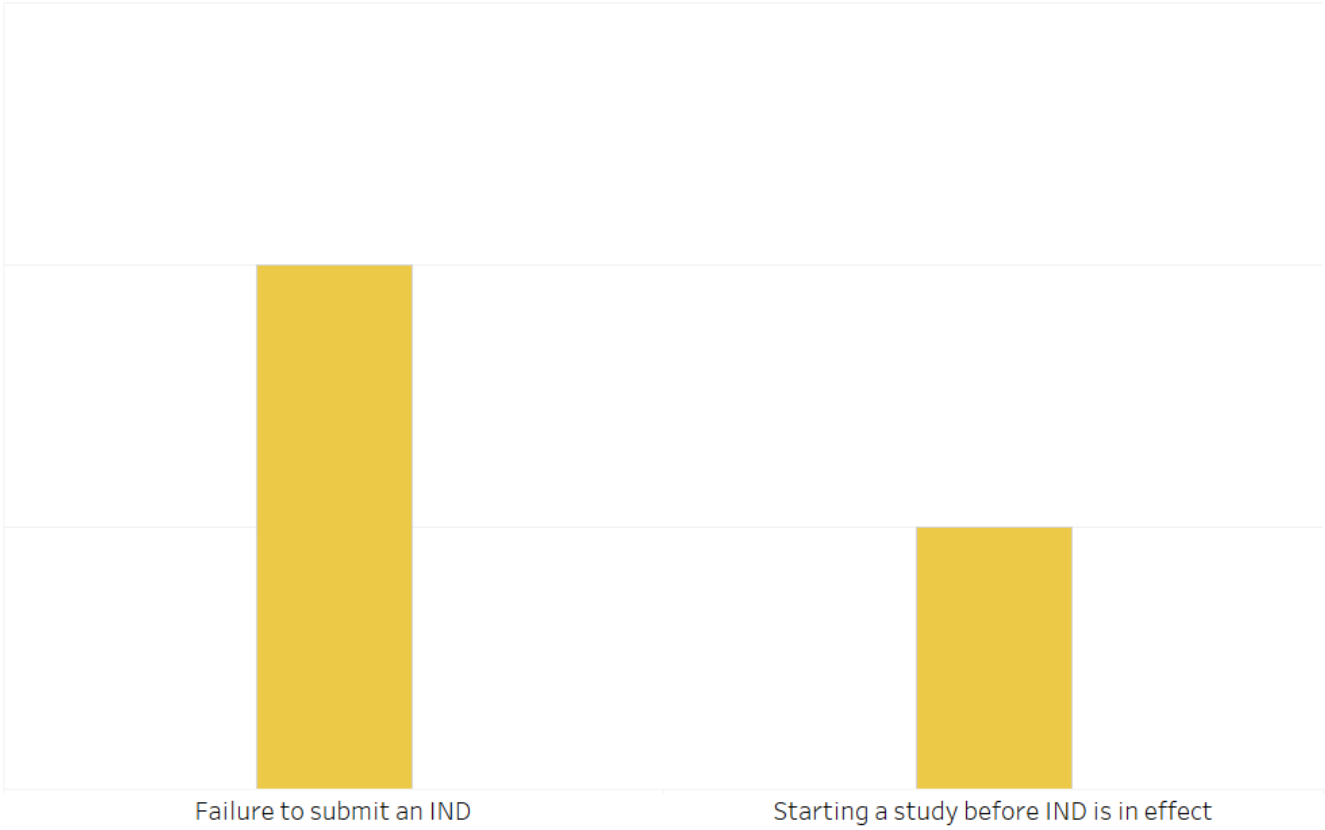
Failure to Submit an IND to FDA Details



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