Office of Scientific Investigations & Office of Study Integrity and Surveillance

CDER BIMO Metrics

Fiscal Year 2023

(Oct 1, 2022 – Sep 30, 2023)

[Data Updated: Feb 22, 2024]

Background

- CDER Bioresearch Monitoring (BIMO) inspections and data audits are conducted to monitor all aspects of the conduct and reporting of FDA-regulated research. The goals of the BIMO program are:
  - To protect the rights, safety, and welfare of human research subjects
  - To verify the accuracy, reliability, and integrity of clinical and nonclinical trial data submitted to FDA
  - To assess compliance with FDA's requirements governing the conduct of clinical and nonclinical trials, Risk Evaluation and Mitigation Strategies, Postmarketing Adverse Drug Experience reporting, and required postmarket studies.

- Annual inspection metrics are provided for the compliance programs overseen by the Office of Scientific Investigations (OSI) and the Office of Study Integrity and Surveillance (OSIS) in FDA’s Center for Drug Evaluation and Research (CDER).

- Most CDER inspection activities are issued/directed by OSI and OSIS and conducted by FDA’s Office of Regulatory Affairs (ORA).

Remote Regulatory Assessments

- Remote Regulatory Assessments (RRAs) were implemented during the COVID-19 public health emergency when FDA's ability to conduct on-site inspections was limited. FDA continues to use RRAs in its mission to protect public health, oversee regulated industry, and ensure all types of regulated products comply with FDA requirements.

- A Remote Regulatory Assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs are a tool FDA may use to support regulatory decisions and oversight activities.

Metrics Overview

- Data source
  - Data obtained from FDA's Complis (Compliance Program Information System) database on Feb 22, 2024 and other data sources as noted.

- Data conventions
  - Metrics are based on key events during the inspection process, including issuing an inspection assignment, starting an inspection, or issuing post-inspectional correspondence to the inspected party.

  - Differences in inspection counts when comparing data across varying sources (e.g., Office of Regulatory Affairs' eNspect & FACTS databases) may be the result of different tallying methods of inspection-related data.

- Time period-based metrics are presented for the last 6 fiscal years. Requests for prior time periods may be submitted to the FDA under the Freedom of Information Act (FOIA).

- Reference to Inspection Activity includes on-site inspections and RRAs.

For further information, please call 301-796-3150.

Metrics Terms

Organizations and Programs

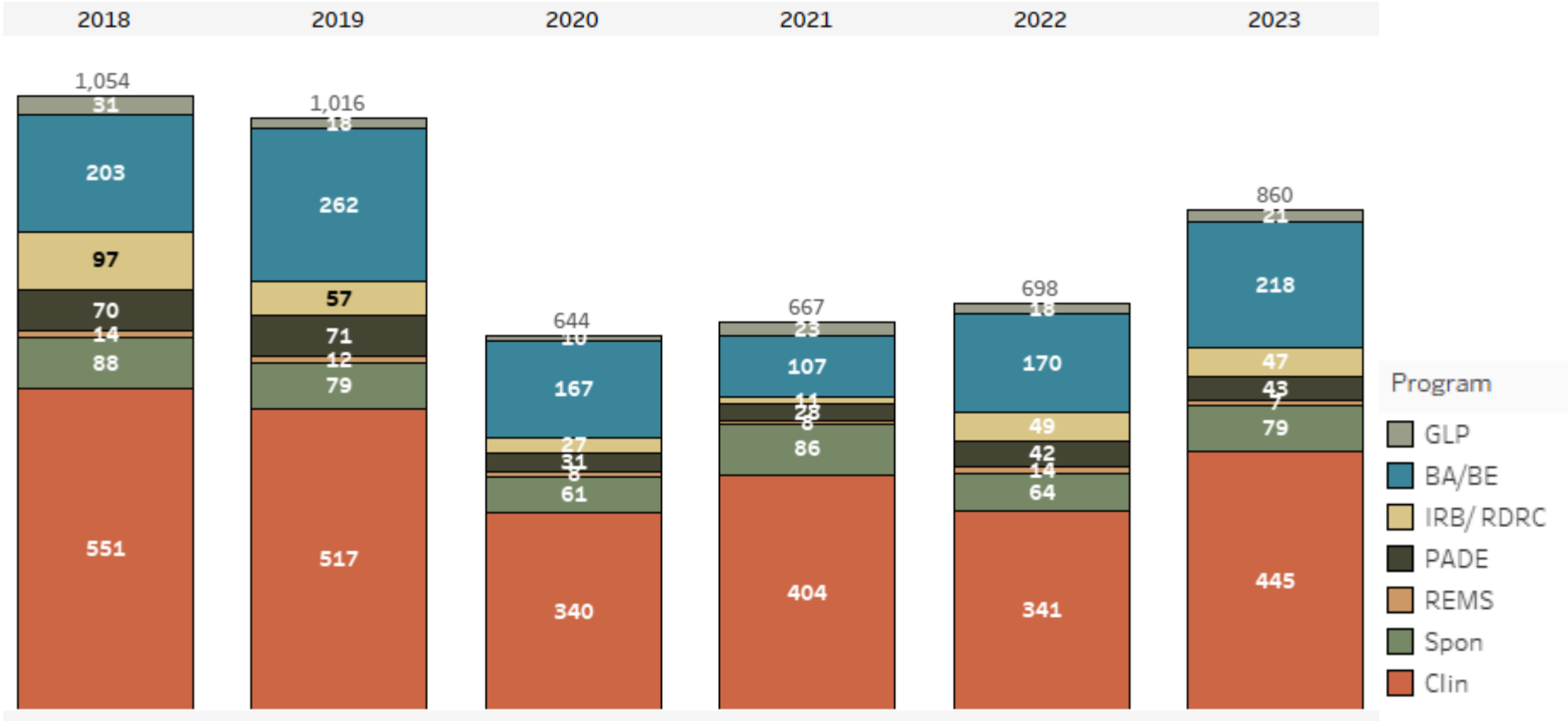
- AR: Animal Rule
- BA/BE: Bioavailability/Bioequivalence
- Clin: Clinical Investigator
- CRO: Contract Research Organization
- GCP: Good Clinical Practice
- GLP: Good Laboratory Practice
- IRB: Institutional Review Board
- PADE: Postmarketing Adverse Drug Experience
- PMR: Postmarketing Requirements
- RDRC: Radioactive Drug Research Committee
- REMS: Risk Evaluation and Mitigation Strategies
- S-I: Sponsor-Investigator

Other Terms

- NAI: No Action Indicated
- NIDPOE: Notice of Initiation of Disqualification Proceedings and Opportunity to Explain
- NOOH: Notice of Opportunity for Hearing
- OAI: Official Action Indicated
- RRA: Remote Regulatory Assessment
- VAI: Voluntary Action Indicated

Inspection Activities Overseen by OSI/OSIS

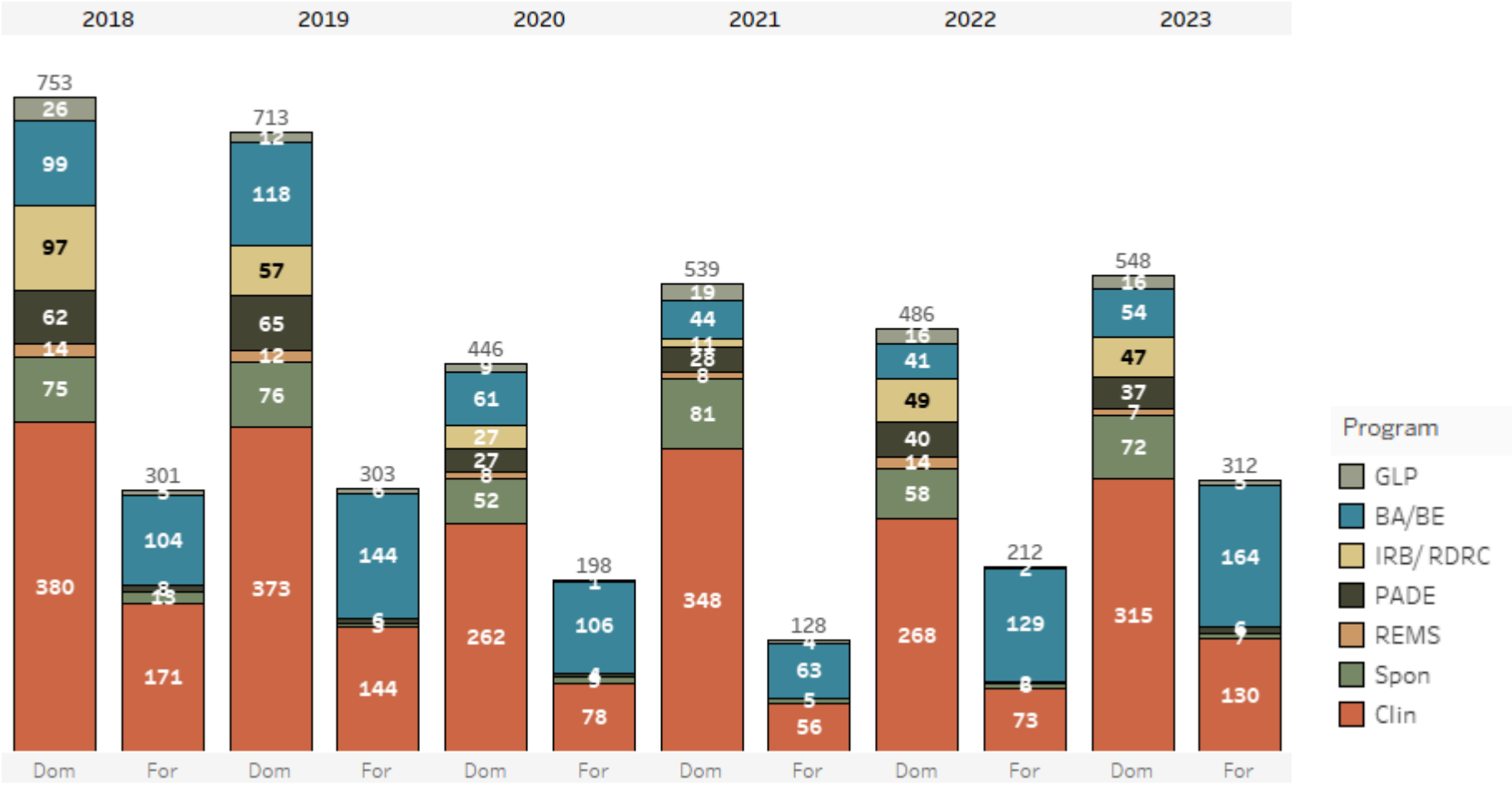
(CDER, FY 2018 - FY 2023)



- Metrics based on Inspection Activity Start Date.
- A single Inspection Activity may involve multiple applications and/or studies.

Domestic vs. Foreign Inspection Activity Overseen by OSI/OSIS

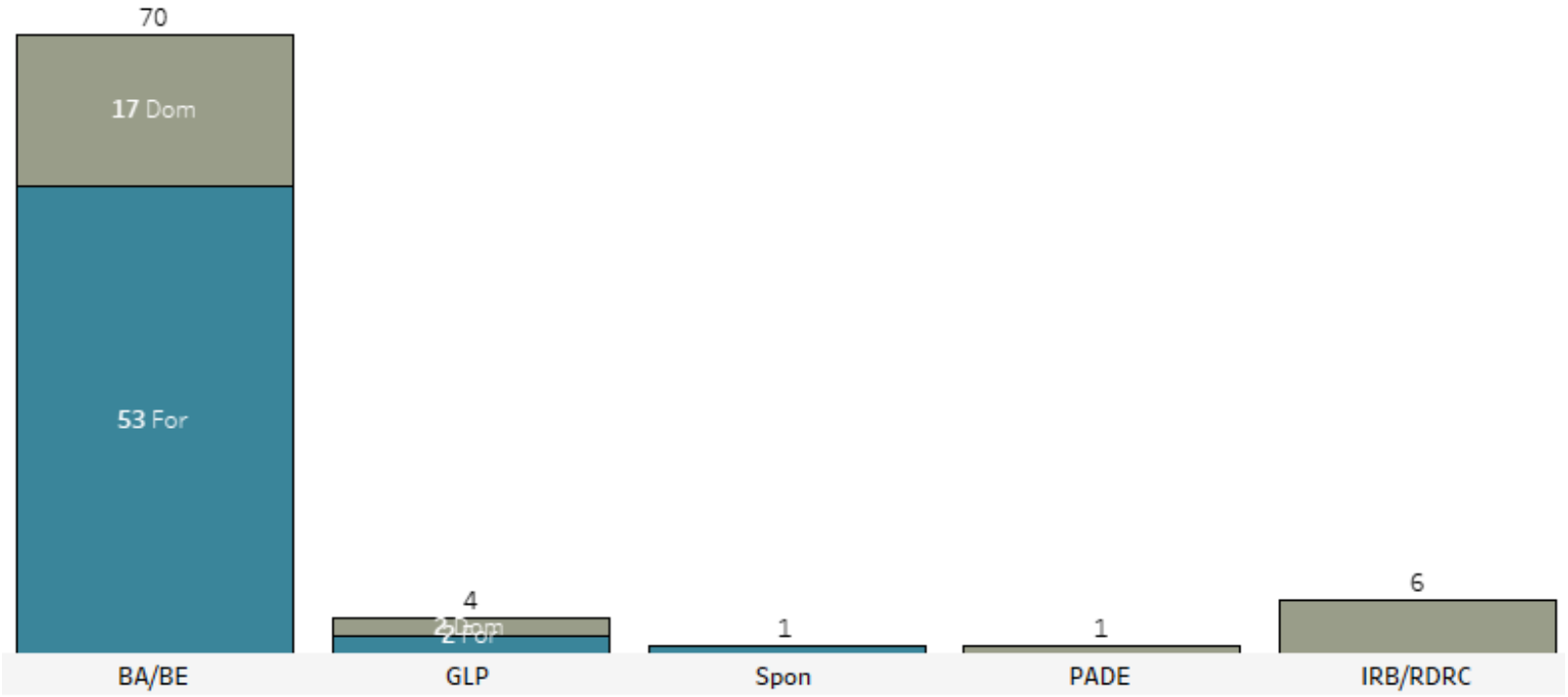
(CDER, FY 2018 - FY 2023)



- Metrics based on Inspection Activity Start Date.
- A single Inspection Activity may involve multiple applications and/or studies.

Remote Regulatory Assessments

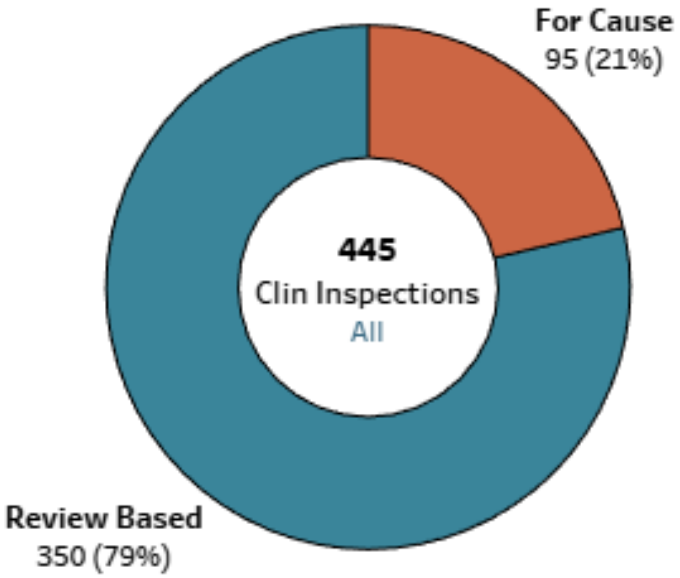
(CDER, FY 2023)



- Metrics based on Inspection Activity Start Date.

Clinical Investigator: Reason for Inspection Activity

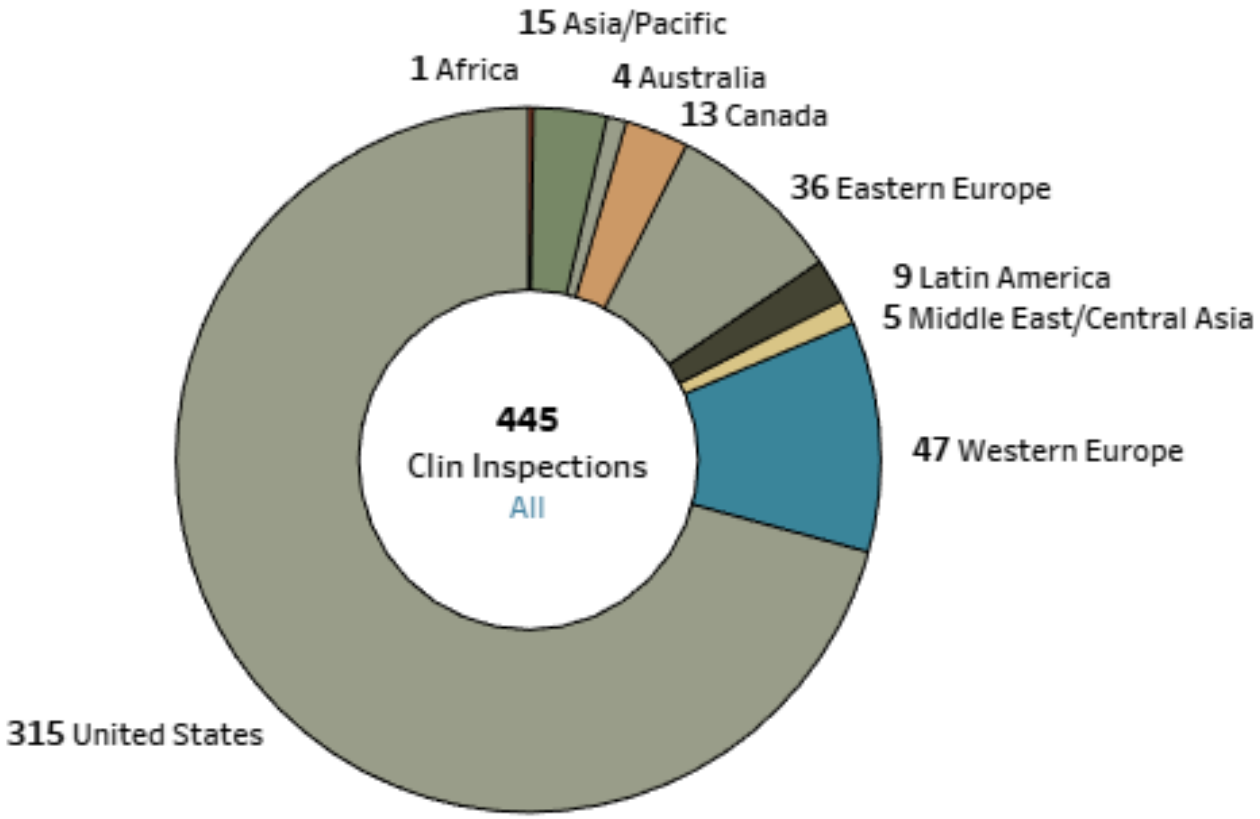
(CDER, FY 2023)



- Metrics based on Inspection Activity Start Date.
- Review Based Inspection Activities are surveillance inspections conducted in support of marketing application reviews, including any follow-up inspections.
- For Cause Inspection Activities are inspections conducted based on referrals (complaints, required reports, IRB/Sponsor notifications, and other internal and external referrals), including any follow-up inspections.

Clinical Investigator Inspection Activity by Location

(CDER, FY 2023)

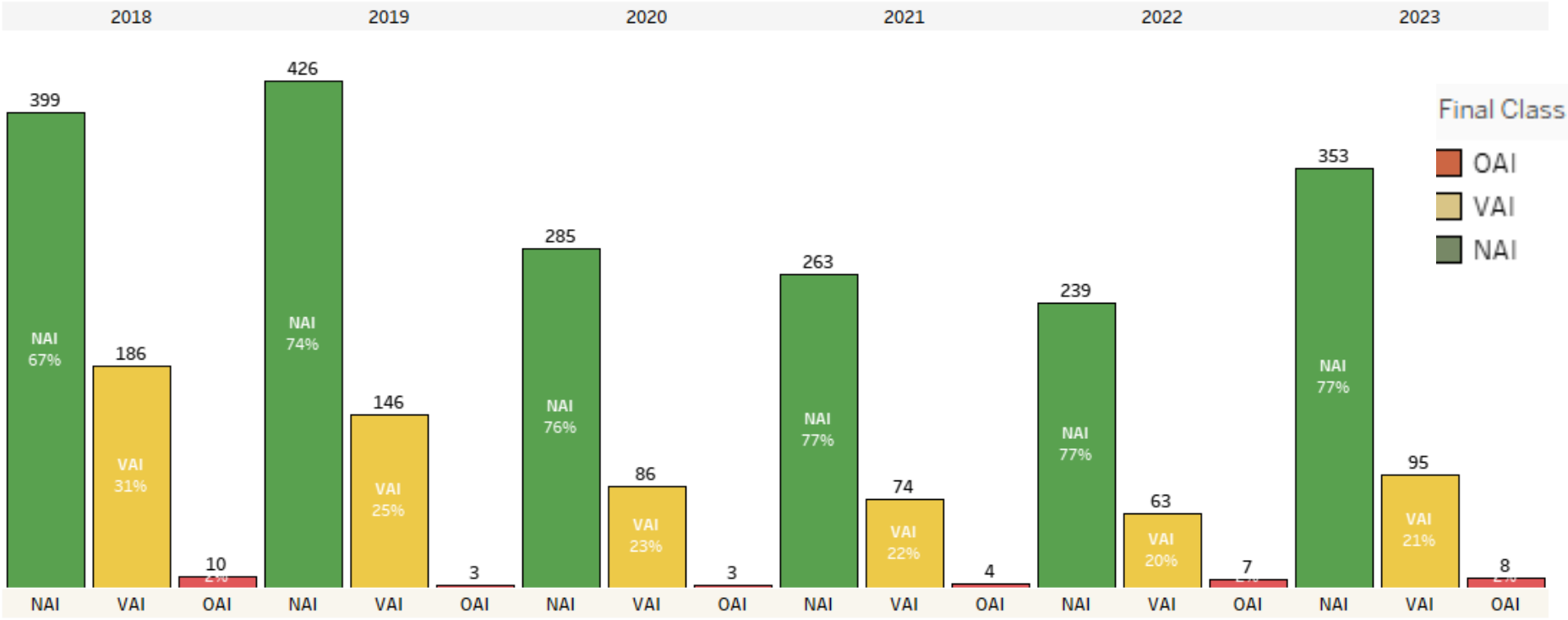


- Metrics based on Inspection Activity Start date.

Clinical Investigator Inspection Activity Final Classification

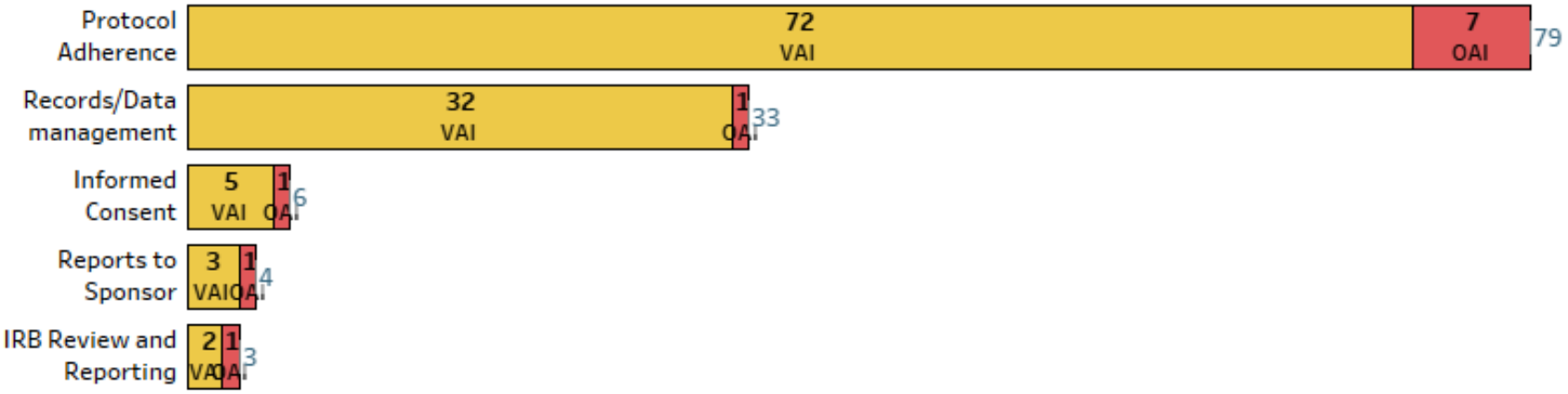
Domestic & Foreign

(CDER, FY 2018 - 2023)



- Metrics based on Letter Issuance (Logout) Date.
- Data for RRAs are not reflected in the final classification charts as they did not result in a final classification.

Clinical Investigator Deficiencies
In Post-Inspection Correspondences Issued
(CDER, FY 2023)

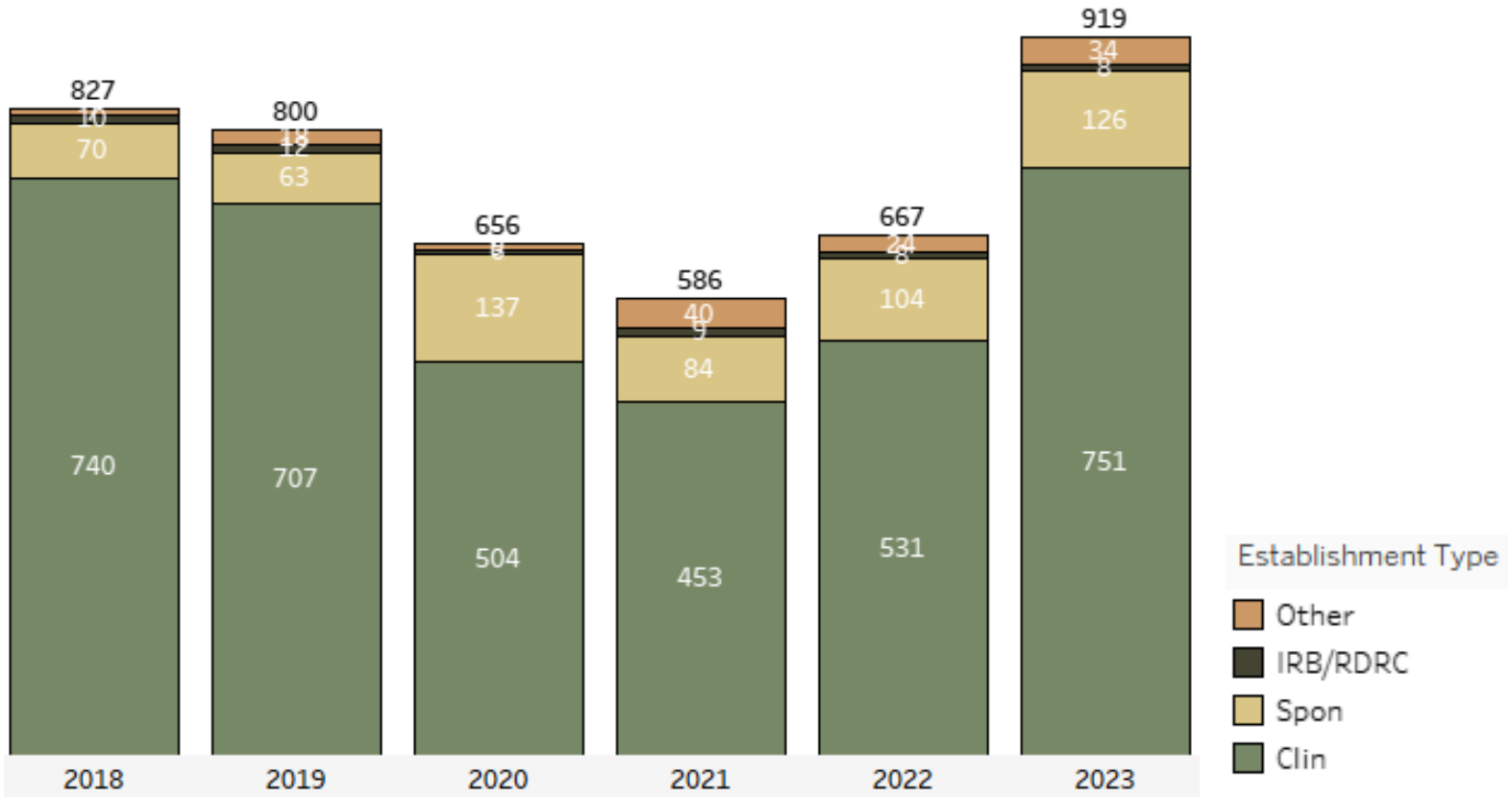


103 Post-Inspection Correspondences

- Metrics based on Letter Issuance (Logout) date.
- Includes deficiencies from post-inspection correspondence for inspections with VAI and OAI classification. One correspondence may include multiple deficiencies.

Referrals Received by Establishment Type

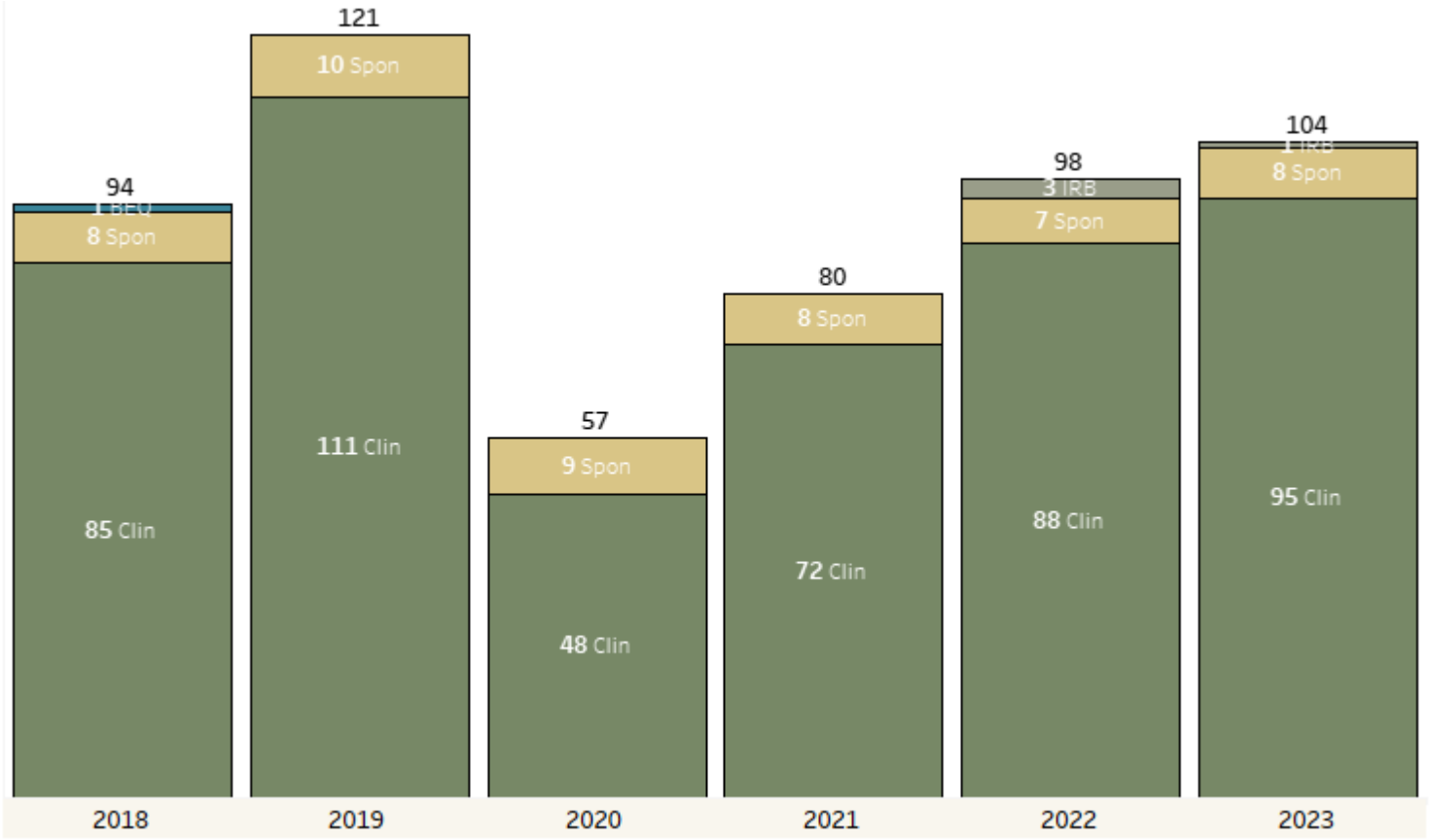
(CDER, FY 2018 - FY 2023)



- Metrics based on referral received date.
- Referrals include complaints, required reports, IRB/Sponsor notifications, and other internal and external referrals.

For Cause Inspection Activity by Program

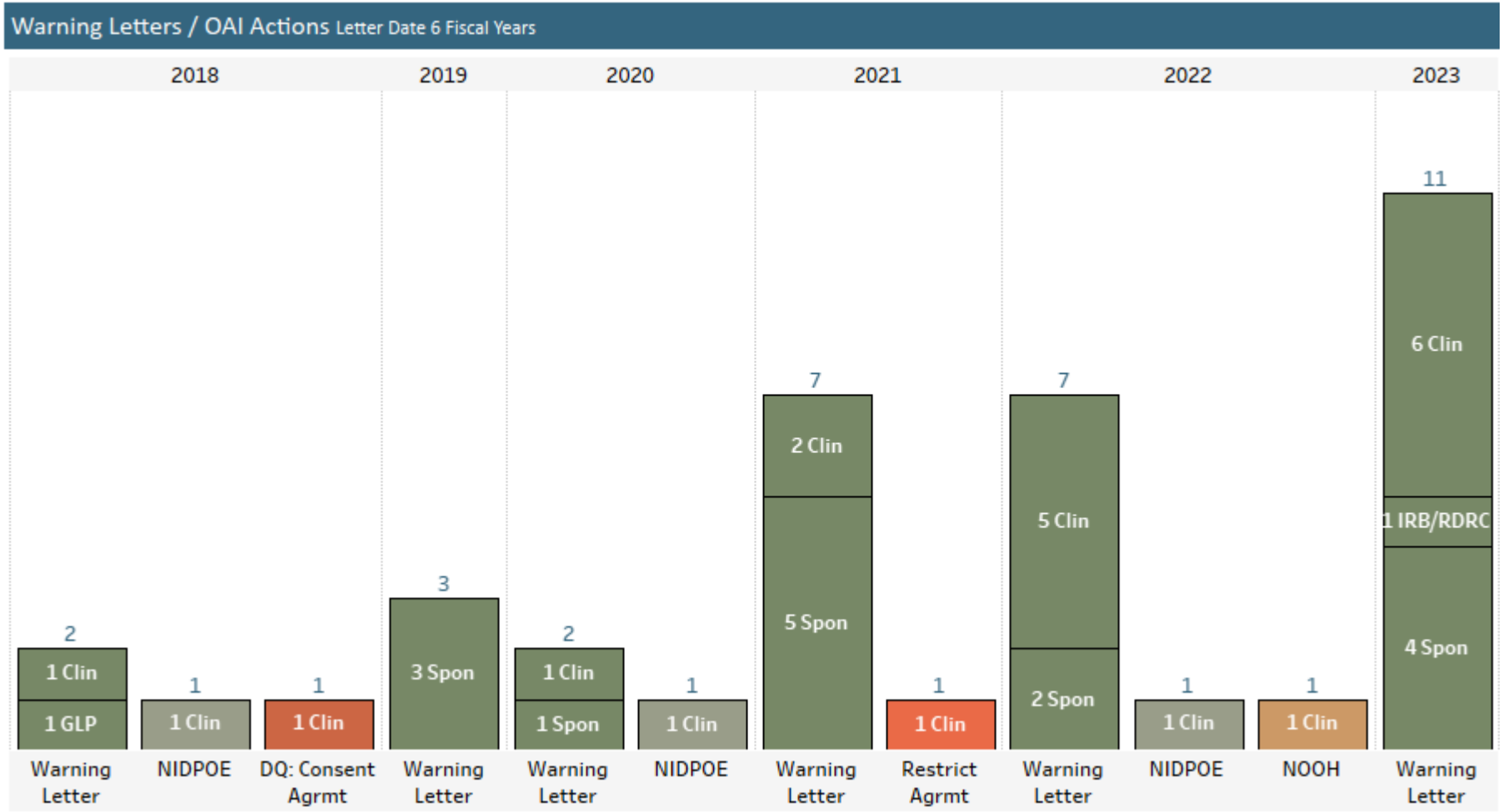
(CDER, FY 2018 - FY 2023)



- Metrics based on Inspection Activity Start date.

BIMO Warning/NIDPOE Letters and Regulatory Actions by Program

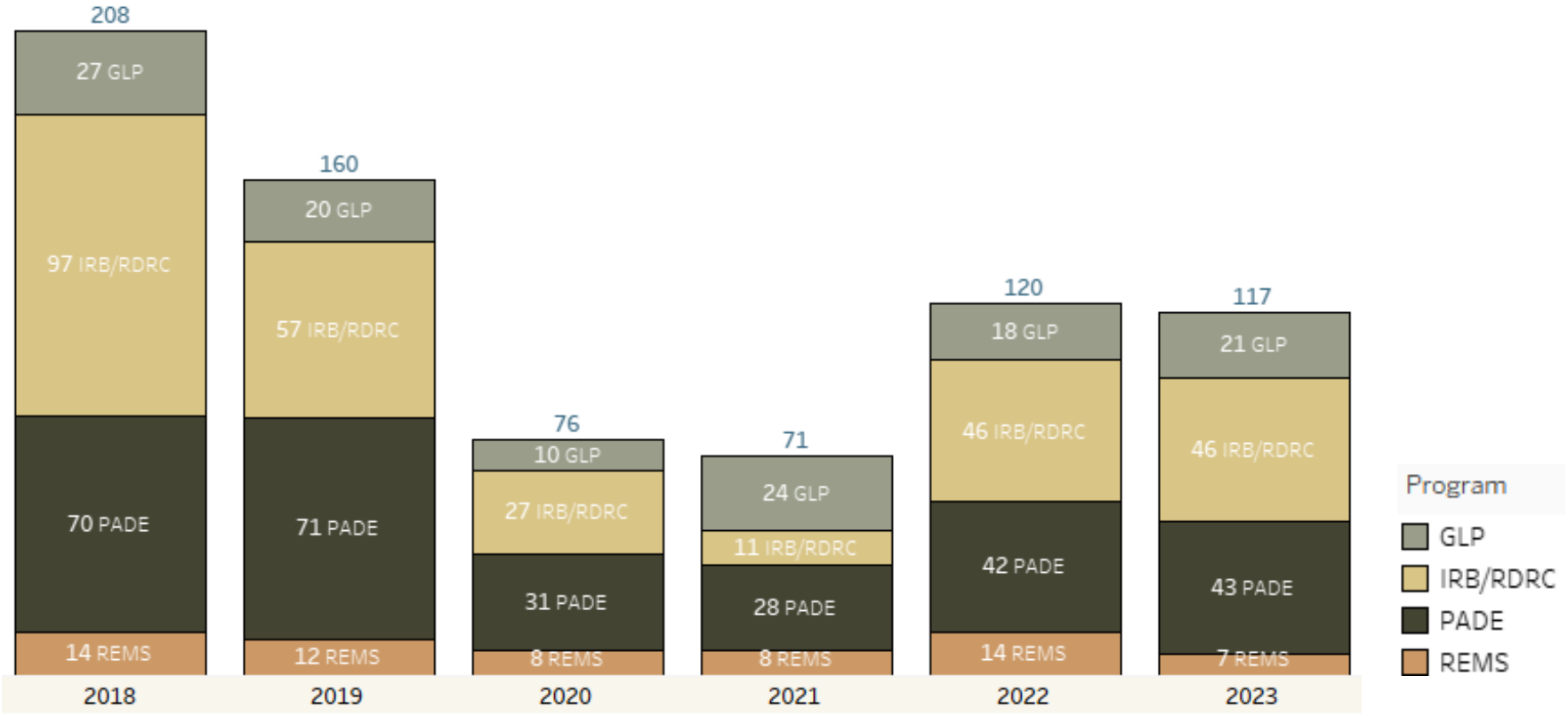
(CDER, FY 2018 - FY 2023)



- Metrics based on Letter Issuance (Logout) date. Inspection Activity may have occurred in prior fiscal year.
- Warning Letters are informal and advisory in nature, not regulatory actions (FDA Regulatory Procedures Manual Chapter 4, Section 1-1).

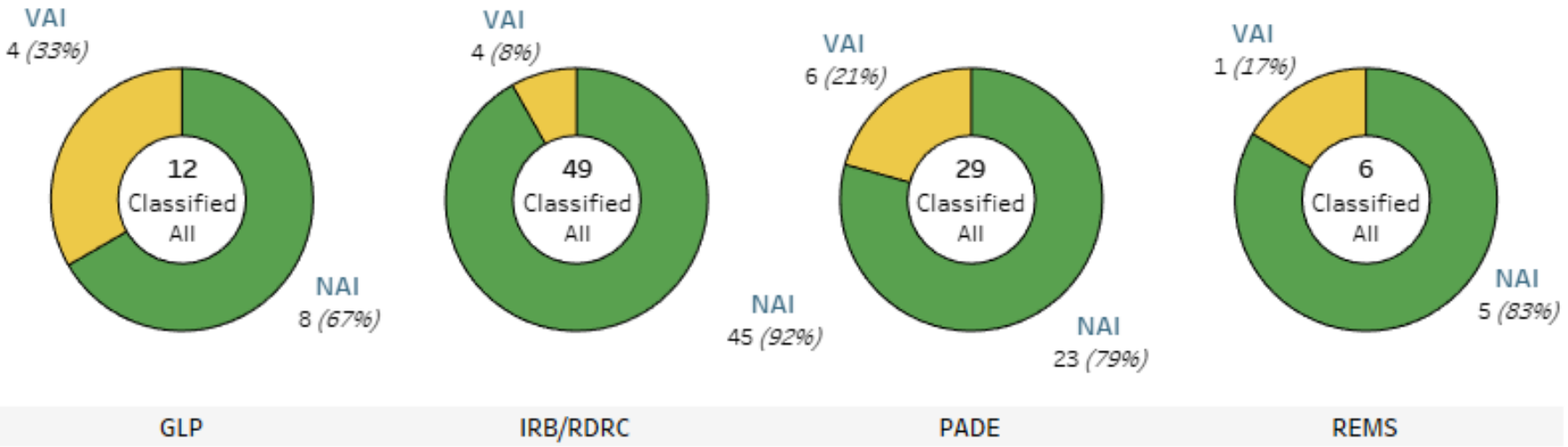
Surveillance Program Inspection Activity

(CDER, FY 2018 - FY 2023)



- Metrics based on Inspection Activity Start date.

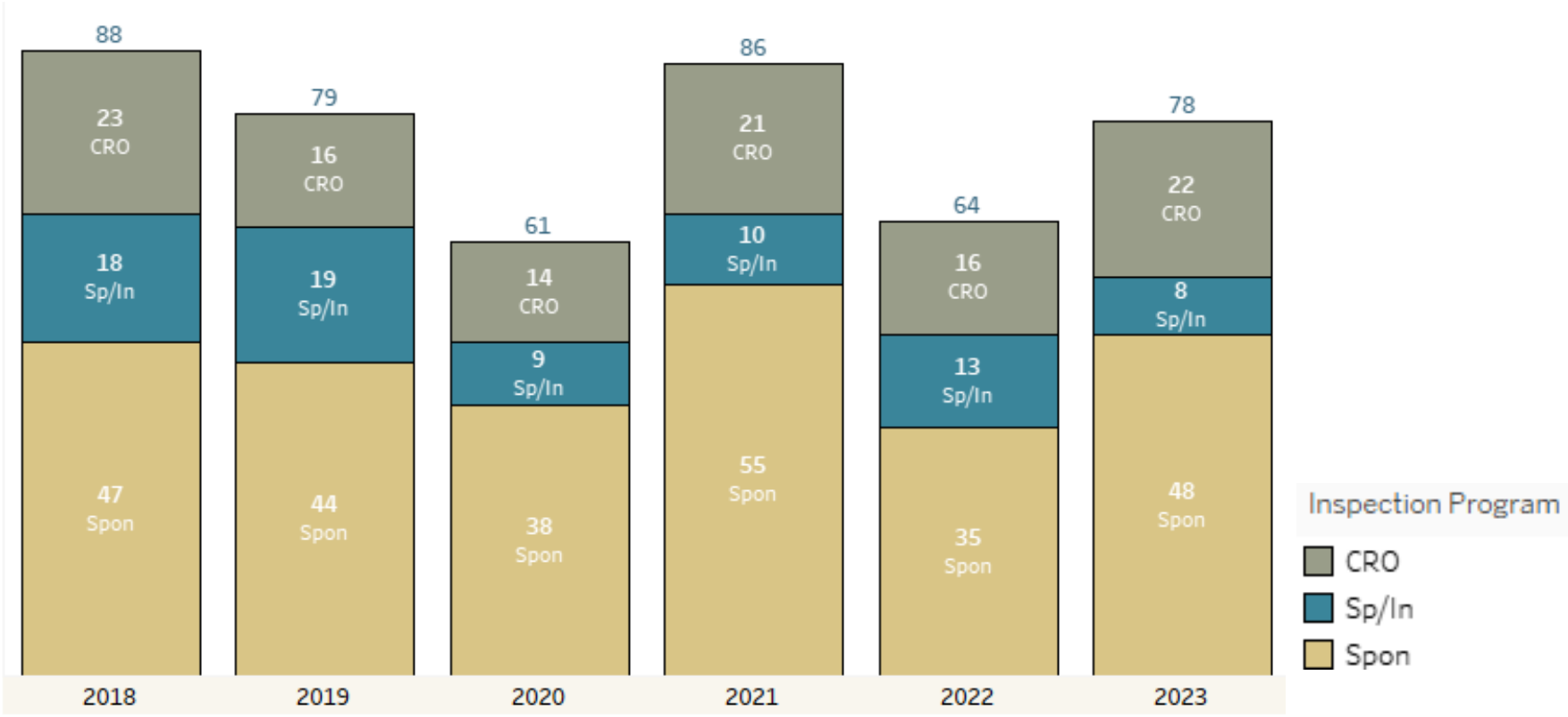
Surveillance Programs
Inspection Final Classifications
(CDER, FY 2023)



- Metrics based on Letter Issuance (Logout) date.
- Due to IT system development impacting the surveillance programs there has been a delay in classification of FY22 surveillance inspections. CDER is continuing to evaluate the outstanding inspections and issue final classification letters.

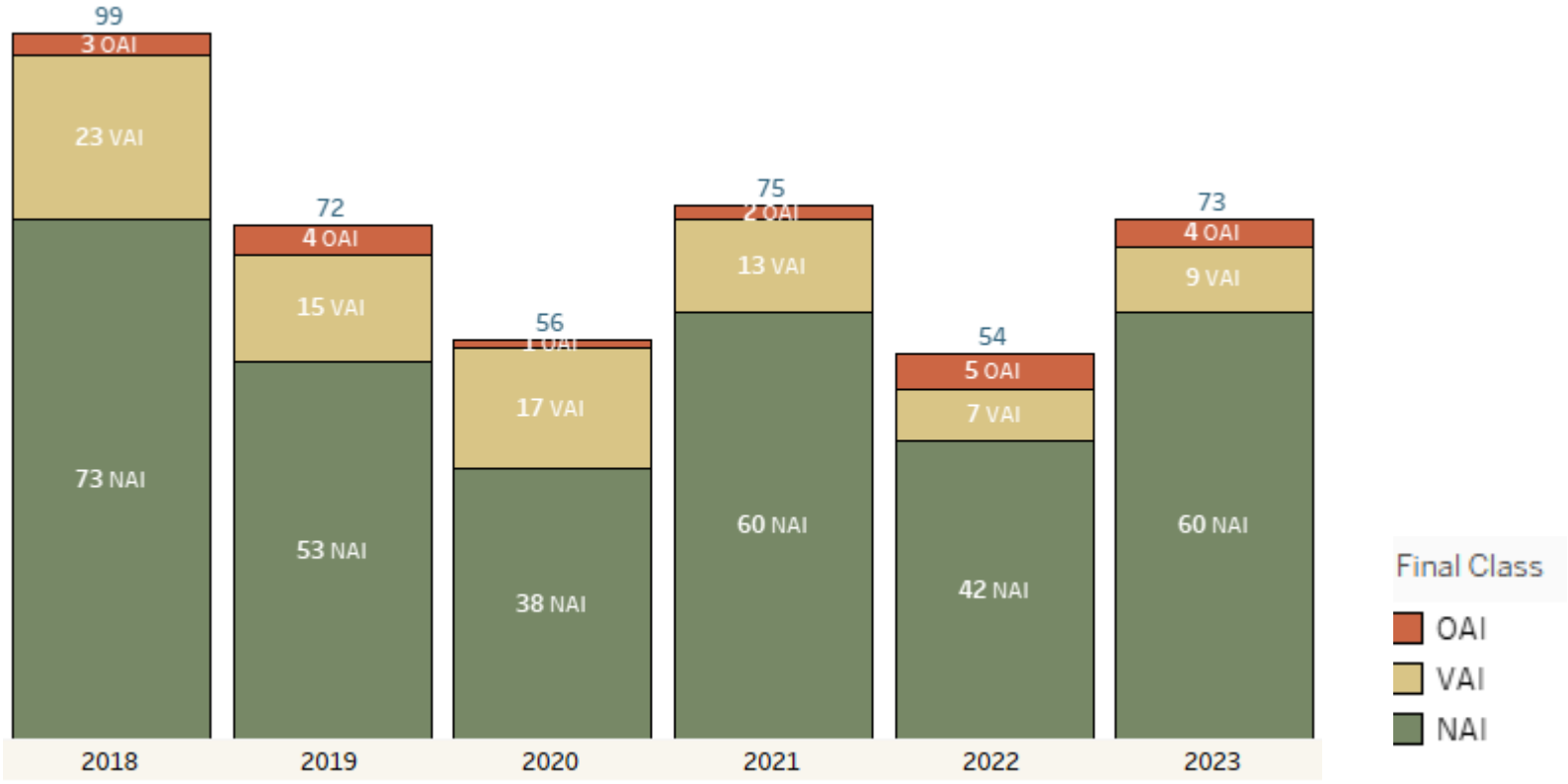
Sponsor/Contract Research Organizational Inspection Activity

(CDER, FY 2023)



- Metrics based on Inspection Activity Start date.
- Metrics include Review Based, For Cause and Surveillance Inspections.

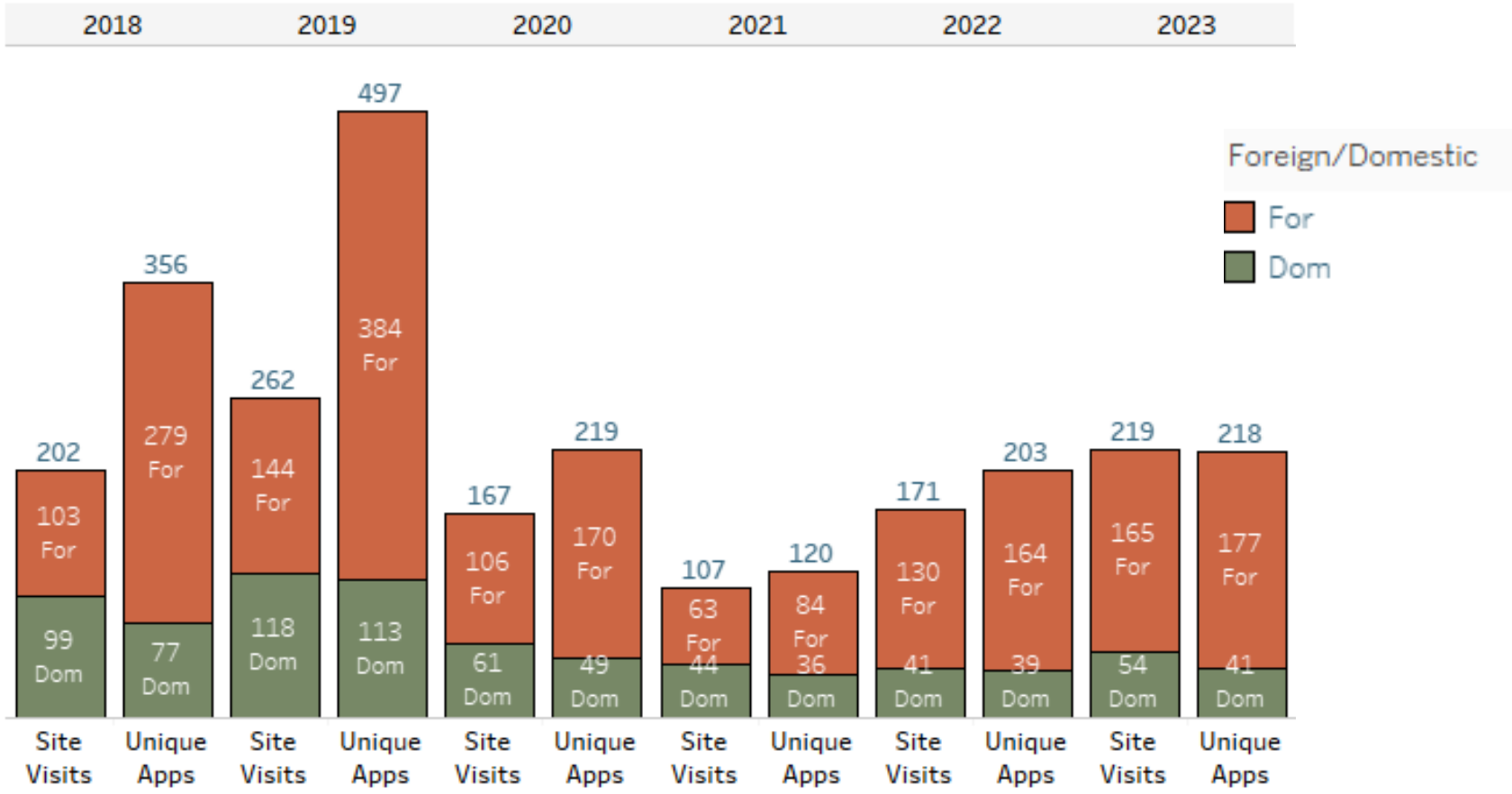
Sponsor/Contract Research Organization Inspection Activity
Final Classification
(CDER, FY 2018 - 2023)



- Metrics based on Letter Issuance (Logout) date.
- Includes Sponsor-Investigator Inspection Activity.

Bioavailability/Bioequivalence Site Visits and Unique Applications Inspected (Foreign/Domestic)

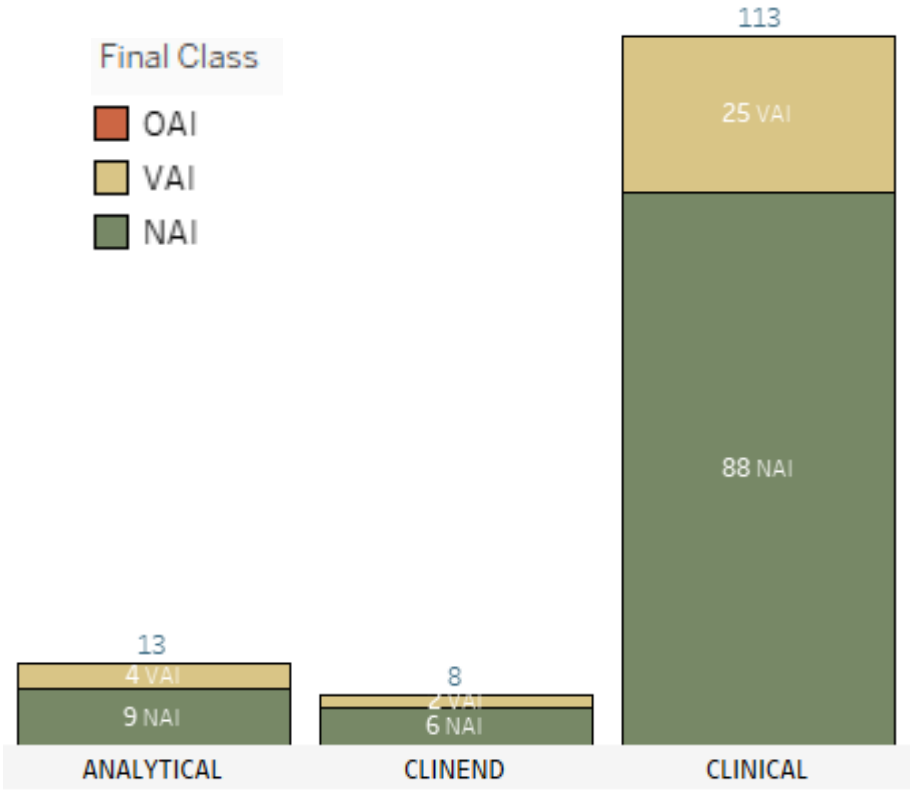
(CDER, FY 2018 - FY 2023)



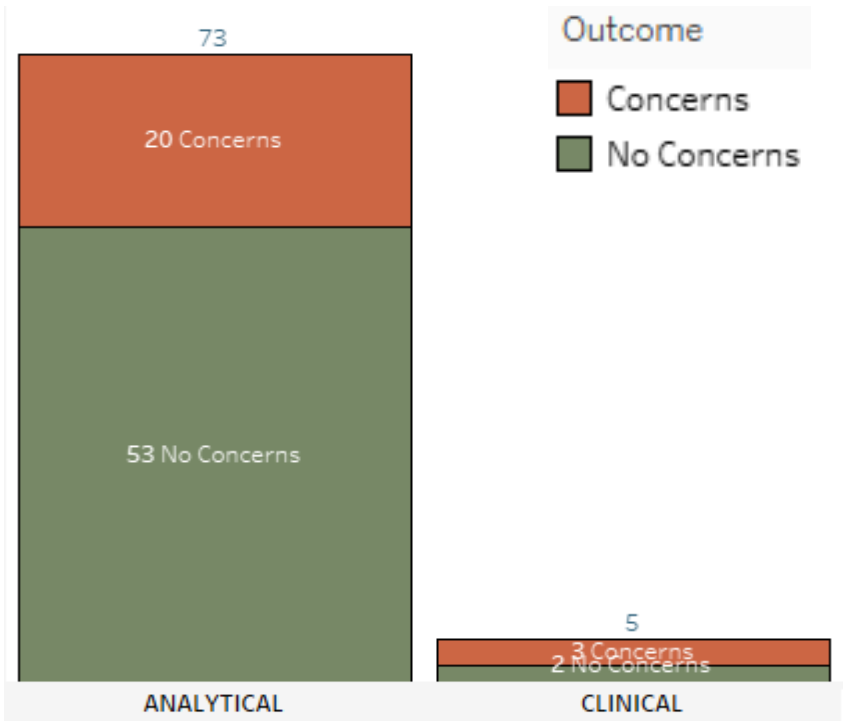
- Metrics based on Inspection Activity Start date.
- Site Visit number includes use of alternative approaches and includes only CDER numbers.

Bioavailability/Bioequivalence Site Visit Final Classifications and RRA Outcomes

(CDER, FY 2023)



Inspection Final Classification

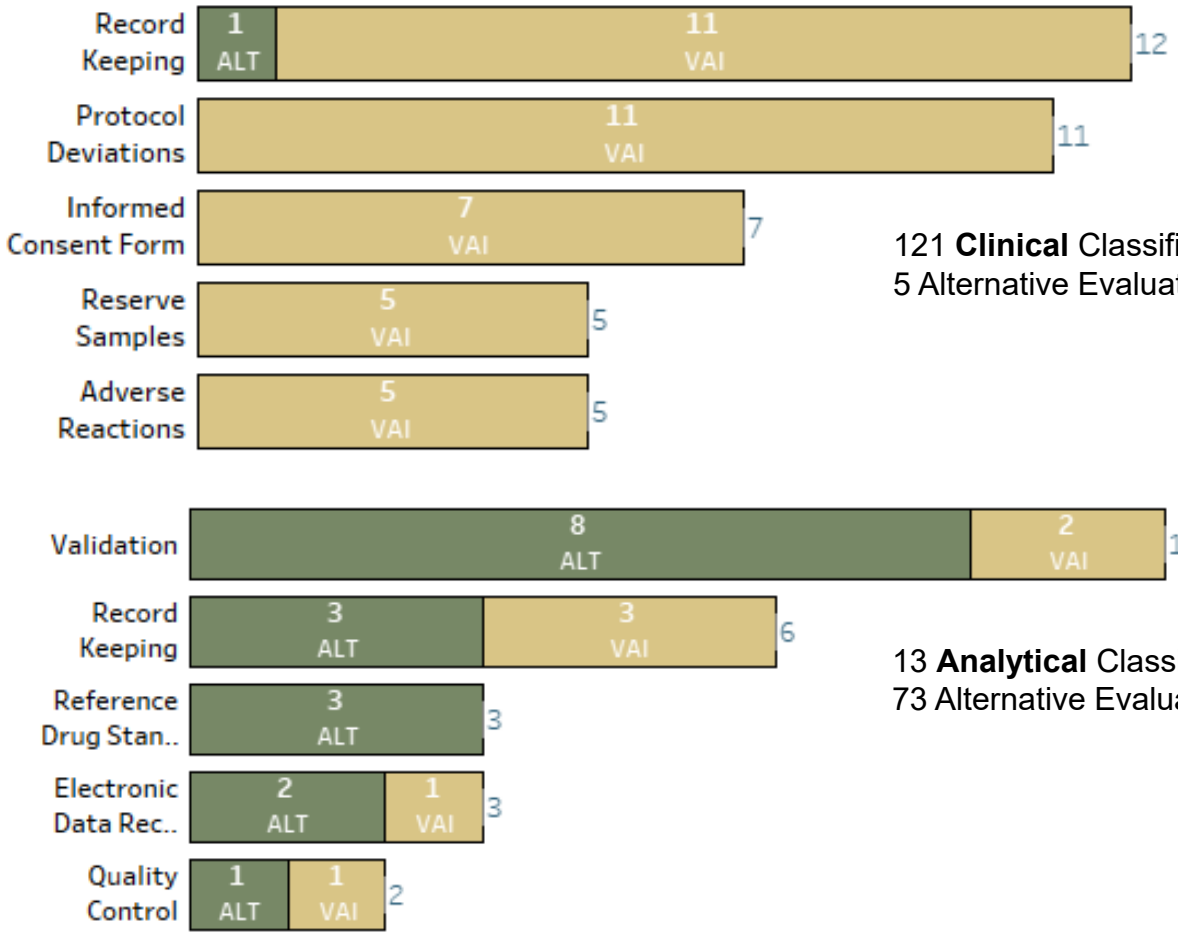


RRA Outcomes

- Metrics based on Letter Issuance (Logout) date and final classification.

Frequency of BA/BE-Related Deficiencies

(CDER, FY 2023)



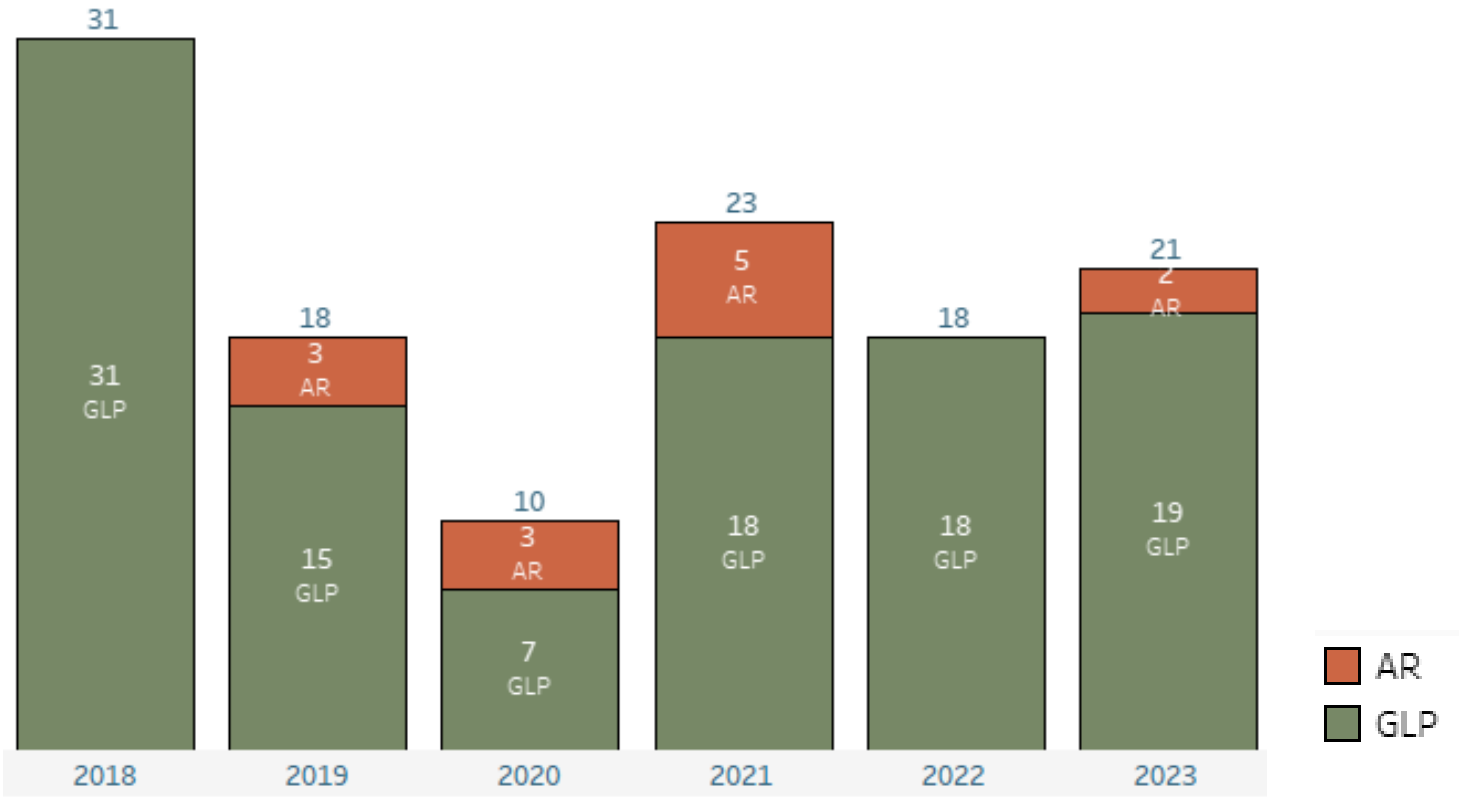
121 **Clinical** Classified Site Visits &
5 Alternative Evaluations

13 **Analytical** Classified Site Visits &
73 Alternative Evaluations

- Metrics based on Letter Issuance (Logout) date and final classification.
- Note that this does not denote number of Inspection Activities completed, but rather number of inspection reports evaluated and closed in the fiscal year. *Site Visits may have multiple deficiencies*.

Good Laboratory Practices/Animal Rule Inspection Activity

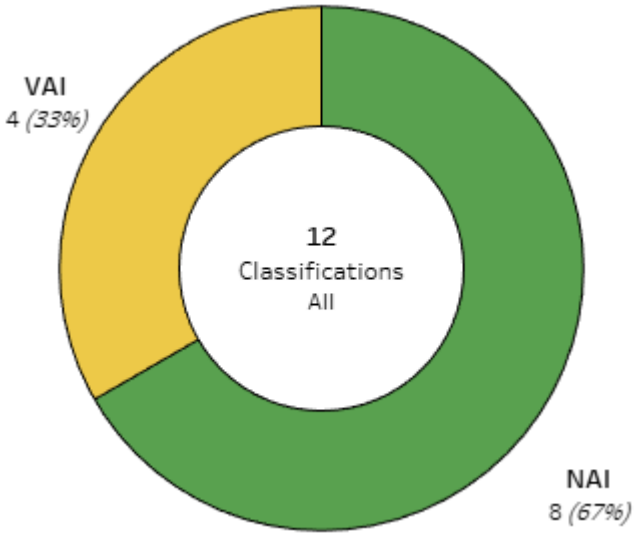
(CDER, FY 2018 - 2023)



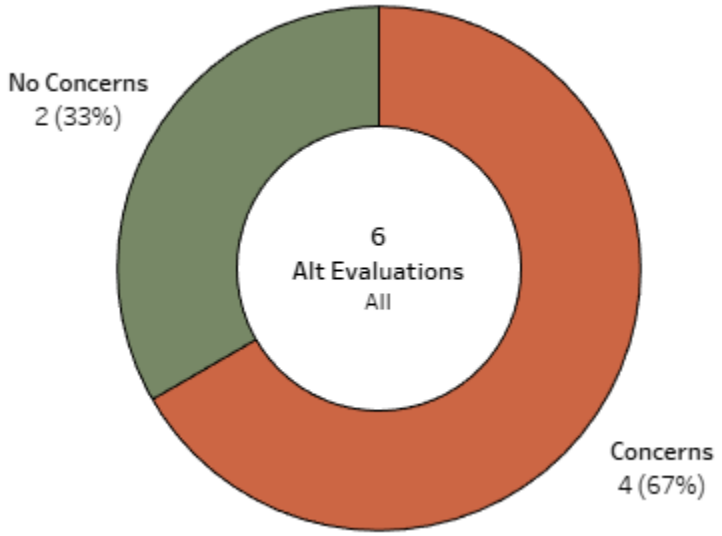
- Metrics based on Inspection Activity Start date.

GLP/AR Inspection Final Classifications and RRAs

(CDER, FY 2023)



Inspection Final Classification



RRA Outcomes

- Metrics based on Letter Issuance (Logout) date.