Bioresearch Monitoring (BIMO) Fiscal Year 2024 Metrics

Inspection Metrics Overview

- The following slides provide annual inspection metrics for the compliance programs within the Bioresearch Monitoring (BIMO) Program overseen by the Food and Drug Administration's (FDA) six product centers:
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Devices and Radiological Health (CDRH)
  - Center for Drug Evaluation and Research (CDER)
  - Human Foods Program (HFP), formerly Center for Food Safety and Applied Nutrition (CFSAN)
  - Center for Tobacco Products (CTP)
  - Center for Veterinary Medicine (CVM)
- The inspections (domestic and foreign) were conducted by FDA's Office of Inspections and Investigations (OII), formerly the Office of Regulatory Affairs (ORA). A portion of the CDER bioequivalence inspections were conducted independently by CDER subject matter experts.
- Metrics included in this presentation are based on the date of center final classification. Only inspections with a center final classification date entered in fiscal year (FY) 2024 are included. Therefore, metrics do not reflect the total number of inspections conducted by FDA in FY24.

Remote Regulatory Assessments

During the COVID-19 pandemic, FDA paused on-site surveillance inspections to protect the safety of our staff and stakeholders. For that period, on-site inspections were conducted if deemed mission-critical by the Agency.

- To continue supporting the mission, BIMO introduced Remote Regulatory Assessments (RRA), which are voluntary remote evaluations of data and processes conducted via video teleconference and/or records review.

- RRAs are a useful tool allow FDA to continue to review study data to aid in marketing application review.

- RRAs are not equivalent to an on-site inspection; however, as of 2025 receive classifications similar to inspections (rNAI, rVAI, rOAI)
  - Data for RRAs are not reflected in the inspection and final classification tables for each program area. Refer to slides 31-32 for a complete breakdown of RRAs.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers

Metrics Terms

Organizations and Programs

- BA/BE or BEQ: Bioavailability/Bioequivalence - clinical and analytical
- BIMO: Bioresearch Monitoring
- CI or Clin: Clinical Investigator
- CRO: Contract Research Organization
- FDA: Food and Drug Administration
- GLP: Good Laboratory Practice
- IRB: Institutional Review Board
- OSIS: Office of Study Integrity and Surveillance
- PADE: Postmarketing Adverse Drug Experience
- PMR: Postmarketing Requirements
- RDRC: Radioactive Drug Research Committee
- REMS: Risk Evaluation and Mitigation Strategy
- S: Sponsor
- SI: Sponsor-Investigator

Inspection Classifications

- NAI: No Action Indicated
- VAI: Voluntary Action Indicated
- OAI: Official Action Indicated

Evaluations

RRA: Remote Regulatory Assessments

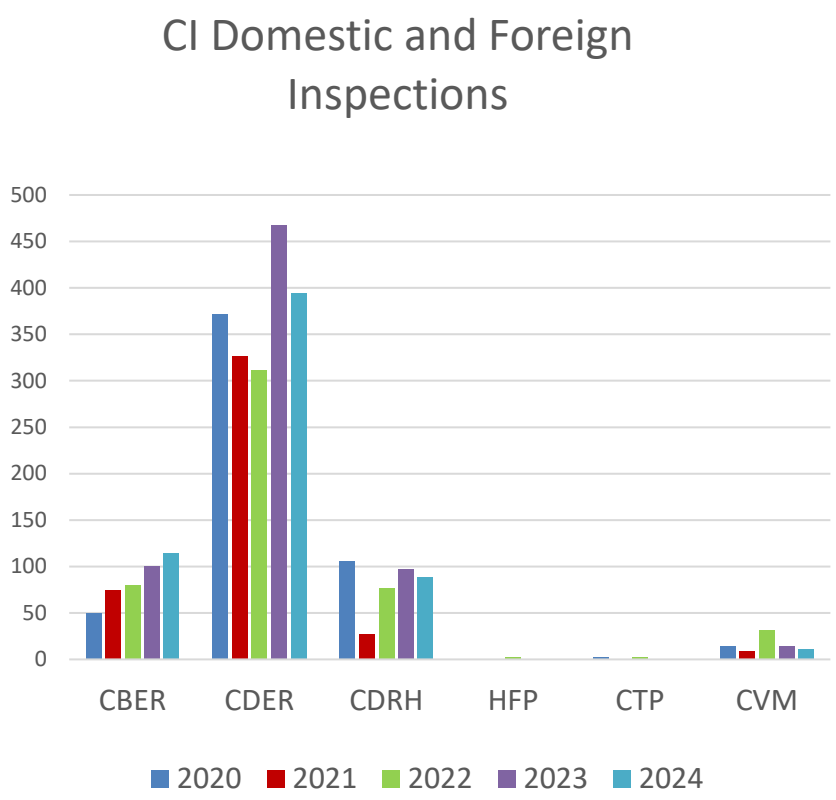
- rNAI – Remote NAI
- rVAI – Remote VAI
- rOAI – Remote NAI
- IRN: Information Received-No Items Noted
- IRI: Information Received-Items Noted
- IRC : Information Received-Compliance Indicated

BIMO Inspection Final Classifications by Center – FY 2024*

Center	CI	IRB	S/CRO	S/I	GLP	BEQ	PADE	REMS	Total
CBER	114	14	7	3	11	0	0	0	149
CDER	395	58	66	7	23	137	77	14	777
CDRH	89	14	25	0	5	0	0	0	133
CVM	11	0	1	0	5	0	0	0	17
Total	609	86	99	10	44	137	77	14	1076

* Includes both Domestic and Foreign inspections. HFP & CTP did not have any FY2024 inspections

Number of Clinical Investigator Inspections Final Classified FY 2020-2024



Center	2020*	2021*	2022	2023	2024
CBER	50	74	80	101	114
CDER	372	327	311	468	395
CDRH	106	27	77	97	89
HFP	0	0	2	0	0
CTP	2	0	2	0	0
CVM	14	9	32	15	11

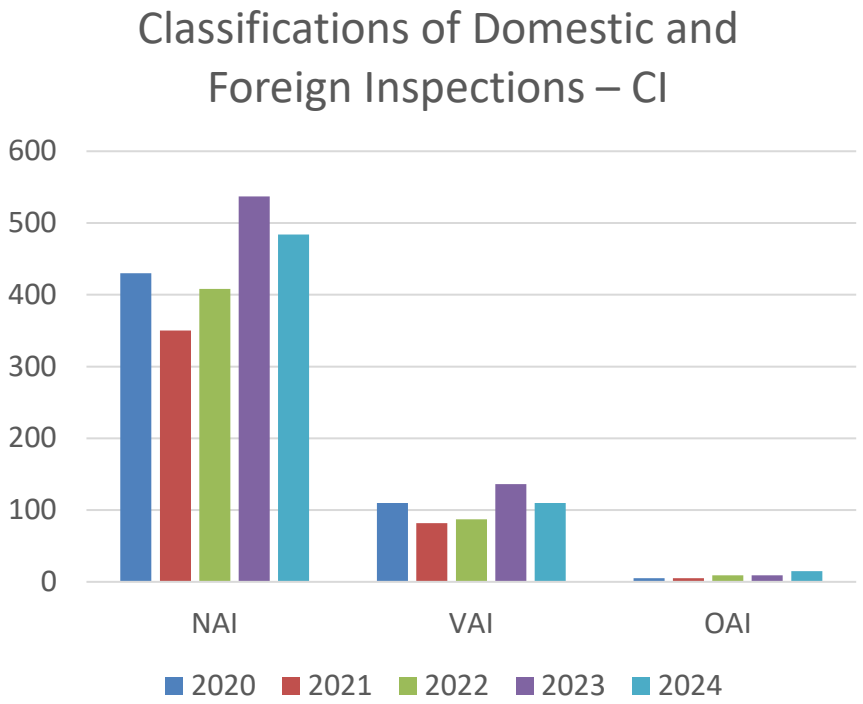
- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Clinical Investigator Inspectional Observations*

- Failure to comply with Form FDA 1572 requirements, protocol compliance
- Inadequate and/or inaccurate case history records; inadequate study records
- Failure to follow the investigational plan; protocol deviations
- Inadequate accountability and/or control of the investigational product records
- Safety reporting; failure to report and/or record adverse events
- Inadequate subject protection; informed consent issues

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

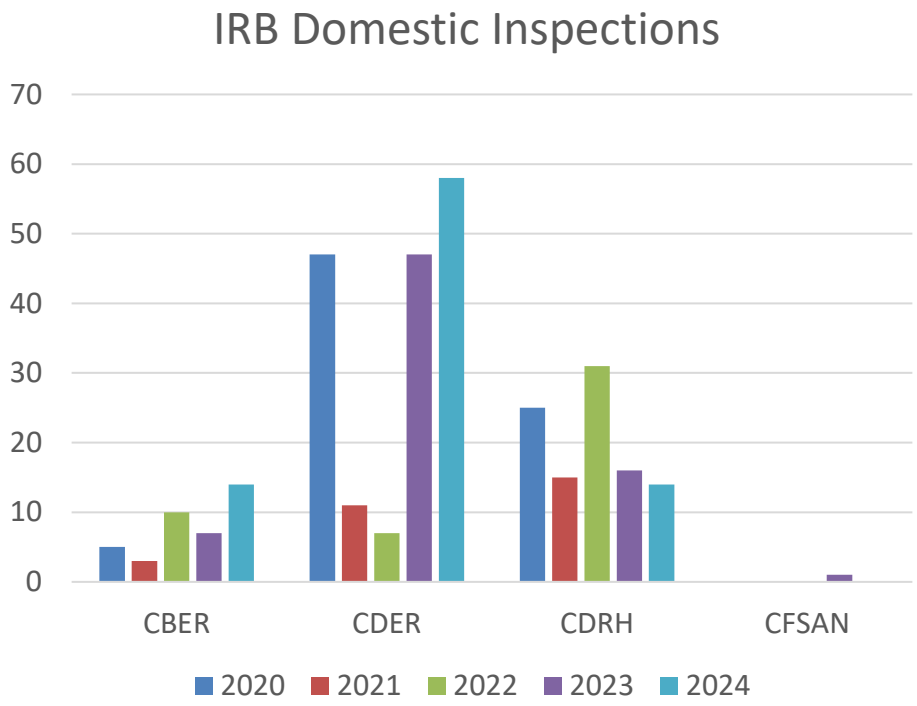
Number of Clinical Investigator Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024
NAI	429	350	408	536	484
VAI	110	82	87	136	110
OAI	5	5	9	9	15

Return to the inspections conducted slide

Number of IRB and RDRC Inspections Final Classified FY 2020- 2024



Center	2020*	2021	2022	2023	2024
CBER	5	3	10	7	14
CDER	47*	11	7	47	58
CDRH	25	15	30	16	14
CFSAN	0	0	1	1	0
Total	77	29	48	71	86

*Includes CDER completed RDRC inspections: FY20: 4

- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

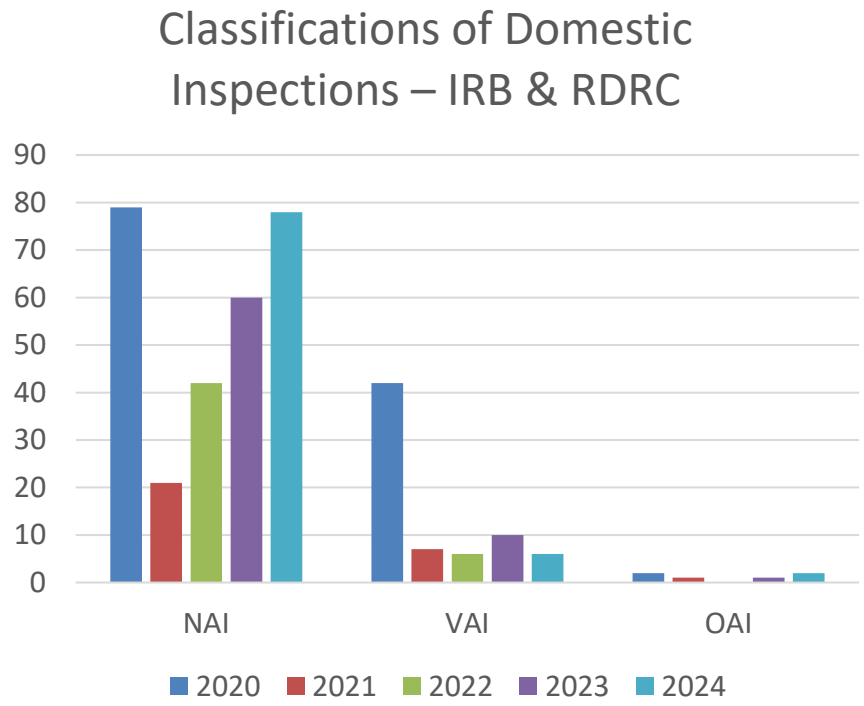
Terms

Common Institutional Review Board Inspectional Observations*

- Failure to have minutes of IRB meetings in sufficient detail to show attendance at the meeting; vote actions, quorum issues
- Failure to conduct initial and/or continuing review of research
- A list of IRB members has not been maintained, identifying members by name, earned degrees and representative capacity
- Changes in contact or chairperson information
- Failure to keep members of the IRB advised of research proposals that have been approved under an expedited review procedure
- Failure to have a majority of IRB members present for review of proposed research for other than expedited reviews

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

Number of IRB and RDRC Inspections Final Classified FY 2020-2024



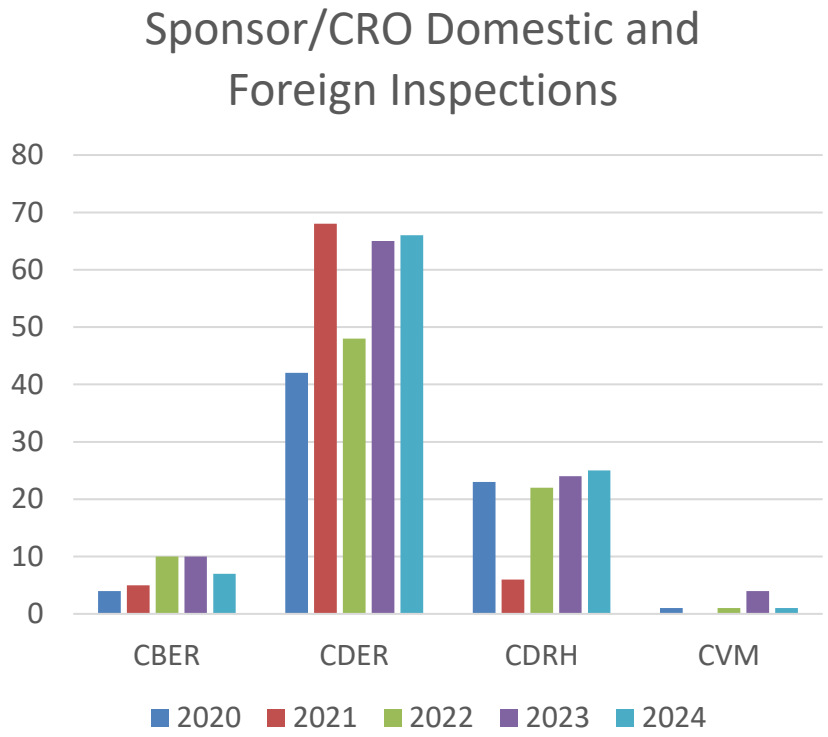
	2020	2021	2022	2023	2024
NAI	45	21	42	60	78
VAI	31*	7	6	10	6
OAI	1	1	0	1	2

* Includes CDER completed RDRC inspections: FY20: 4

- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Return to the inspections conducted slide

Number of Sponsor/CRO Inspections Final Classified FY 2020-2024



Center	2020*	2021*	2022*	2023*	2024*
CBER	4	5	10	10	7
CDER	42	68	48	65	66
CDRH	23	6	22	24	25
CVM	1	0	1	4	1
Total	70	79	81	103	99

- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

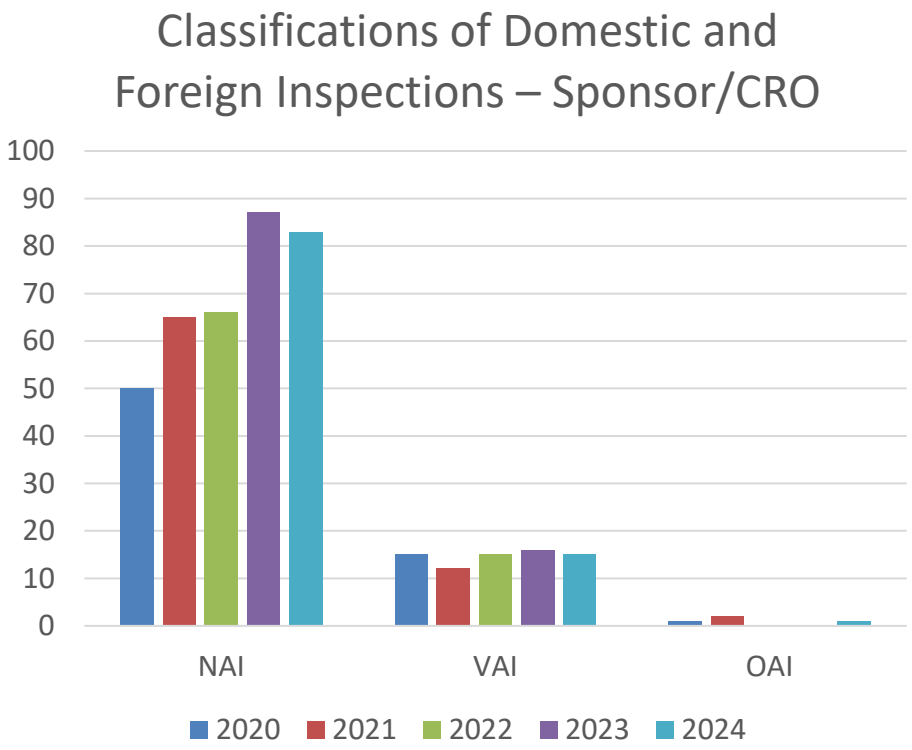
Terms

Common Sponsor/CRO Inspectional Observations*

- Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.
- Failure to ensure that an investigation was conducted in accordance with the general investigational plan and protocols as specified in the Investigational New Drug (IND).
- Failure to submit an IND application; IND safety report.

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

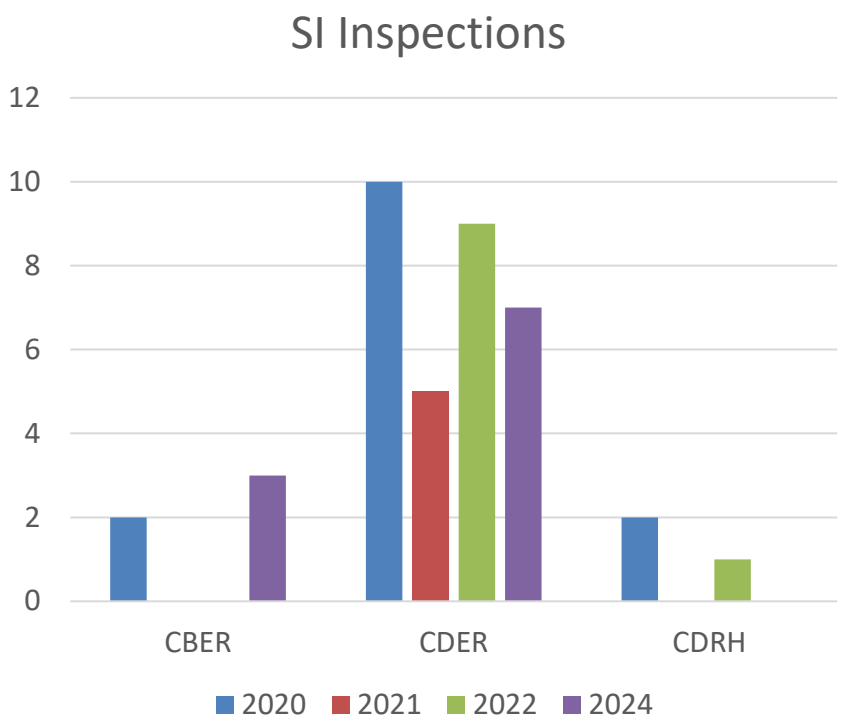
Number of Sponsor/CRO Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024
NAI	53	65	66	87	83
VAI	16	12	15	16	15
OAI	1	2	0	0	1

Return to the inspections conducted slide

Number of Sponsor-Investigator Inspections Final Classified FY 2020-2024



Center	2020*	2021*	2022*	2023*	2024*
CBER	2	0	0	2	3
CDER	10	5	9	9	7
CDRH	2	0	1	2	0
Total	14	5	10	13	10

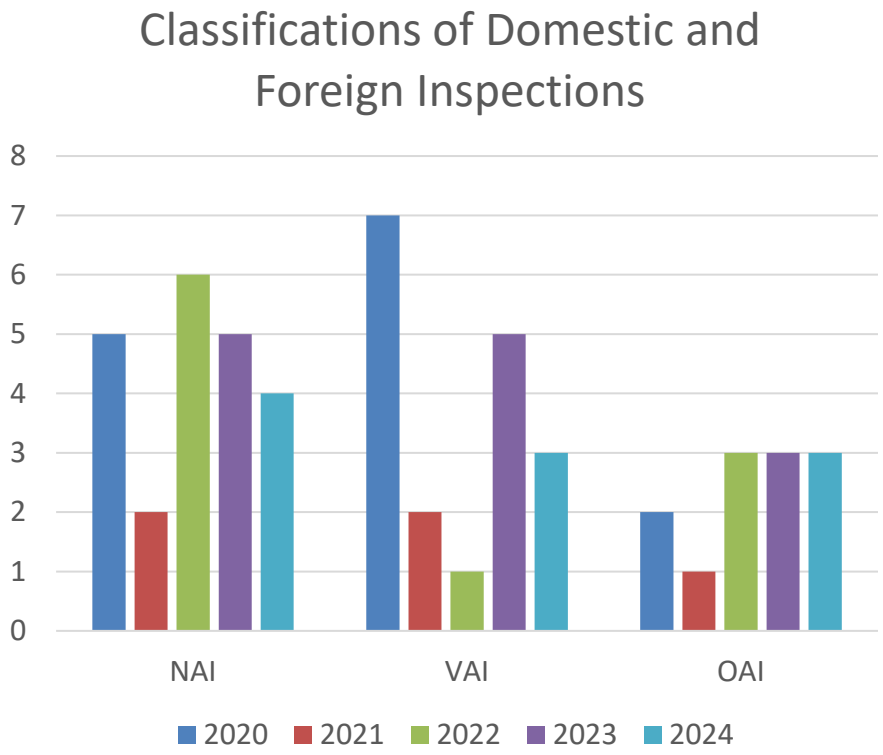
- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Sponsor-Investigator Inspectional Observations*

- Failure to maintain statement of investigator (Form FDA 1572);
- Failure to prepare or maintain adequate and accurate case histories with respect to observations and data pertinent to the investigation.
- Failure to conduct an investigation in accordance with the signed statement of investigator and investigational plan.
- Failure to report serious adverse events to the sponsor.
- Failure to maintain Accountability records
- Failure to obtain informed consent in accordance with 21 CFR Part 50 from each human subject prior to drug administration and conducting study-related tests.

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

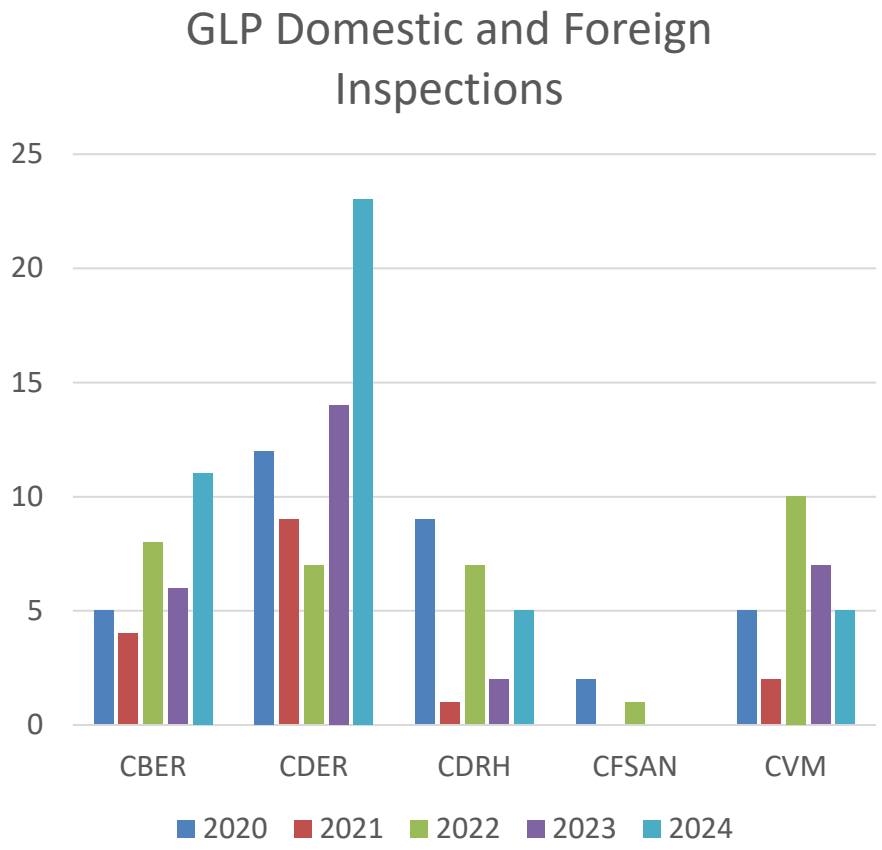
Number of Sponsor-Investigator Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024
NAI	5	2	6	5	4
VAI	7	2	1	5	3
OAI	2	1	3	3	3

Return to the inspections conducted slide

Number of Good Laboratory Practice Inspections Final Classified FY 2020-2024



Center	2020*	2021*	2022*	2023*	2024*
CBER	5	4	8	6	11
CDER	12	9	7	14	23
CDRH	9	1	7	2	5
CFSAN	2	0	1	0	0
CVM	5	2	10	7	5
Total	33	16	33	29	44

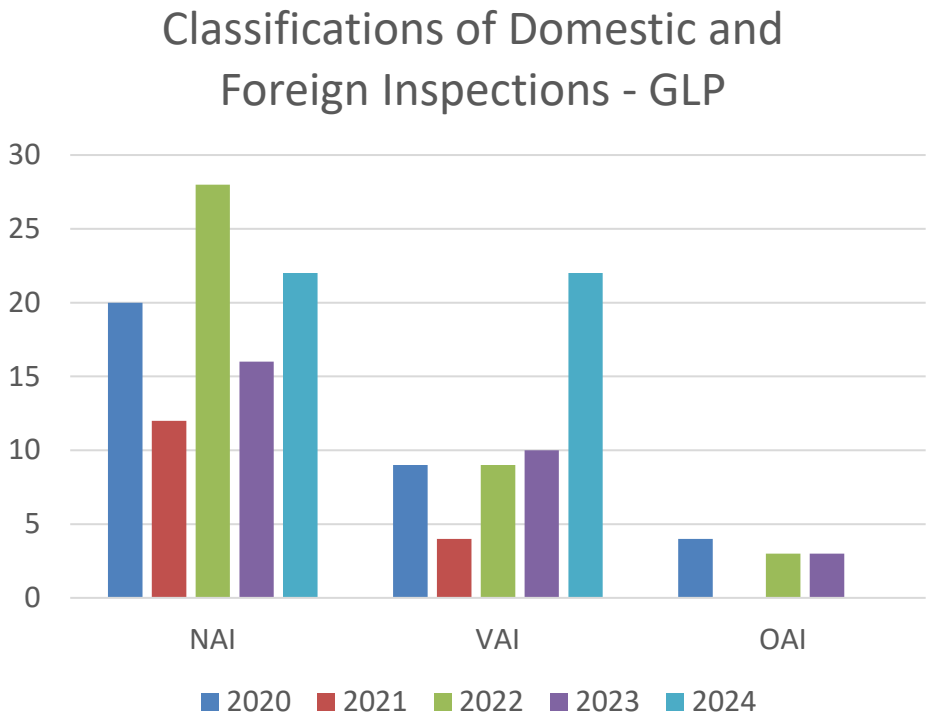
- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Good Laboratory Practice Inspectional Observations*

- Missing standard operating procedures (SOPs)
- Quality Assurance Unit (QAU) failed to determine if deviations from approved protocols had been made without proper authorization and documentation
- Equipment; appropriate design and adequate capacity; inspection, cleaning and maintenance
- Lack of authorization and documentation of deviations
- Study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.
- Equipment calibration, equipment used for measurement or assessment was not adequately tested, calibrated and/or standardized

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

Number of Good Laboratory Practice Inspections Final Classified FY 2020-2024

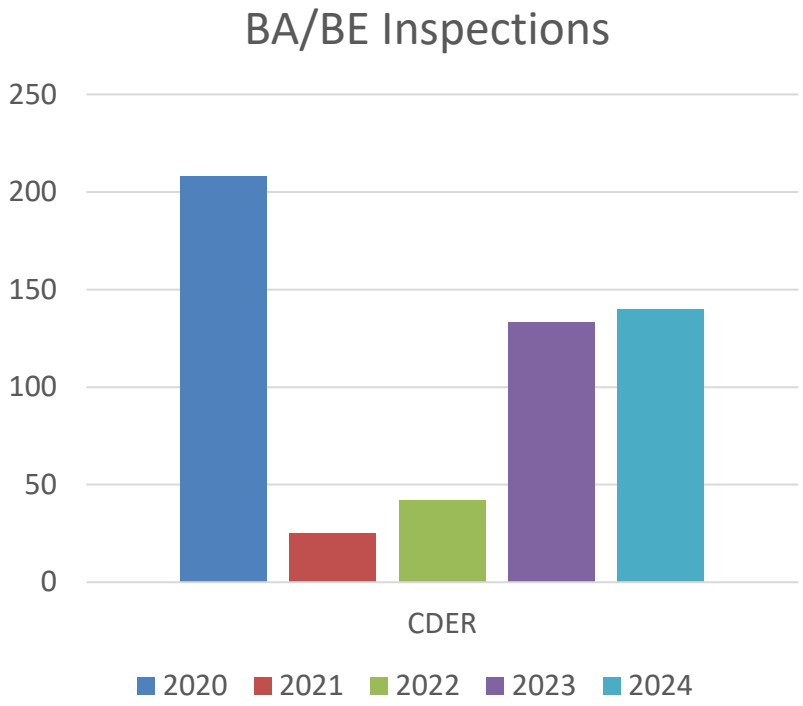


	2020	2021	2022	2023	2024
NAI	20	12	21	16	22
VAI	9	4	9	10	22
OAI	4	0	3	3	0

This data represents all centers that conducted GLP inspections.

Return to the inspections conducted slide

Number of Bioavailability/Bioequivalence Inspections Final Classified FY 2020-2024



Center	2020	2021	2022	2023	2024
CDER	208	25	42	133	137

- CDER Specific Program

- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Bioavailability/Bioequivalence Inspectional/RRA Observations*

Clinical

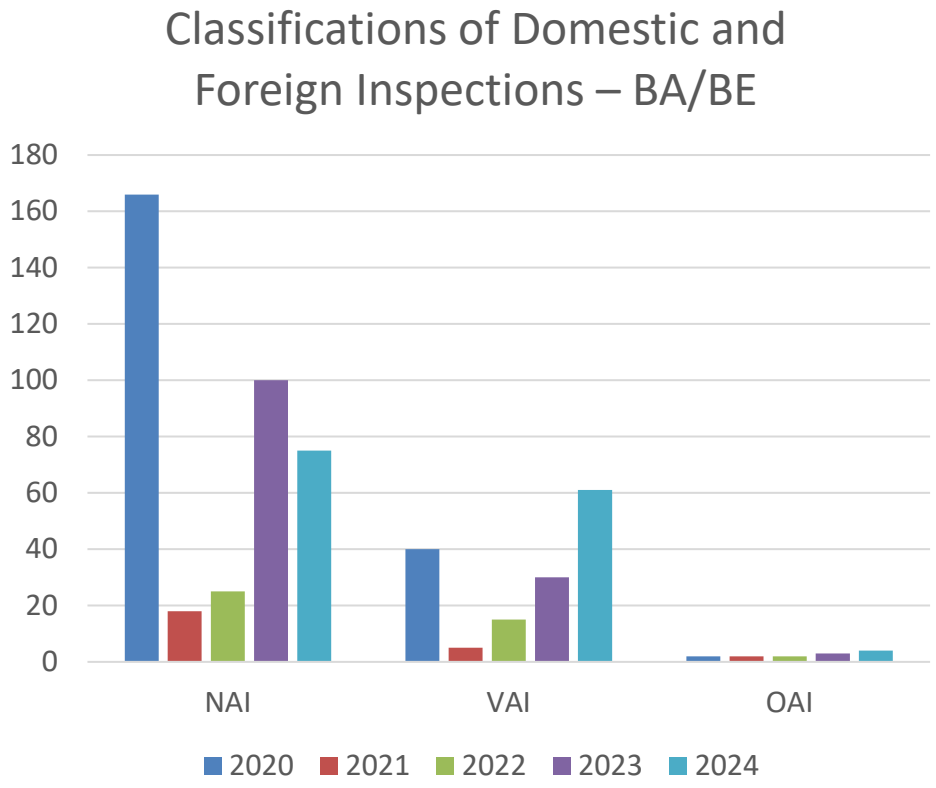
- Inadequate record keeping; inadequate drug accountability
- Did not follow the investigational plan; protocol deviations
- Inadequate subject protection; informed consent

Analytical

- Inadequate method validation
- Analytical run related unjustified data rejection
- Inadequate record keeping; inadequate drug accountability

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations or were shared with establishment post-RRA

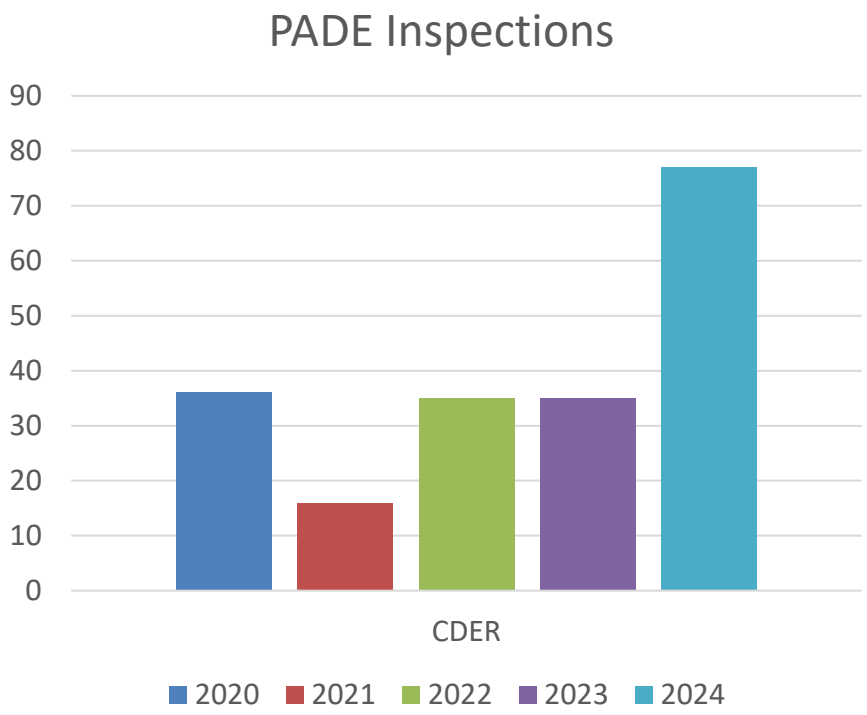
Number of Bioavailability/Bioequivalence Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024
NAI	166	18	25	100	73
VAI	40	5	15	30	63
OAI	2	2	2	3	1

- CDER Specific Program

Number of Postmarketing Adverse Drug Experience Inspections Final Classified FY 2020-2024



Center	2020	2021	2022	2023	2024*
CDER	36	16	35	35	77

- CDER Specific Program

*3 CDER-led RRAs were conducted for this program in FY24

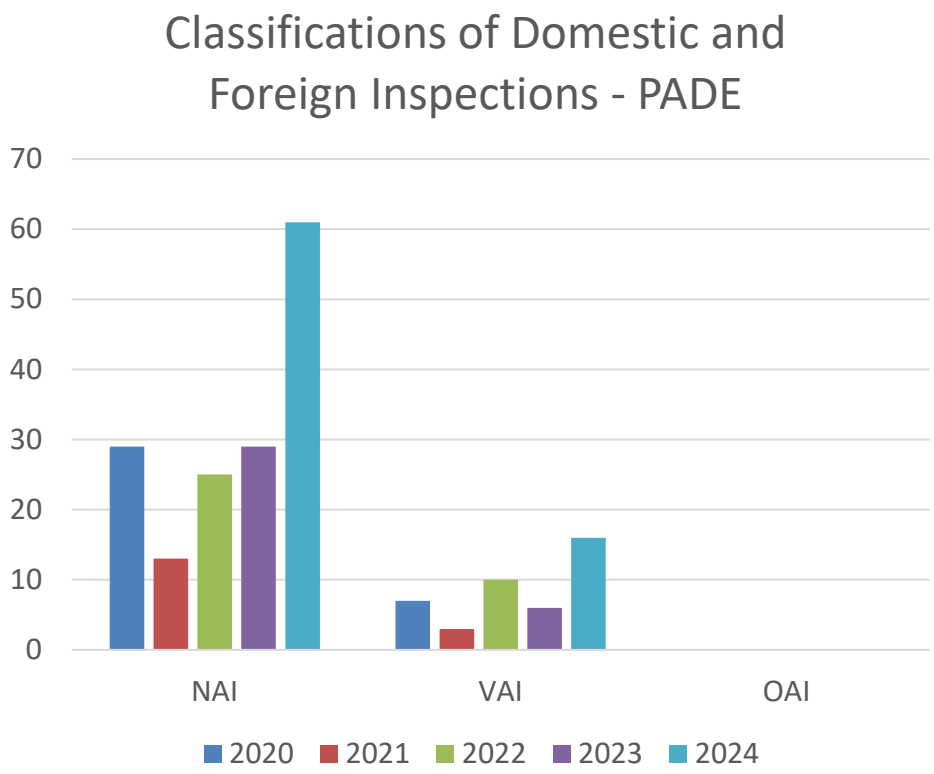
- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Postmarketing Adverse Drug Experience Inspectional Observations*

- Failure to develop written procedures for the surveillance, receipt, evaluation, and/or reporting of post-marketing adverse drug experiences (ADEs)
- Failure to report all ADEs that are both serious and unexpected to FDA within 15 calendar days of initial receipt of information
- Failure to promptly investigate all ADEs that are the subject of 15-day Alert reports and failure to submit follow-up reports within 15 calendar days of receipt of new information
- Failure to submit all quarterly and/or annual periodic ADEs reports (PADERs) within the required timeframe
- Failure to submit individual case safety reports for all serious and expected ADEs and all nonserious ADEs within the required timeframe

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

Number of PADE Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024*
NAI	29	13	25	29	61
VAI	7	3	10	6	16
OAI	0	0	0	0	0

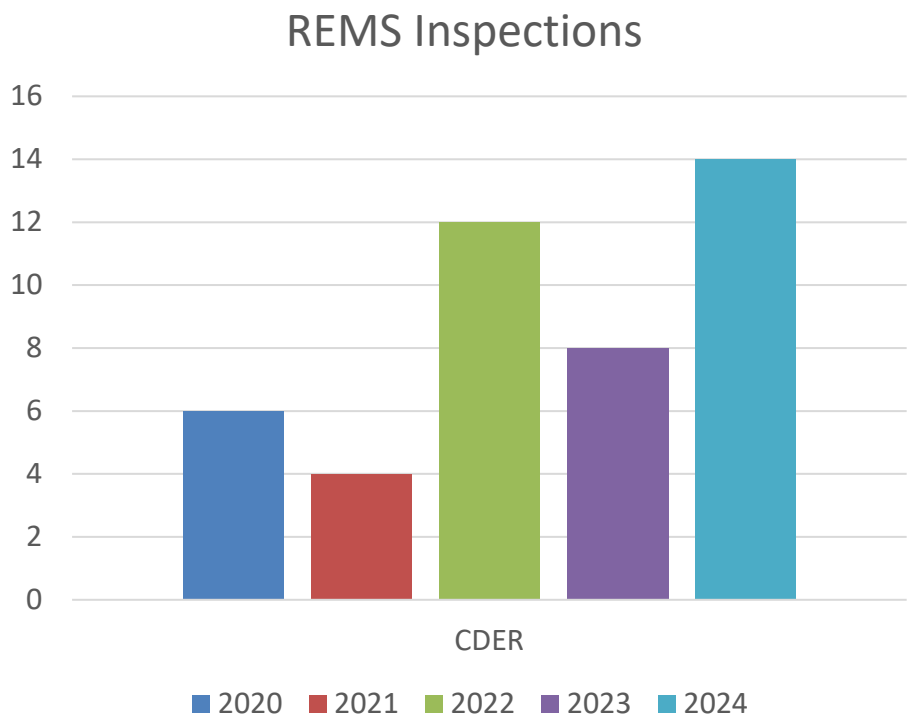
- CDER Specific Program

*3 Center-led RRAs were conducted for this program in FY24

- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Terms

Number of Risk Evaluation and Mitigation Strategies Inspections Final Classified FY 2020-2024



Center	2020	2021	2022	2023	2024
CDER	6	4	12	8	14

- CDER Specific Program

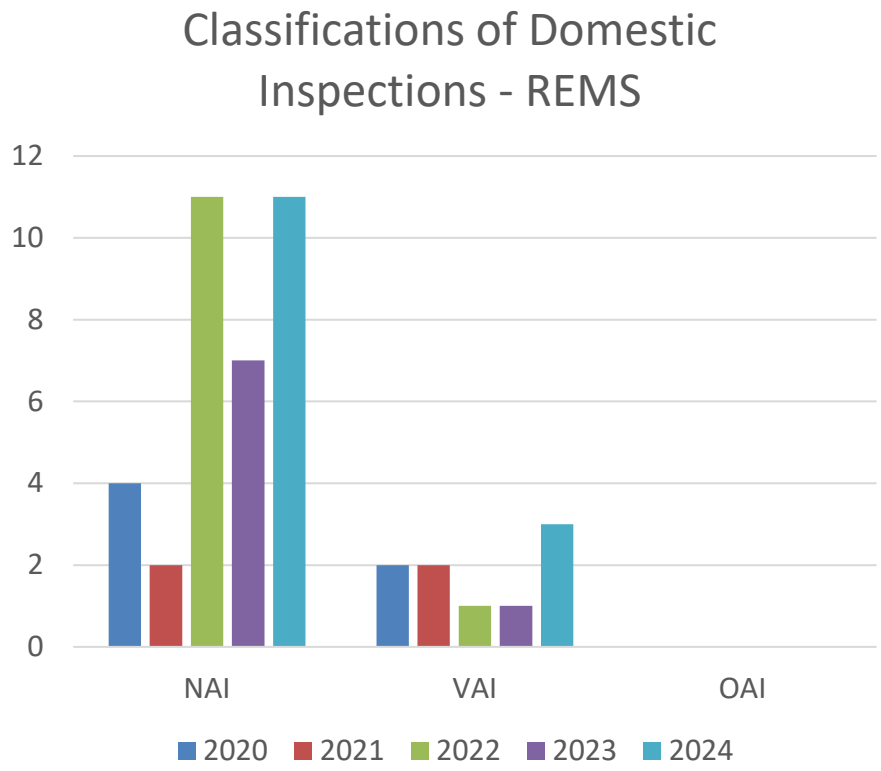
- RRAs are not reflected in the above table. See slide 31 for more details on RRAs.

Common Risk Evaluation and Mitigation Strategies Inspectional Observations*

- Failure to comply with REMS Implementation System; An application holder did not maintain a Support / Call Center or a REMS Program website, as required by approved REMS Implementation System
- Failure to comply with REMS Elements to Assure Safe Use (ETASU) Parts A, B, C,D,F

*Most common observations collected from issued Form FDA 483s, reflect a summarization of the observations and are not verbatim from the regulations

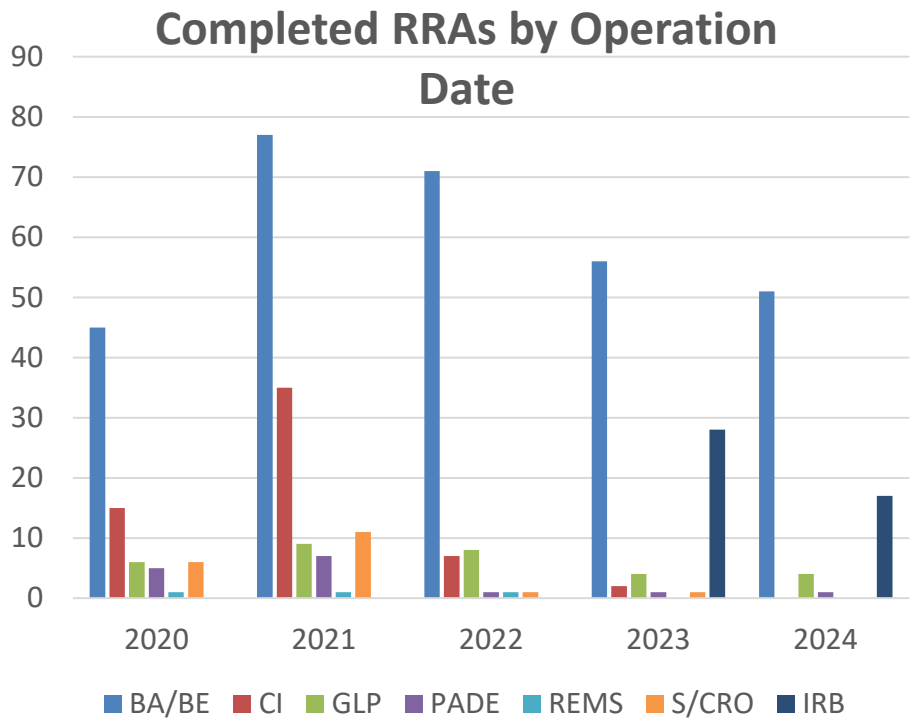
Number of REMS Inspections Final Classified FY 2020-2024



	2020	2021	2022	2023	2024
NAI	4	2	11	7	11
VAI	2	2	1	1	3
OAI	0	0	0	0	0

- CDER Specific Program

Number of Remote Regulatory Assessments Completed FY 2020-2024



This data represents the RRAs that were completed by operation date.

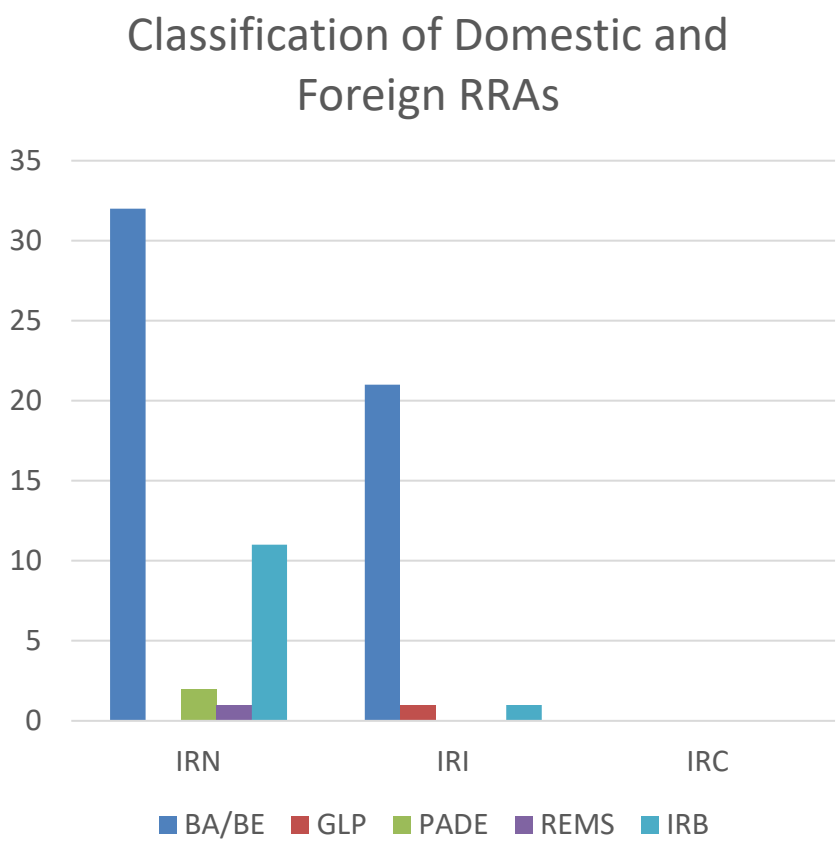
Program area	2020	2021	2022	2023	2024
Bioavailability/ Bioequivalence	41*	77*	90*	70*	48*
Clinical Investigator	15	35	7	2	0
Good Laboratory Practice	6	9*	9*	4*	3*
Postmarketing Adverse Drug Experience	5	7	1	1	1
Risk Evaluation and Mitigation Strategies	1	1	1	0	0
Sponsor/Contract Research Organization	6	11	1	1	0
Institutional Review Board	0	0	0	28	17
Totals	74	140	109	106	75

*CDER/OSIS Completed RRAs:

- FY20: 36 BA/BE RRAs (14 Clinical, 22 Analytical)
- FY21: 68 BA/BE RRAs (18 Clinical, 50 Analytical); 7 GLP RRAs
- FY22: 79 analytical BA/BE RRAs; 9 GLP RRAs
- FY23: 61 analytical BA/BE RRAs; 4 GLP RRAs
- FY24: 48 analytical BA/BE RRAs; 3 GLP RRAs

Terms

Number of Remote Regulatory Assessments Final Classified FY 2024



Program area	IRN	IRI	IRC	total
Bioavailability/ Bioequivalence	32	21	0	51
Clinical Investigator	0	0	0	0
Good Laboratory Practice	2	1	0	3
Postmarketing Adverse Drug Experience	1	0	0	1
Risk Evaluation and Mitigation Strategies	1	0	0	1
Sponsor/Contract Research Organization	0	0	0	0
Institutional Review Board	11	1	0	12
total	46	23	0	69

- IRN: Information Received- No Items Noted (equivalent to NAI)
- IRI: Information Received- Items Noted (equivalent to VAI)
- IRC : Information Received- Compliance Indicated (equivalent to OAI)

Locations of Firms that were assessed by RRA

This GeoMap represents the number of firms that were evaluated by RRA per geo area.

Created using Maptive.com

References

- FDA's Bioresearch Monitoring Compliance Programs:
  - In Vivo Bioavailability-Bioequivalence Studies - Clinical, 7348.003
  - In Vivo Bioavailability-Bioequivalence Studies - Analytical, 7348.004
  - Inspections of Nonclinical Laboratories Conducting Animal Rule-Specific Studies, 7348.007
  - Good Laboratory Practice (Nonclinical Laboratories), 7348.808
  - Good Laboratory Practice Program (Nonclinical Laboratories) EPA Data Audit Inspections, 7348.808A
  - Institutional Review Board, 7348.809
  - Radioactive Drug Research Committee, 7348.809A
  - Sponsors and Contract Research Organizations, 7348.810
  - Clinical Investigators and Sponsor-Investigators, 7348.811
  - Postmarketing Adverse Drug Experience (PADE) Reporting Inspections, 7353.001
  - Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections, 7353.001C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