U.S. FOOD & DRUG ADMINISTRATION

Bioresearch Monitoring (BIMO)
Fiscal Year 2018
Metrics

FY2018* BIMO[1] Inspections Classified

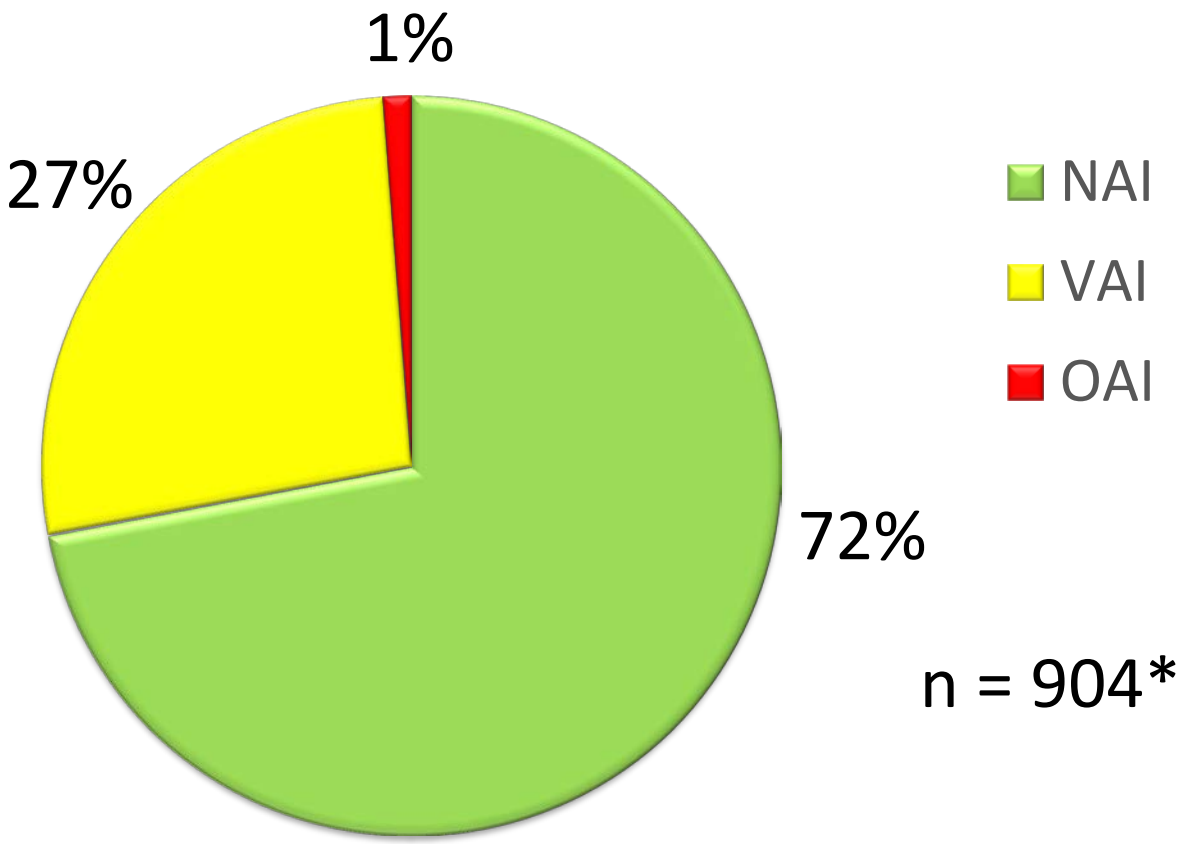
Center	CI	IRB	S/M/CRO	S/I	GLP	BEQ	PADE	REMS	Total
CBER	75	3	13	7	0	0	0	0	98
CDER	591	105[2]	85	13	35	241	72	11	1153
CDRH	225	55	53	2	12	0	0	0	347
CVM	13	0	2	0	9	0	0	0	24
Totals	904	163	153	22	56	241	72	11	1622

* **Data includes domestic and international inspections classified in fiscal year 2018**

[1]The FDA's Bioresearch Monitoring (BIMO Program) consists of all six product centers: CBER,CDER, CDRH, CFSAN, CTP, and CVM. In FY18, CFSAN and CTP did not classify any inspections based on Center final classification date.

[2] The number of Institutional Review Board (IRB) inspections includes 4 Radioactive Drug Research Committee (RDRC) inspections.

FY18 Clinical Investigator Inspections Classified



***Data includes domestic and international inspections classified in fiscal year 2018**

*Inspections classified in FY18 by CBER, CDER, CDRH and CVM. Some inspections may have occurred in a different FY.

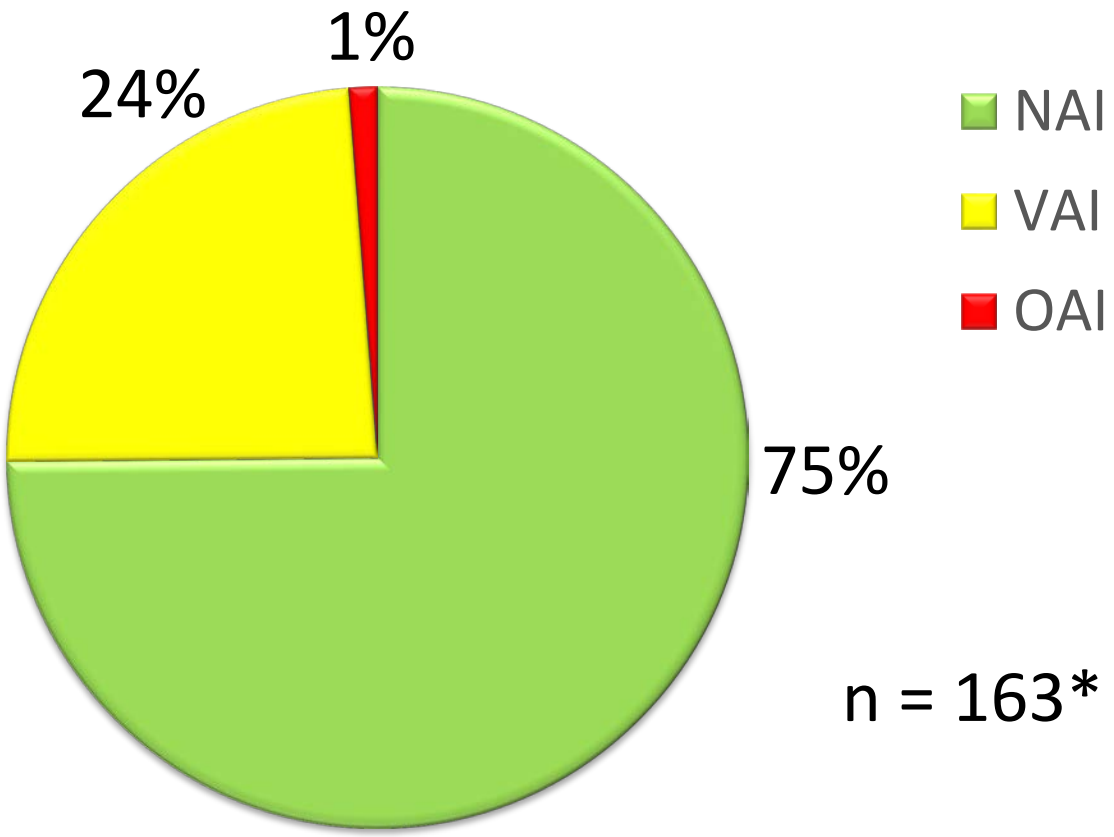
Common Clinical Investigator Observations*

- Failure to conduct an investigation in accordance with the signed investigator statement or agreement/investigational plan/applicable regulations
- Inadequate or inaccurate case histories
- Investigator's subject records inadequate
- Inadequate drug/device disposition records
- Failure to obtain informed consent in accordance with Part 50

* Clinical Investigator (CP 7348.811) observations identified in FDA Form 483 issued at close of inspections.

FY18 Institutional Review Board Inspections Classified

Includes 4 RDRC



n = 163*

***Data includes domestic and international inspections classified in fiscal year 2018**

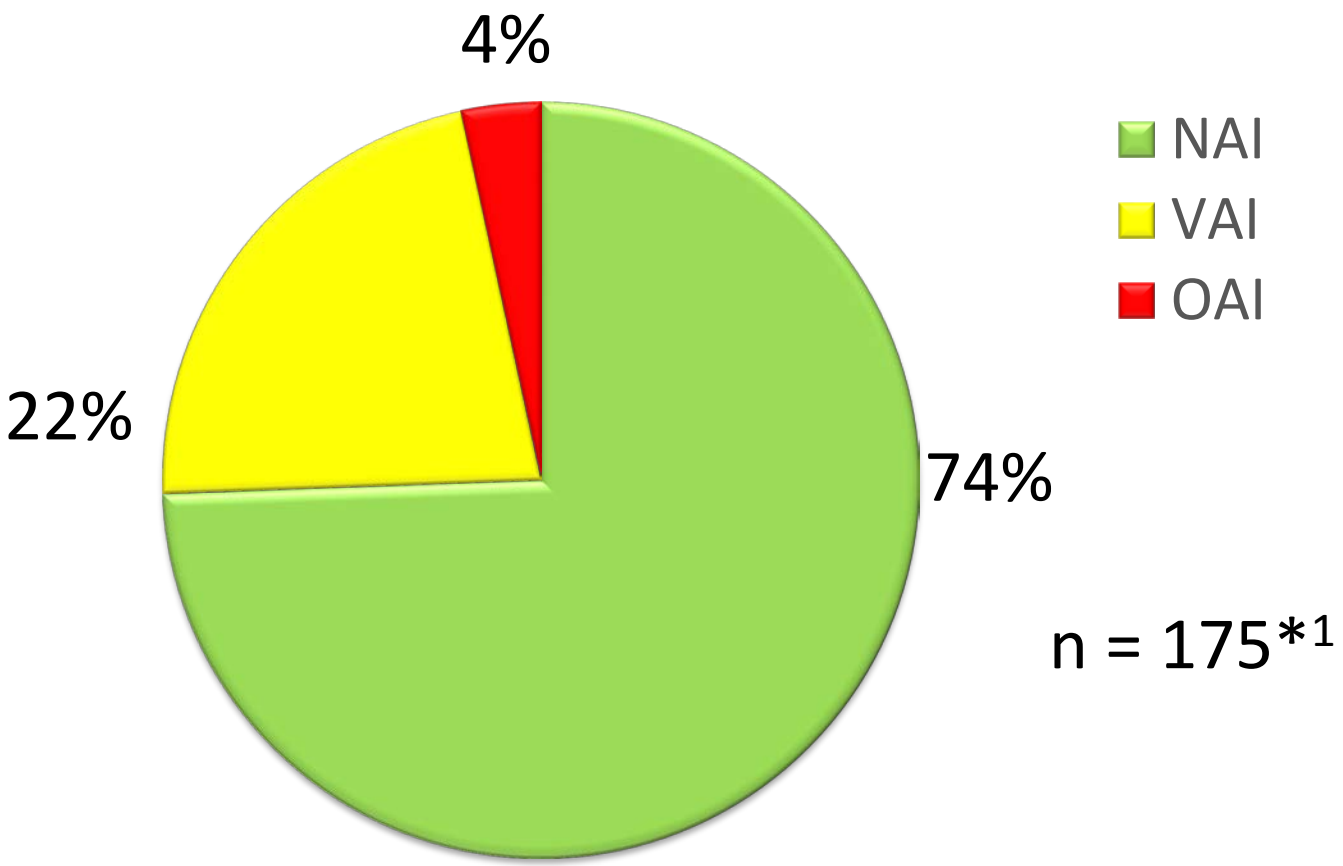
*Inspections classified in FY18 by all Centers with jurisdiction over studies involving human subjects. Some inspections may have occurred in a different FY.

Common IRB Observations*

- Inadequate meeting minutes
- Inadequate membership rosters
- Inadequate initial and continuing review of research
- Inadequate written procedures for prompt reporting of non-compliance, suspension or termination
- Quorum issues

*Institutional Review Board (CP 7348.809) observations identified in FDA Form 483 issued at close of inspections.

FY18 Sponsor/Monitor/CRO/SI[1] Inspections Classified



***Data includes domestic and international inspections classified in fiscal year 2018** by CBER, CDER, CDRH and CVM.

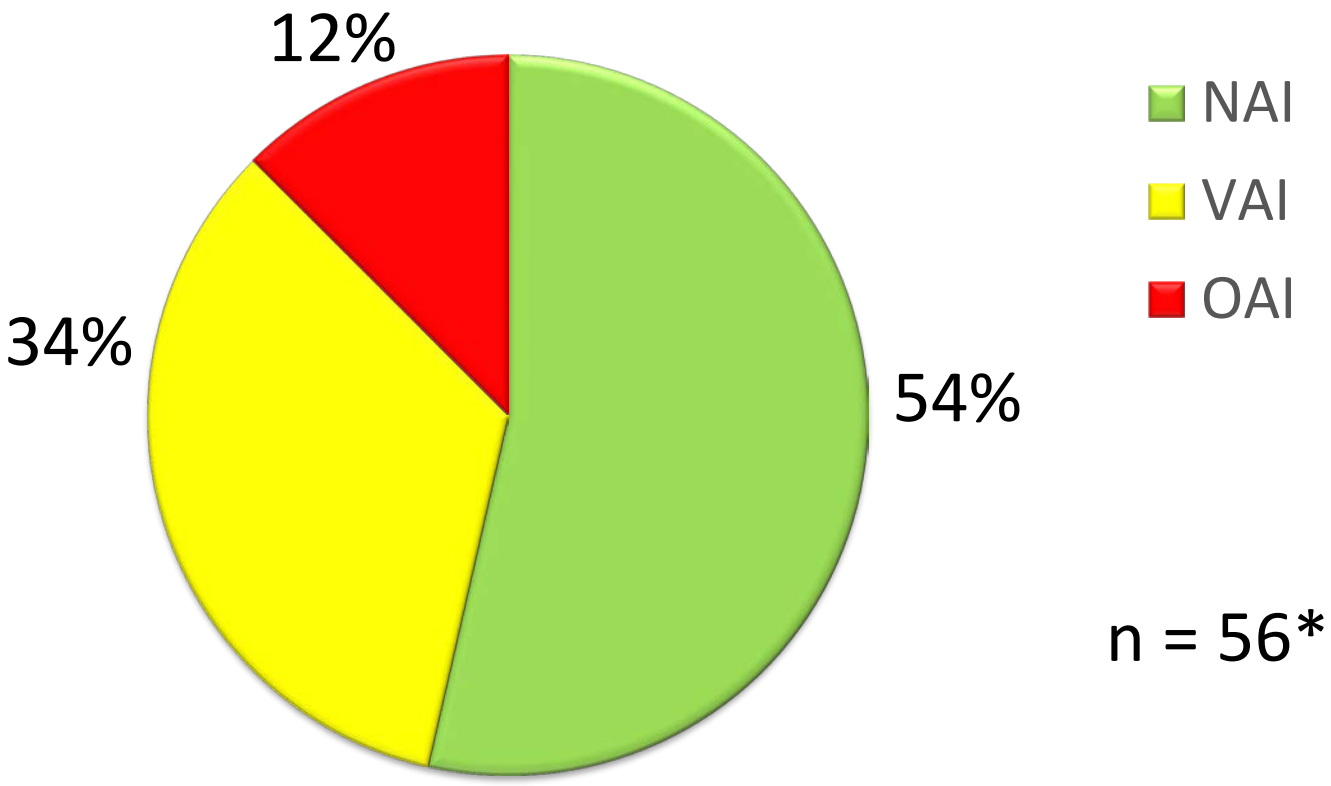
[1]Includes Sponsor-Investigator inspections: 153 (S/M/CRO) + 22 (SI) = 175 Some inspections may have occurred in a different FY.

Common S/M/CRO/SI Observations*

- Failure to ensure proper monitoring
- Failure to ensure the investigation is conducted in accordance with the general investigational plan and protocol(s)
- Failure to secure compliance or terminate an investigator's participation in the investigation
- Failure to ensure the FDA/IRB/investigators are informed of significant new information or significant new adverse effects

*Sponsors, Contract Research Organizations, Monitors (CP 7348.810) and Sponsor Investigator inspection observations identified in FDA Form 483 issued at close of inspections.

FY18 Good Laboratory Practice Inspections Classified



***Data includes domestic and international inspections classified in fiscal year 2018**

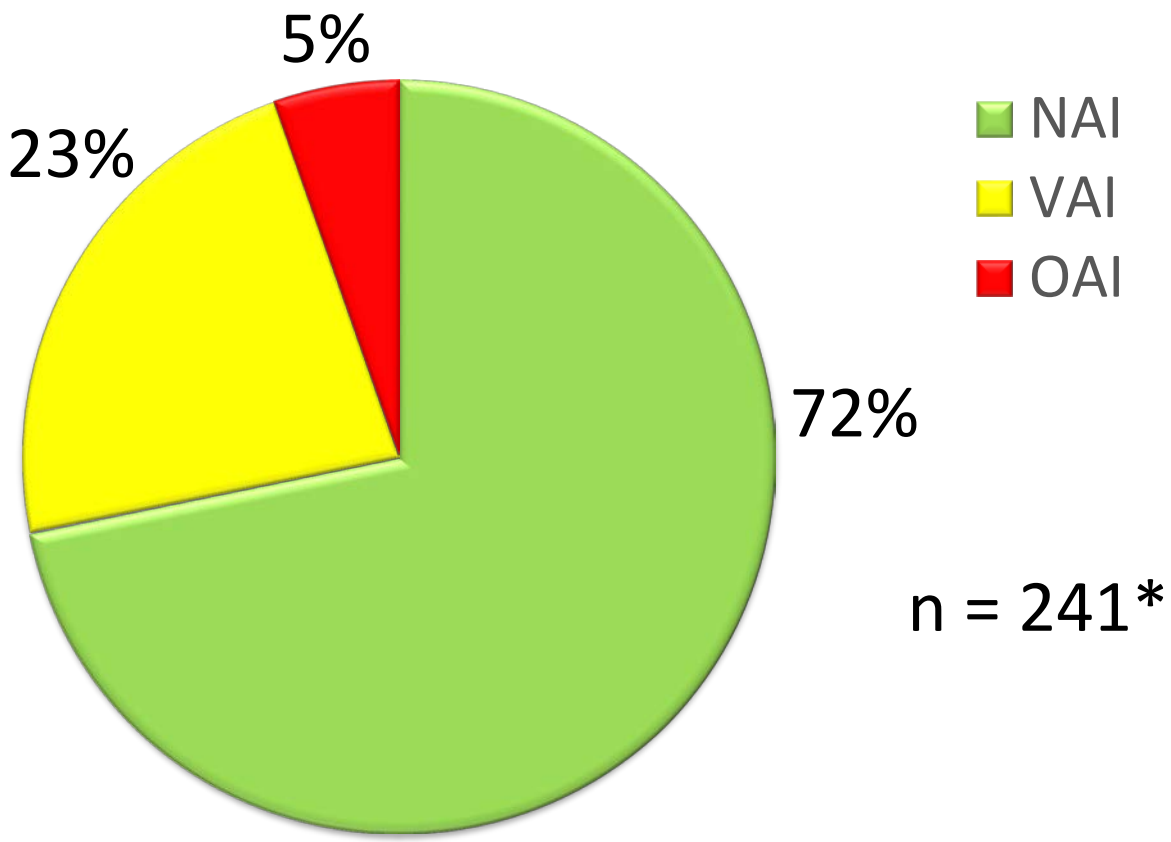
*Inspections classified in FY18 by CDER, CDRH and CVM . Some inspections may have occurred in a different FY.

Common GLP Observations*

- Inadequate equipment calibration
- Protocol deviations
- Inadequate monitoring of facilities
- Incomplete/inadequate/no study records
- Inadequate archiving

* GLP (CP 7348.808) observations identified in FDA Form 483 issued at close of inspections.

FY18 Bioequivalence Inspections Classified



***Data includes domestic and international site visit inspections classified in fiscal year 2018**

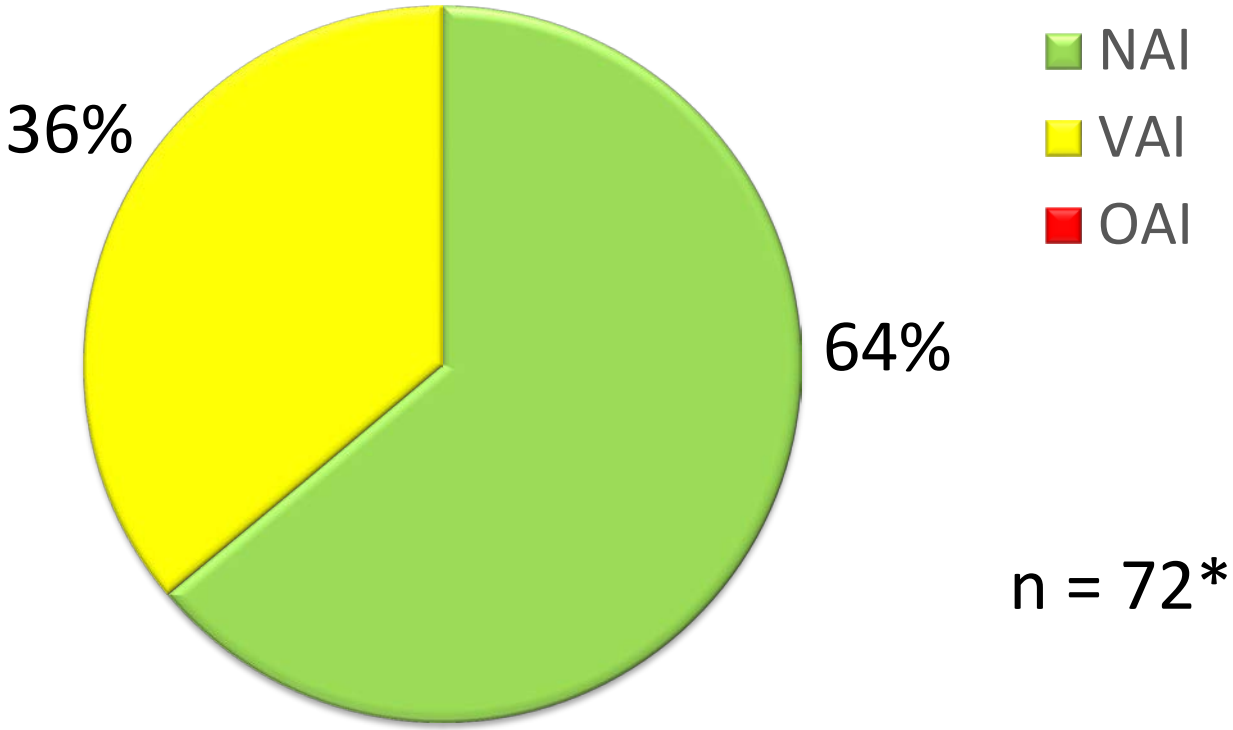
*CDER specific program. Includes Analytical inspections. Some inspections may have occurred in a different FY.

Common Bioequivalence Observations*

- Recordkeeping
- Blinding Codes
- SOPs
- Inclusion/exclusion criteria issues
- Analytical concerns:
  - Validation
  - Stability
  - Chromatography
  - Calibration Curve

*Bioequivalence (CP 7348.001) observations identified in FDA Form 483 issued at close of inspections.

FY18 Postmarketing Adverse Drug Experience (PADE) Inspections Classified



***Data includes domestic and international inspections classified in fiscal year 2018**

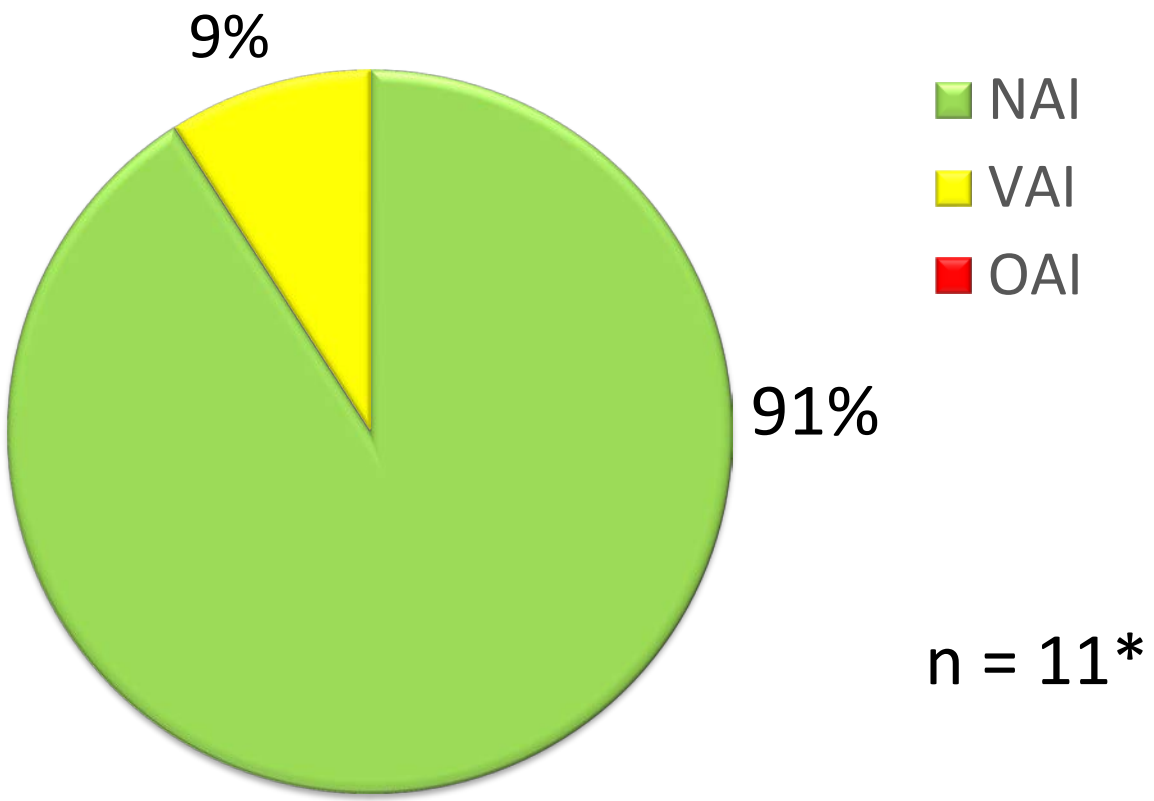
*CDER specific program. Some inspections may have occurred in a different FY.

Common PADE Observations*

- Failure to develop written procedures
- Late submission of 15-day Alert reports
- Late submission of annual report
- Late submission of quarterly safety reports

*Postmarketing Adverse Drug Experience (CP 7353.001) observations identified in FDA Form 483 issued at close of inspections.

FY18 Risk Evaluation Mitigation Strategies (REMS) Inspections Classified



***Data includes domestic and international inspections classified in fiscal year 2018**

*CDER specific program. Inspections classified in FY18. Some inspections may have occurred in a different FY.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