U.S. FOOD & DRUG ADMINISTRATION

Bioresearch Monitoring (BIMO)

Fiscal Year 2017

Metrics

FY 2017 BIMO[1] Inspections Classified

Center	CI	IRB	S/M/CRO[2]	GLP	Total
CBER	84	10	3	0	97
CDER[3]	419	79[4]	55	28	581
CDRH	198	35	48	6	287
Totals	701	124	106	34	965

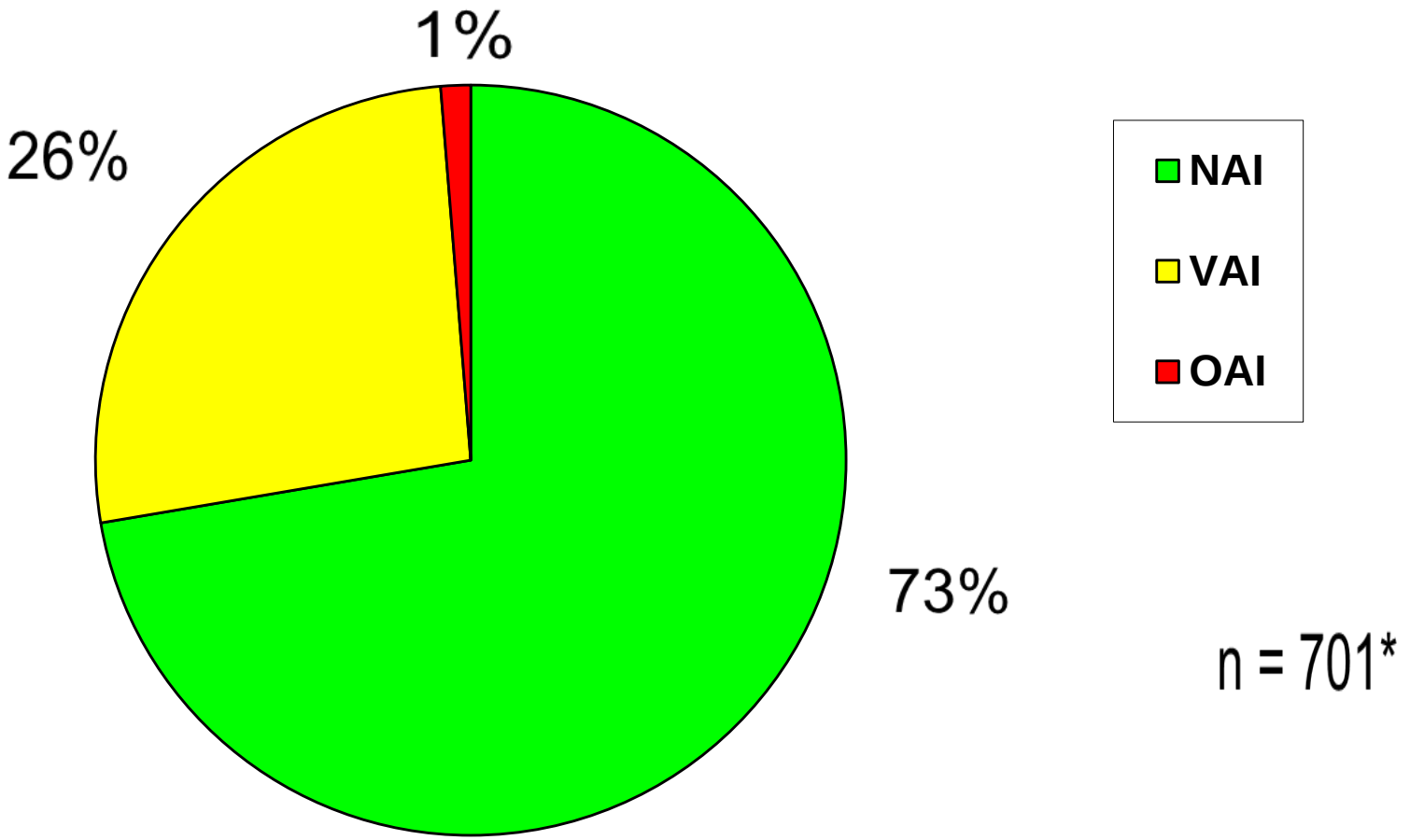
[1]The FDA's Bioresearch Monitoring (BIMO Program) consists of all six product centers: CBER,CDER, CDRH, CFSAN, CTP, and CVM. In FY17, CFSAN, CVM and CTP did not classify any inspections. After ORA's Program Alignment, the BIMO Program now includes Postmarketing Adverse Events (PADE) and Risk Evaluation Mitigation Strategies (REMS) Compliance Programs.

[2]Sponsor/Monitor/CRO inspection totals include Sponsor/Investigator inspections.

[3] In FY17, CDER classified 355 inspections of bioavailability/bioequivalence sites (CP 7348.001), 97 inspections for PADE (CP 7353.001), and 15 inspections for REMS (CP 7353.001), raising FDA's total classified BIMO inspections in FY17 to **1432** (965 + 355 +97+15 = 1432).

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

FY17 Clinical Investigator Inspections Classified*



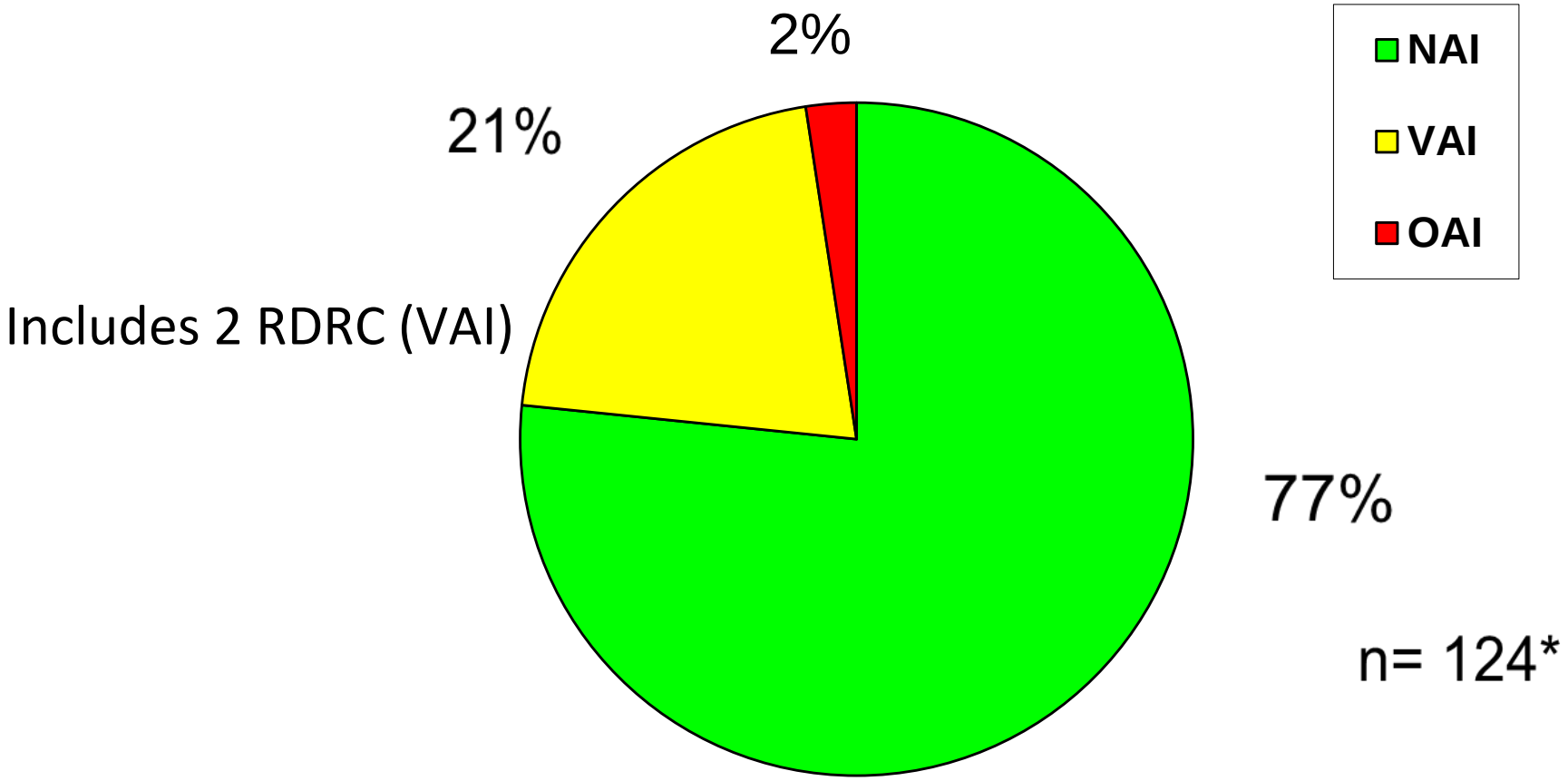
*Inspections classified in FY17 by CBER, CDER, and CDRH. Some inspections may have occurred in a different FY.

Common Clinical Investigator Deficiencies*

- Failure to follow the investigational plan/agreement or regulations, or both
- Protocol deviations
- Inadequate recordkeeping
- Inadequate subject protection – informed consent issues, failure to report AEs
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Investigational product represented as safe/effective

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

FY 17 Institutional Review Board Inspections Classified



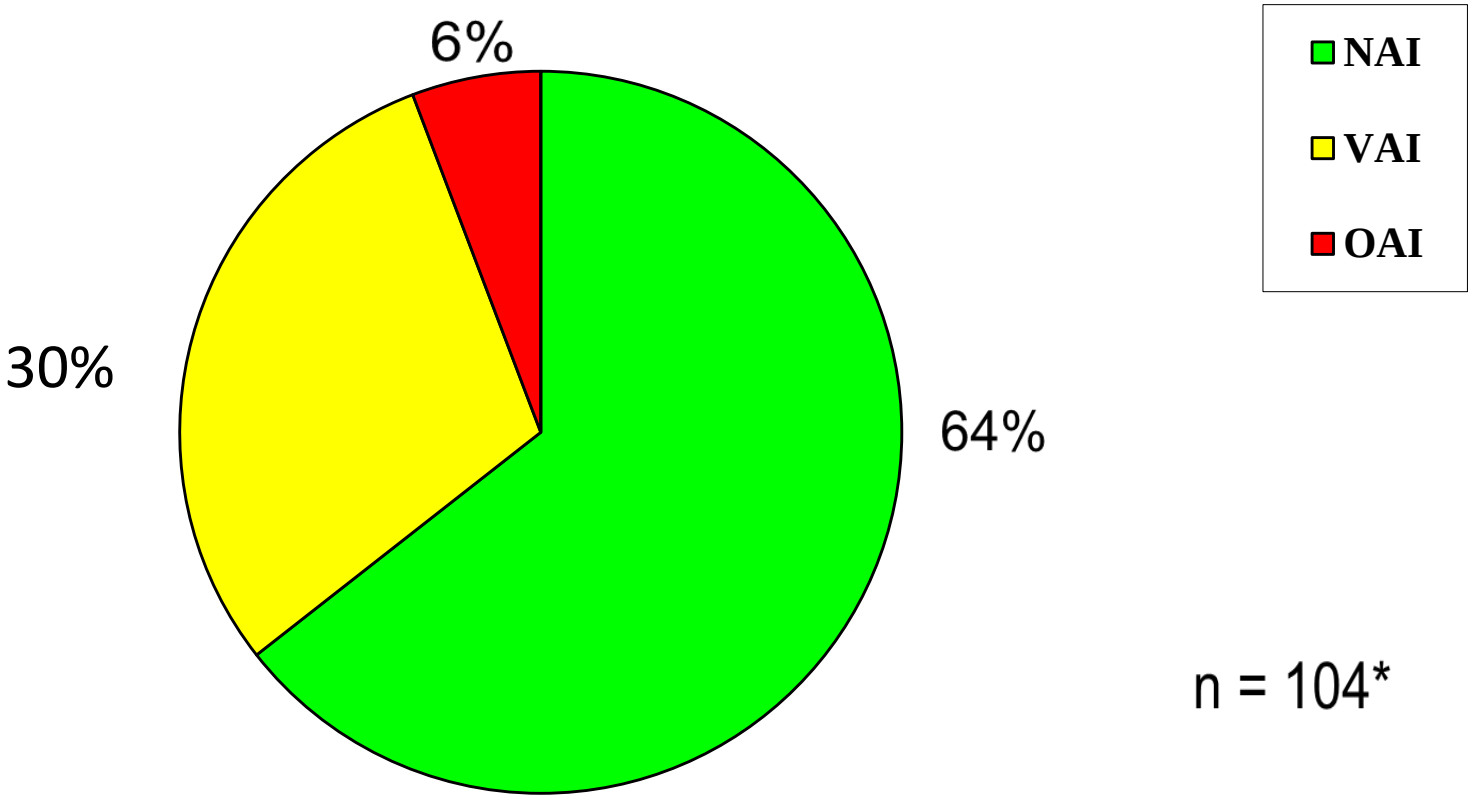
*Inspections classified in FY17 by all Centers with jurisdiction over studies involving human subjects. Some inspections may have occurred in a different FY.

Common IRB Deficiencies*

- Inadequate initial and/or continuing review
- Inadequate written procedures
- Inadequate meeting minutes, membership rosters
- Quorum issues
- Prompt reporting of non-compliance, suspension or termination
- Subpart D - Additional Safeguard for Children in Clinical Investigations issues
- Lack of or incorrect Significant Risk/Nonsignificant Risk determination

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

FY17 Sponsor/Monitor/CRO Inspections Classified



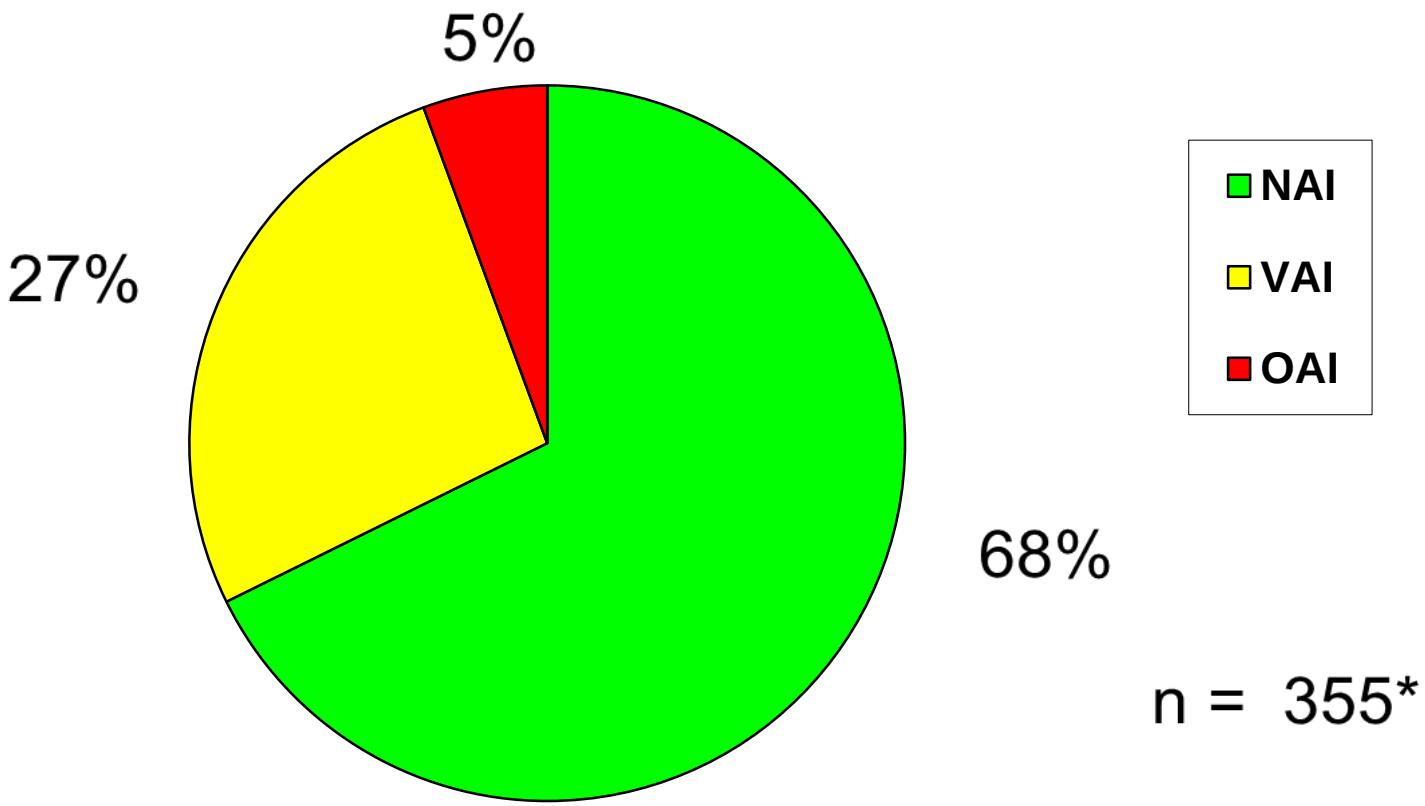
*Inspections classified in FY 17 by CBER, CDER and CDRH. Some inspections may have occurred in a different FY. Includes Sponsor-Investigator inspections.

Common S/M/CRO Deficiencies*

- Inadequate monitoring
- Failure to bring investigators into compliance
- Inadequate accountability for the investigational product
- Failure to obtain FDA and/or IRB approval prior to study initiation

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

FY17 Bioequivalence Inspections Classified



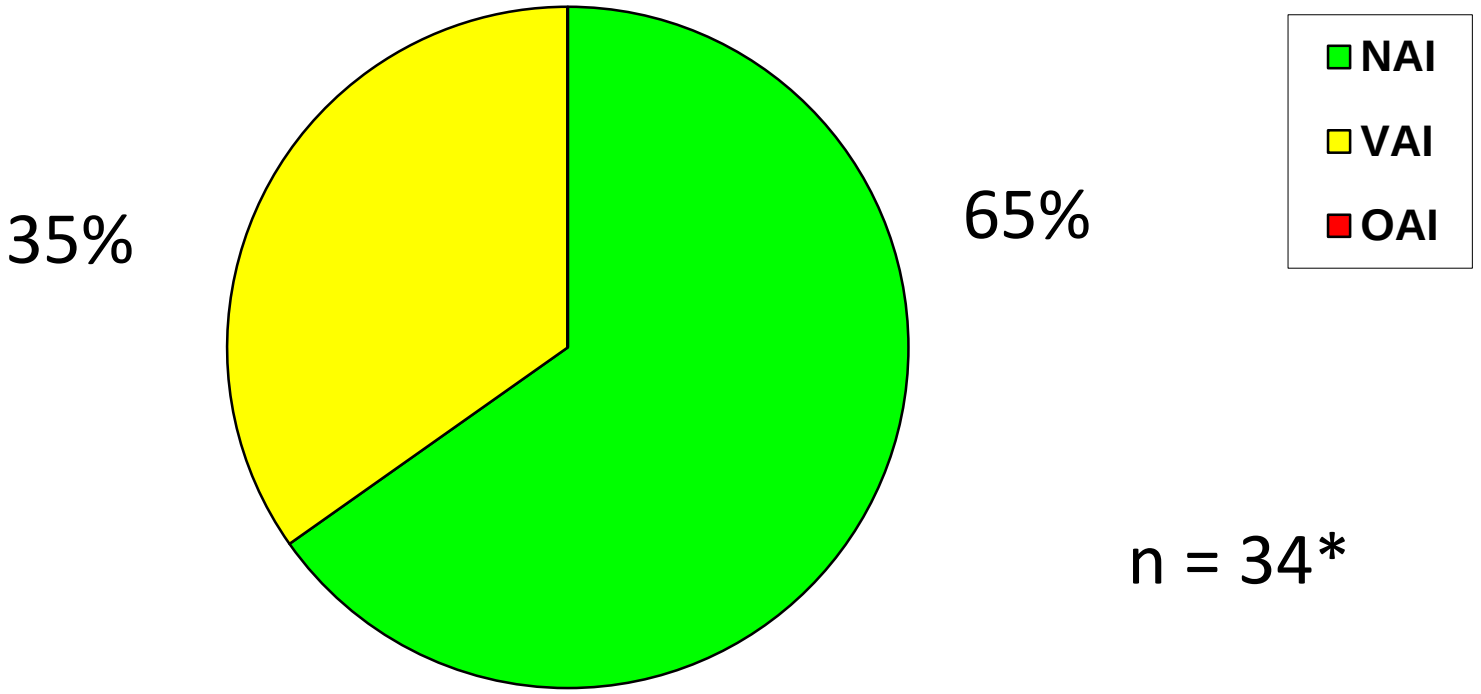
*CDER specific program. Inspections classified in FY17. Some inspections may have occurred in a different FY17.

Common Bioequivalence Deficiencies*

- Recordkeeping
- Inclusion/exclusion criteria issues
- Informed consent issues
- Dosage issues
- Analytical concerns
  - Validation
  - Stability
- Reserve Samples

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

FY 17 Good Laboratory Practice Inspections Classified



*Inspections classified in FY17 by CDER and CDRH. Some inspections may have occurred in a different FY.

Common GLP Deficiencies*

- Organizational and/or Personnel inadequacies
- Incomplete/inadequate/no study records
- Inadequate archiving
- Inadequate/no standard operating procedures (SOPs)
- Protocol deviations

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

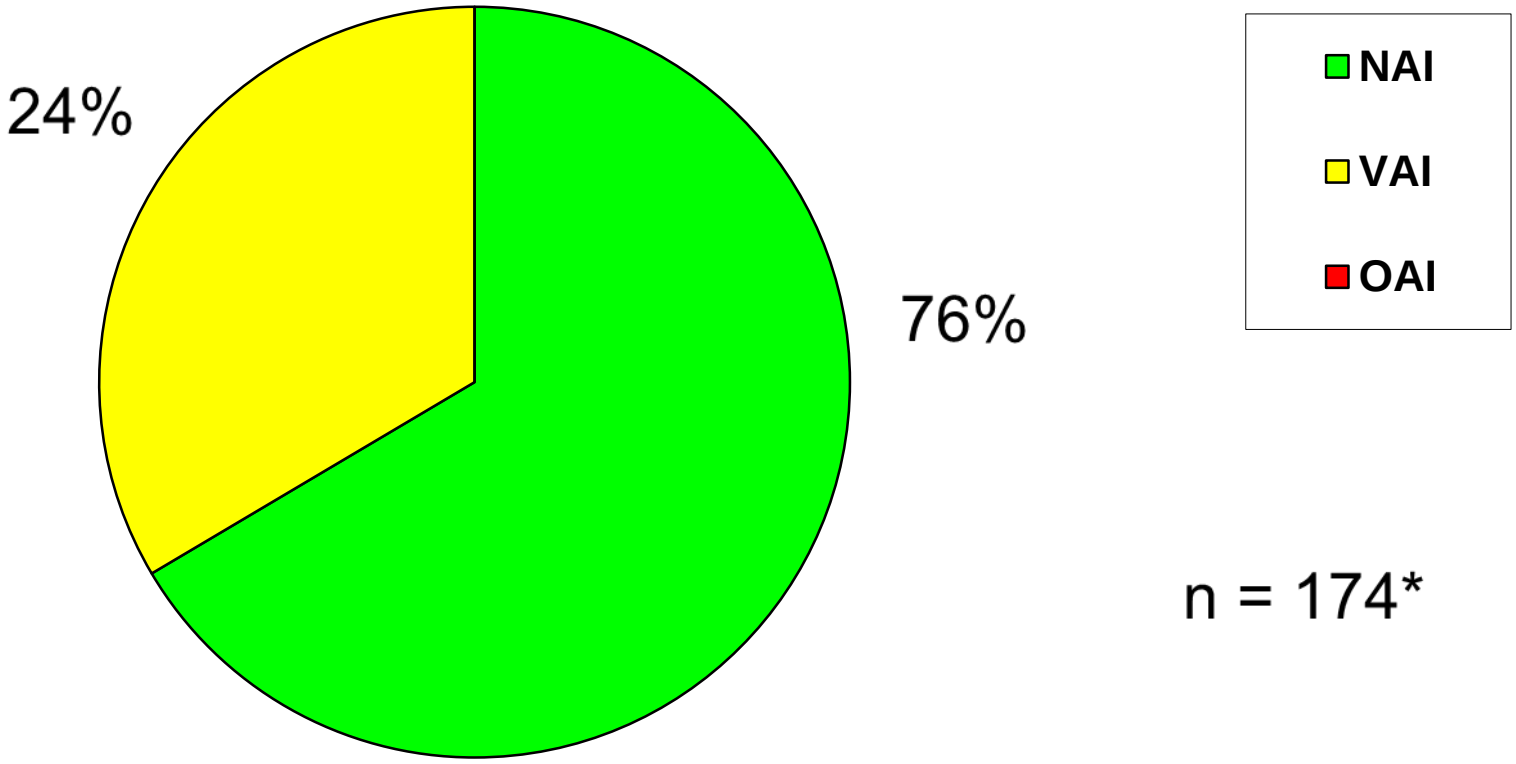
FY 2017[1] BIMO International Inspections Classified

Center	CI	S/M/CRO	GLP	BEQ	Total
CBER	18	0	0	n/a	18
CDER[2]	143	10	5	165	323
CDRH	13	4	1	n/a	18
Totals	174	14	6	165	359

[1]CFSAN, CVM, and CTP did not classify international inspections in FY17.

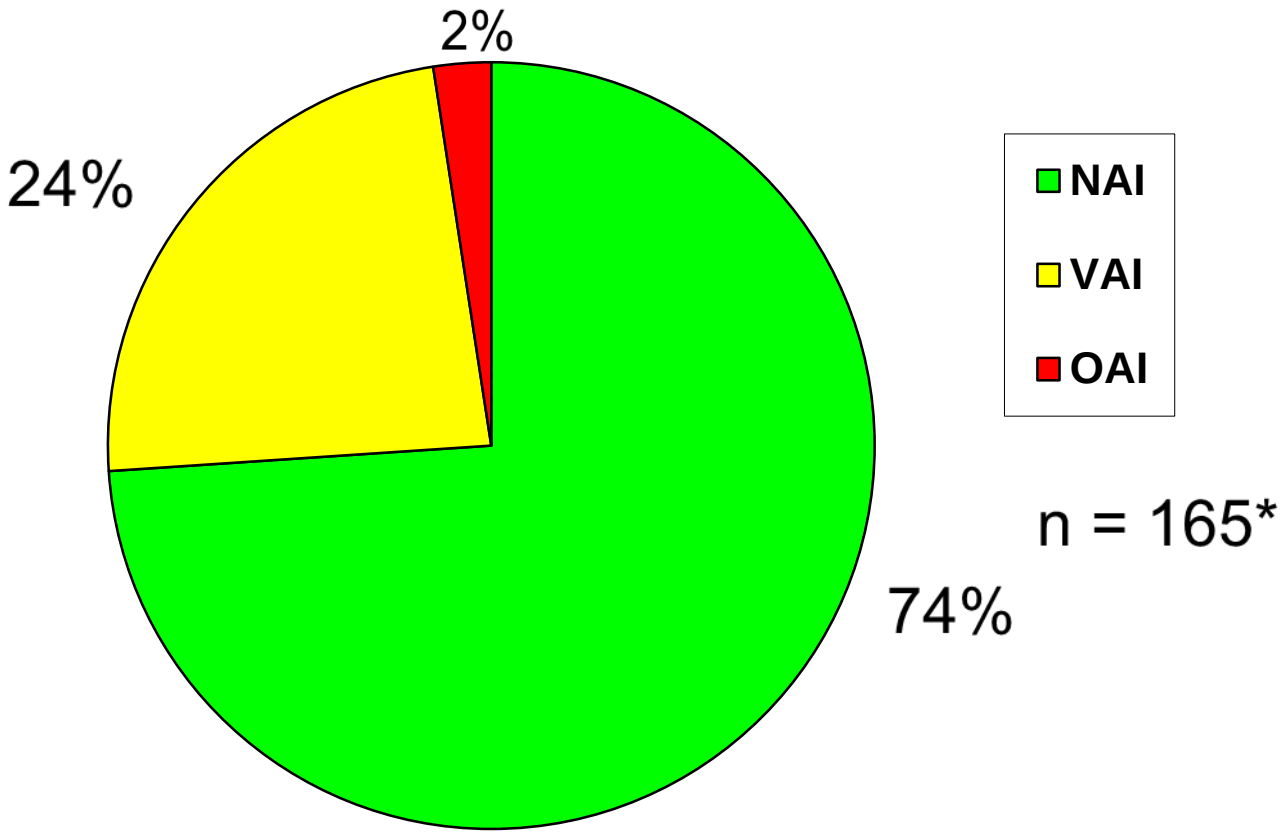
[2]In FY17, CDER classified 7 PADE inspections, raising the total international BIMO inspections in FY17 to **366** (359+7 = 366).

FY17* International CI Inspections Classified



*Clinical Investigator Inspections classified in FY17 by CBER, CDER, and CDRH. Some inspections may have occurred in a different FY.

FY17 International BEQ Inspections Classified



*Bioequivalence inspections classified by CDER in FY17. Some inspections may have occurred in a different FY.

Other International Inspections Classified in FY17*

Sponsor/Monitor/CRO

- CDER – 10 (9 NAI, 1 VAI)
- CDRH – 4 (2 NAI, 1 VAI, 1 OAI)

GLP

- CDER – 5 (1 NAI, 4 VAI)
- CDRH – 1 (1 NA1)

PADE

- CDER – 7 (4 NAI, 3 VAI)

*Some inspections may have occurred in a different FY.

Common International* Deficiencies

- Similar to domestic inspectional findings
- Sponsor inspections
  - Inadequate monitoring
  - Failure to bring investigators into compliance
- CI inspections
  - Protocol deviations
  - Inadequate investigational product accountability
  - Inadequate subject protections

*Deficiencies identified in FDA Form 483 issued at close of inspections.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