

**Bioresearch
Monitoring (BIMO)
Metrics – FY'15**

BIMO Inspections Classified FY 2015

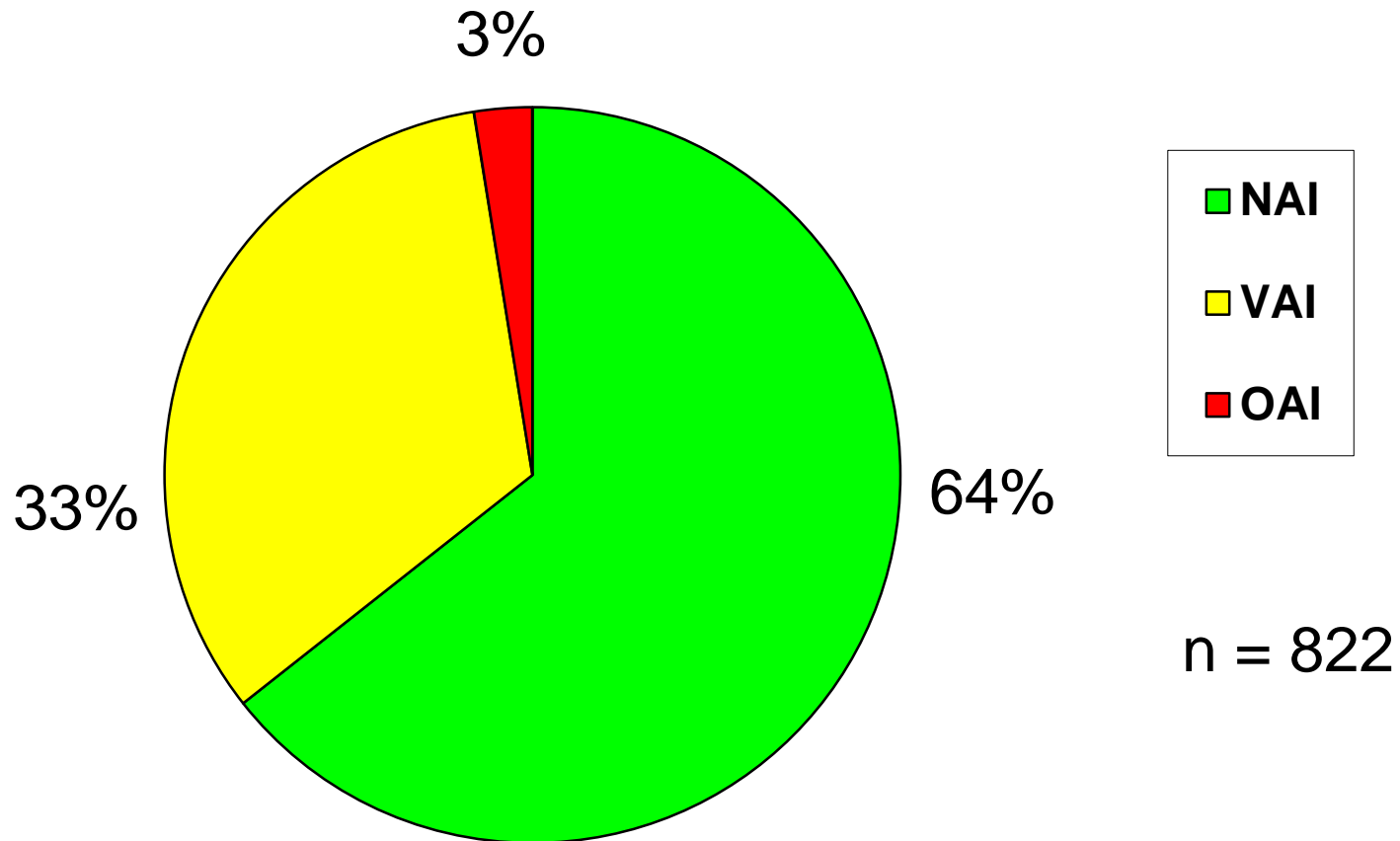
<u>Center</u>	<u>CI</u>	<u>IRB</u>	<u>Spon/Mon/CRO¹</u>	<u>GLP</u>	<u>Total</u>
CBER	101	11	1	2	115
CDER²	483	83 ³	66	24	656
CDRH	211	42	47	1	301
CFSAN	1	2	0	1	4
CVM	23	n/a	3	8	34
CTP	<u>3</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>3</u>
Totals²	822	138	117	36	1113

¹ Sponsor/Monitor/CRO inspection totals include Sponsor/Investigator inspections.

² CDER also performed 275 inspections of bioequivalence facilities (CPGM 7348.001). Grand Total of BIMO inspections in FY 2015: 1113 + 275 = **1388**

³ The number of IRB inspections includes 4 Radioactive Drug Research Committee (RDRC) inspections.

FY'15 CI Inspections Classified*

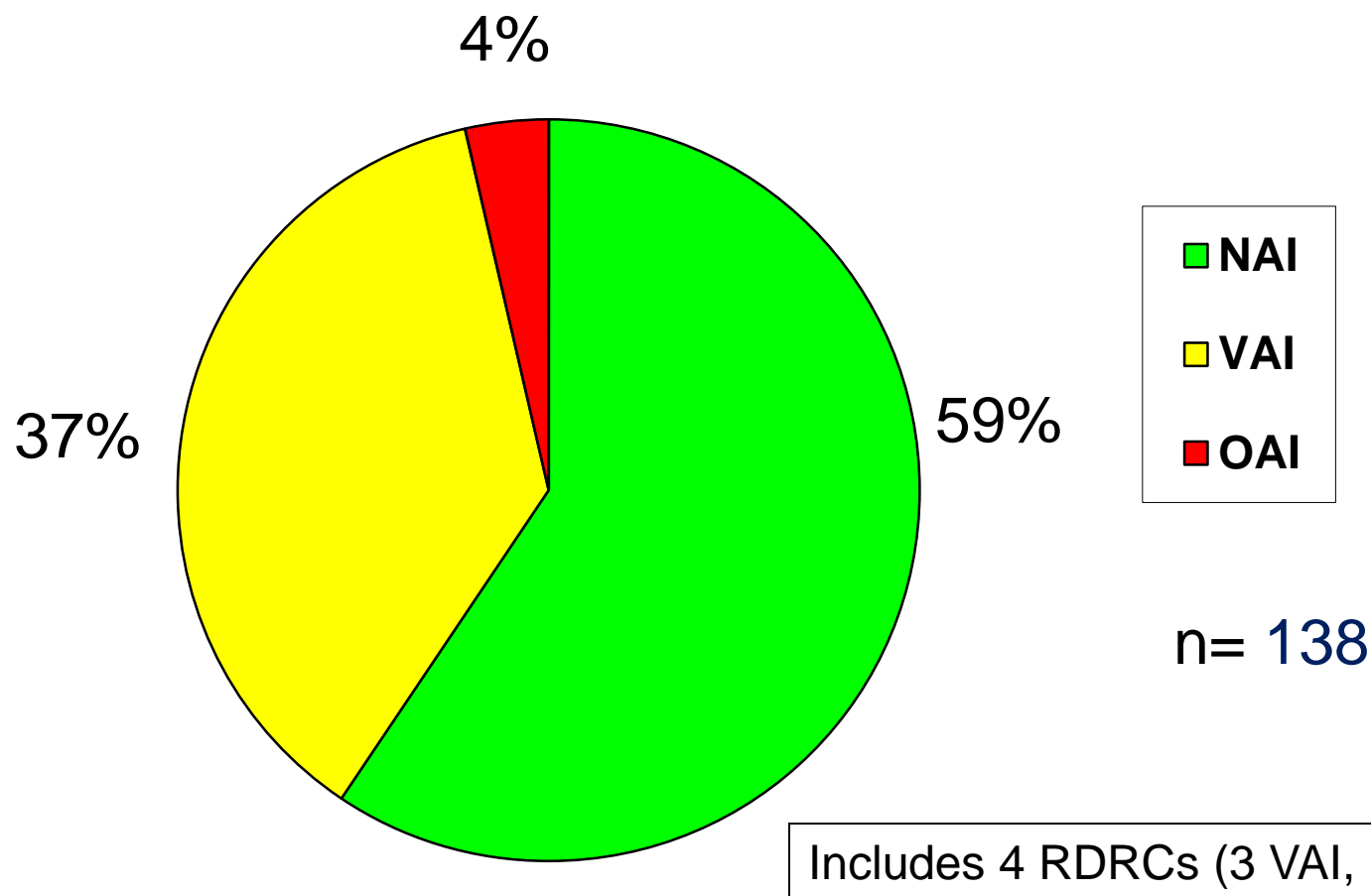


*Inspections classified in FY'15 by all Centers including CVM. Some inspections may have occurred in a different FY.

Most Common CI Deficiencies

- Failure to follow the investigational plan and/or regulations
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Inadequate subject protection – failure to report AEs and informed consent issues

FY'15 IRB Inspections Classified*



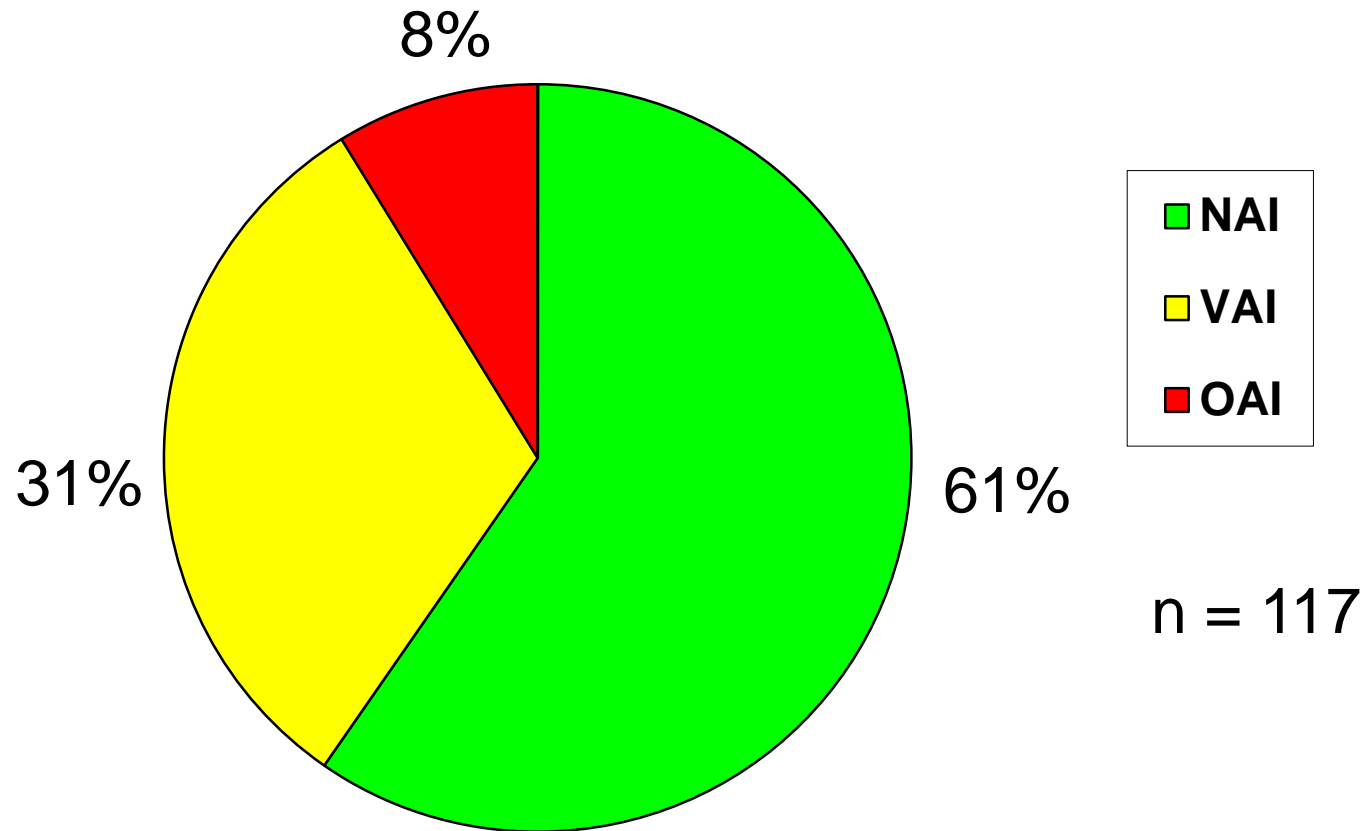
*Inspections classified in FY'15 by CFSAN, CBER, CDER, and CDRH.
Some inspections may have occurred in a different FY.

Most common IRB deficiencies

- Inadequate initial and/or continuing review
- Inadequate SOPs
- Inadequate membership rosters
- Inadequate meeting minutes
- Quorum issues
- Subpart D issues
- Inadequate communication with CI/institution

Specific to devices – lack of or incorrect SR/NSR determination

FY'15 Sponsor/Monitor/CRO Inspections Classified*

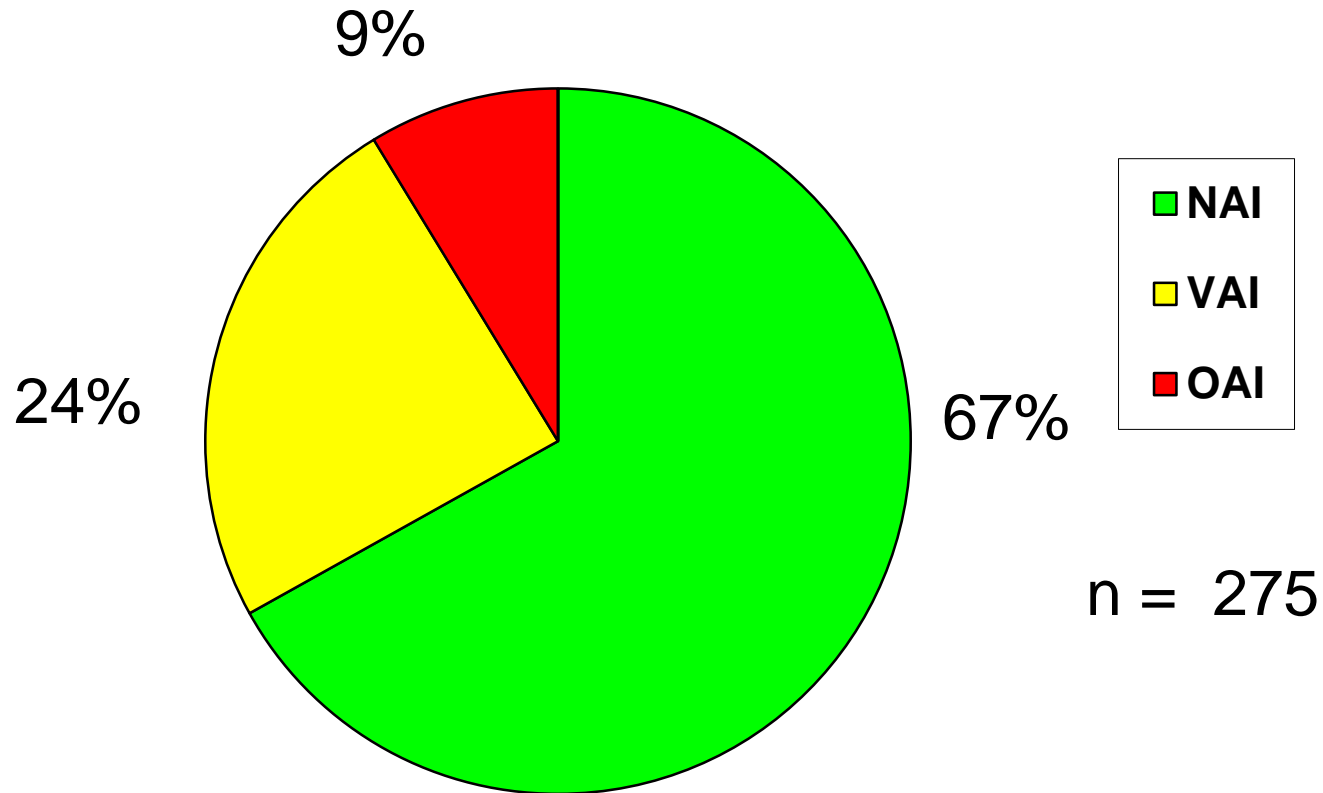


*Inspections classified in FY'15 by CBER, CDER, CDRH, and CVM. Some inspections may have occurred in a different FY. Includes Sponsor-Investigator inspections.

Most common S/M 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

FY'15 BEQ inspections classified*

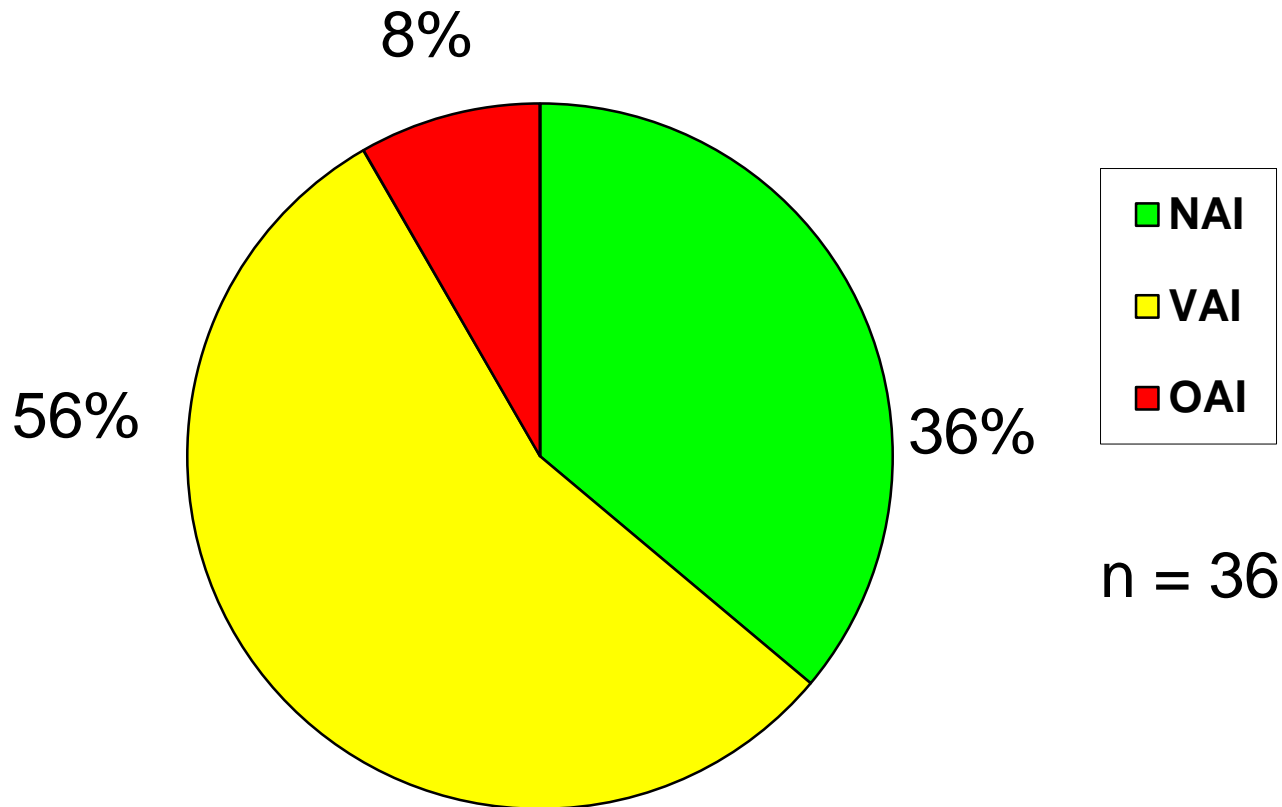


*CDER specific program. Inspections classified in FY'15. Some inspections may have occurred in a different FY.

Most common BEQ deficiencies

- Recordkeeping
- Inclusion/exclusion criteria issues
- Informed consent issues
- Dosage issues
- Analytical concerns
 - Validation
 - Stability
- Inadequate SOPs

FY'15 GLP inspections classified All Centers*



*Inspections classified in FY'15 by CBER, CDER, CDRH, CFSAN, and CVM. Some inspections may have occurred in a different FY.

Most common GLP deficiencies

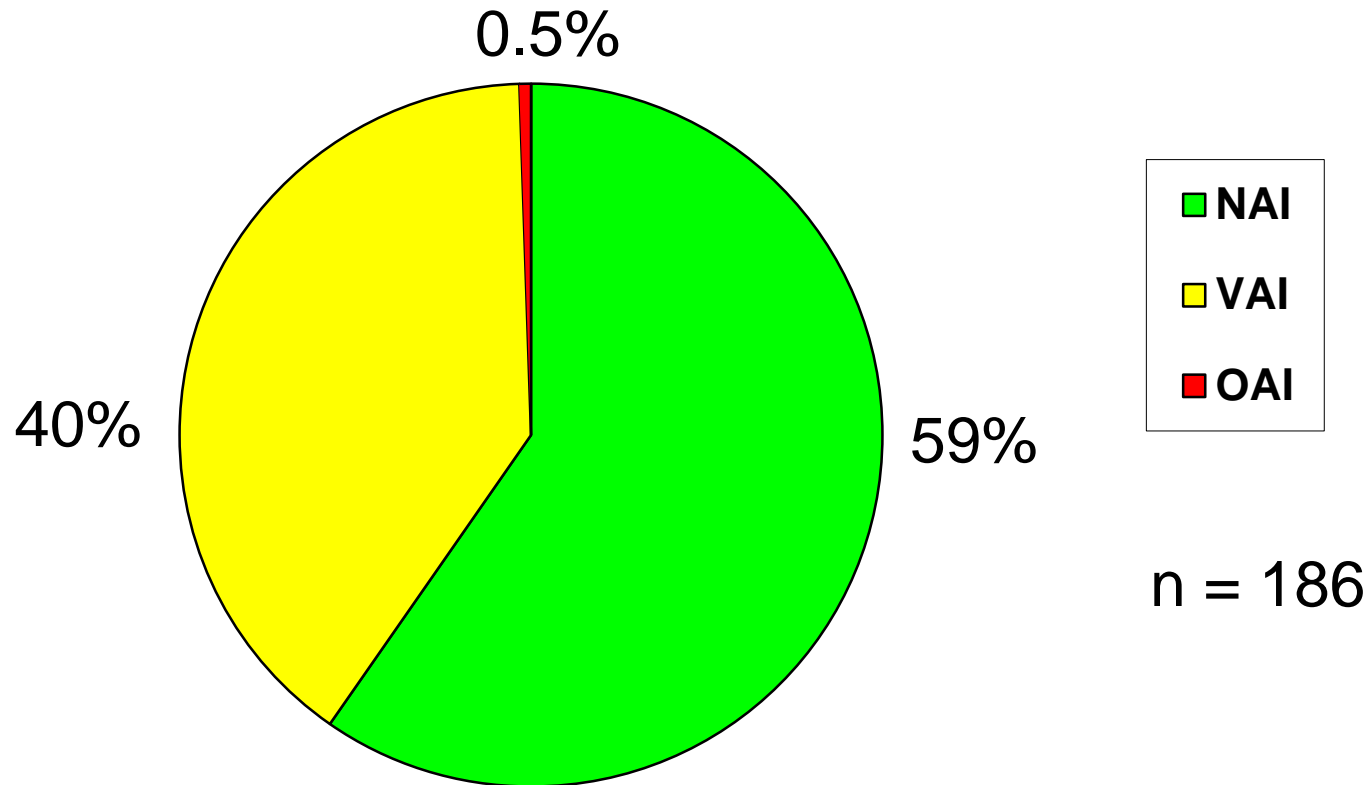
- Organizational and/or Personnel inadequacies
- Incomplete/inadequate/no study records
- Inadequate archiving
- Inadequate/no standard operating procedures (SOPs)
- Protocol deviations

International Inspections Classified: FY 2015*

<u>Center</u>	<u>CI</u>	<u>Sponsor</u>	<u>GLP</u>	<u>BEQ</u>	<u>Total</u>
CBER	23	0	0	n/a	23
CDER	148	6	3	163	320
CDRH	12	0	0	n/a	12
CTP	2	0	0	n/a	2
CVM	1	0	1	n/a	2
Totals	186	6	4	163	359

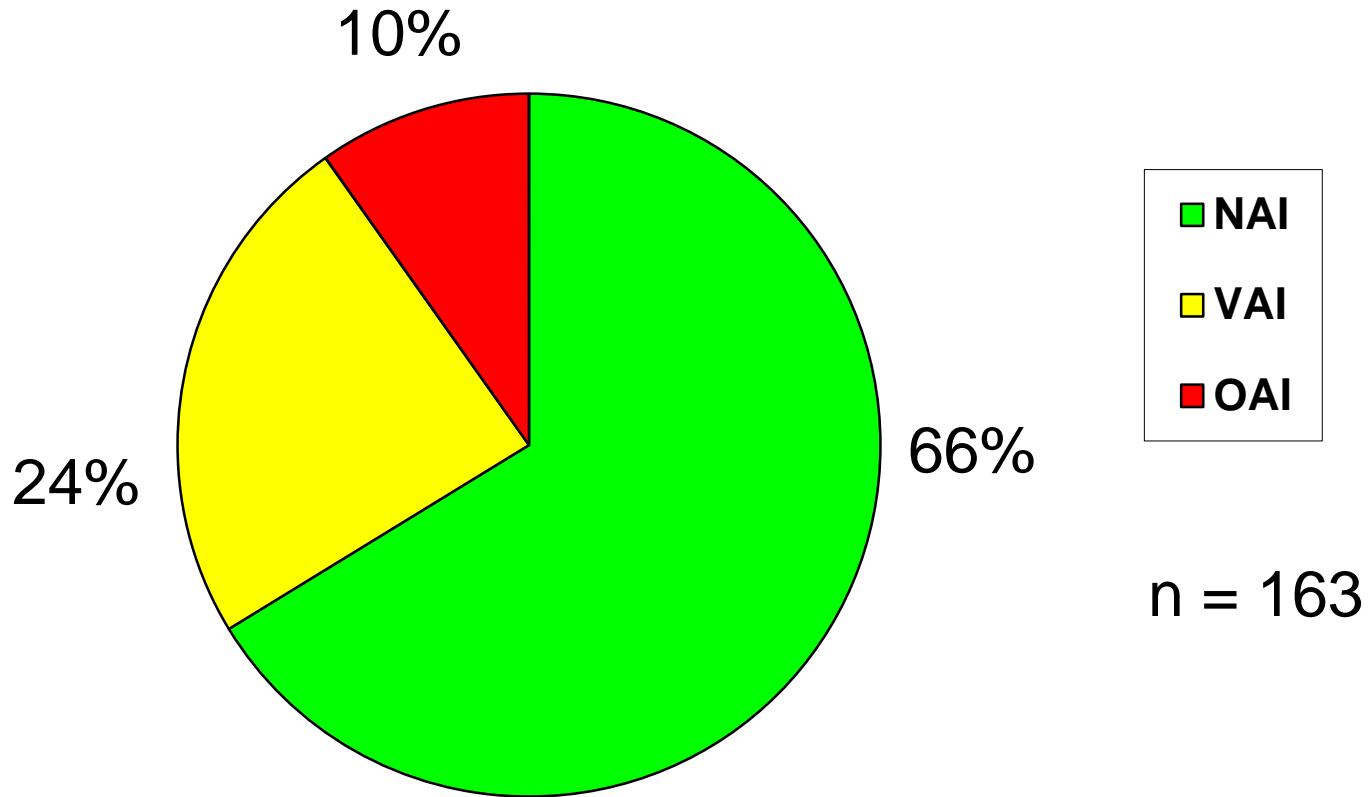
*CFSAN did not classify any international inspections in FY'15.

FY'15 International CI Inspections Classified All Centers*



*Inspections classified in FY'15 by CBER, CDER, CDRH, CTP, and CVM.
Some inspections may have occurred in a different FY.

FY'15 International BEQ Inspections Classified*



*BEQ inspections classified by CDER in FY15. Inspection may have occurred in a different FY.

Other International Inspections Classified in FY'15*

Sponsor/CRO

- CDER – 6 (4 NAI, 1 VAI, 1 OAI)

GLP

- CDER – 3 (2 VAI, 1 NAI)
- CVM – 1 (NAI)

*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