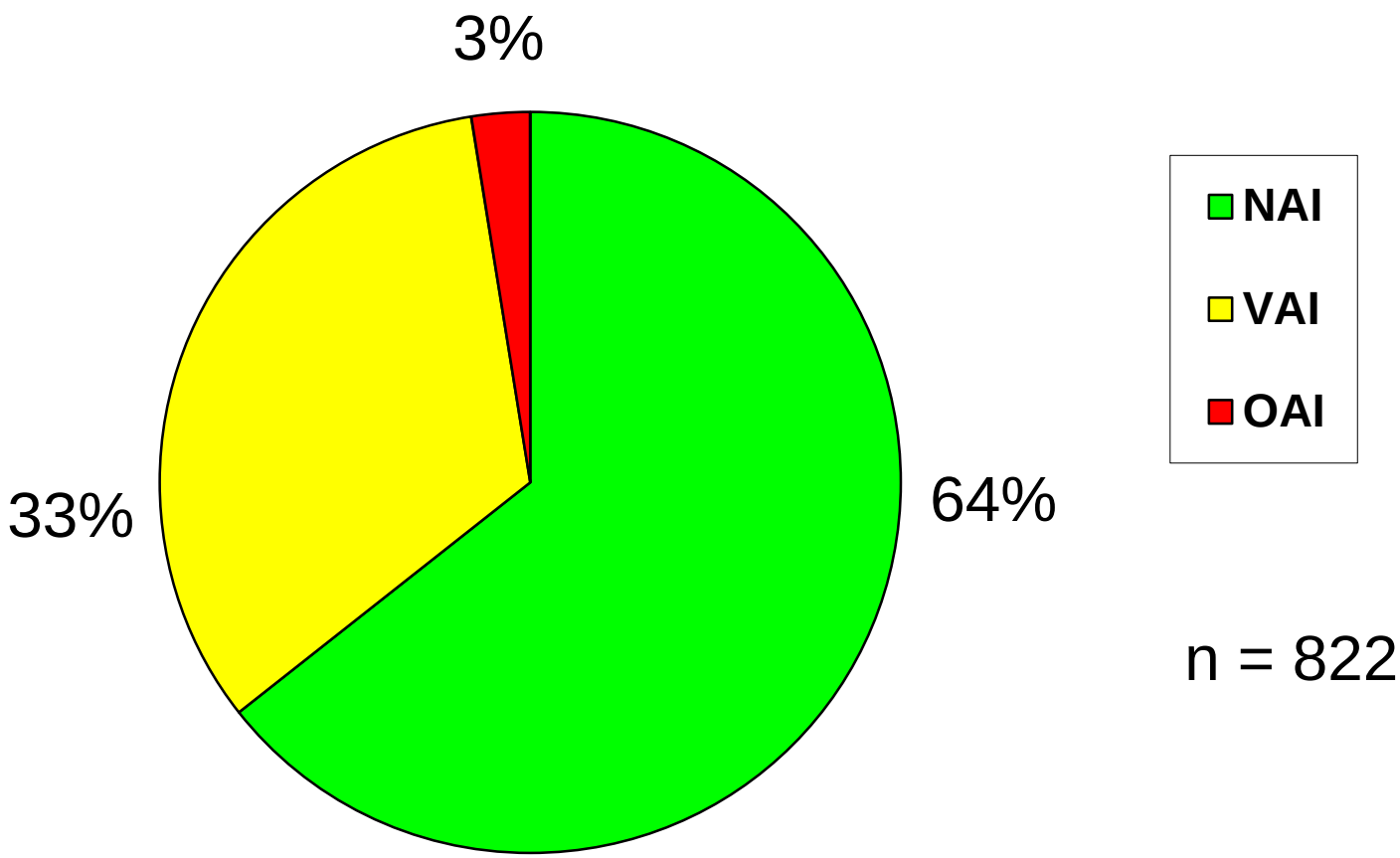
Bioresearch Monitoring (BIMO) Metrics – FY'15

BIMO Inspections Classified FY 2015

Center	CI	IRB	Spon/Mon/CRO[1]	GLP	Total
CBER	101	11	1	2	115
CDER[2]	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	3	0	0	0	3
Totals[2]	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*

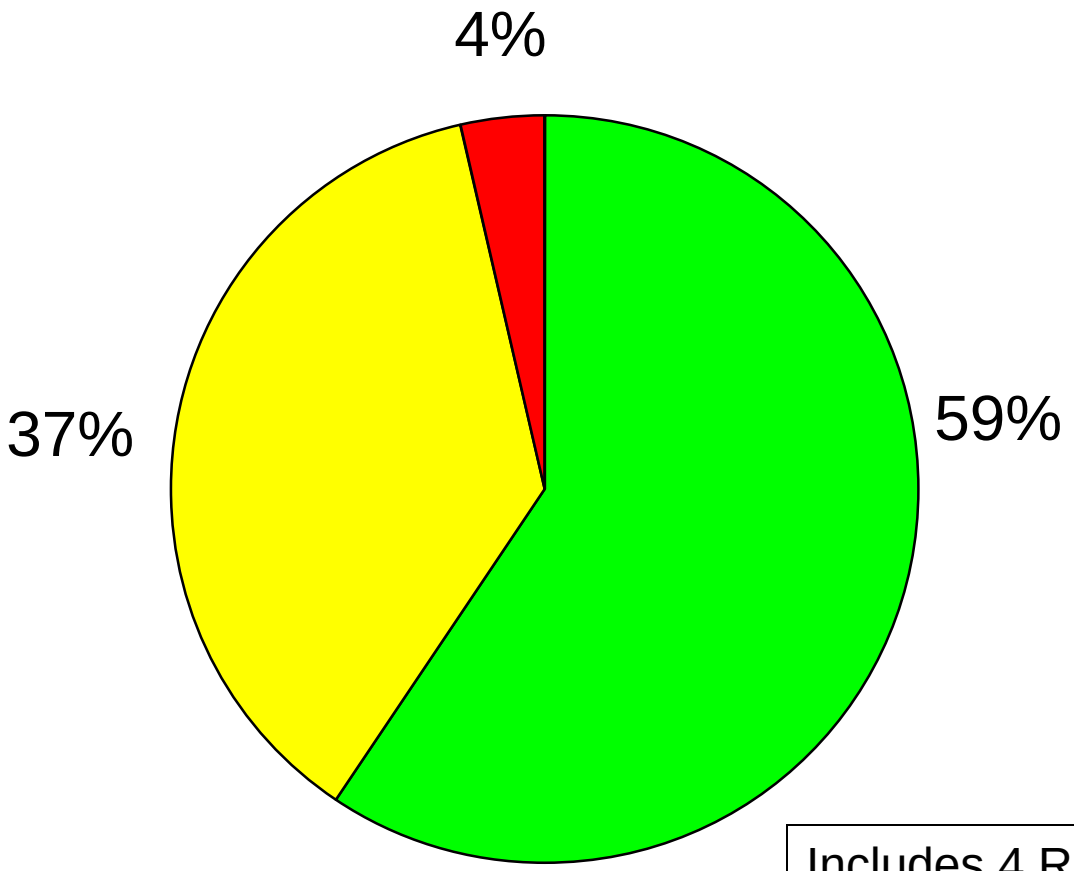


*Inspections classified in FY'15 by all Centers including CVM. Some inspections may have occurred in a different FY.

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*



n= 138

Includes 4 RDRCs (3 VAI, 1 NAI)

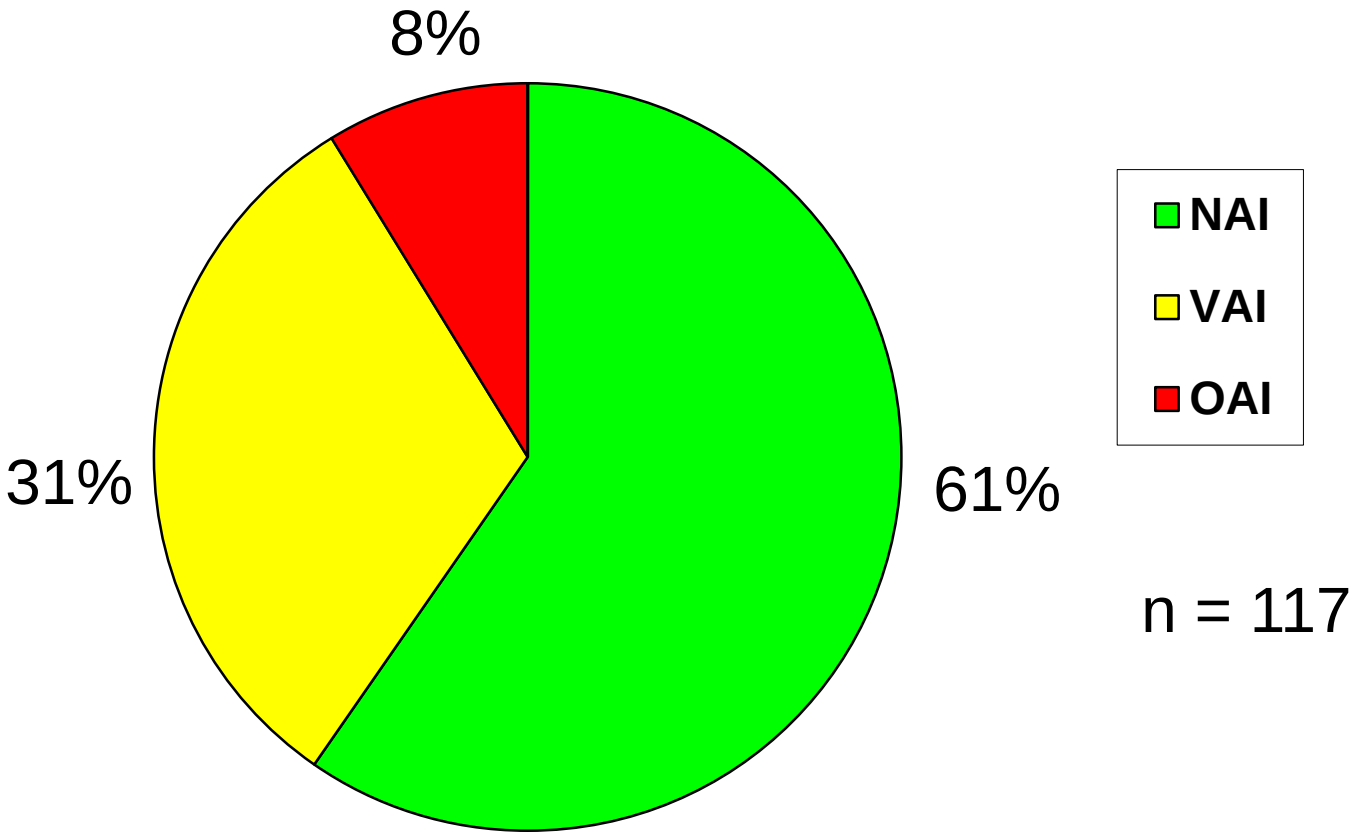
*Inspections classified in FY'15 by CFSAN, CBER, CDER, and CDRH.
Some inspections may have occurred in a different FY.

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*

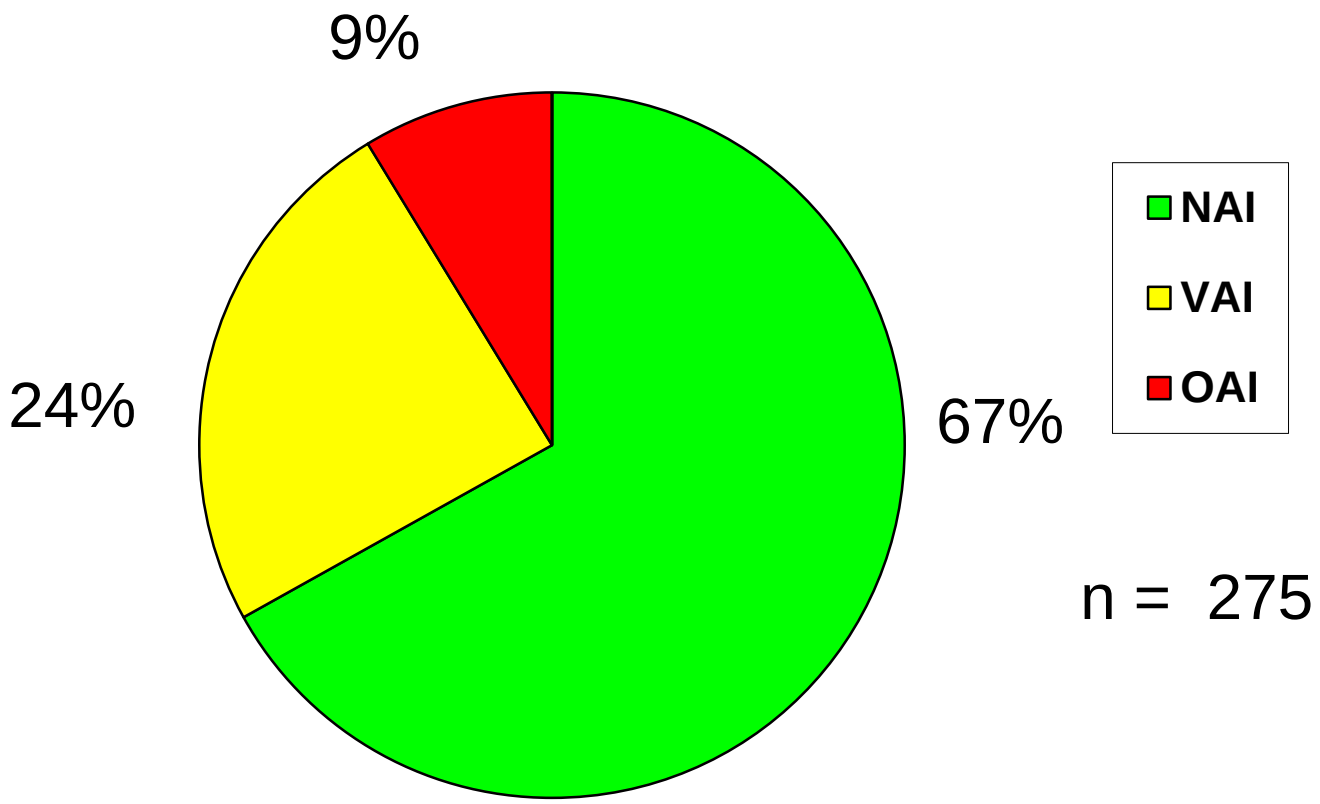


*Inspections classified in FY'15 by CBER, CDER, CDRH, and CVM. Some inspections may have occurred in a different FY. Includes Sponsor-Investigator inspections.

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*

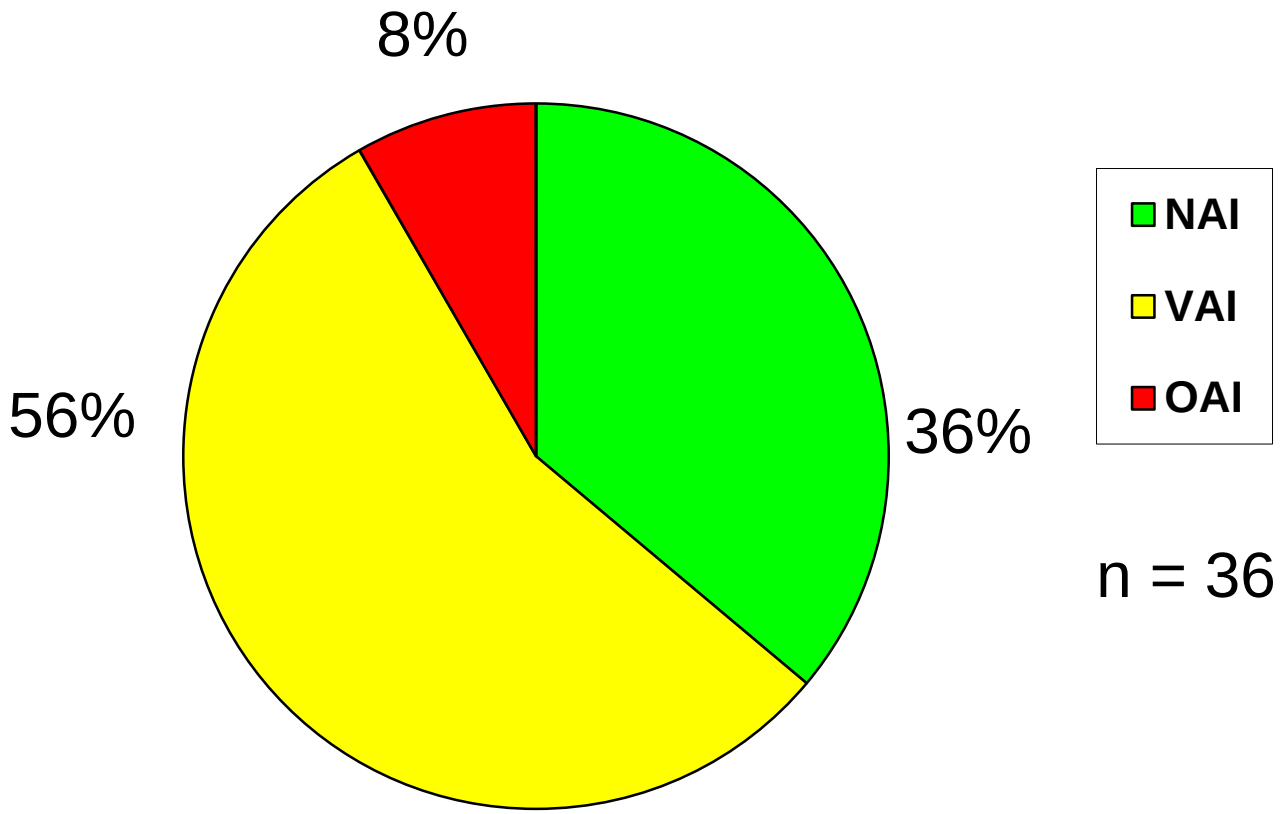


*CDER specific program. Inspections classified in FY’15. Some inspections may have occurred in a different FY.

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

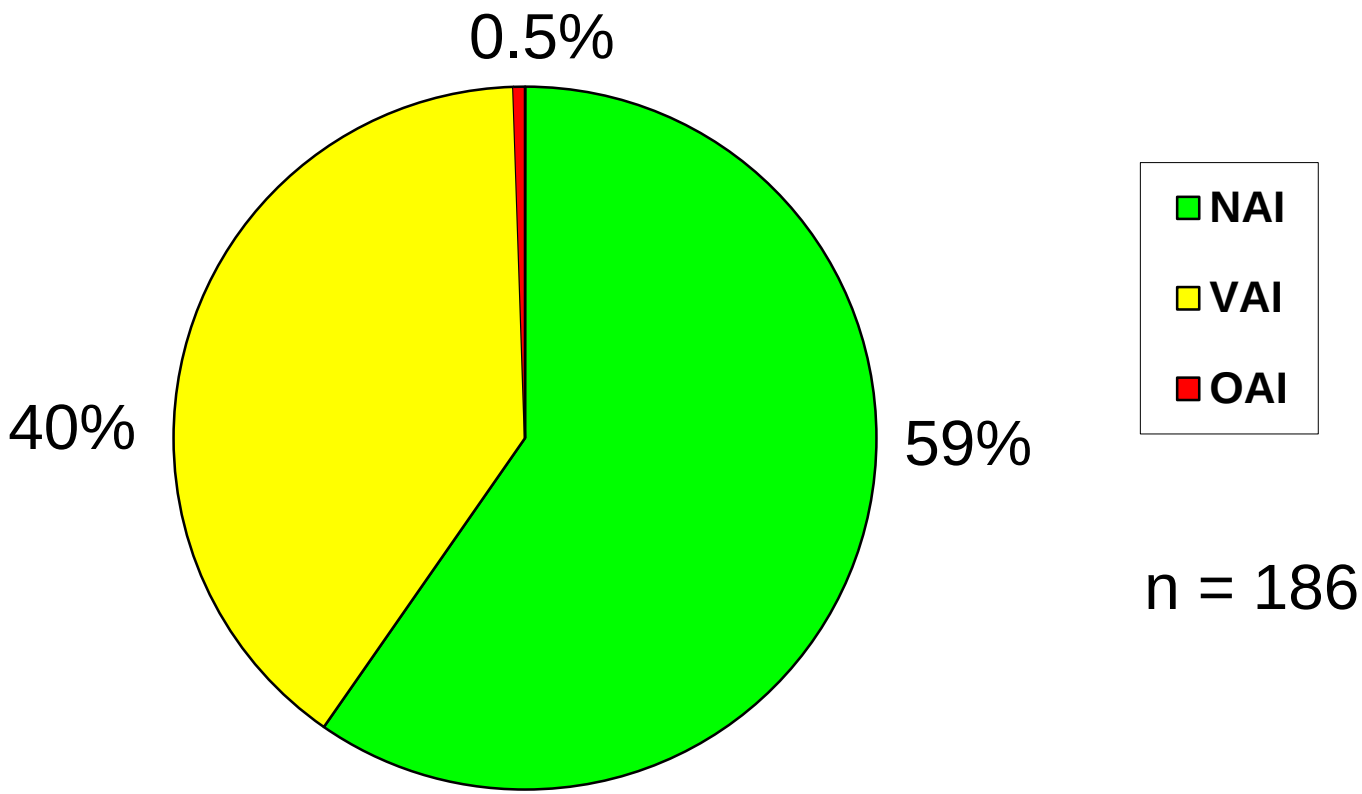
- Organizational and/or Personnel inadequacies
- Incomplete/inadequate/no study records
- Inadequate archiving
- Inadequate/no standard operating procedures (SOPs)
- Protocol deviations

International Inspections Classified: FY 2015*

Center	CI	Sponsor	GLP	BEQ	Total
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

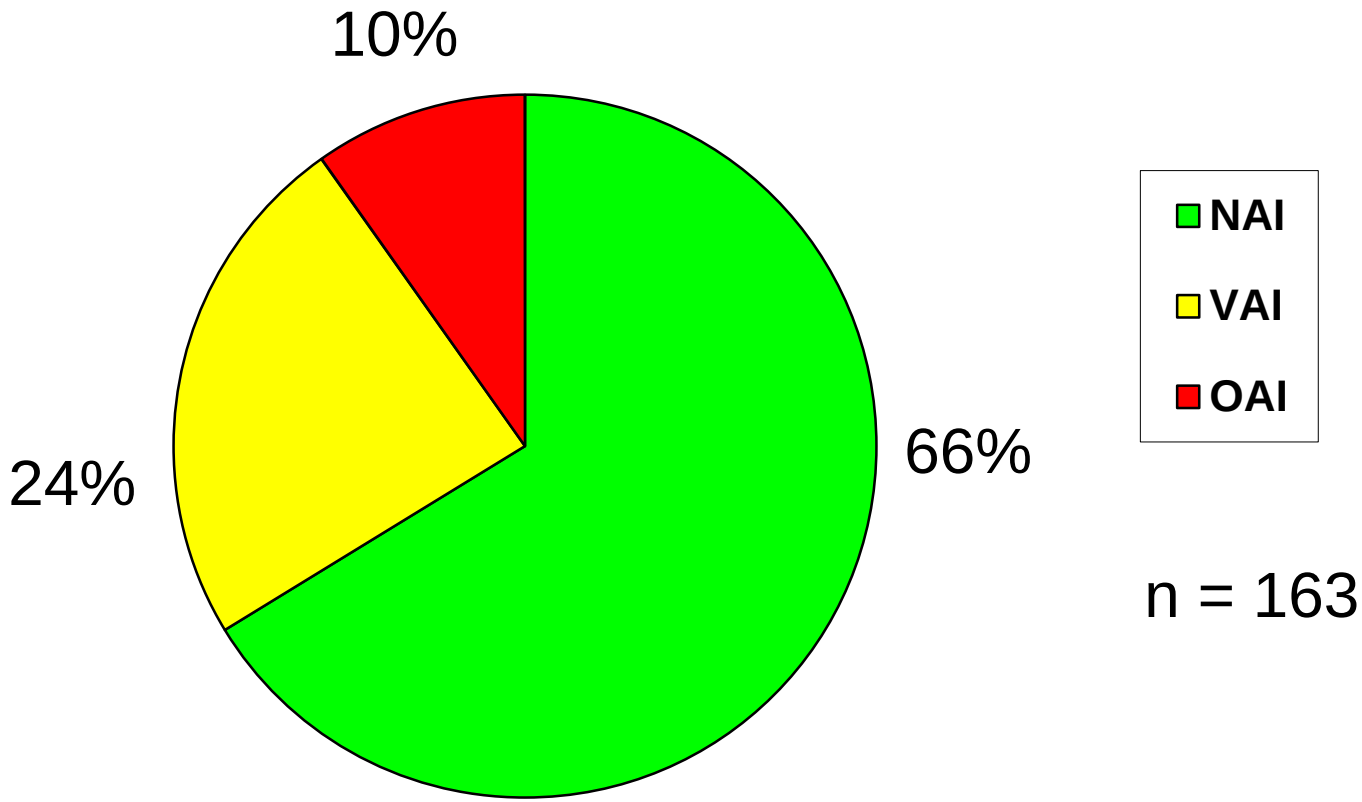
*CFSAN did not classify any international inspections in FY'15.

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