

**Bioresearch
Monitoring (BIMO)
Metrics – FY'16**

BIMO Inspections Classified FY 2016

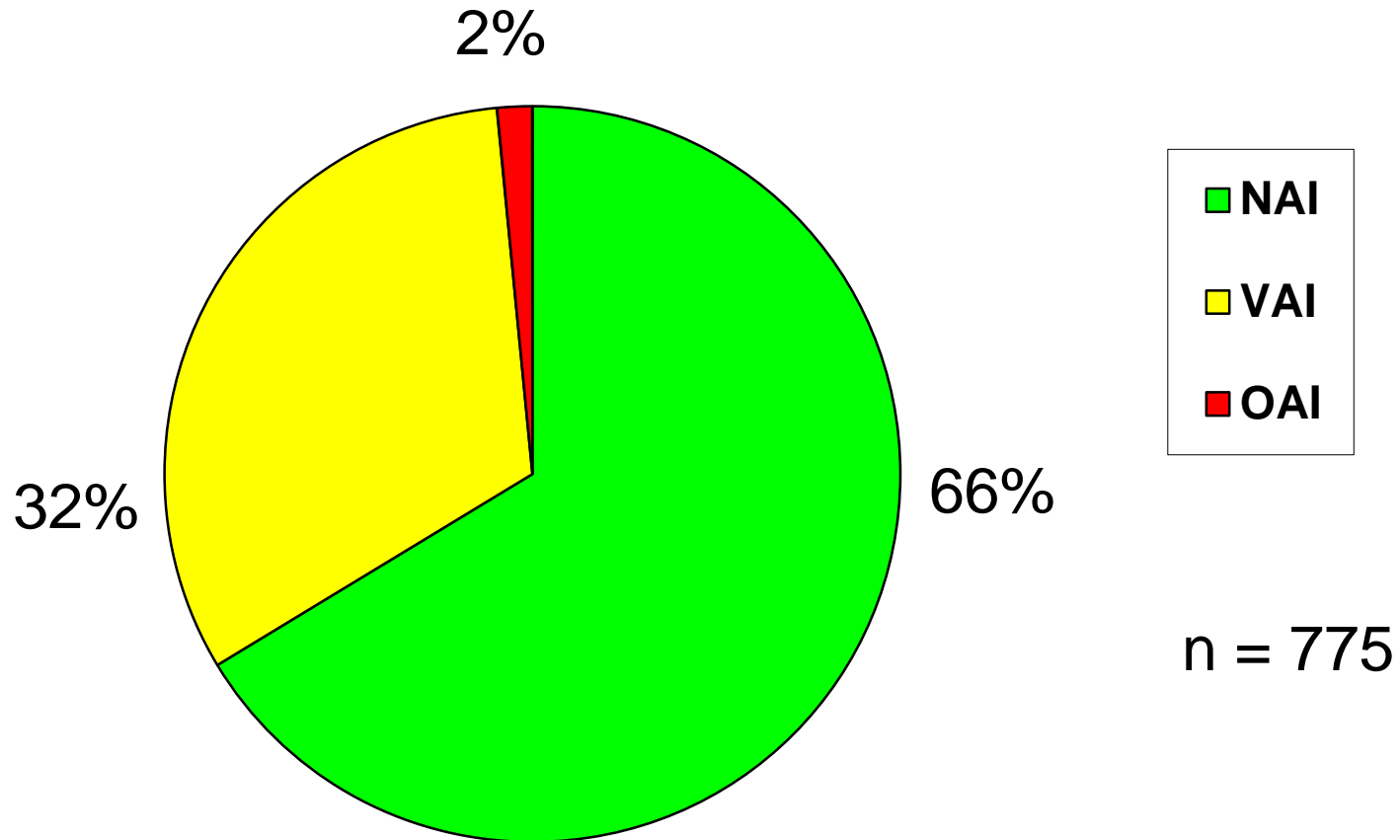
<u>Center</u>	<u>CI</u>	<u>IRB</u>	<u>Spon/Mon/CRO¹</u>	<u>GLP</u>	<u>Total</u>
CBER	93	7	6	0	106
CDER²	478	81 ³	58	32	649
CDRH	184	35	46	5	270
CFSAN	1	1	0	1	3
CTP	0	0	0	0	0
CVM	<u>19</u>	n/a	<u>2</u>	<u>6</u>	<u>27</u>
Totals²	775	124	112	44	1055

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

² In FY 2016, CDER classified 362 inspections of bioavailability/bioequivalence sites (CPGM 7348.001), raising the total BIMO inspections in FY 2016 to **1417**. (1055 + 362 = 1417)

³ The number of IRB inspections includes 1 Radioactive Drug Research Committee (RDRC) inspection.

FY'16 CI Inspections Classified*

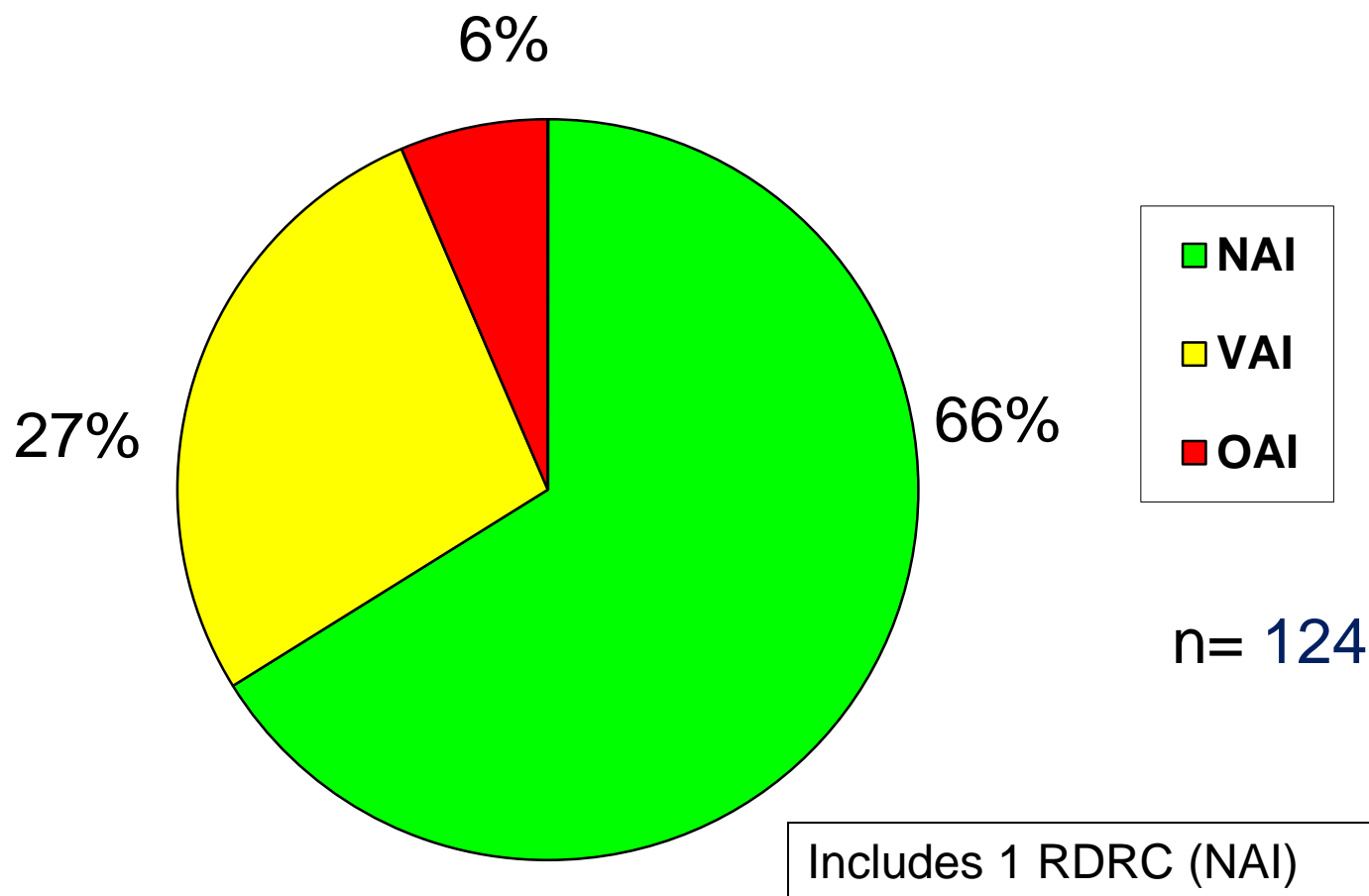


*Inspections classified in FY'16 by all Centers. Some inspections may have occurred in a different FY.

Common CI 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

FY'16 IRB Inspections Classified*

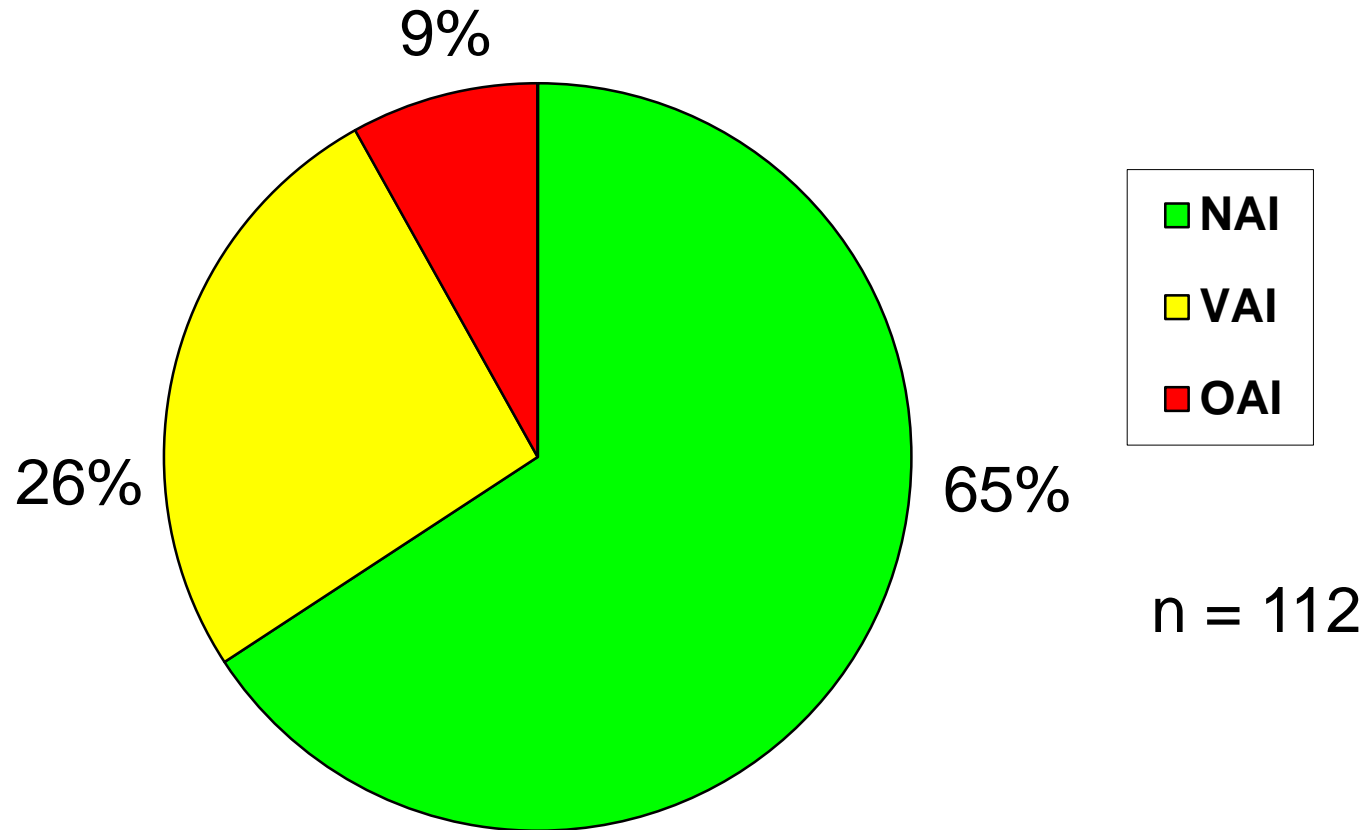


*Inspections classified in FY'16 by all Centers with jurisdiction over studies involving human subjects. Some inspections may have occurred in a different FY.

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/termination
- Subpart D issues
- Lack of or incorrect SR/NSR determination

FY'16 Sponsor/Monitor/CRO Inspections Classified*

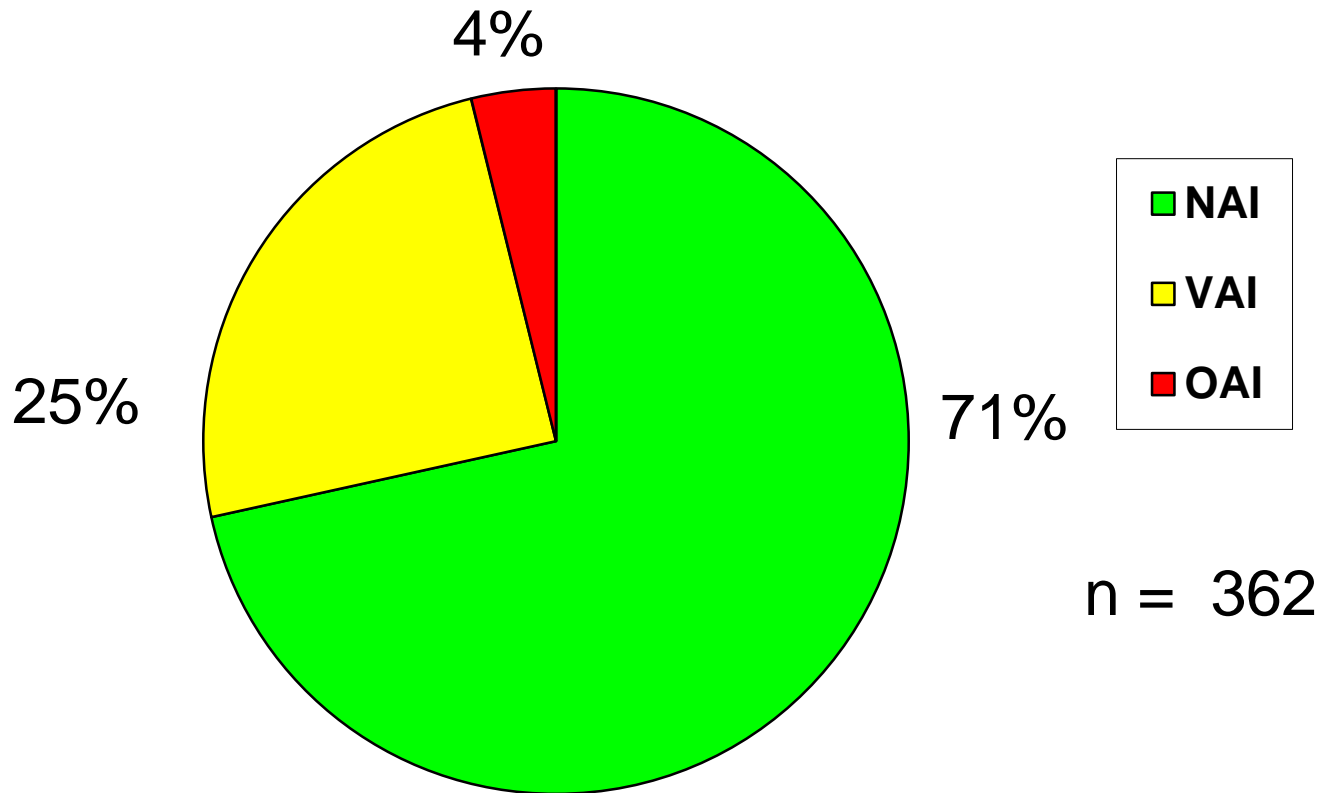


*Inspections classified in FY'16 by all Centers. Some inspections may have occurred in a different FY. Includes Sponsor-Investigator inspections.

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

FY'16 BEQ Inspections Classified*

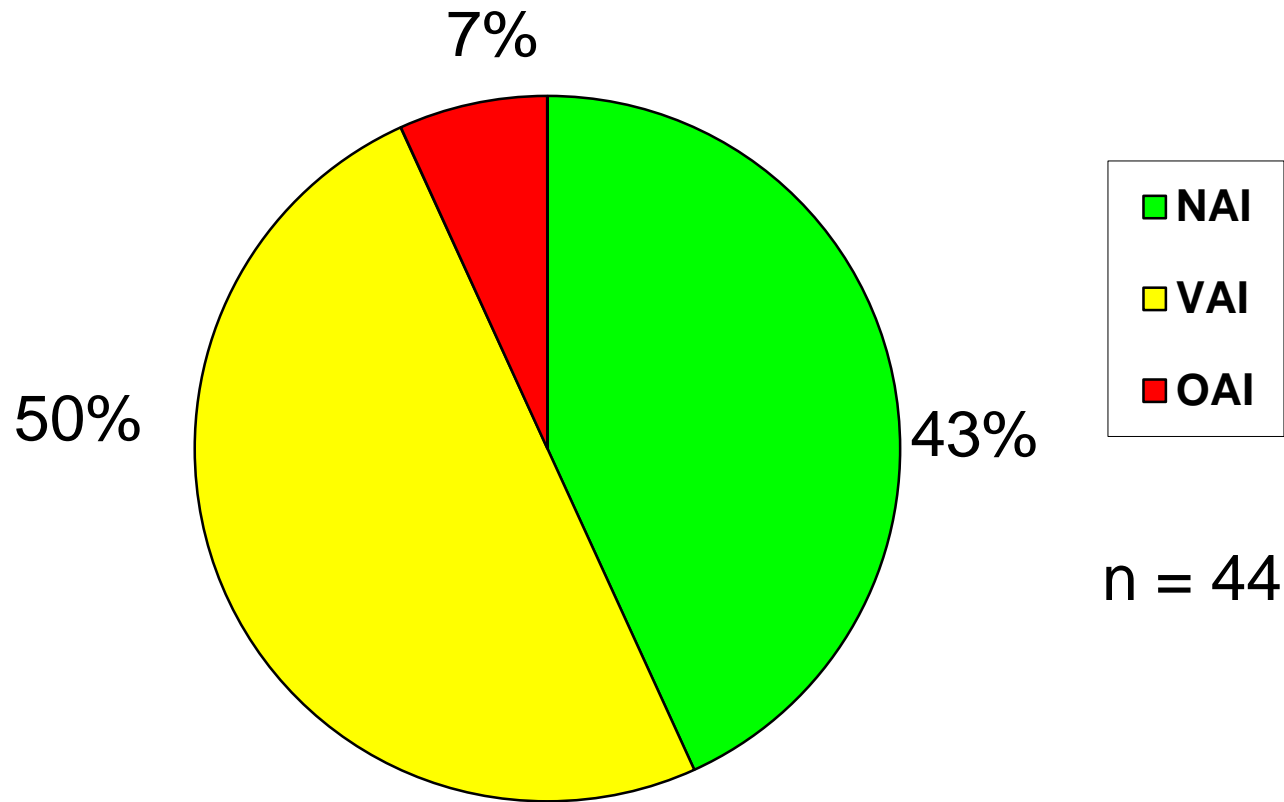


*CDER specific program. Inspections classified in FY'16. Some inspections may have occurred in a different FY.

Common BEQ Deficiencies

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

FY'16 GLP Inspections Classified*



*Inspections classified in FY'16 by all Centers. Some inspections may have occurred in a different FY.

Common GLP Deficiencies

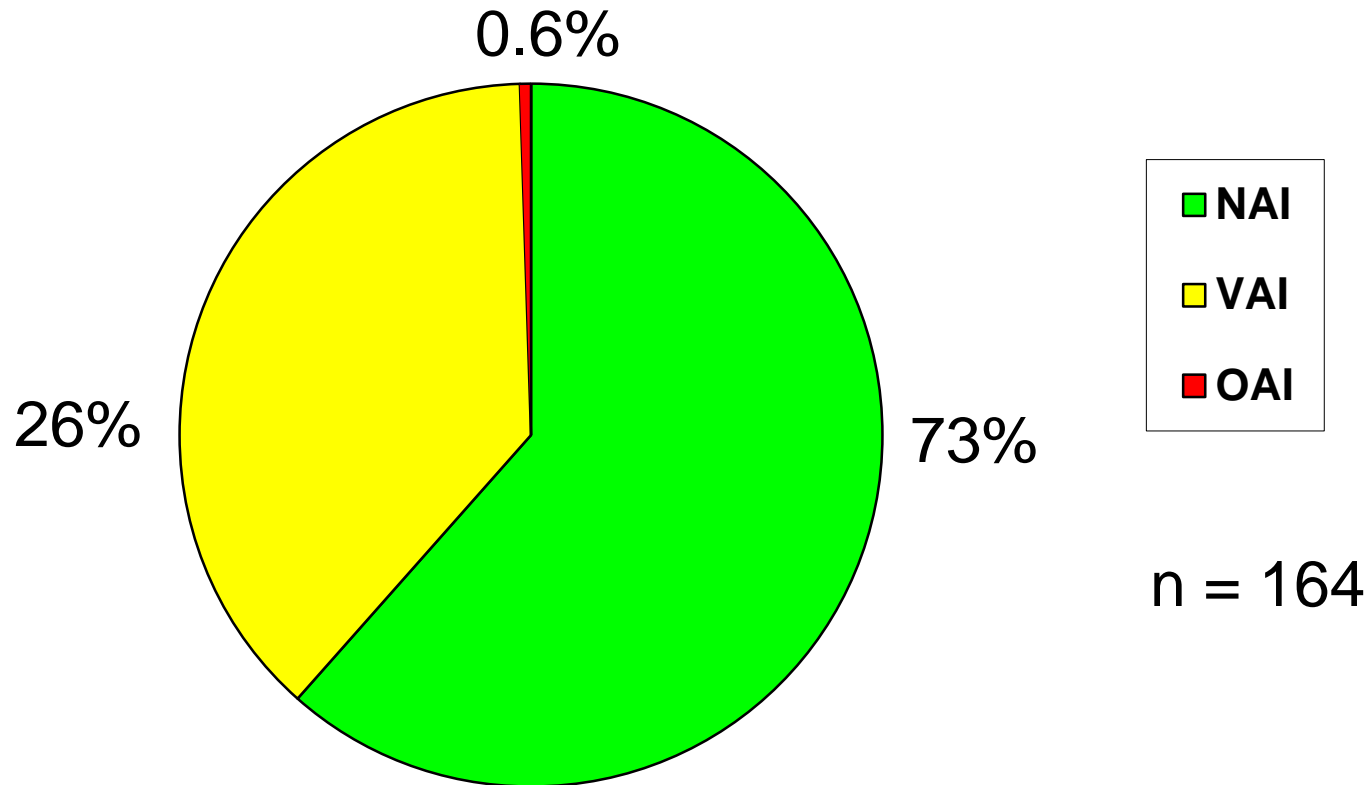
- Organizational and/or Personnel inadequacies
- Incomplete/inadequate/no study records
- Inadequate archiving
- Inadequate/no standard operating procedures (SOPs)
- Protocol deviations

International Inspections Classified: FY 2016*

<u>Center</u>	<u>CI</u>	<u>Sponsor</u>	<u>GLP</u>	<u>BEQ</u>	<u>Total</u>
CBER	21	0	0	n/a	21
CDER	129	7	8	206	350
CDRH	14	2	0	n/a	16
CVM	0	0	2	n/a	2
Totals	164	9	10	206	389

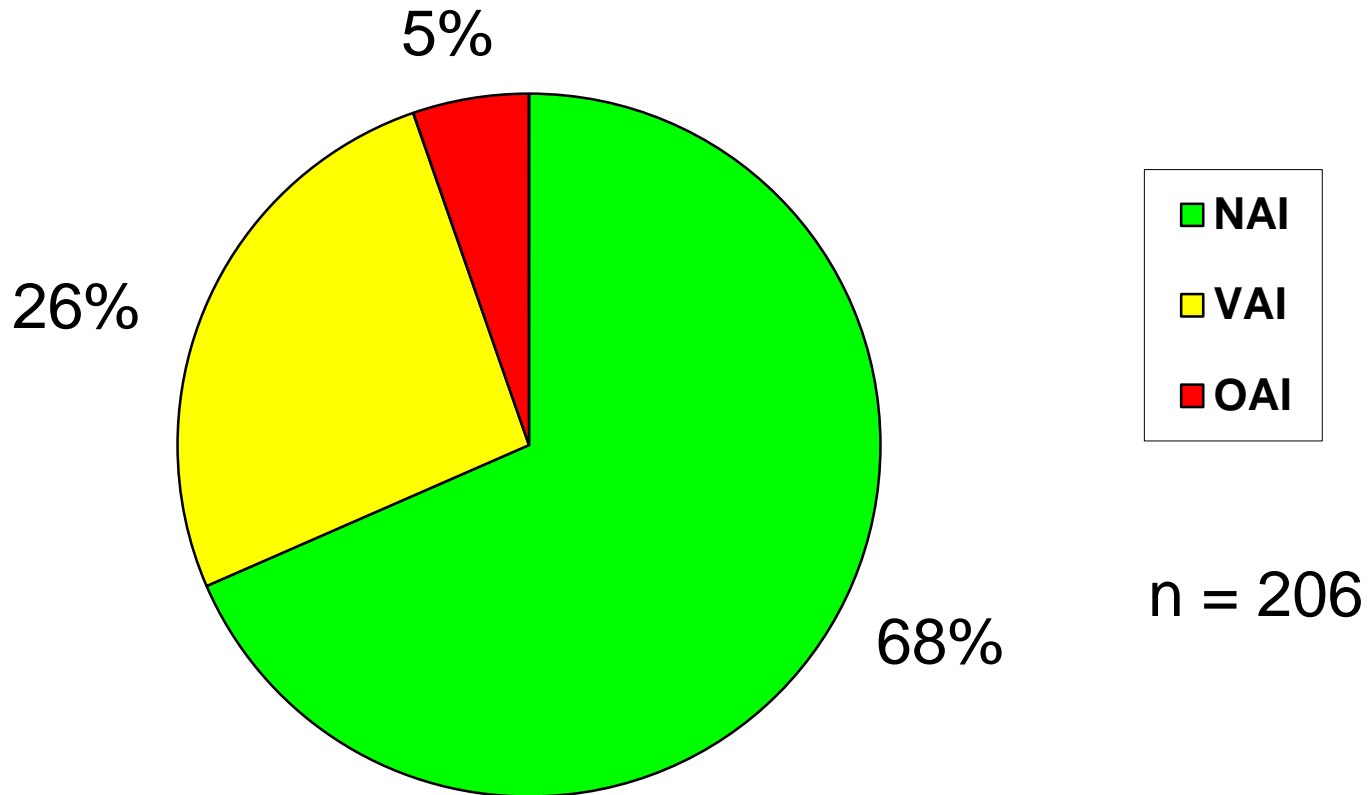
*CFSAN and CTP did not classify any international inspections in FY'16.

FY'16 International CI Inspections Classified All Centers*



*Inspections classified in FY'16 by CBER, CDER, CDRH. Some inspections may have occurred in a different FY.

FY'16 International BEQ Inspections Classified*



*BEQ inspections classified by CDER in FY16. Some inspections may have occurred in a different FY.

Other International Inspections Classified in FY'16*

Sponsor/CRO

- CDER – 7 (4 NAI, 3 VAI)
- CDRH – 2 (1 NAI, 1 VAI)

GLP

- CDER – 8 (2 NAI, 6 VAI)
- CVM – 2 (1 NAI, 1 OAI)

*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