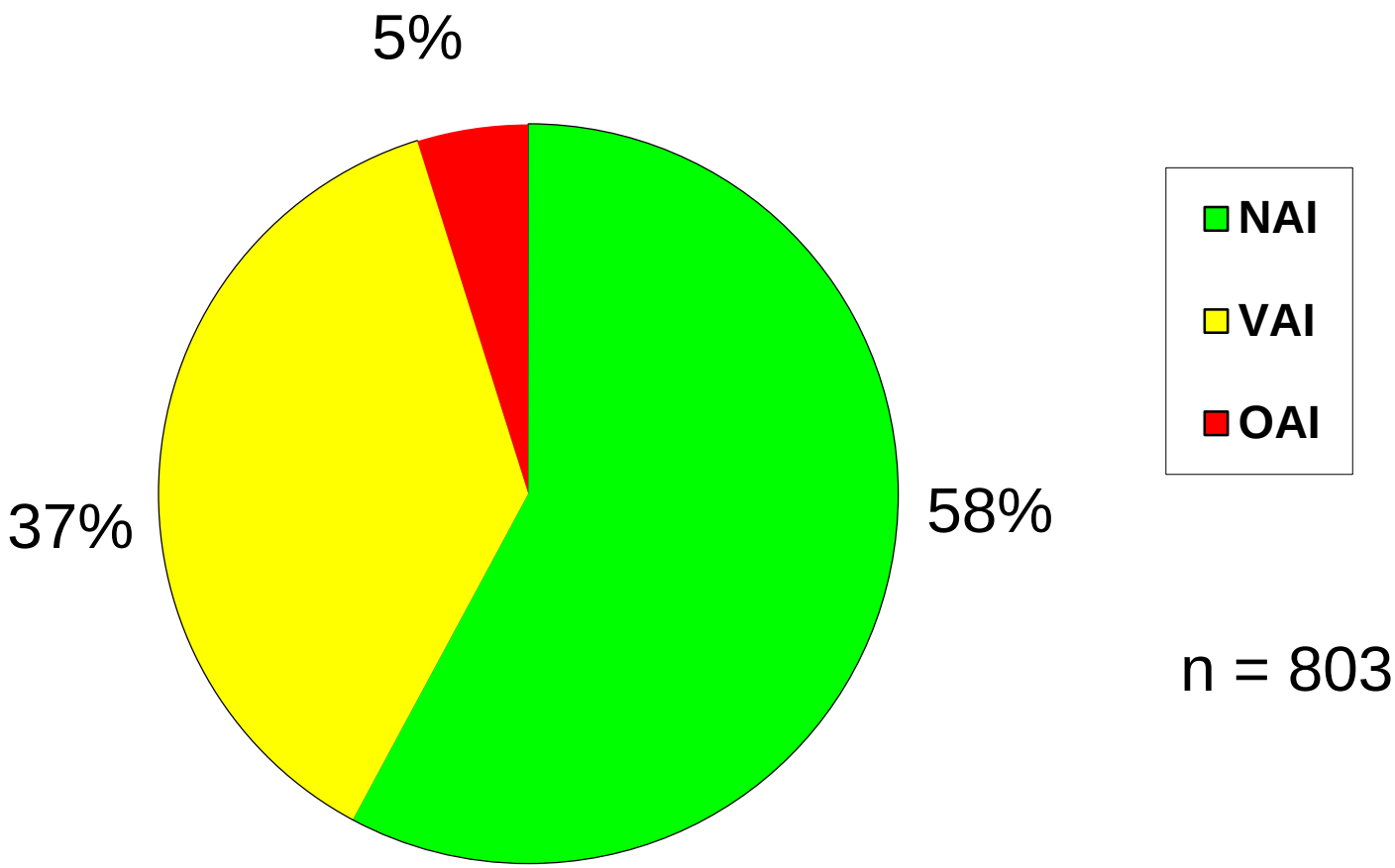
Bioresearch Monitoring (BIMO) Metrics – FY'14

BIMO Inspections Classified FY 2014

Center[1]	CI	IRB	Spon/Mon/CRO[2]	GLP	Total
CBER	109	8	3	1	121
CDER[3]	472	91[4]	83	29	675
CDRH	203	52	51	7	313
CFSAN	1	1	0	*	2
CVM	18	**n/a**	1	6	25
Totals[3]	803	152	138	43	1136

[1] Center for Tobacco Products (CTP) did not conduct any BIMO inspections in 2014.
[2] Sponsor/Monitor/CRO inspection totals include Sponsor/Investigator inspections.
[3] CDER also performed 190 BEQ inspections (CDER specific) Grand Total of all BIMO inspections in FY 2014: 1326.
[4] The number of IRB inspections includes 1 Radioactive Drug Research Committee (RDRC) inspection.
* CFSAN issued 1 GLP assignment, but the firm had gone out of business.

FY'14 CI Inspections Classified All Centers*



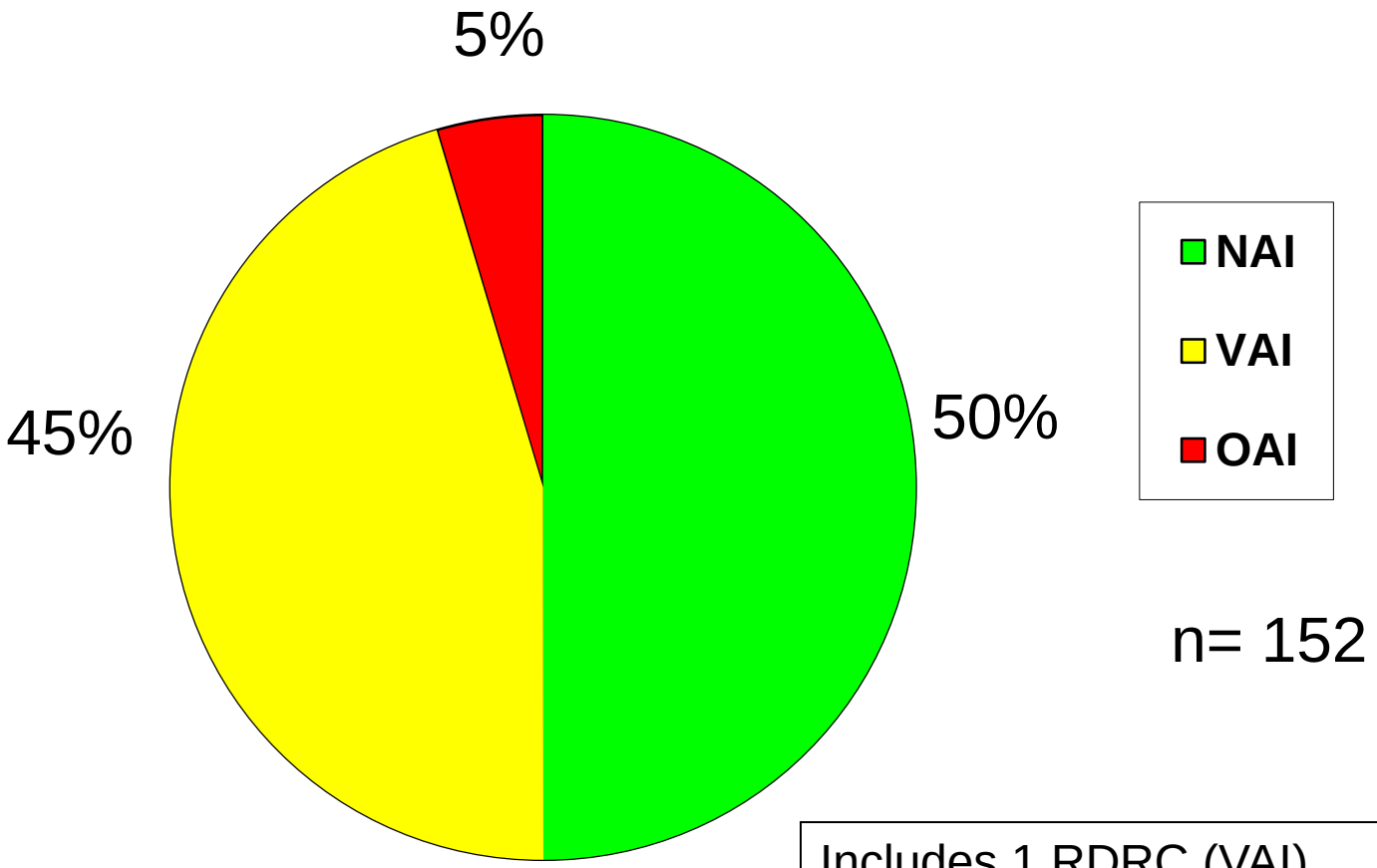
n = 803

*Inspections classified by all Centers in FY'14. 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'14 IRB Inspections Classified All Centers*



n= 152

Includes 1 RDRC (VAI)

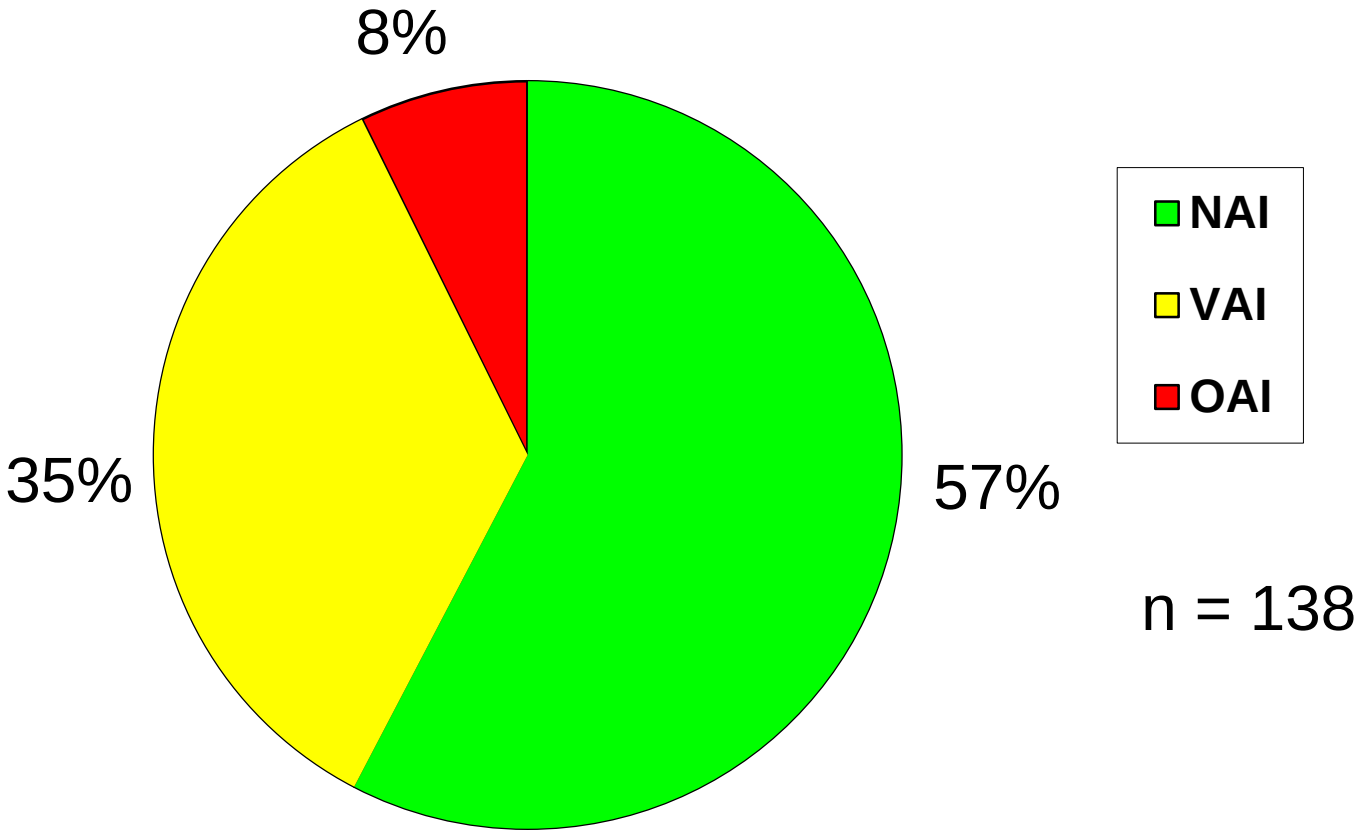
*Inspections classified in FY'14 by CBER, CDER, CDRH, and CFSAN.
Some inspections may have occurred in a different FY.

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'14 Sponsor/Monitor/CRO Inspections Classified - All Centers*

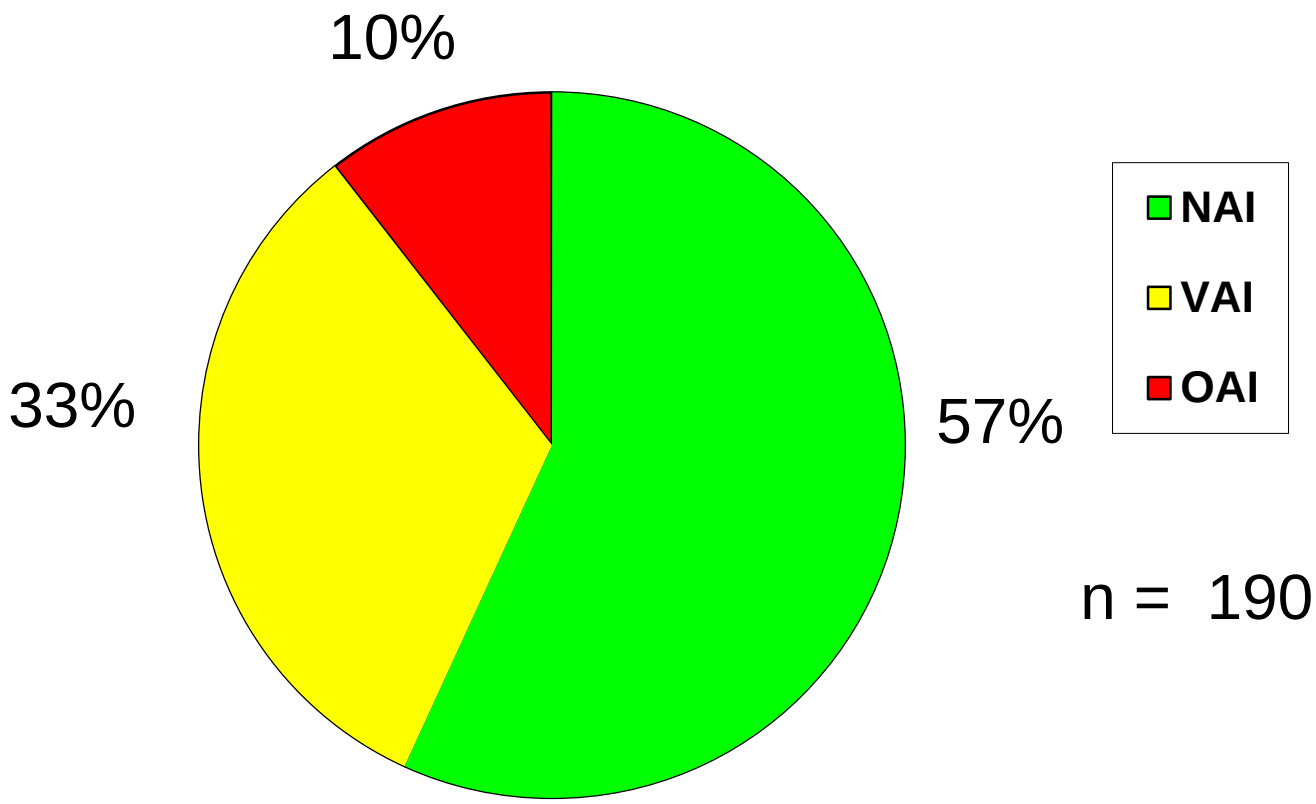


*Inspections classified in FY'14 by CBER, CDER, CDRH and CVM. Some inspections may have occurred in a different FY. Includes Sponsor-Investigator inspections.

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’14 BEQ inspections classified*

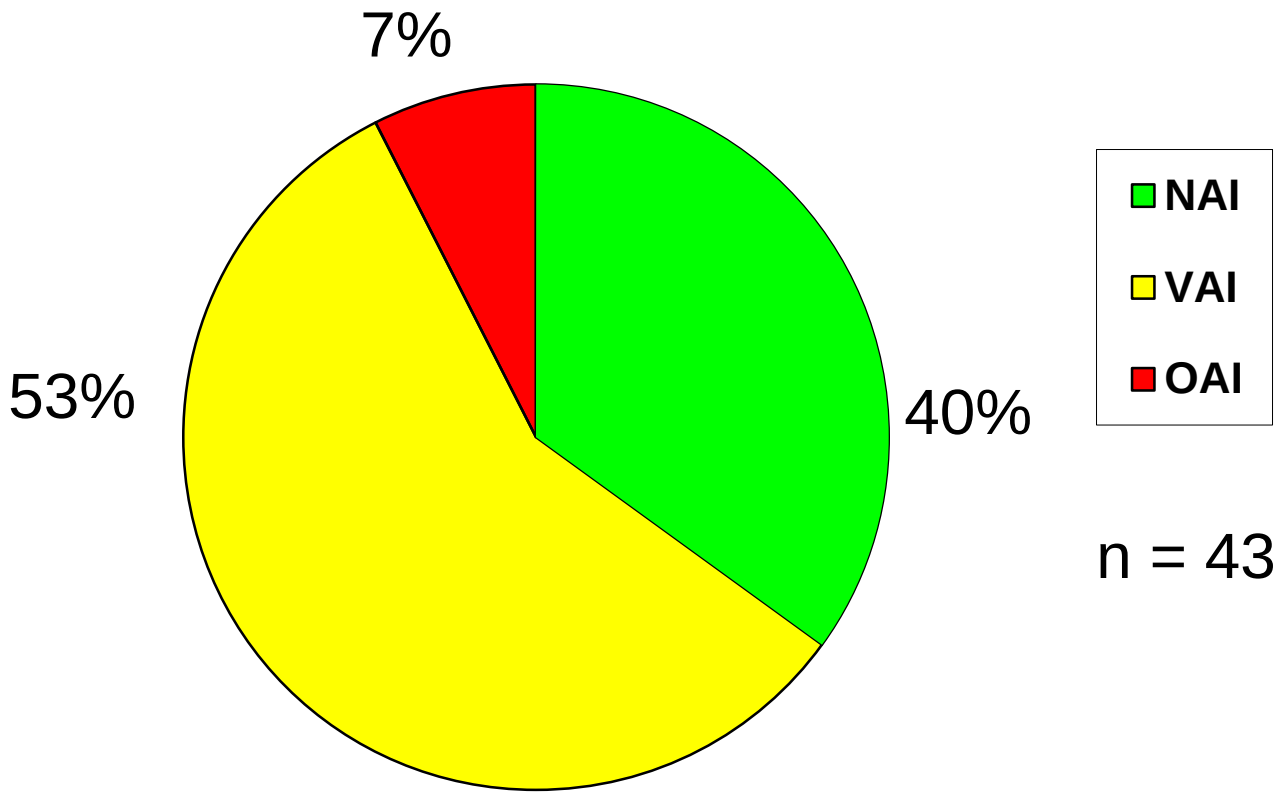


*CDER specific program. Inspections classified in FY’14. Some inspections may have occurred in a different FY.

Most common BEQ deficiencies

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

FY'14 GLP inspections classified All Centers*



*Inspections classified in FY'14 by CBER, CDER, CDRH and CVM.
Some inspections may have occurred in a different FY.

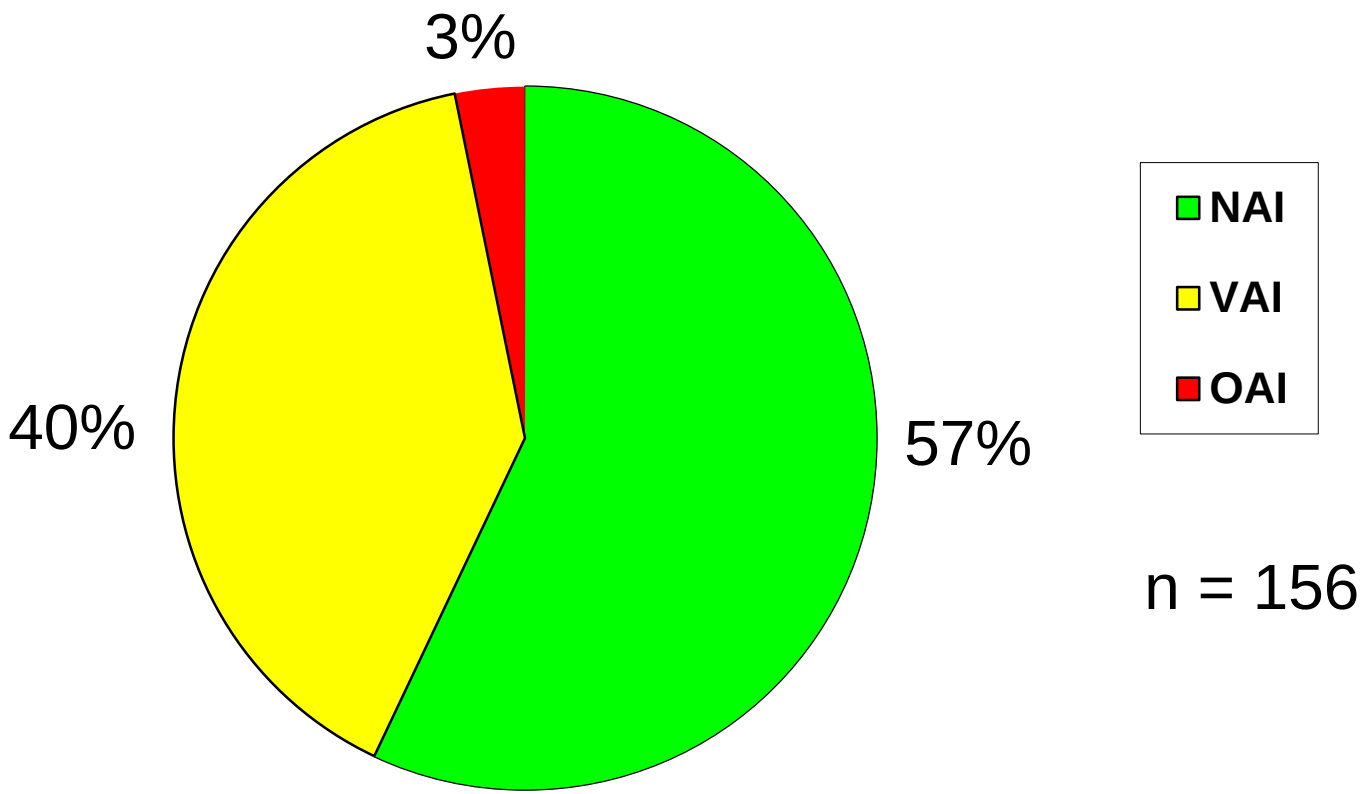
Most common GLP deficiencies

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

International Inspections Classified: FY 2014

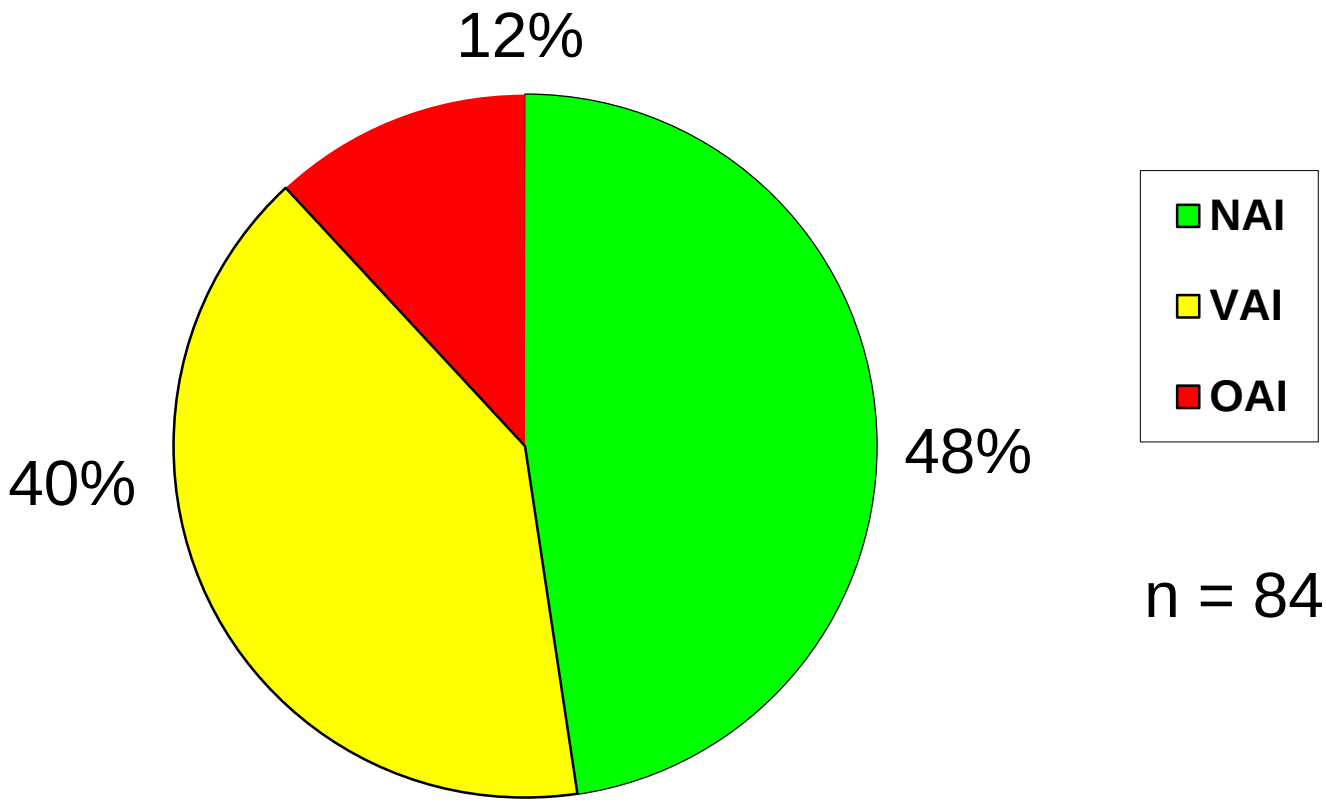
Center	CI	Sponsor	GLP	BEQ	Total
CBER	22	1	0	n/a	23
CDER	116	10	4	84	214
CDRH	18	0	0	n/a	18
Totals	156	11	4	84	255

FY'14 International CI Inspections Classified All Centers*



*Inspections classified in FY'14 by CBER, CDER, and CDRH. Some inspections may have occurred in a different FY.

FY'14 International BEQ Inspections Classified*



*BEQ inspections classified in FY 14 no matter when the inspections occurred

Other International Inspections Classified in FY'14*

Sponsor/CRO

- CDER – 10, all NAI
- CBER – 1, NAI

GLP

- CDER – 4, all VAI

*Inspections classified in FY'14 by CDER, CBER and CDRH. 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