Bioresearch Monitoring (BIMO) Metrics – FY'13

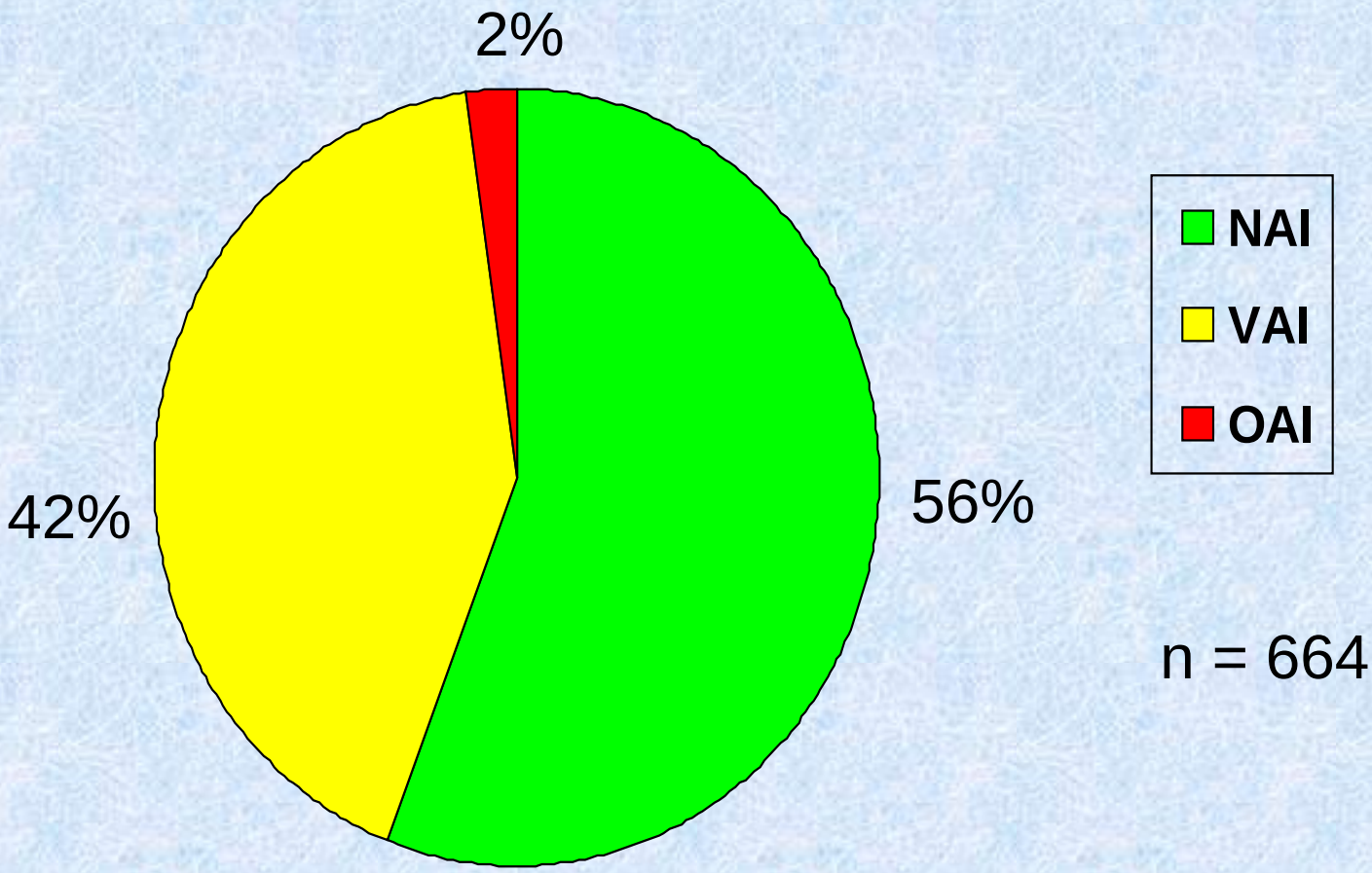
BIMO Inspections Completed FY 2013

Center	CI	IRB	Spon/CRO	GLP	Total
CBER	91	8	4	1	104
CDER*	344	90	62	28	524
CDRH	193	76	53	10	332
CFSAN**	0	0	0	0	0
CVM	36	na	1	22	59
All Centers	664	174	120	61	1019

***3 IRB = RDRC; + 205 BEQ** inspections (CDER specific) ⇨ total = 1224

****CFSAN's BIMO Program remains under reorganization**

FY'13 CI Inspections Classified* All Centers



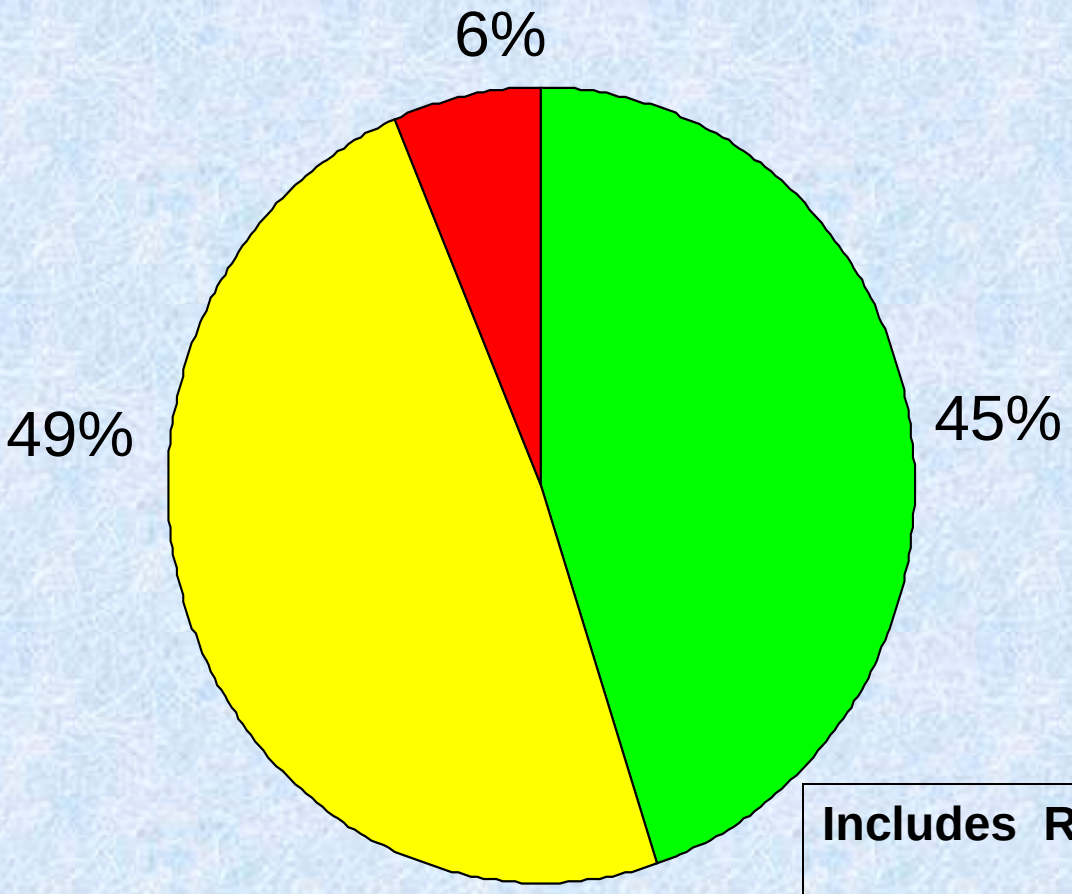
n = 664

*inspections classified in FY'13 no matter when inspection occurred

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'13 IRB Inspections Classified* – All Centers



n= 171

Includes RDRC classifications

1 NAI, 1 VAI

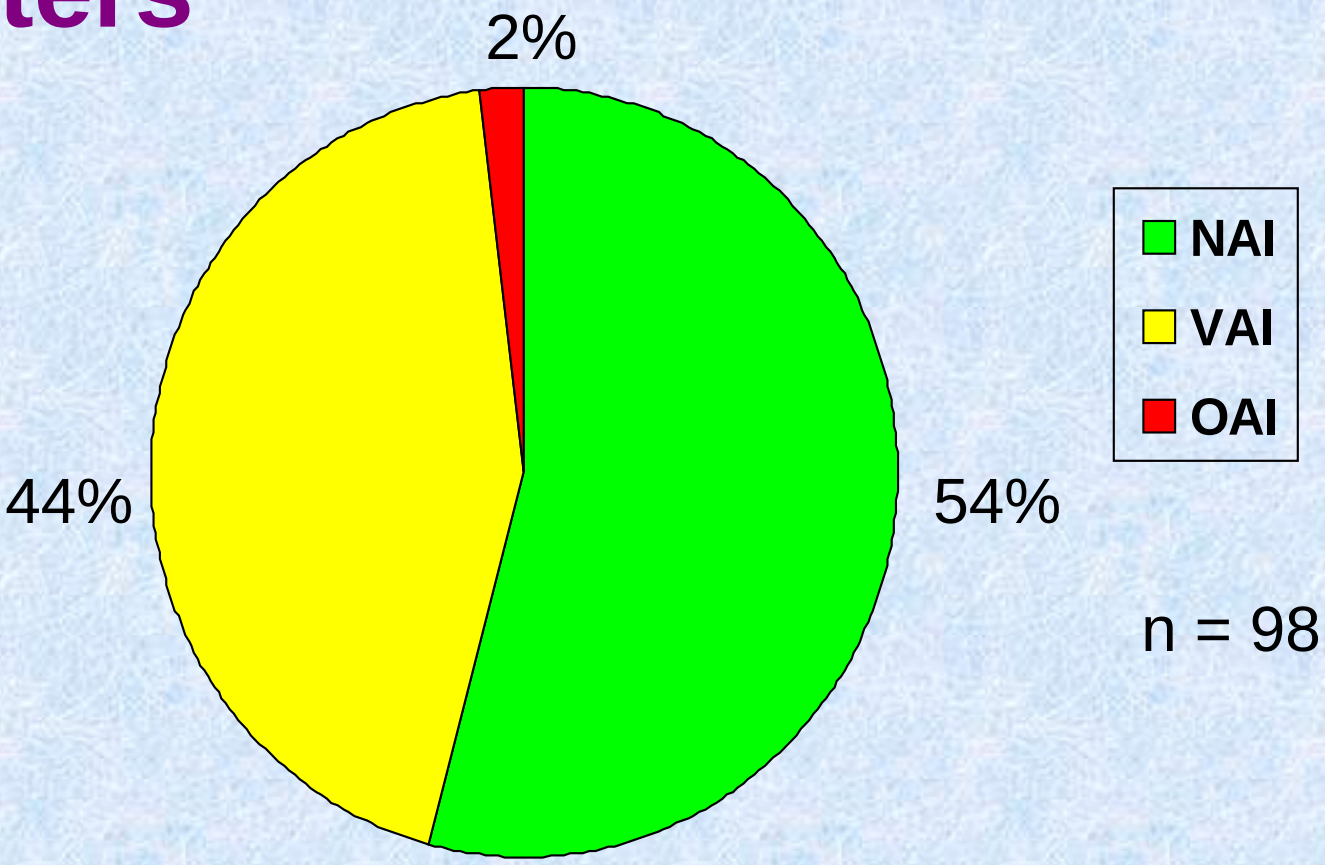
*inspections classified in FY'13 no matter when inspection occurred

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'13 Sponsor/Monitor/CRO Inspections Classified* – All Centers

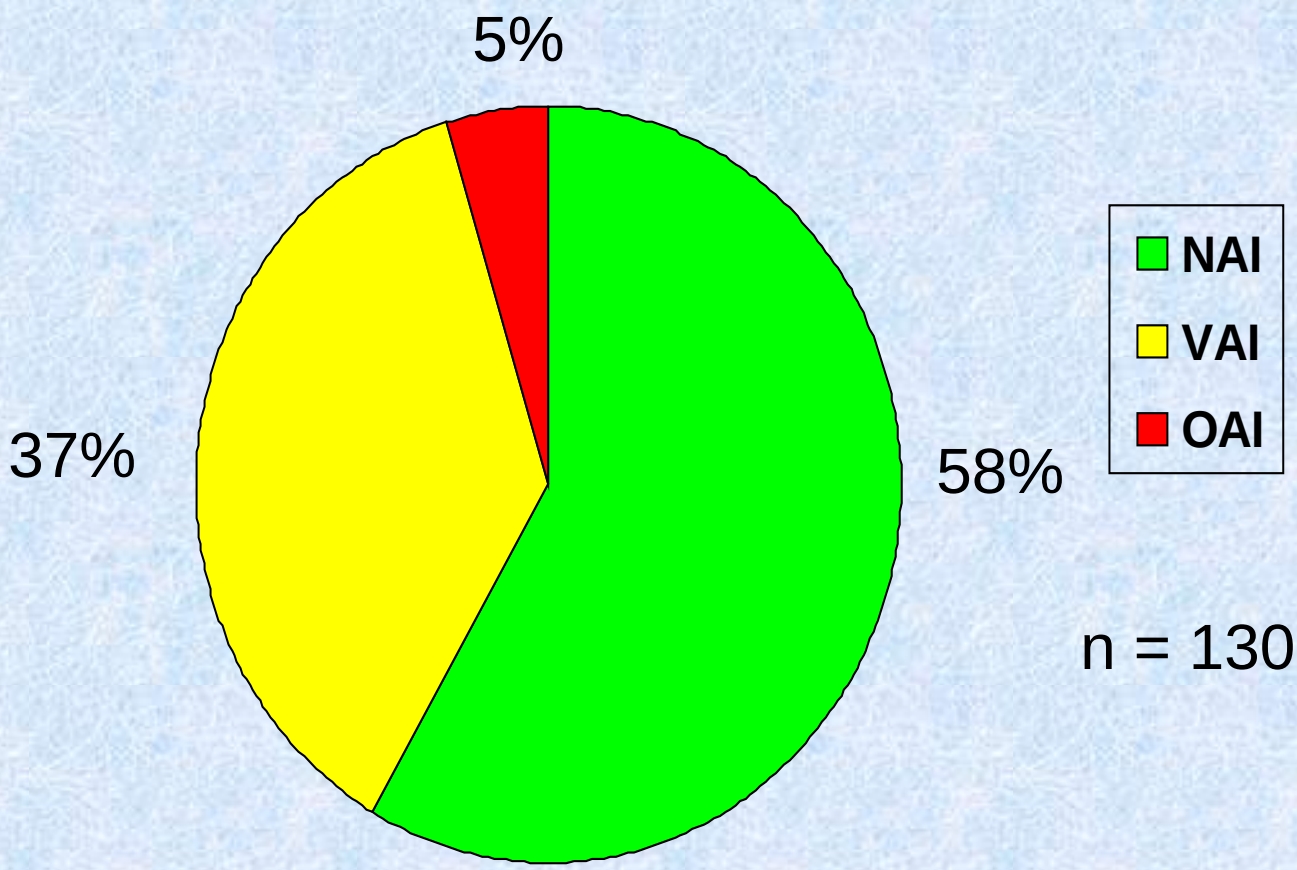


*inspections classified in FY'13 no matter when inspection occurred

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’13 BEQ inspections classified*

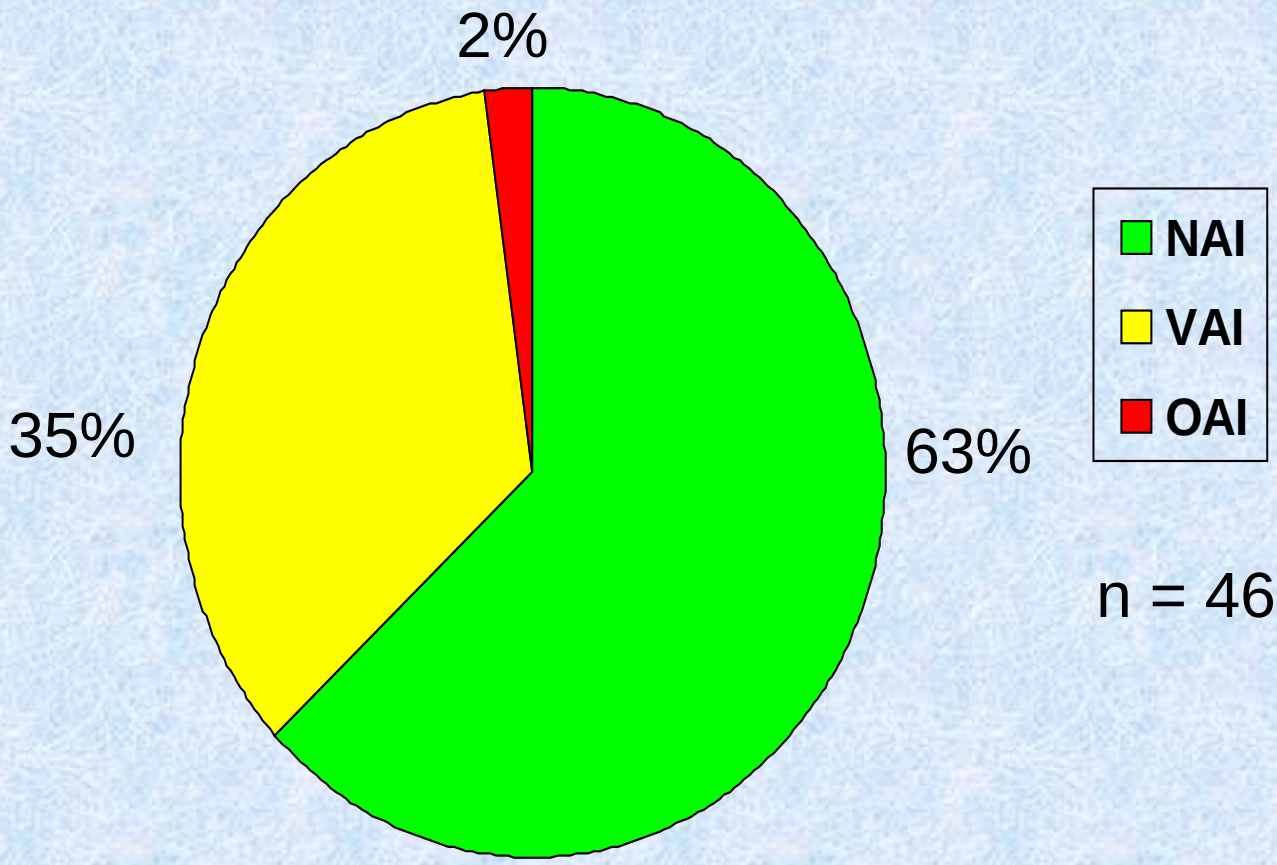


*inspections classified in FY’13 no matter when inspection occurred

Most common BEQ deficiencies

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

FY’13 GLP inspections classified* All Centers



*inspections classified in FY’13 no matter when inspection occurred

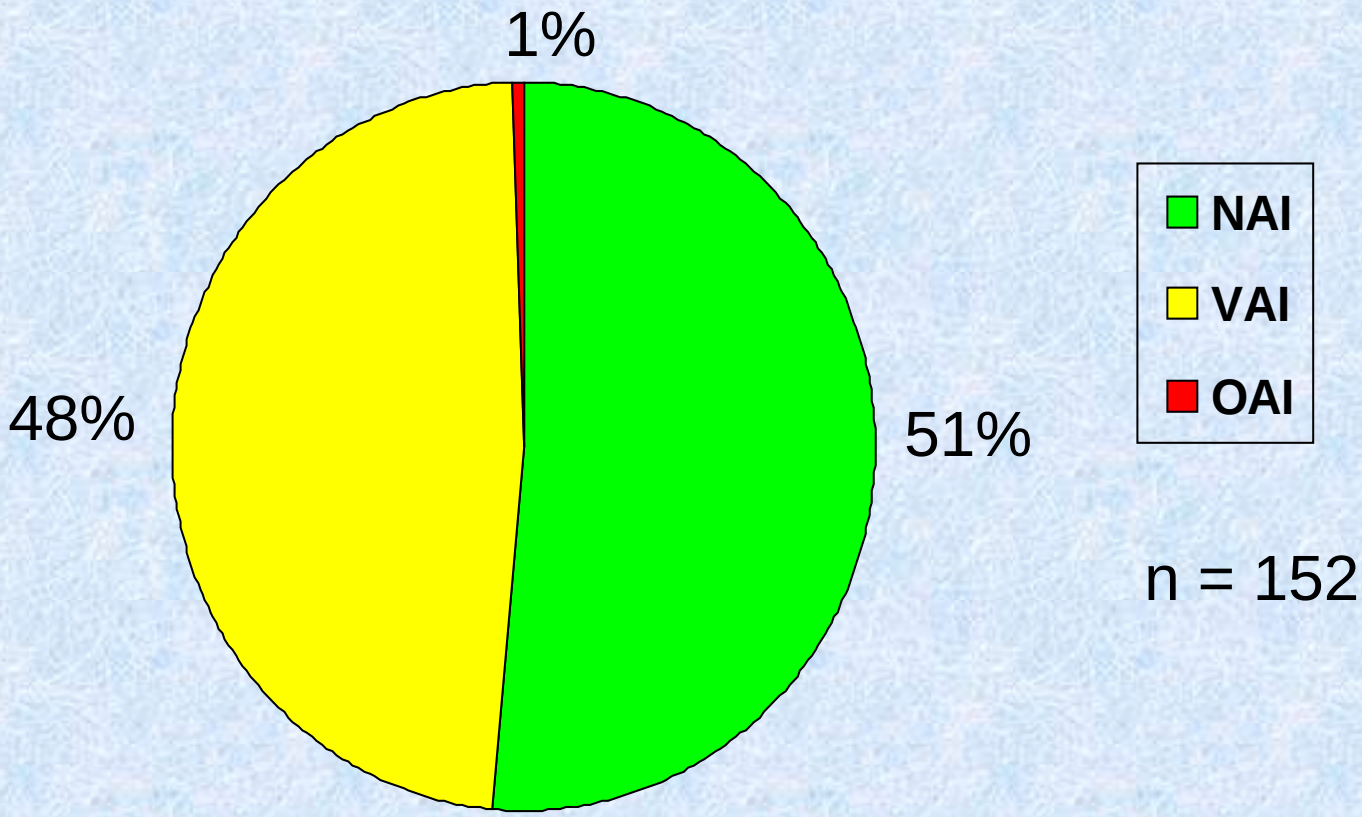
Most common GLP deficiencies

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

International Inspections Completed: FY 2013

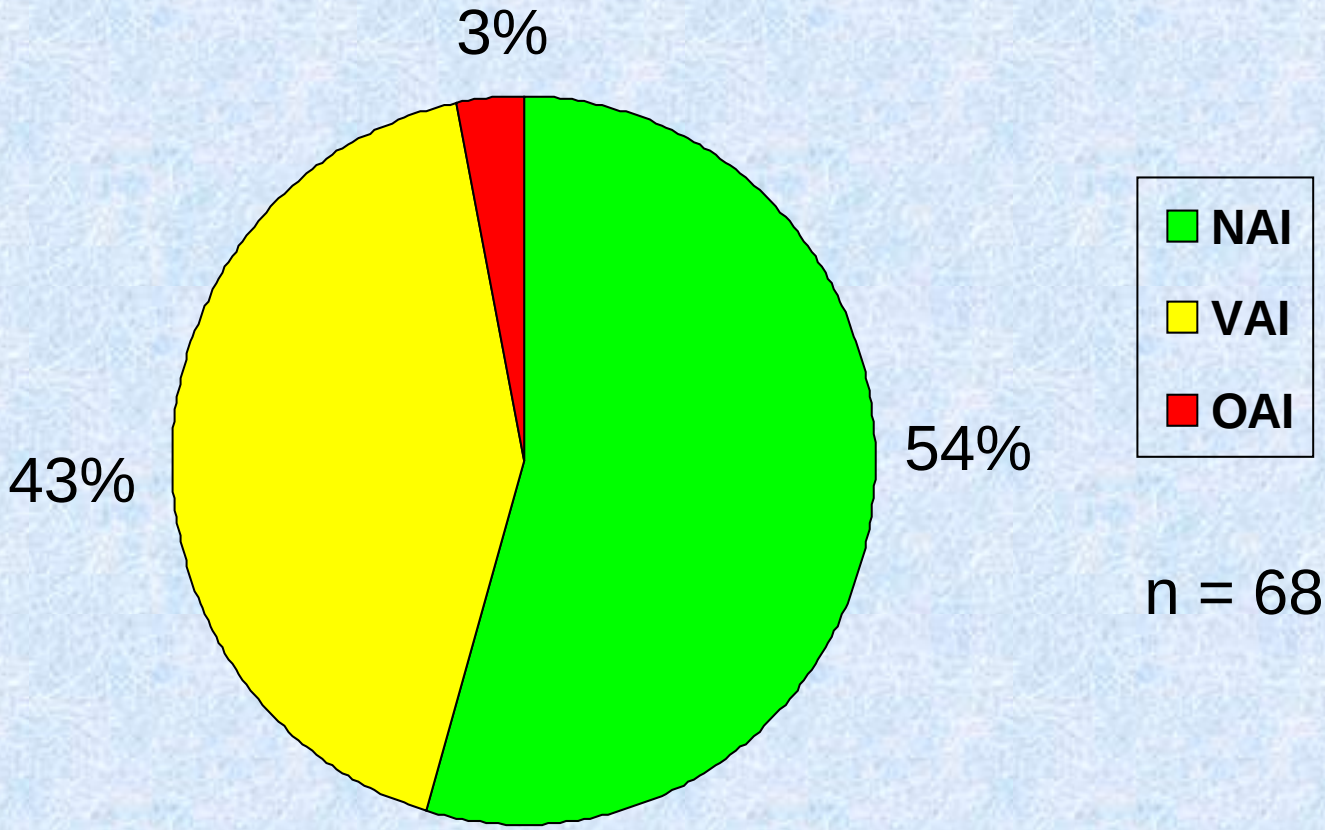
Center	CI	Sponsor	GLP	BEQ	Total
CBER	24				24
CDER	98		2	102	202
CDRH	12	6	2		20
Totals	134	6	4	102	246

FY'13 International CI Inspections Classified* – All Centers



*inspections classified in FY'13 no matter when inspection occurred

FY’13 International BEQ Inspections Classified*



*inspections classified in FY’13 no matter when inspection occurred

Other International Inspections Classified in FY'13*

Sponsor/CRO

- CDER – 5 NAI, 1 VAI; CDRH – 1 VAI, 1 OAI

GLP

- CDER – 1 VAI; CDRH – 1 NAI

*inspections classified in FY'13 no matter when inspection occurred

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