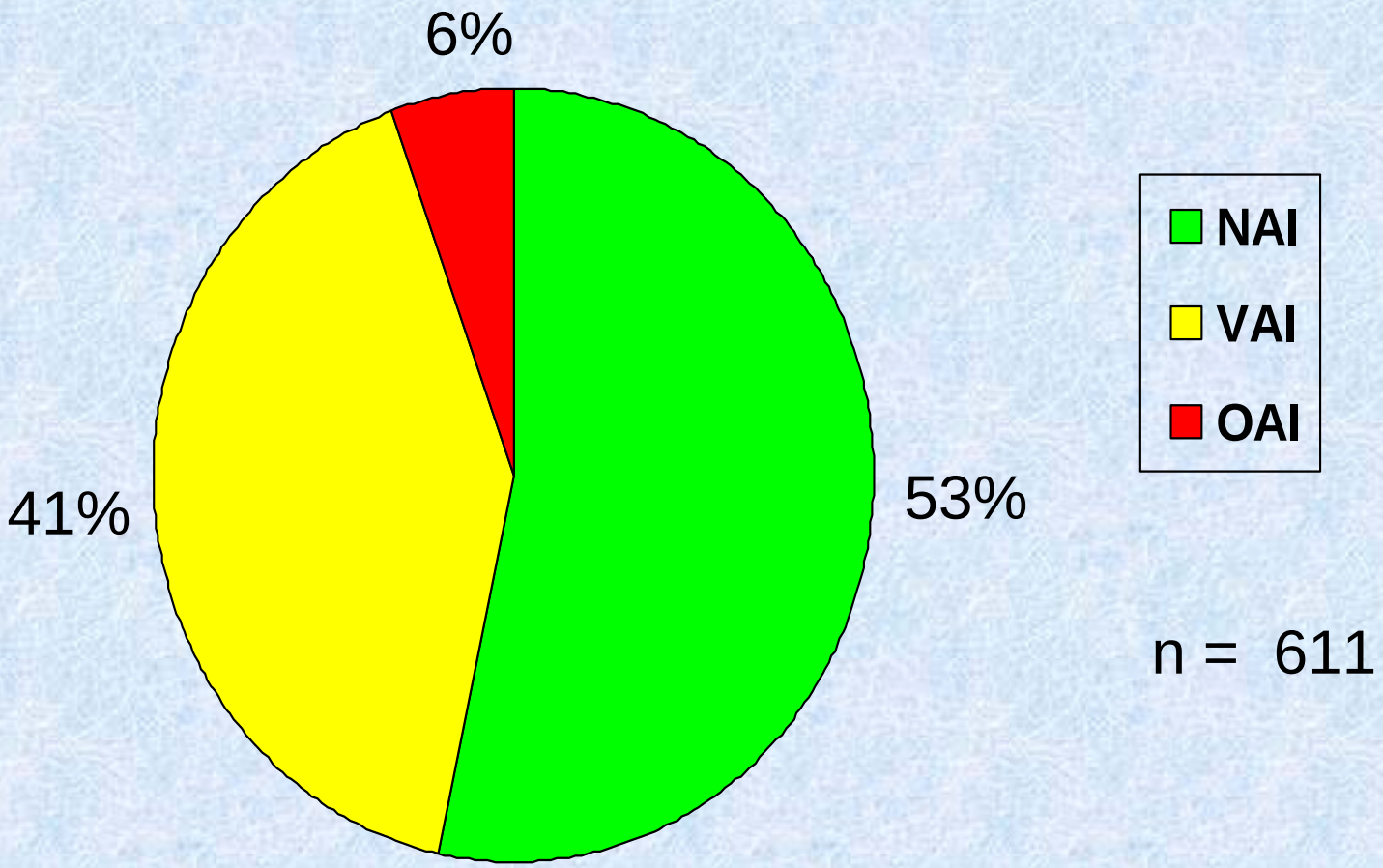
Bioresearch Monitoring (BIMO) Metrics – FY'11

BIMO Inspections Completed FY 2011

Center	CI	IRB	Spon/Mon	GLP	Total
CBER	62	22	12	3	99
CDER*	315	103	45	27	489
CDRH	173	62	78	8	321
CFSAN**	0	0	0	0	0
CVM	26	na	6	7	39
All Centers	576	187	141	45	949

***** 3 **IRB = RDRC; +** 194 **BEQ** inspections (CDER specific)
⇨ total = **1143**
**** CFSAN's BIMO Program is under reorganization**

FY'11 CI Inspections Classified* All Centers



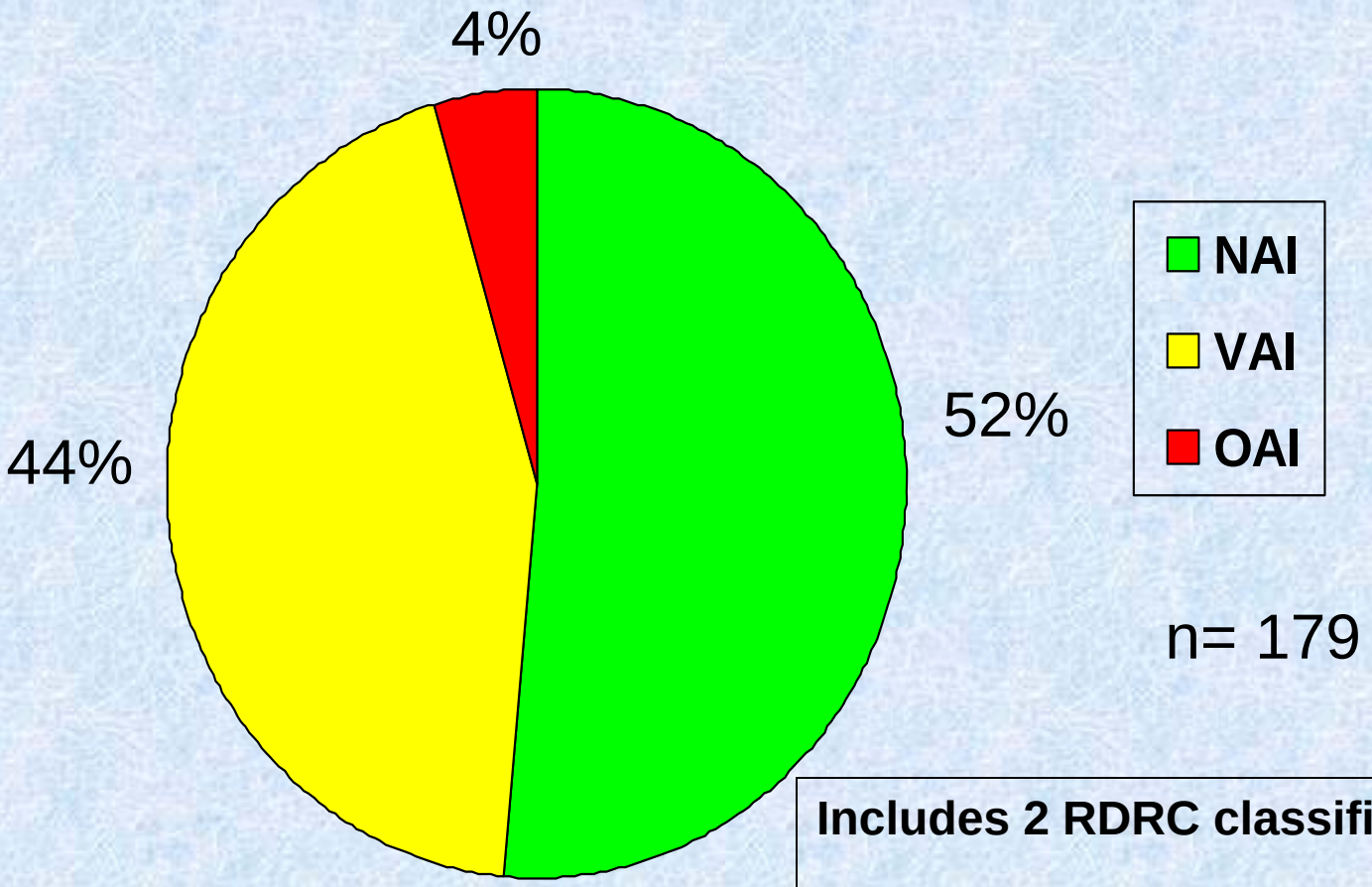
n = 611

*inspections classified in FY'11 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 – including informed consent issues

FY'11 IRB Inspections Classified* – All Centers



n= 179

Includes 2 RDRC classifications

1 VAI, 1 OAI

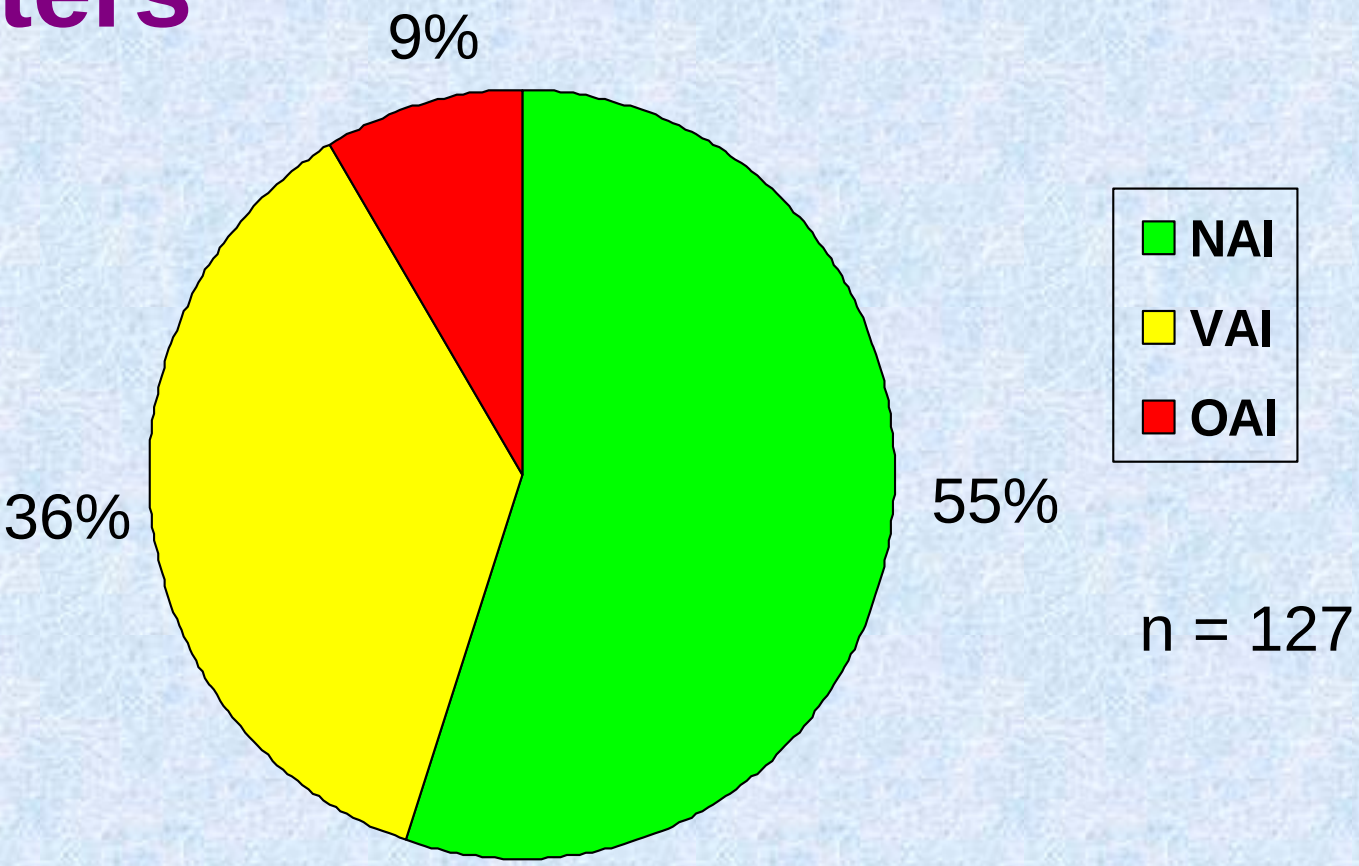
*inspections classified in FY'11 no matter when inspection occurred

Most common IRB deficiencies

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

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

FY'11 Sponsor/Monitor/CRO Inspections Classified* – All Centers

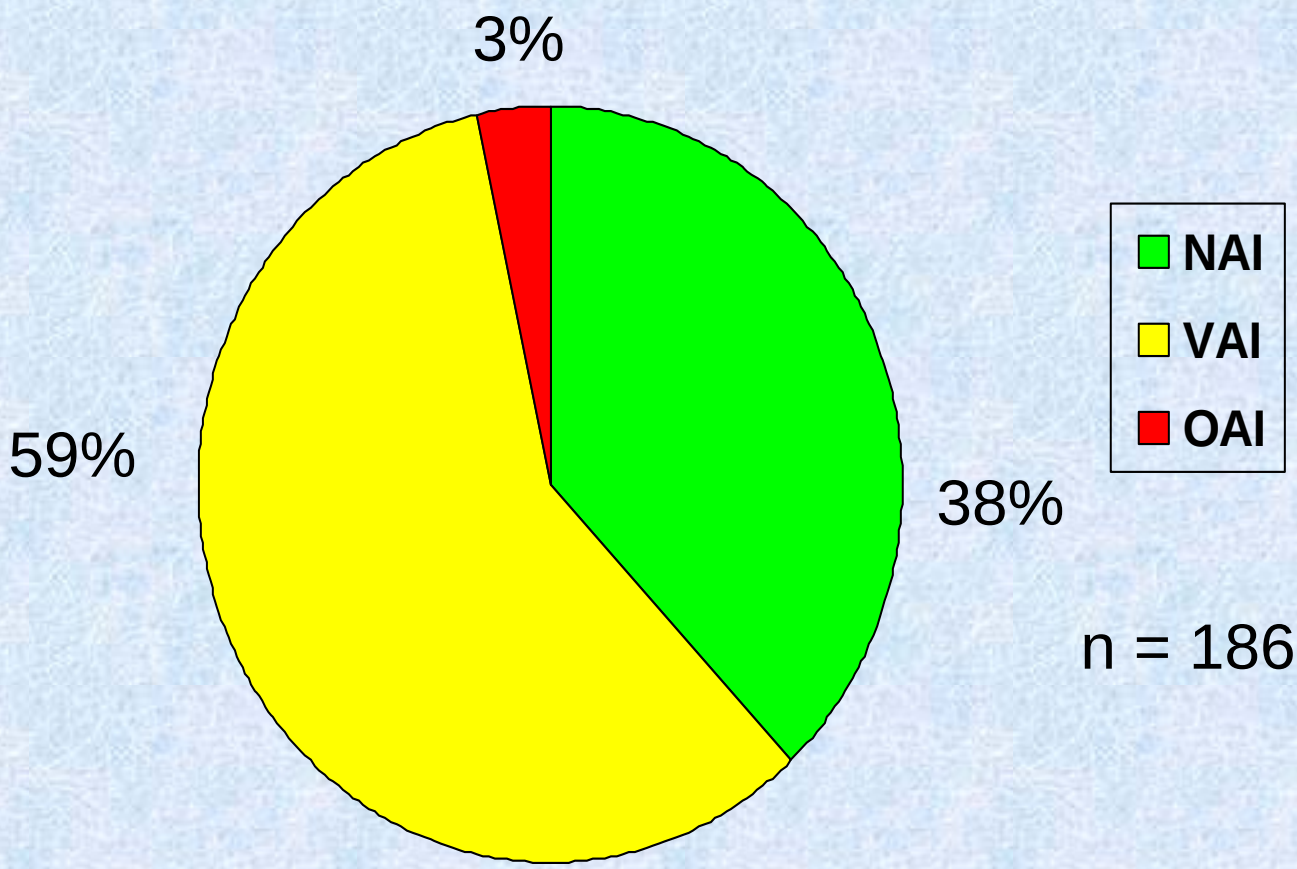


*inspections classified in FY'11 no matter when inspection occurred

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’11 BEQ inspections classified*

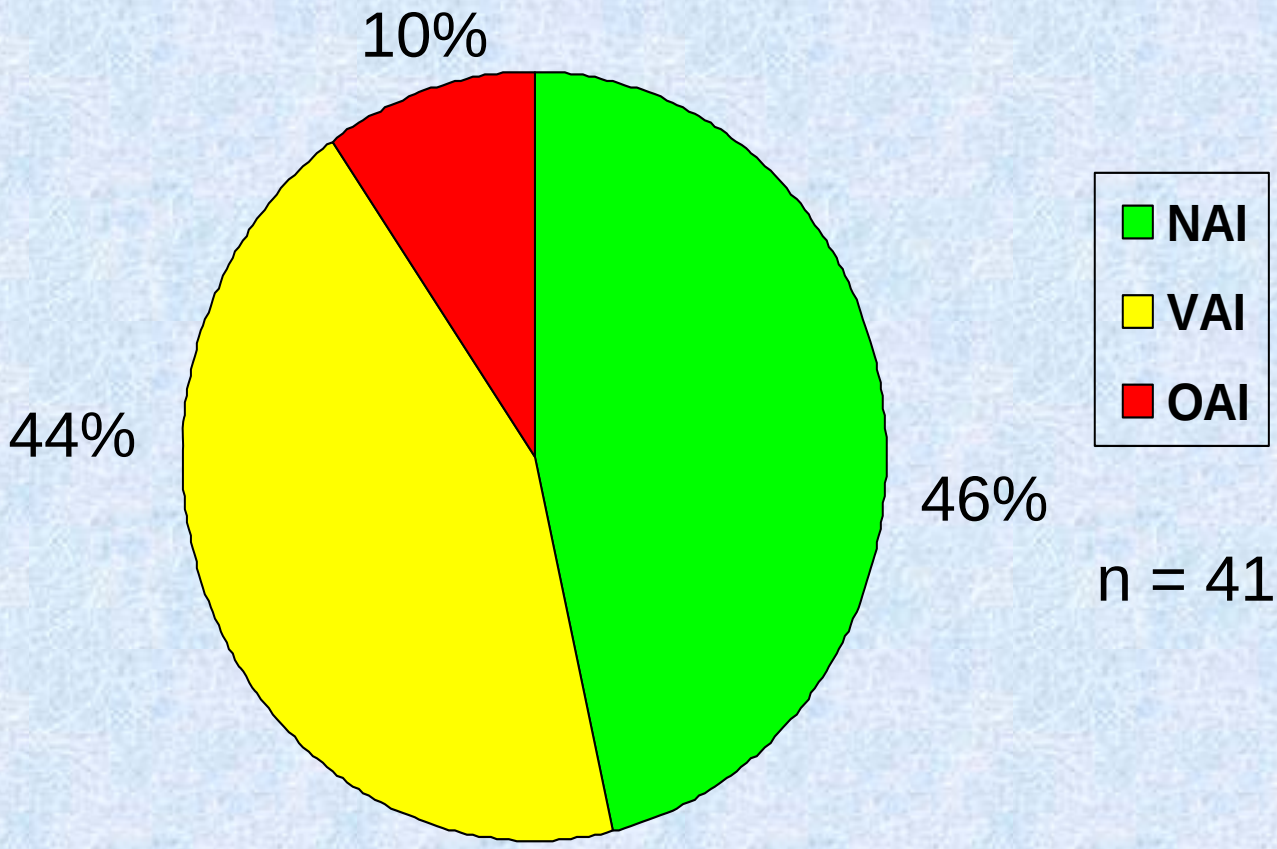


*inspections classified in FY’11 no matter when inspection occurred

Most common BEQ deficiencies

- Recordkeeping
- Dosage issues
- Analytical concerns
  - Validation
  - Stability

FY’11 GLP inspections classified* All Centers



*inspections classified in FY’11 no matter when inspection occurred

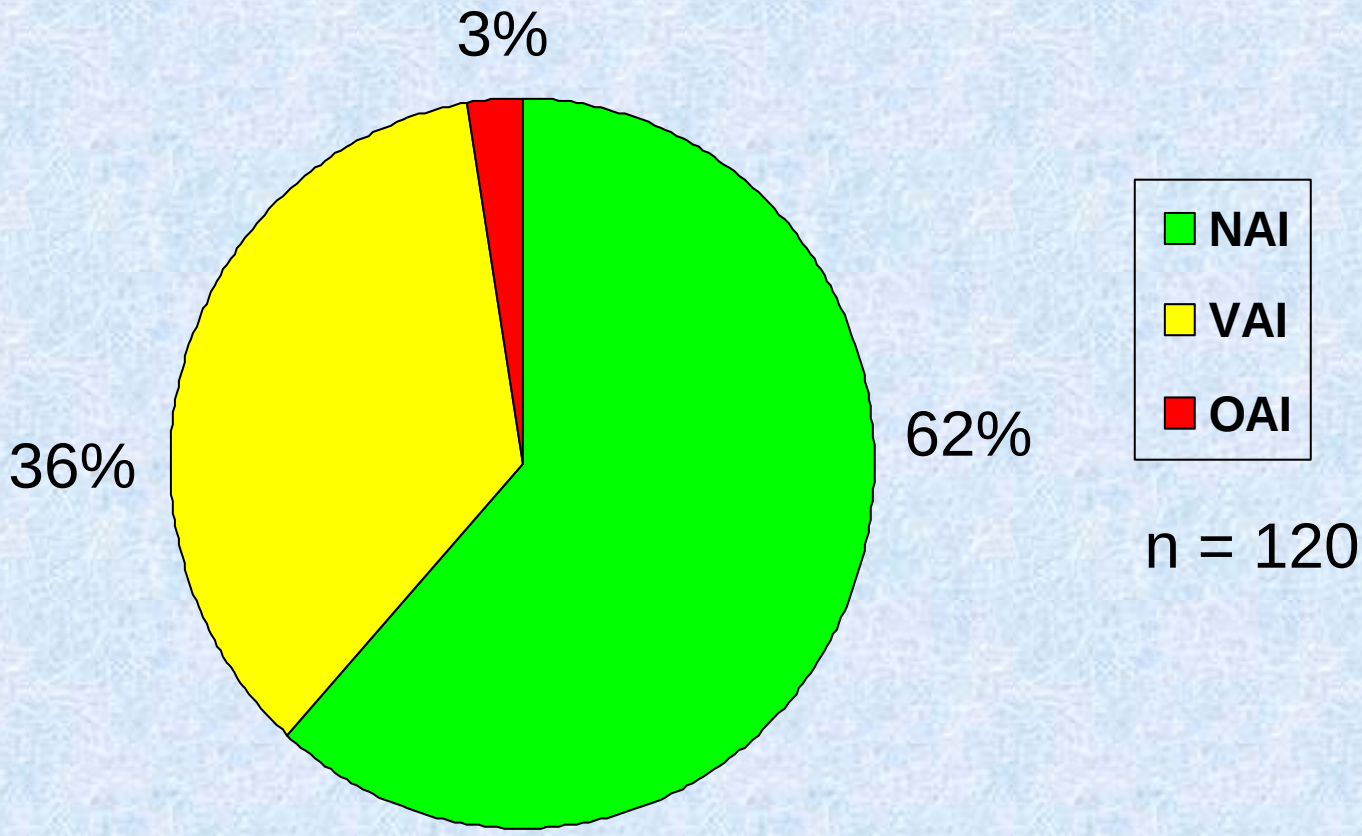
Most common GLP deficiencies

- Organizational and/or Personnel inadequacies
- Incomplete/inadequate/no study records
- Inadequate/no standard operating procedures (SOPs)
- Archived documents/samples improperly/not filed and/or not readily retrievable
- Incomplete/inaccurate study reports

International Inspections Completed: FY 2011

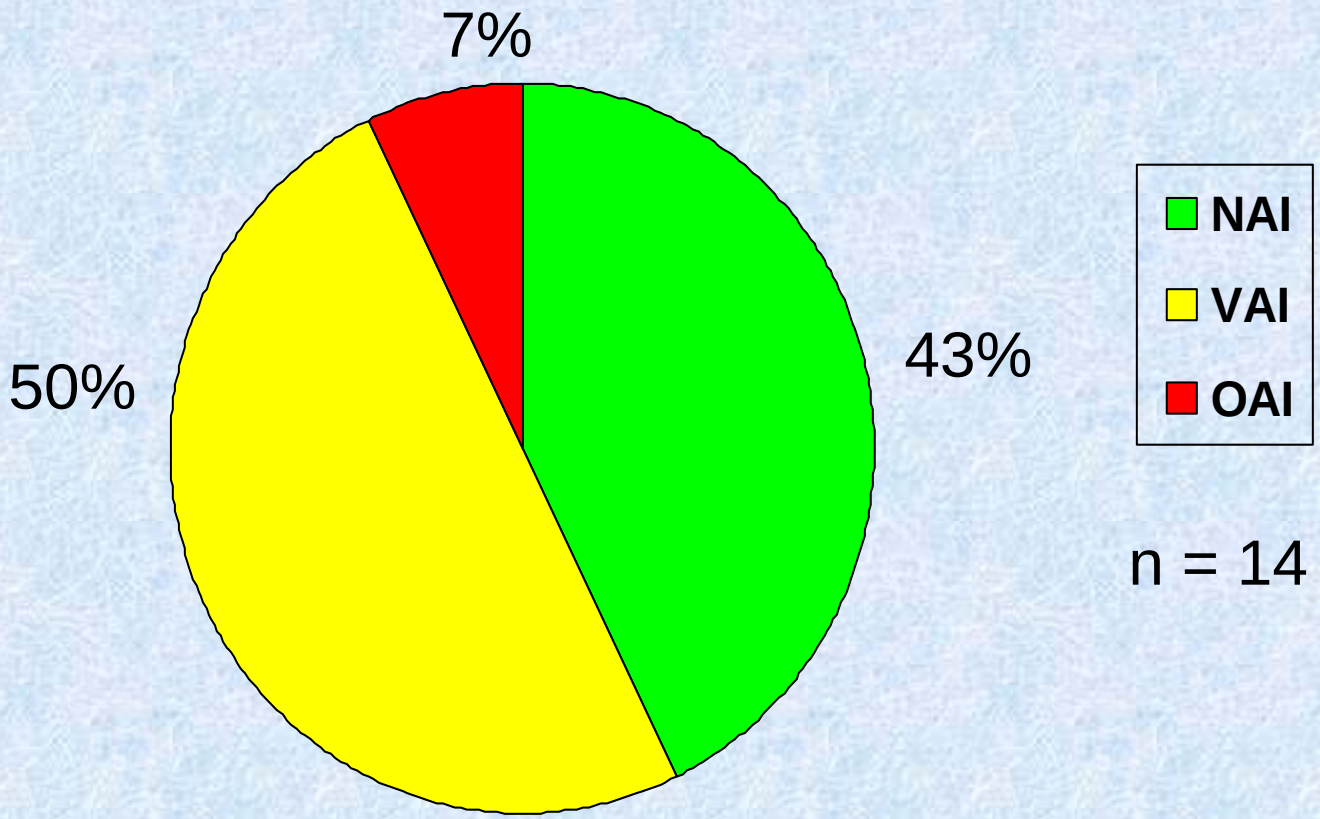
Center	CI	Sponsor	GLP	BEQ	Total
CBER	8	1			9
CDER	100	7		99	206
CDRH	13	3	1		17
CVM		1			1
Totals	121	12	1	99	233

FY’11 International CI Inspections Classified* – All Centers



*inspections classified in FY’11 no matter when inspection occurred

FY'11 International Sponsor/CRO/Monitor Inspections Classified* – All Centers



*inspections classified in FY'11 no matter when inspection occurred

Other International Inspections Classified in FY'11*

GLP

- CDRH – 1 – OAI

BEQ

- CDER – 87 – 25 NAI, 62 VAI

*inspections classified in FY'11 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