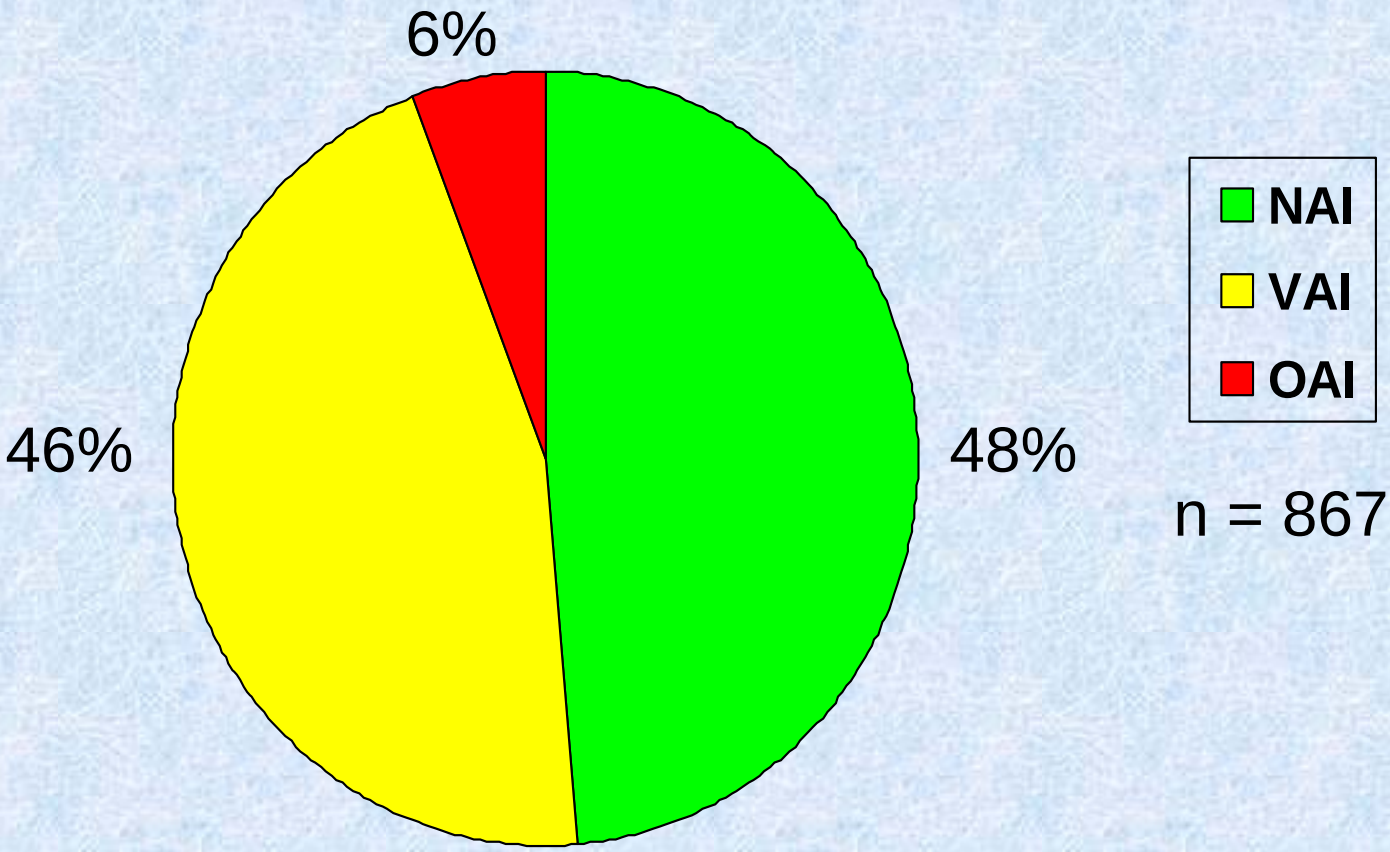
Bioresearch Monitoring (BIMO) Metrics – FY'09

BIMO Inspections Completed FY 2009

Center	CI	IRB	Spon/Mon	GLP	Total
CBER	83	15	11	6	115
CDER*	458	102	73	36	669
CDRH	163	79	59	4	305
CFSAN	0	0	0	1	1
CVM	26	na	4	15	45
All Centers	730	196	147	53	1135

* + 137 **BEQ** inspections (CDER specific) ⇨ total = 1272

FY'09 CI Inspections Classified* All Centers

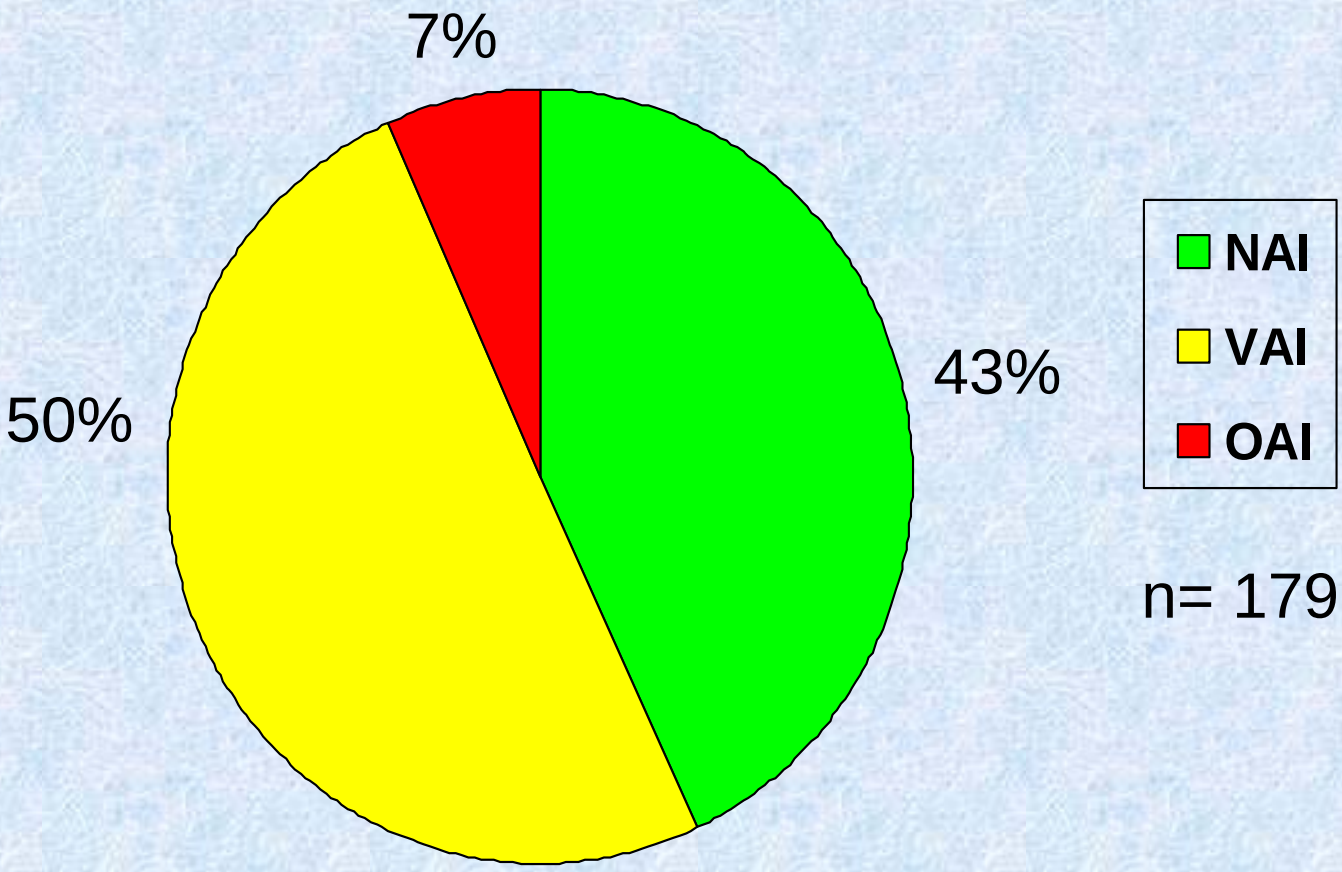


*inspections classified in FY'09 no matter when inspection occurred

Most Common CI Deficiencies

- Failure to follow the investigational plan
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate subject protection – including informed consent issues

FY'09 IRB Inspections Classified* – All Centers



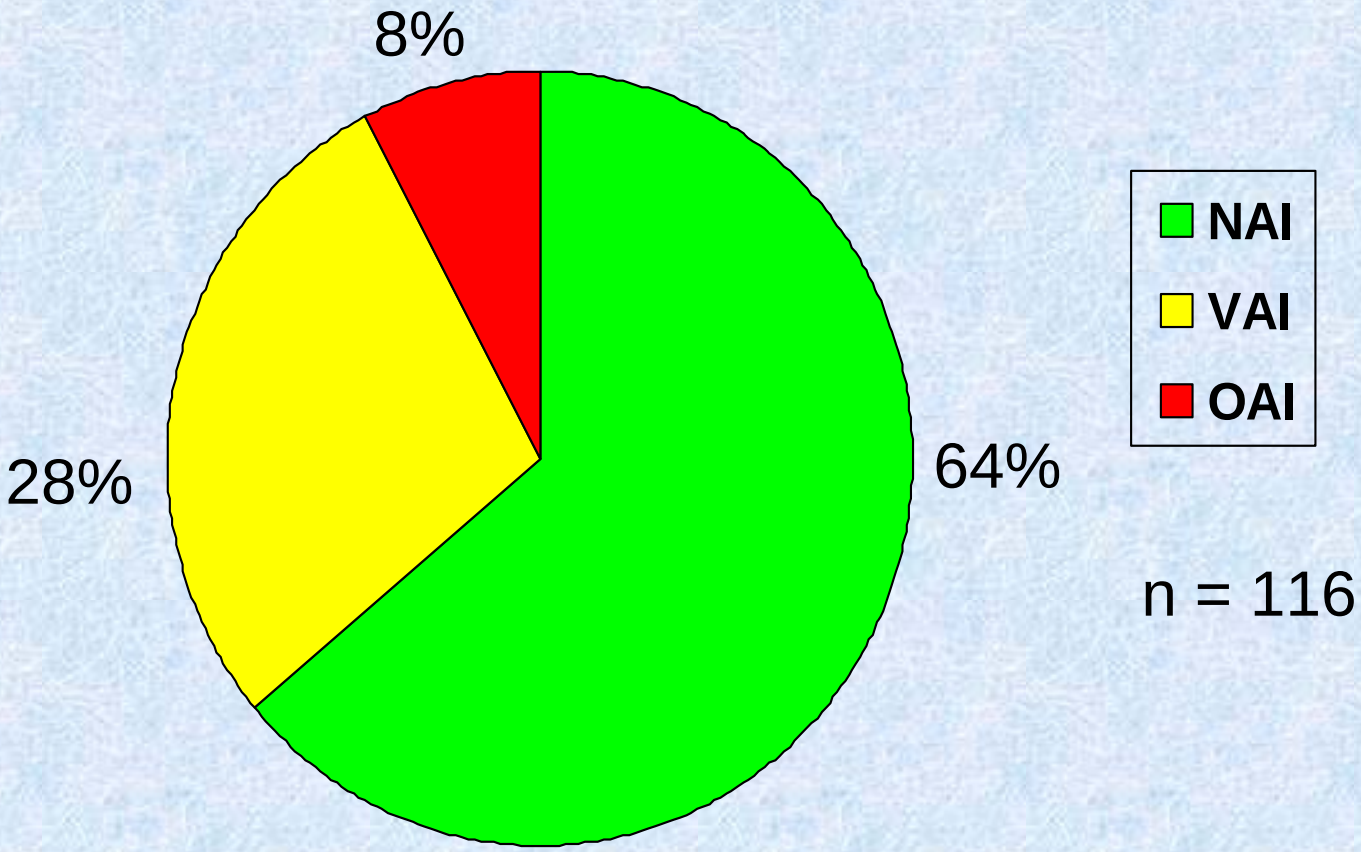
*inspections classified in FY'09 no matter when inspection occurred

Most common IRB deficiencies

- Inadequate initial and/or continuing review
- Inadequate SOPs
- Inadequate membership rosters
- Inadequate meeting minutes

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

FY'09 Sponsor/Monitor Inspections Classified* – All Centers

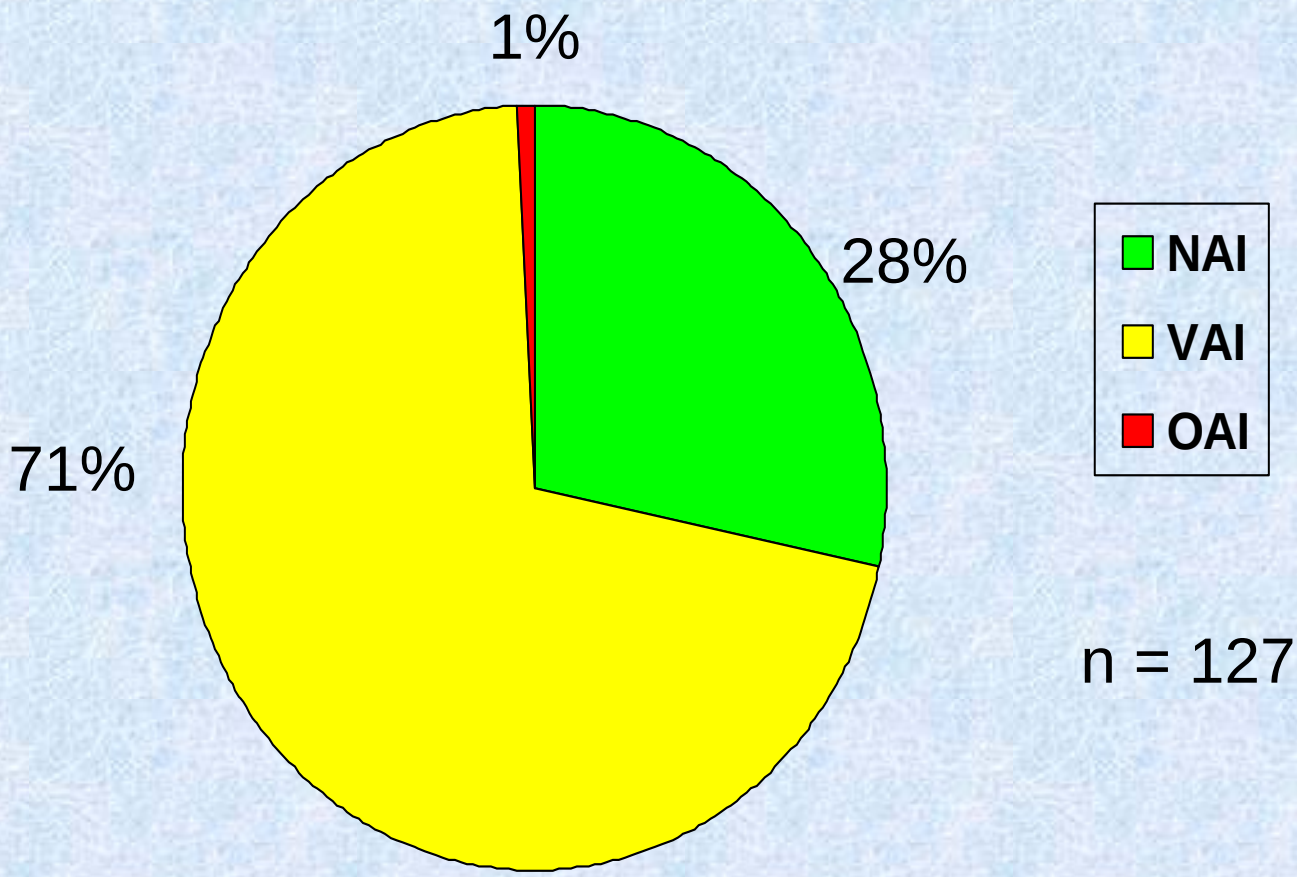


*inspections classified in FY'09 no matter when inspection occurred

Most common S/M deficiencies

- Inadequate monitoring
- Failure to bring investigators into compliance
- Inadequate accountability for the investigational product

FY’09 BEQ inspections classified*



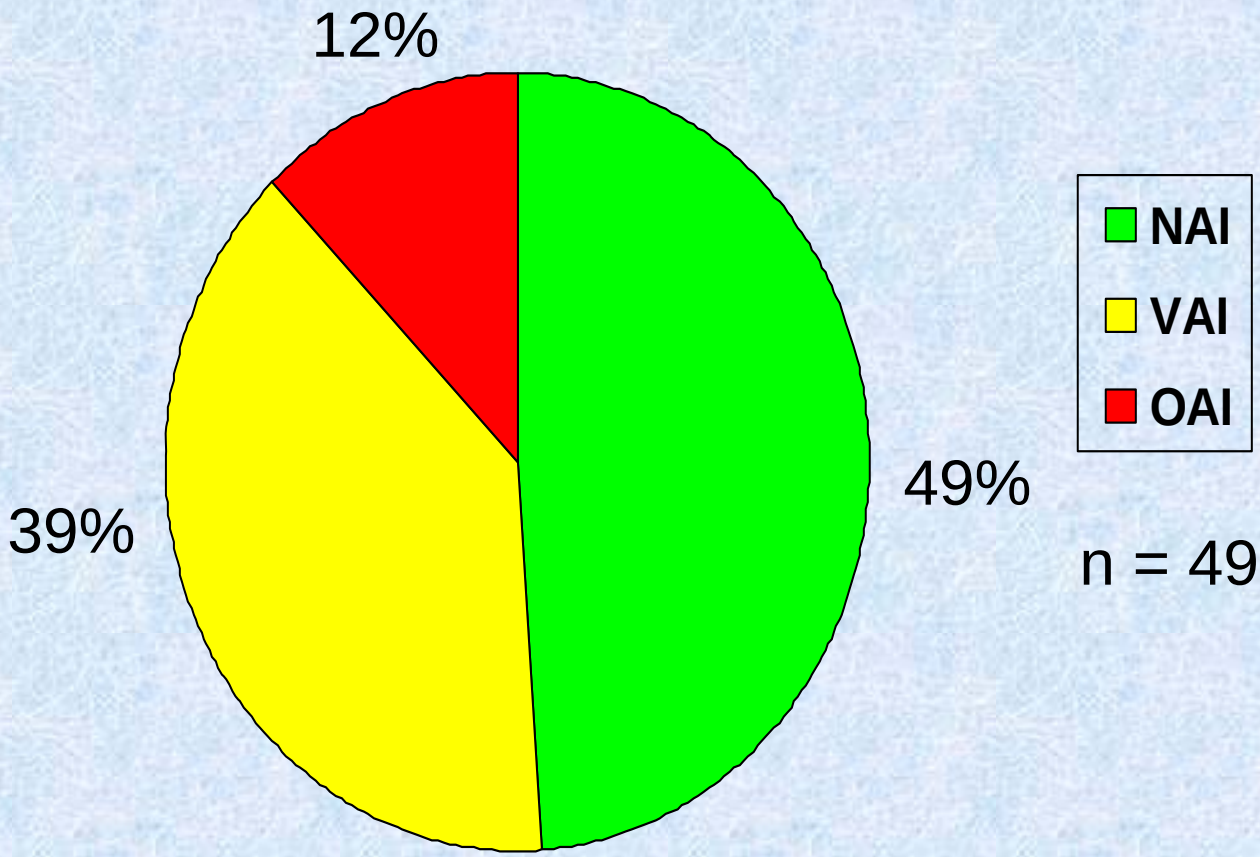
n = 127

*inspections classified in FY’09 no matter when inspection occurred

Most common BEQ deficiencies

- Dosage issues
- Analytical concerns

FY’09 GLP inspections classified* All Centers



*inspections classified in FY’09 no matter when inspection occurred

Most common GLP deficiencies

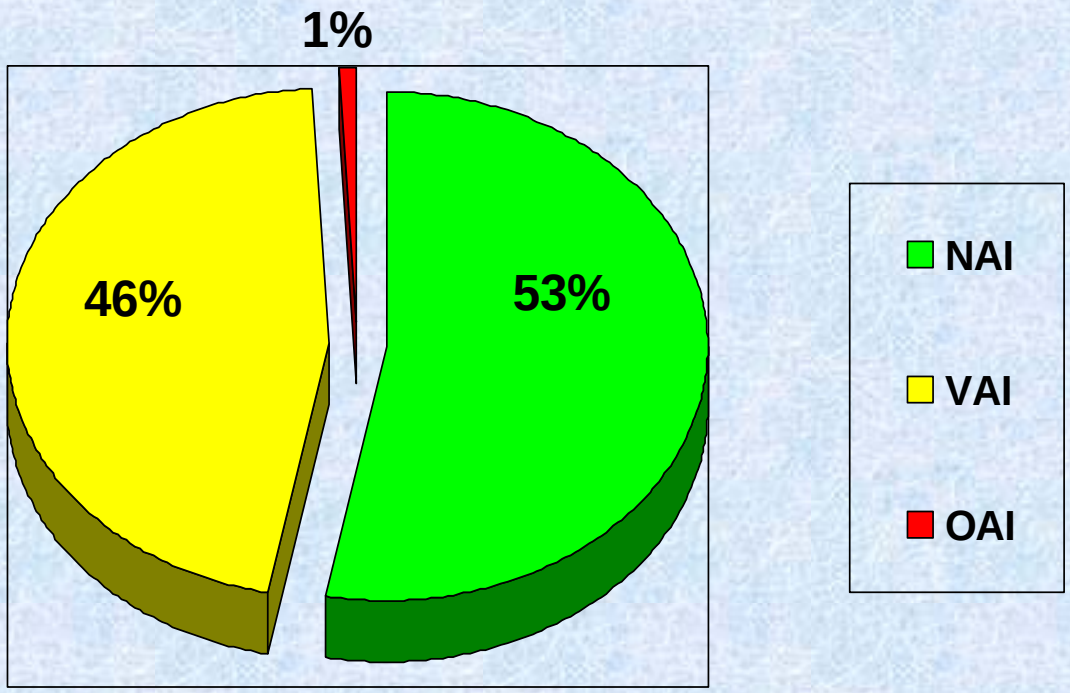
- Incomplete/inaccurate study reports
- Incomplete/inadequate/no study records
- Inadequate/no standard operating procedures (SOPs)
- Personnel failure to fulfill responsibilities, e.g.:
  - Study Director failure to assure all raw documentation was archived
  - Management failure to designate a study director prior to study initiation
- Archived documents improperly filed and/or not readily retrievable

International Inspections Completed: FY 2009

Center	Total
CBER	3*
CDER	119
CDRH	12**
CVM	0
Totals	134

*2 CI and 1 sponsor; **10 CI and 2 sponsor

CDER CI International Inspections Classified* in FY 2009



Total inspections classified = 120

***Based on Letter Issued Date**

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