Bioresearch Monitoring (BIMO) Metrics – FY'10

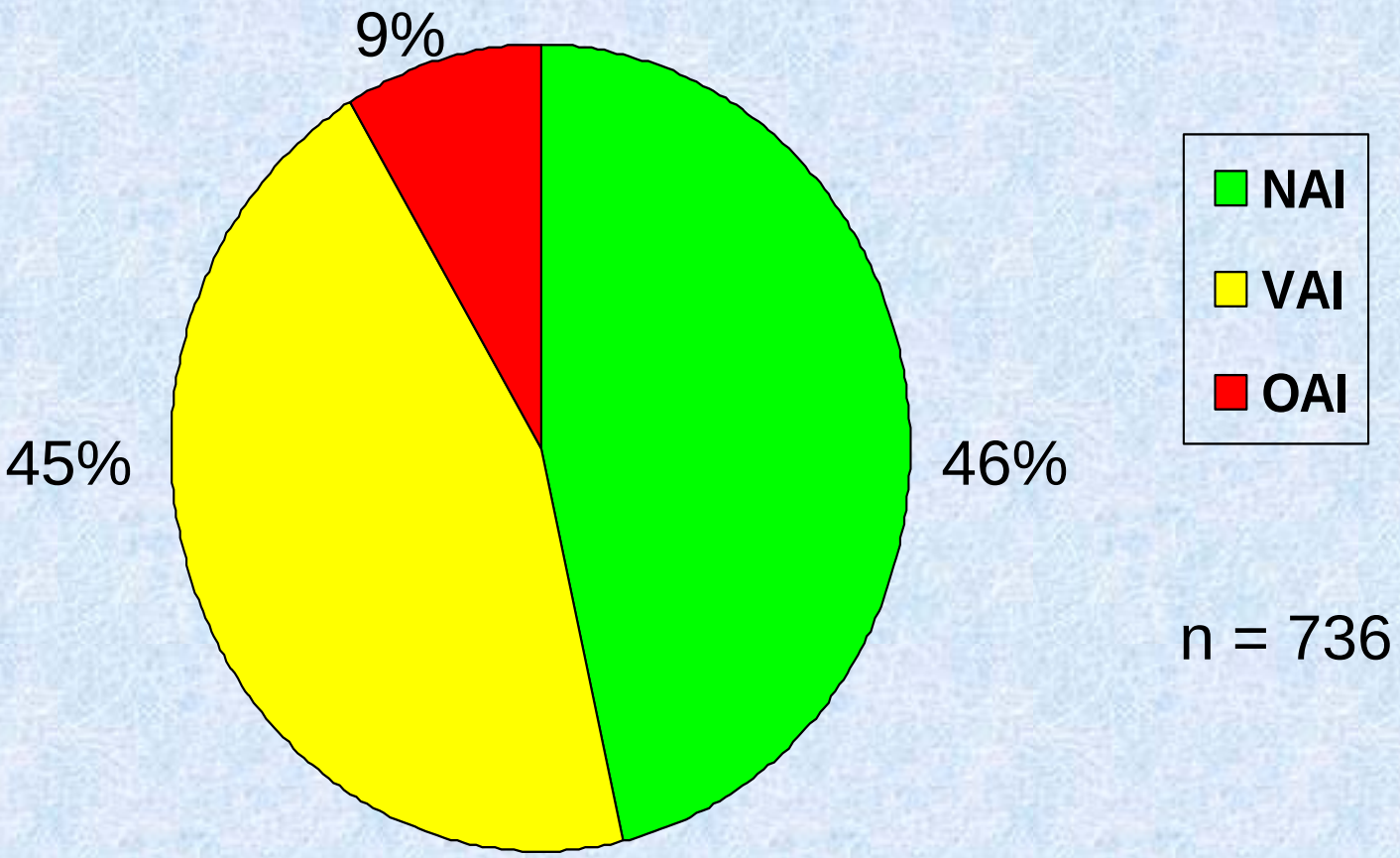
BIMO Inspections Completed FY 2010

Center	CI	IRB	Spon/Mon	GLP	Total
CBER	75	25	14	11	125
CDER*	387	97	60	33	577
CDRH	218	81	80	7	386
CFSAN**	0	0	0	0	0
CVM	45	na	1	26	72
All Centers	725	203	155	77	1160

***+** 182 **BEQ** inspections (CDER specific) ⇨ total = 1342

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

FY'10 CI Inspections Classified* All Centers



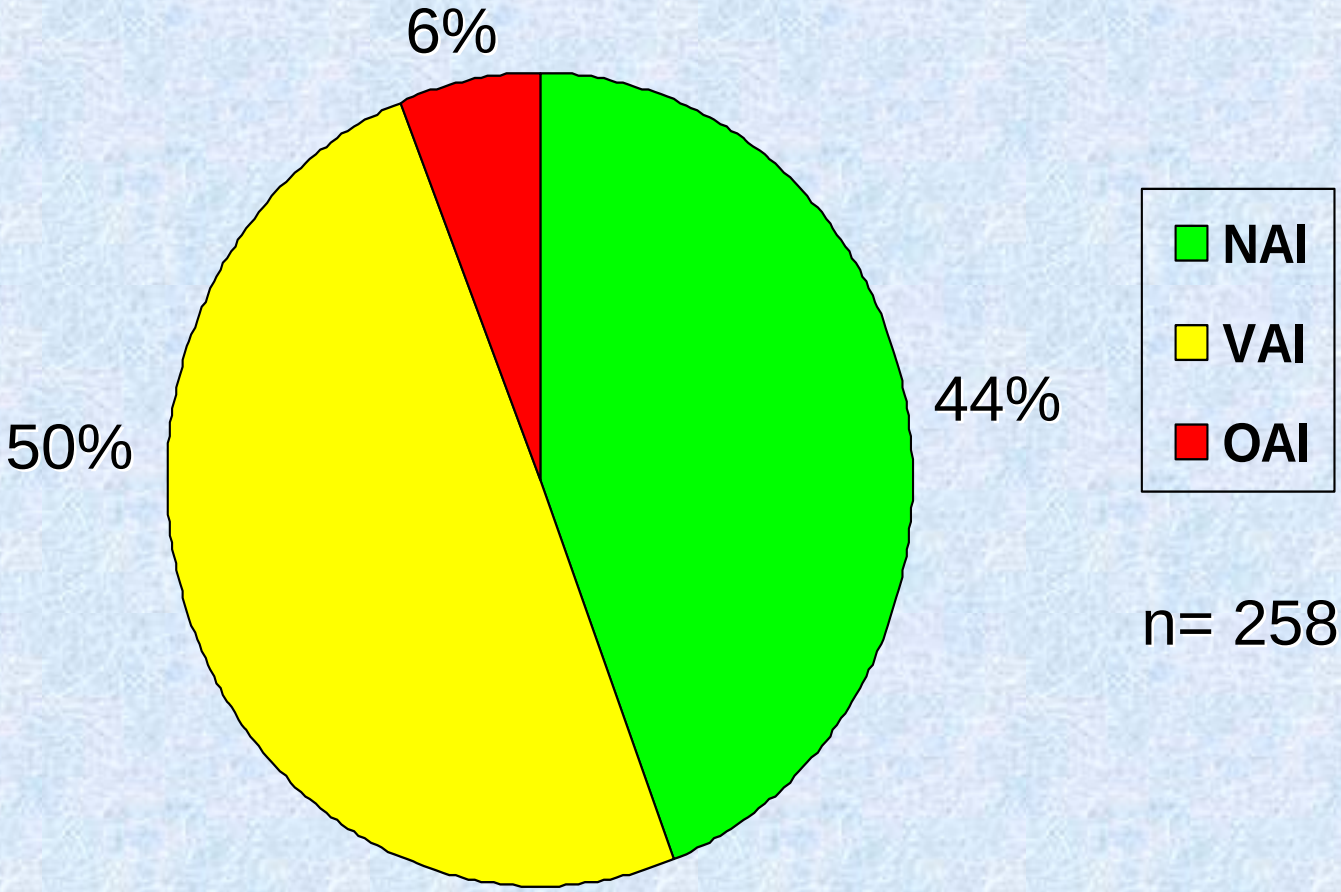
n = 736

*inspections classified in FY'10 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'10 IRB Inspections Classified* – All Centers



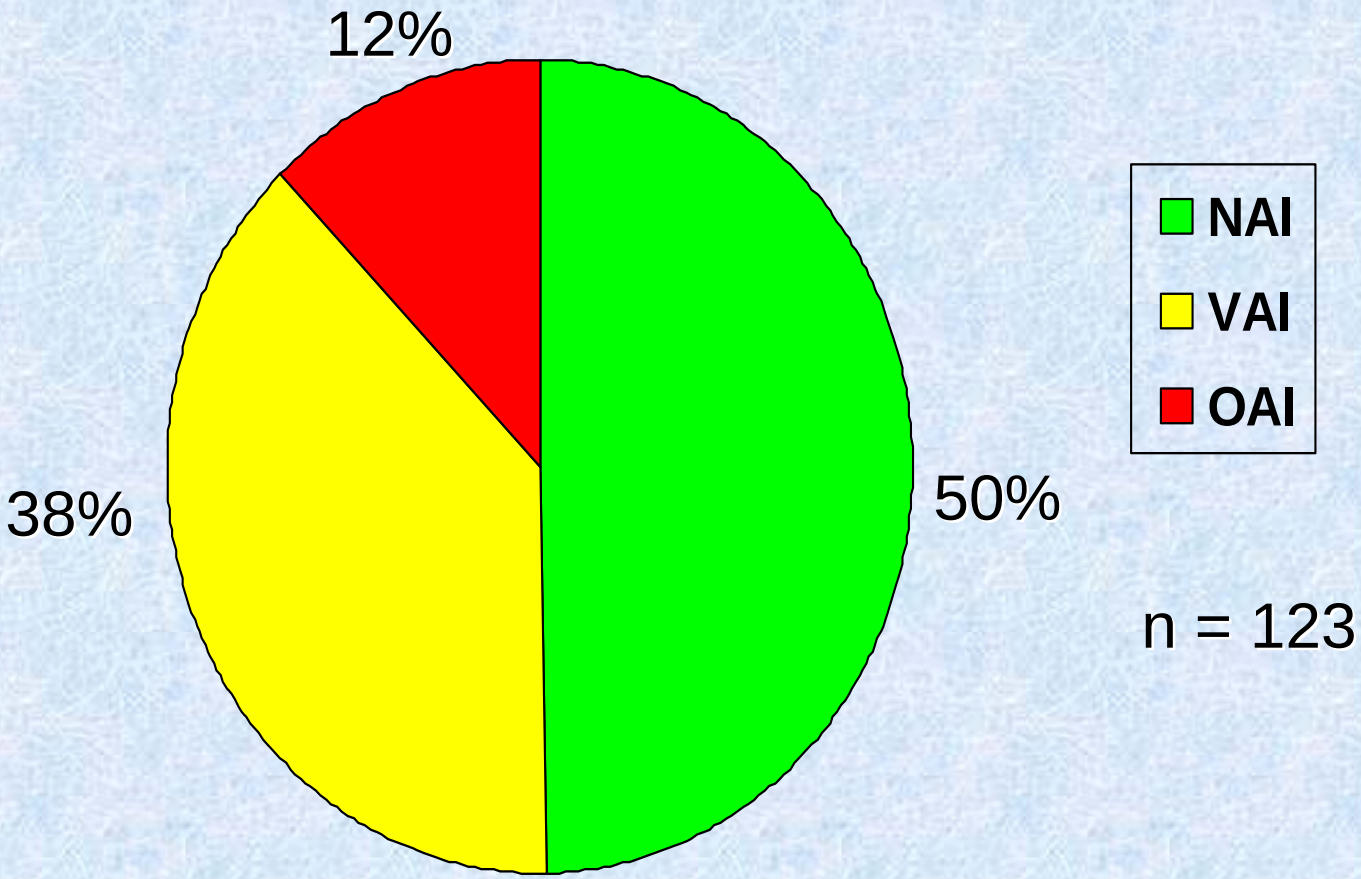
*inspections classified in FY'10 no matter when inspection occurred

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'10 Sponsor/Monitor Inspections Classified* – All Centers

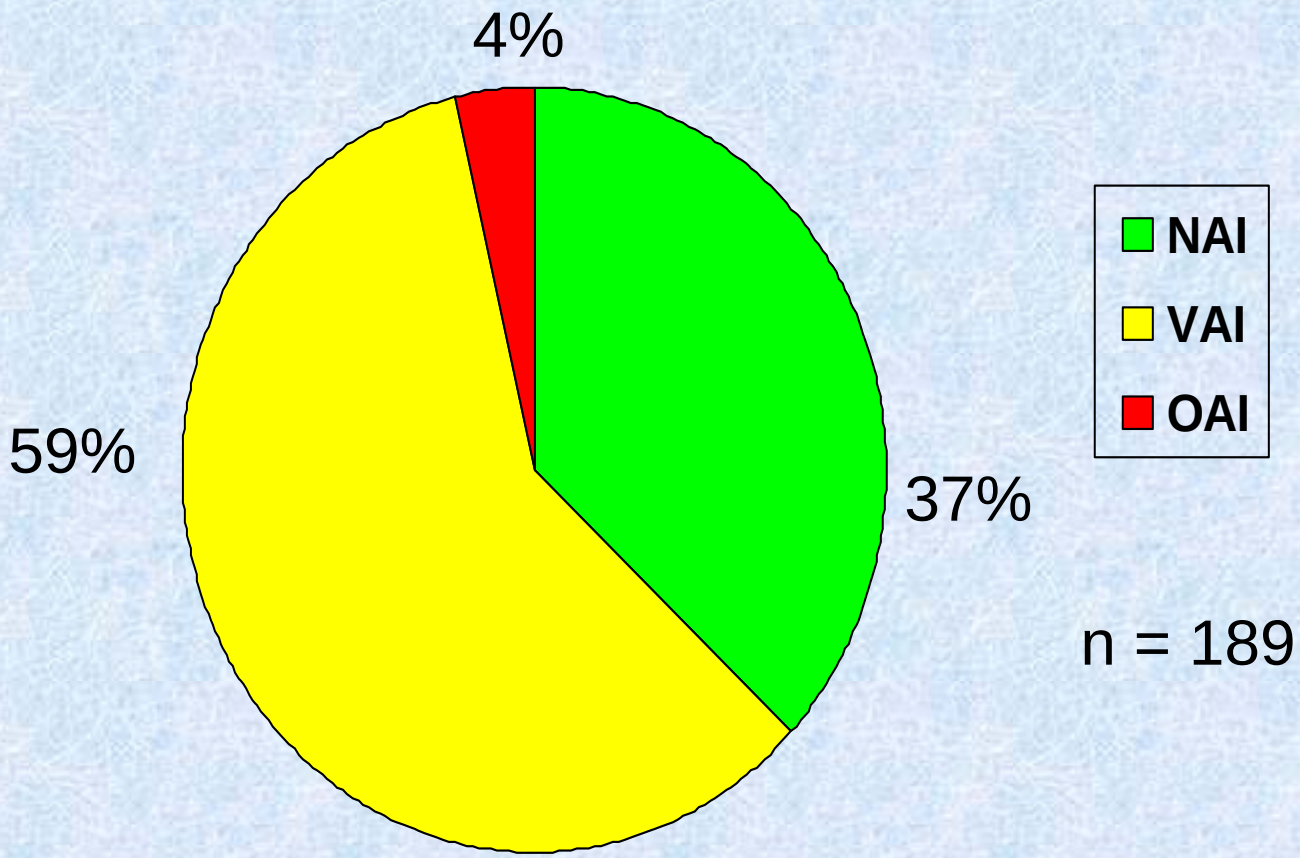


*inspections classified in FY'10 no matter when inspection occurred

Most common S/M deficiencies

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

FY’10 BEQ inspections classified*



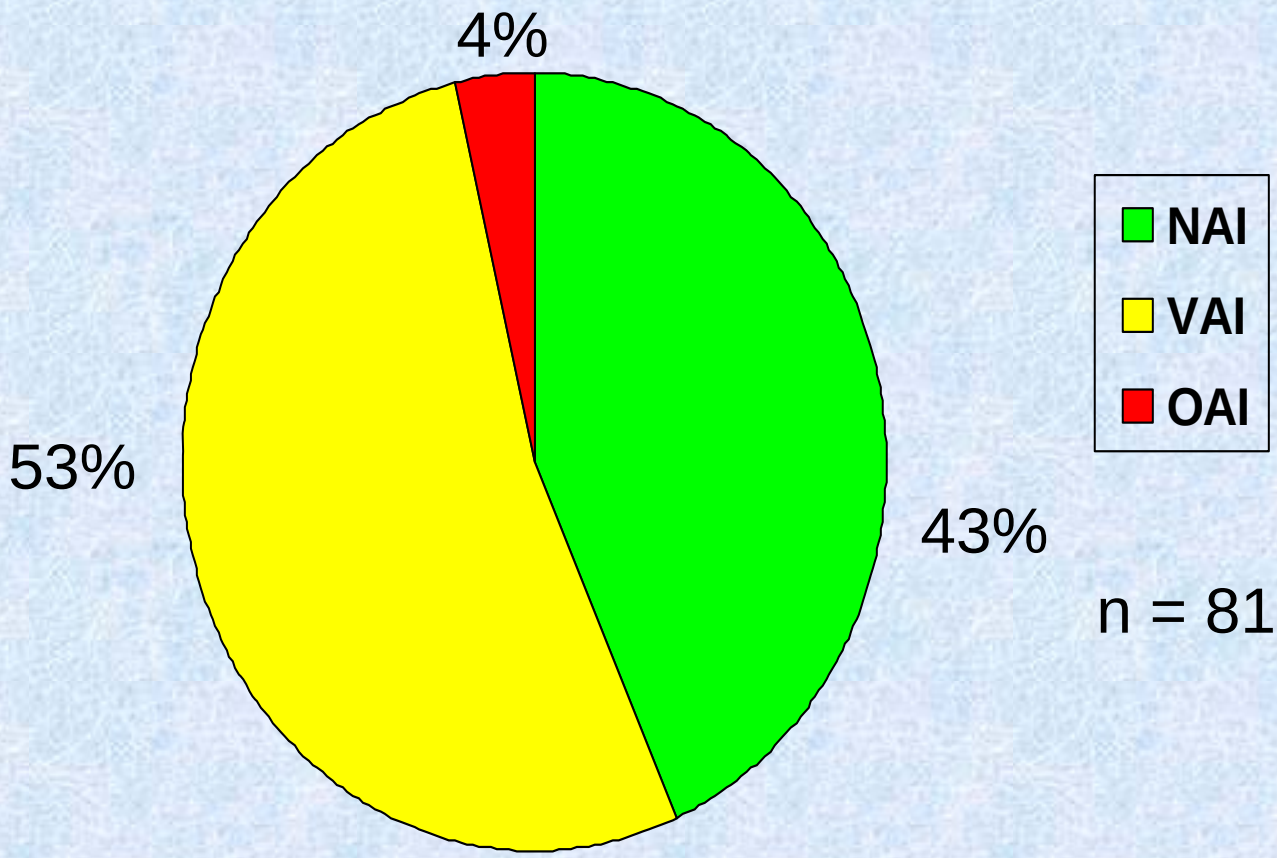
n = 189

*inspections classified in FY’10 no matter when inspection occurred

Most common BEQ deficiencies

- Dosage issues
- Analytical concerns

FY’10 GLP inspections classified* All Centers



*inspections classified in FY’10 no matter when inspection occurred

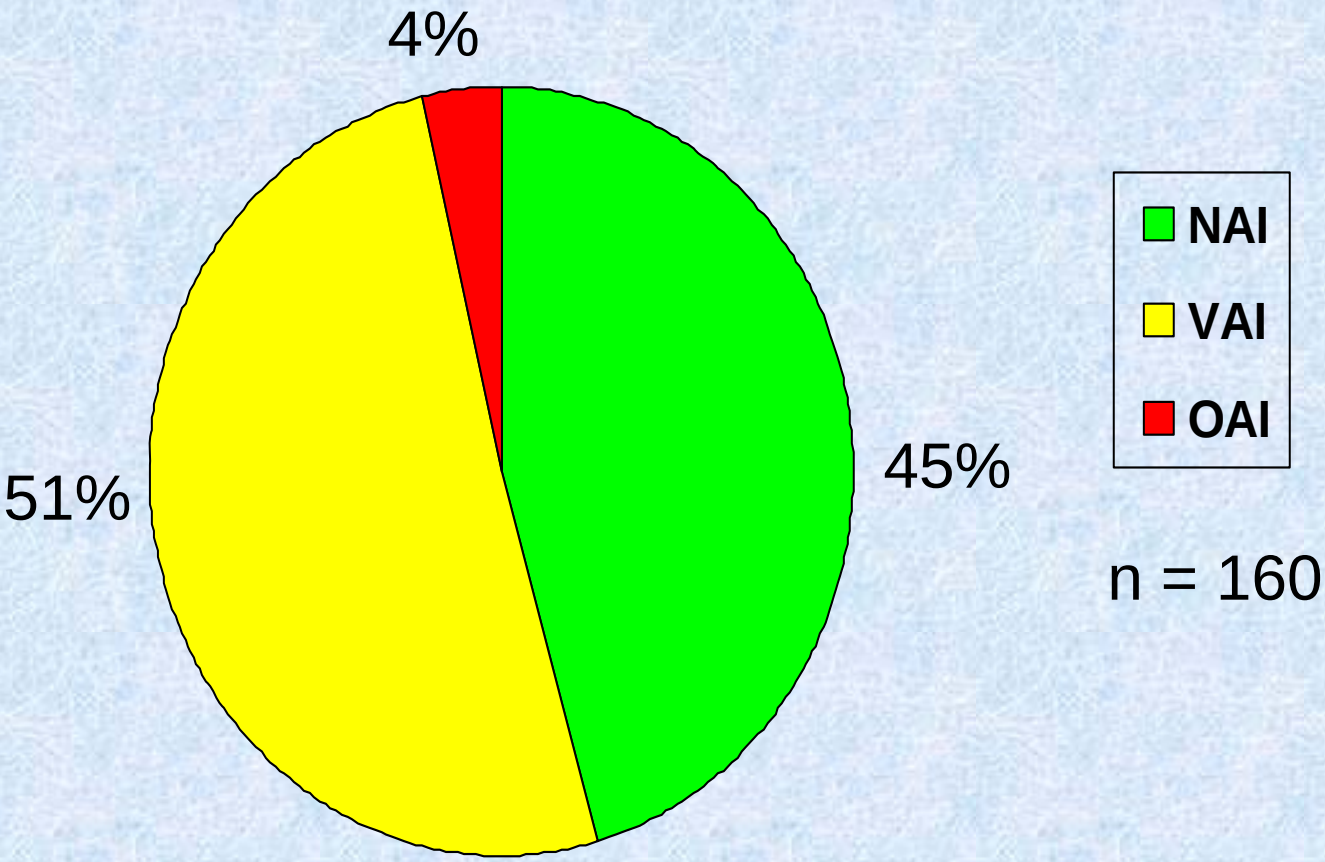
Most common GLP deficiencies

- 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 2010

Center	CI	Sponsor	Total
CBER	9	1	10
CDER	111	0	111
CDRH	17	3	20
CVM	0	1	1
Totals	137	5	142

FY'10 International CI Inspections Classified* – All Centers



*inspections classified in FY'10 no matter when inspection occurred

FY’10 International Sponsor Inspections Classified*

- CBER – 1 – NAI
- CDRH – 1 – VAI

*inspections classified in FY’10 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