

**Bioresearch  
Monitoring (BIMO)  
Metrics – FY'08**

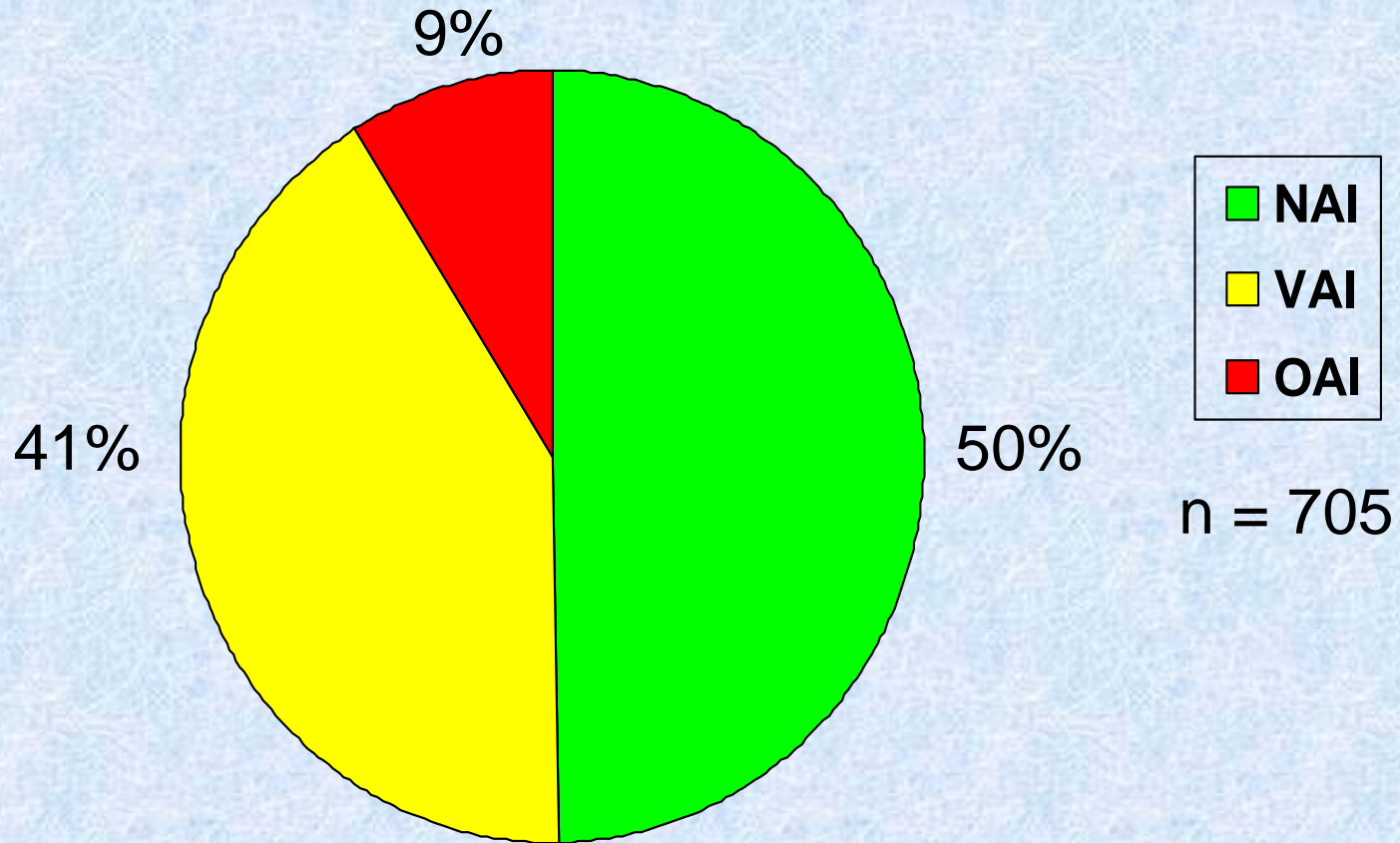
# BIMO Inspections Completed FY 2008

<u>Center</u>	<u>CI</u>	<u>IRB</u>	<u>Spon/Mon</u>	<u>GLP</u>	<u>Total</u>
<b>CBER</b>	77	19	6	4	106
<b>CDER*</b>	405	72	43	27	547
<b>CDRH</b>	155	88	57	1	301
<b>CFSAN</b>	0	0	0	1	1
<b>CVM</b>	38	na	3	14	55
<b>All Centers</b>	675	179	109	47	1010

\* + 116 **BEQ** inspections (CDER specific) ⇒ total = 1126

# FY'08 CI Inspections Classified\*

## All Centers

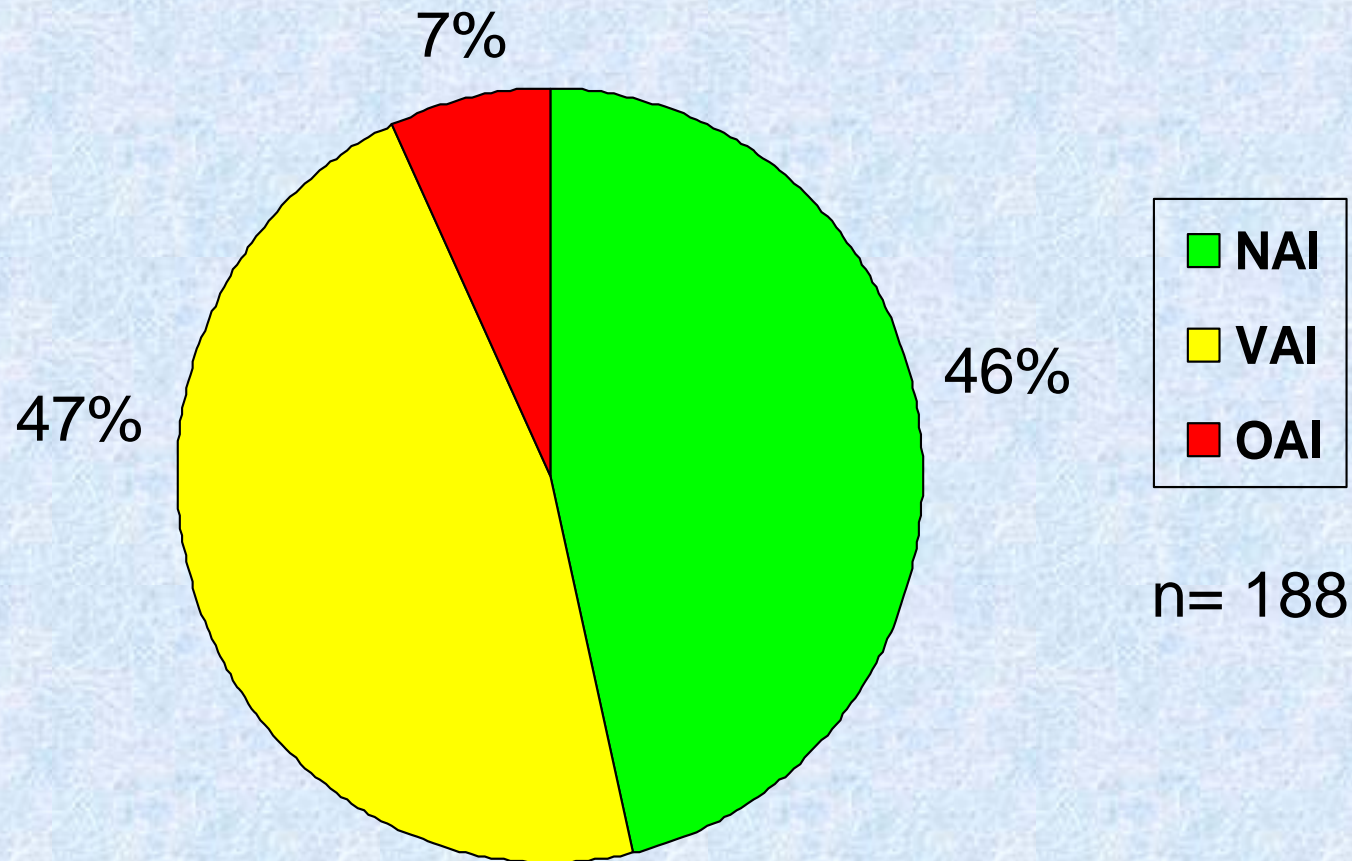


\*inspections classified in FY'08 no matter when inspection occurred

# 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'08 IRB Inspections Classified\* – All Centers



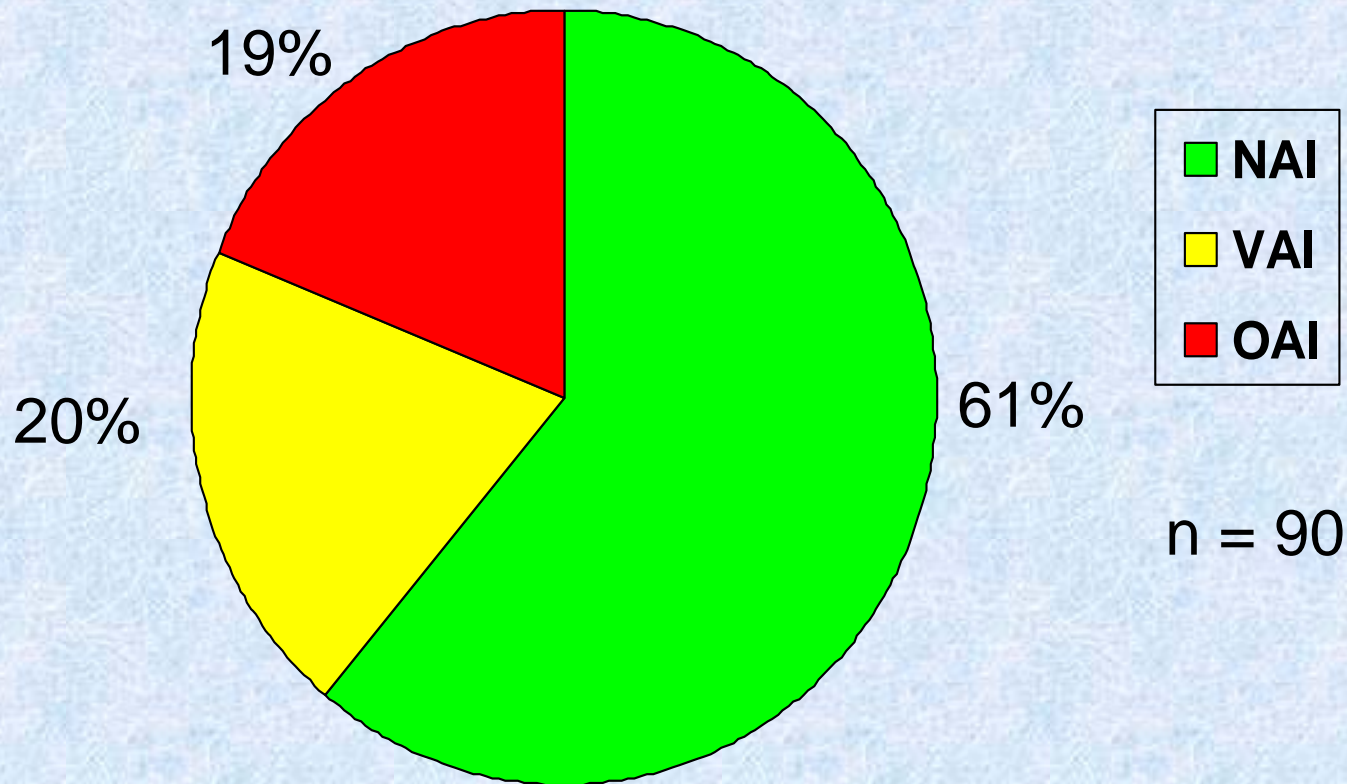
\*inspections classified in FY'08 no matter when inspection occurred

# 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'08 Sponsor/Monitor Inspections Classified\* – All Centers



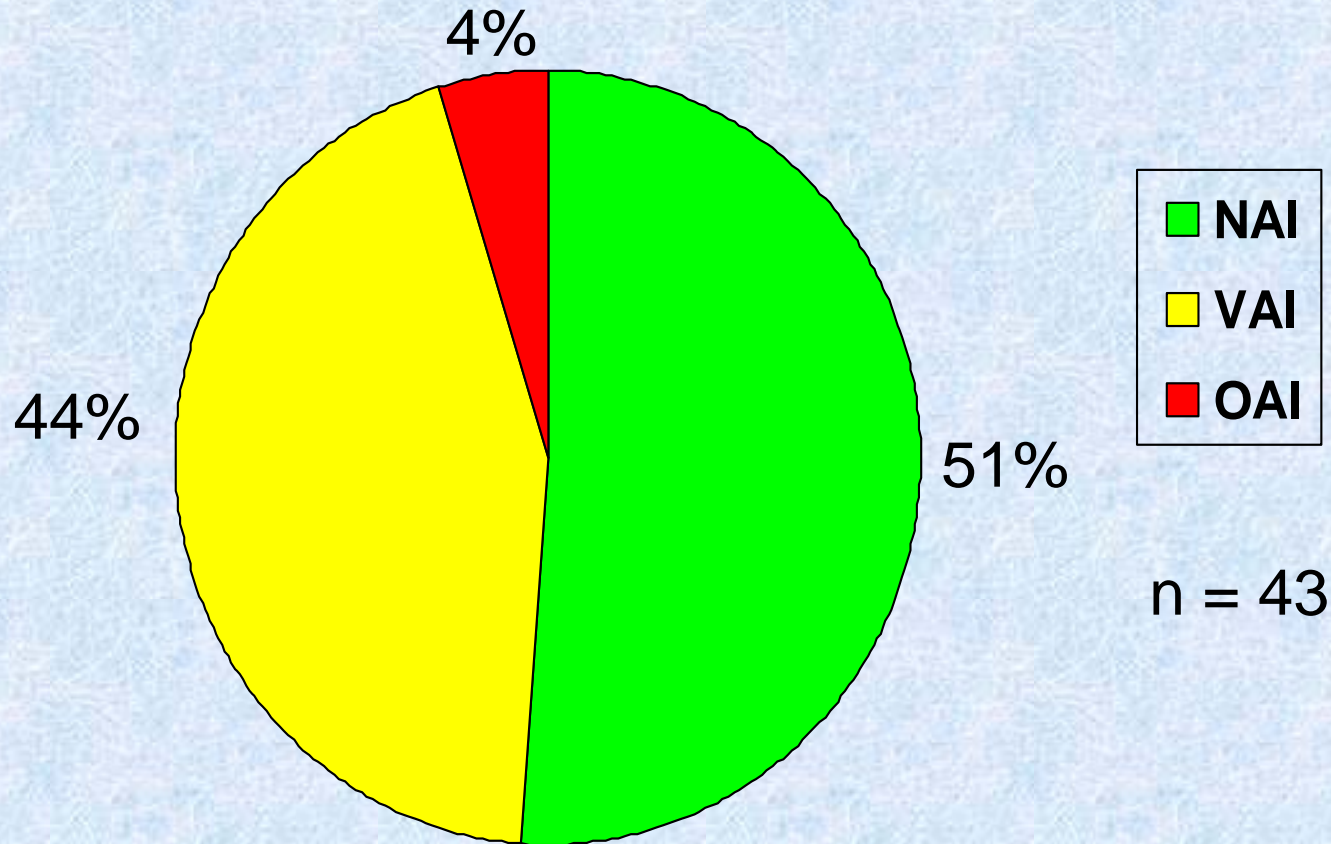
\*inspections classified in FY'08 no matter when inspection occurred

# Most Common Sponsor/Monitor Deficiencies

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

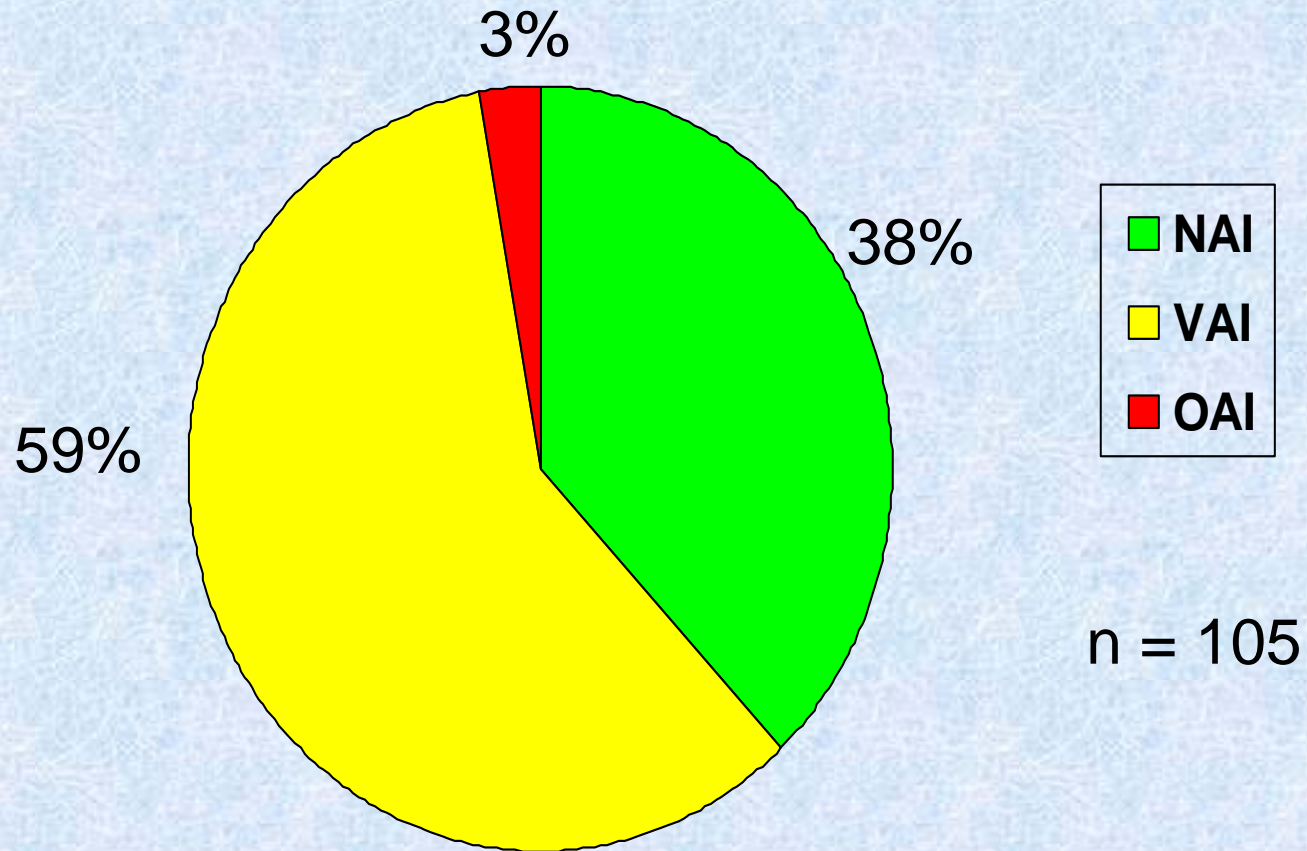


# FY'08 GLP Inspections Classified\* – All Centers



\*inspections classified in FY'08 no matter when inspection occurred

# FY'08 BEQ inspections classified\*



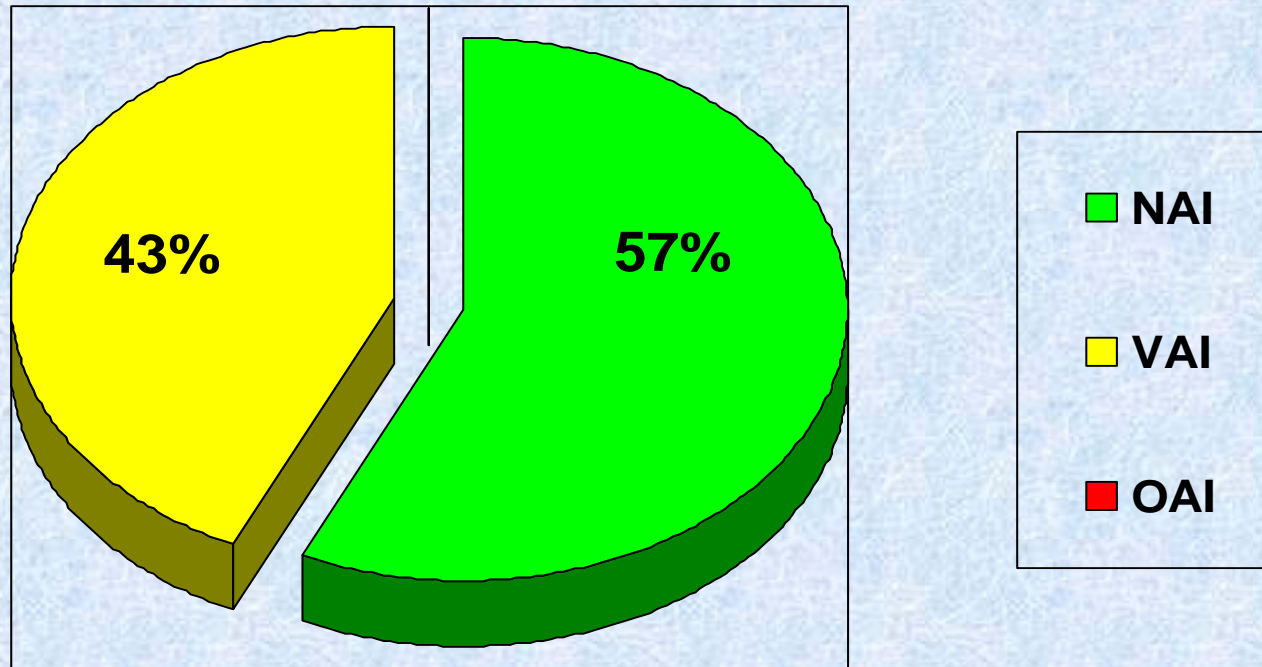
\*inspections classified in FY'08 no matter when inspection occurred

# International CI Inspections Completed: FY 2008

<u>Center</u>	<u>Total</u>
CBER	0
CDER	87
CDRH	15*
Totals	102

\* 14 CI and 1 sponsor

# CDER CI International Inspections Final Classification\* FY 2008

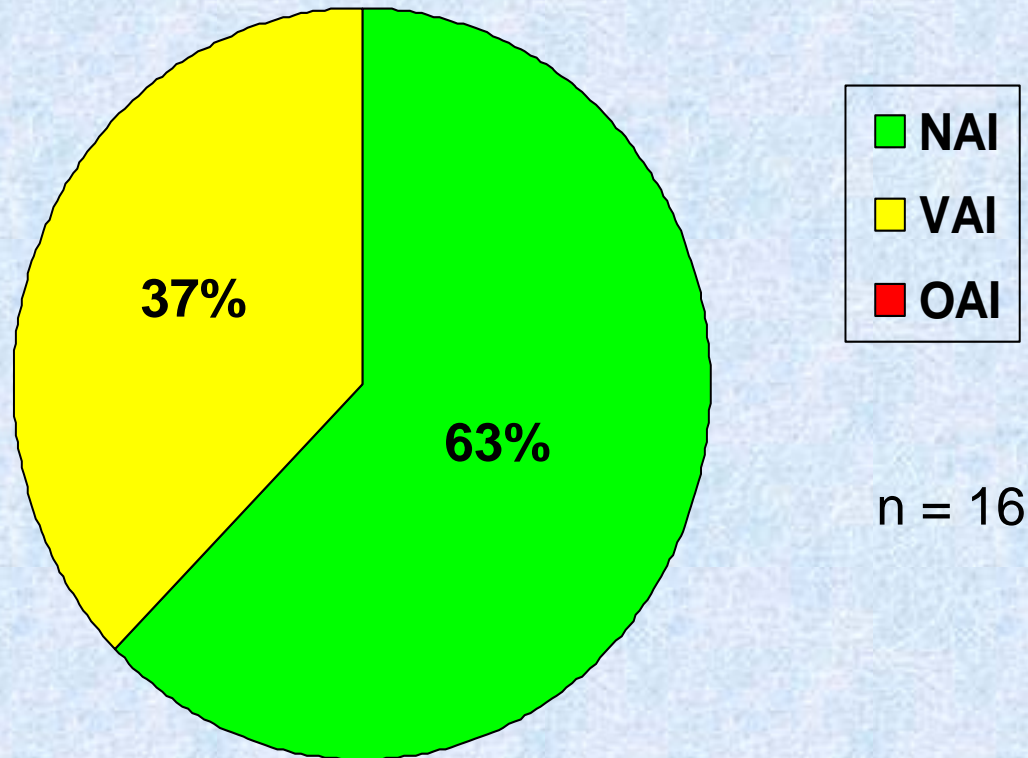


**Total inspections with final classification = 70**

\*Based on Letter Issued Date (Courtesy of CDER/DSI)

11/13/08

# CDRH CI International Inspections classified\* in FY'08



\*inspections classified in FY'08 no matter when inspection occurred

# Common deficiencies – international inspections

- 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