Bioresearch Monitoring (BIMO) Metrics – FY’09
# BIMO Inspections Completed FY 2009

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

* + 137 BEQ inspections (CDER specific) ⇒ total = 1272
FY’09 CI Inspections Classified* All Centers

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

n = 867
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*

*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

n = 49
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**

<table>
<thead>
<tr>
<th>Center</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBER</td>
<td>3*</td>
</tr>
<tr>
<td>CDER</td>
<td>119</td>
</tr>
<tr>
<td>CDRH</td>
<td>12**</td>
</tr>
<tr>
<td>CVM</td>
<td>0</td>
</tr>
<tr>
<td>Totals</td>
<td>134</td>
</tr>
</tbody>
</table>

*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