Bioresearch Monitoring (BIMO)  
Fiscal Year 2018  
Metrics
### FY2018* BIMO\(^1\) Inspections Classified

<table>
<thead>
<tr>
<th>Center</th>
<th>CI</th>
<th>IRB</th>
<th>S/M/CRO</th>
<th>S/I</th>
<th>GLP</th>
<th>BEQ</th>
<th>PADE</th>
<th>REMS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBER</td>
<td>75</td>
<td>3</td>
<td>13</td>
<td>7</td>
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<tr>
<td>CDER</td>
<td>591</td>
<td>105(^2)</td>
<td>85</td>
<td>13</td>
<td>35</td>
<td>241</td>
<td>72</td>
<td>11</td>
<td>1153</td>
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<td>CDRH</td>
<td>225</td>
<td>55</td>
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<td>2</td>
<td>12</td>
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<td>CVM</td>
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<td>0</td>
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</tr>
<tr>
<td>Totals</td>
<td>904</td>
<td>163</td>
<td>153</td>
<td>22</td>
<td>56</td>
<td>241</td>
<td>72</td>
<td>11</td>
<td>1622</td>
</tr>
</tbody>
</table>

* Data includes domestic and international inspections classified in fiscal year 2018

\(^1\)The FDA’s BioResearch Monitoring (BIMO Program) consists of all six product centers: CBER, CDER, CDRH, CFSAN, CTP, and CVM. In FY18, CFSAN and CTP did not classify any inspections based on Center final classification date.

\(^2\)The number of Institutional Review Board (IRB) inspections includes 4 Radioactive Drug Research Committee (RDRC) inspections.
FY18 Clinical Investigator Inspections Classified

- **NAI**: 72%
- **VAI**: 1%
- **OAI**: 27%

n = 904*

*Data includes domestic and international inspections classified in fiscal year 2018

*Inspections classified in FY18 by CBER, CDER, CDRH and CVM. Some inspections may have occurred in a different FY.
Common Clinical Investigator Observations*

- Failure to conduct an investigation in accordance with the signed investigator statement or agreement/investigational plan/applicable regulations
- Inadequate or inaccurate case histories
- Investigator’s subject records inadequate
- Inadequate drug/device disposition records
- Failure to obtain informed consent in accordance with Part 50

* Clinical Investigator (CP 7348.811) observations identified in FDA Form 483 issued at close of inspections.
FY18 Institutional Review Board Inspections Classified

Includes 4 RDRC

- NAI: 75%
- VAI: 24%
- OAI: 1%

n = 163*

*Data includes domestic and international inspections classified in fiscal year 2018
*Inspections classified in FY18 by all Centers with jurisdiction over studies involving human subjects. Some inspections may have occurred in a different FY.
Common IRB Observations*

• Inadequate meeting minutes
• Inadequate membership rosters
• Inadequate initial and continuing review of research
• Inadequate written procedures for prompt reporting of non-compliance, suspension or termination
• Quorum issues

*Institutional Review Board (CP 7348.809) observations identified in FDA Form 483 issued at close of inspections.
FY18 Sponsor/Monitor/CRO/SI\(^1\) Inspections Classified

- **74%**: NAI
- **22%**: VAI
- **4%**: OAI

\( n = 175*\(^1\) \)

*Data includes domestic and international inspections classified in fiscal year 2018 by CBER, CDER, CDRH and CVM.*

\(^1\)Includes Sponsor-Investigator inspections: 153 (S/M/CRO) + 22 (SI) = 175 Some inspections may have occurred in a different FY.
Common S/M/CRO/Sl Observations*

• Failure to ensure proper monitoring
• Failure to ensure the investigation is conducted in accordance with the general investigational plan and protocol(s)
• Failure to secure compliance or terminate an investigator’s participation in the investigation
• Failure to ensure the FDA/IRB/investigators are informed of significant new information or significant new adverse effects

*Sponsors, Contract Research Organizations, Monitors ([CP 7348.810](https://www.fda.gov)) and Sponsor Investigator inspection observations identified in FDA Form 483 issued at close of inspections.
FY18 Good Laboratory Practice Inspections Classified

- NAI: 54%
- VAI: 34%
- OAI: 12%

n = 56*

*Data includes domestic and international inspections classified in fiscal year 2018
*Inspections classified in FY18 by CDER, CDRH and CVM. Some inspections may have occurred in a different FY.
Common GLP Observations*

- Inadequate equipment calibration
- Protocol deviations
- Inadequate monitoring of facilities
- Incomplete/inadequate/no study records
- Inadequate archiving

* GLP (CP 7348.808) observations identified in FDA Form 483 issued at close of inspections.
FY18 Bioequivalence Inspections Classified

*Data includes domestic and international site visit inspections classified in fiscal year 2018
*CDER specific program. Includes Analytical inspections. Some inspections may have occurred in a different FY.
Common Bioequivalence Observations*

• Recordkeeping
• Blinding Codes
• SOPs
• Inclusion/exclusion criteria issues
• Analytical concerns:
  – Validation
  – Stability
  – Chromatography
  – Calibration Curve

*Bioequivalence (CP 7348.001) observations identified in FDA Form 483 issued at close of inspections.
FY18 Postmarketing Adverse Drug Experience (PADE) Inspections Classified

- NAI: 64%
- VAI: 36%
- OAI: n = 72*

*Data includes domestic and international inspections classified in fiscal year 2018
*CDER specific program. Some inspections may have occurred in a different FY.
Common PADE Observations*

- Failure to develop written procedures
- Late submission of 15-day Alert reports
- Late submission of annual report
- Late submission of quarterly safety reports

*Postmarketing Adverse Drug Experience (CP 7353.001) observations identified in FDA Form 483 issued at close of inspections.
FY18 Risk Evaluation Mitigation Strategies (REMS) Inspections Classified

91%

9%

n = 11*

*Data includes domestic and international inspections classified in fiscal year 2018
*CDER specific program. Inspections classified in FY18. Some inspections may have occurred in a different FY.