Progress in Data Quality, Participation, and Transparency at FDA

Center for Devices and Radiological Health (CDRH)

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Outline

• 2013 FDASIA 907 Report:
  >> CDRH findings & identified areas for improvement

• 2014 FDASIA 907 Action Plan:
  >> CDRH’s commitments & progress

• Ongoing challenges & need for collaborative solutions
FDASIA 907 Timeline

What Did We Evaluate

• Reviewed 37 original PMA applications approved in 2011:
  – 46 pivotal clinical studies

• Demographic data variables:
  – Sex, Age, Race, Ethnicity

• Documents reviewed:
  – PMA applications submitted by industry
  – Final labeling (industry public info)
  – FDA internal review documentation
  – SSED: Summaries of Safety & Effectiveness Data (FDA public decision summaries)
Representation Varies by Disease/Condition

Figure 2-2: Sex Composition by Submission (CDRH)
### Need for Improved Consistency in Analysis and Transparency

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
<th>Public Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td>88%</td>
<td>63%</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>70%</td>
<td>57%</td>
</tr>
<tr>
<td><strong>Race &amp; Ethnicity</strong></td>
<td>27%</td>
<td>16%</td>
</tr>
</tbody>
</table>
FDASIA 907 Timeline

Action Plan Priorities

- Participation
- Quality
- Transparency
Quality

- **CDRH – Completed**
  - Final FDA Guidance: Evaluation of Sex-Specific Guidance in Medical Device Clinical Studies
  - Incorporated recommendations from sex-specific guidance (Priority 1.1)
    - Incorporated details of demographic subgroup analyses in review templates
    - Launched webinar presentation to external stakeholders
Quality

• **CDRH – In Progress**
  – Draft FDA Guidance: Evaluation & Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies (Priority 1.1)
  – Staff training on demographic subgroup data inclusion, analysis, and communication (Priority 1.3)
Transparency

• CDRH – In Progress
  – Explore approaches for public user-friendly ways of posting demographic info from medical device studies (Priority 3.1)
  – Conduct a study with health care professionals to improve usability and understanding of medical device labeling, including instructions for use (Priority 3.2)
Participation

• CDRH – Needs Collaboration
  – Collaborate with industry to ensure appropriate use of enrollment criteria in clinical trial protocols (Priority 2.2)
  – Explore various ways to communicate to demographic subgroups about clinical trial participation (Priority 2.4)
CDRH – Related Activities

• Hired Chief Medical Officer – Pediatrics and Special Populations, Dr. Vasum Peiris
• Parallel review with CMS, to streamline decisions related to Medicare population
• Home Use & Patient Labeling Initiatives
• Variety of efforts and activities related to pediatrics & other special populations, including draft guidance on leveraging clinical data for extrapolation to pediatric uses of medical devices
Needs Collaboration

• **Your** input toward collaborative solutions
  – Ensure appropriate use of enrollment criteria in clinical trial protocols (Priority 2.2)
  – Explore various ways to communicate to demographic subgroups about clinical trial participation (Priority 2.4)
  – Explore approaches for public user-friendly ways of posting demographic info from medical device studies (Priority 3.1)
In Summary

- CDRH has completed significant Action Plan commitments and is on track for many others
- Collaborative solutions are needed to overcome long-standing challenges in key areas:
  - Participation – enrollment criteria, diverse participation
  - Quality – improving quality of demographic analyses in industry submissions and labeling
  - Transparency – communicating demographic info in the context of overall study results
- Important to keep in mind unique issues related to medical devices (manufacturing, clinical study conduct, regulatory framework, etc)
Thank you