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:

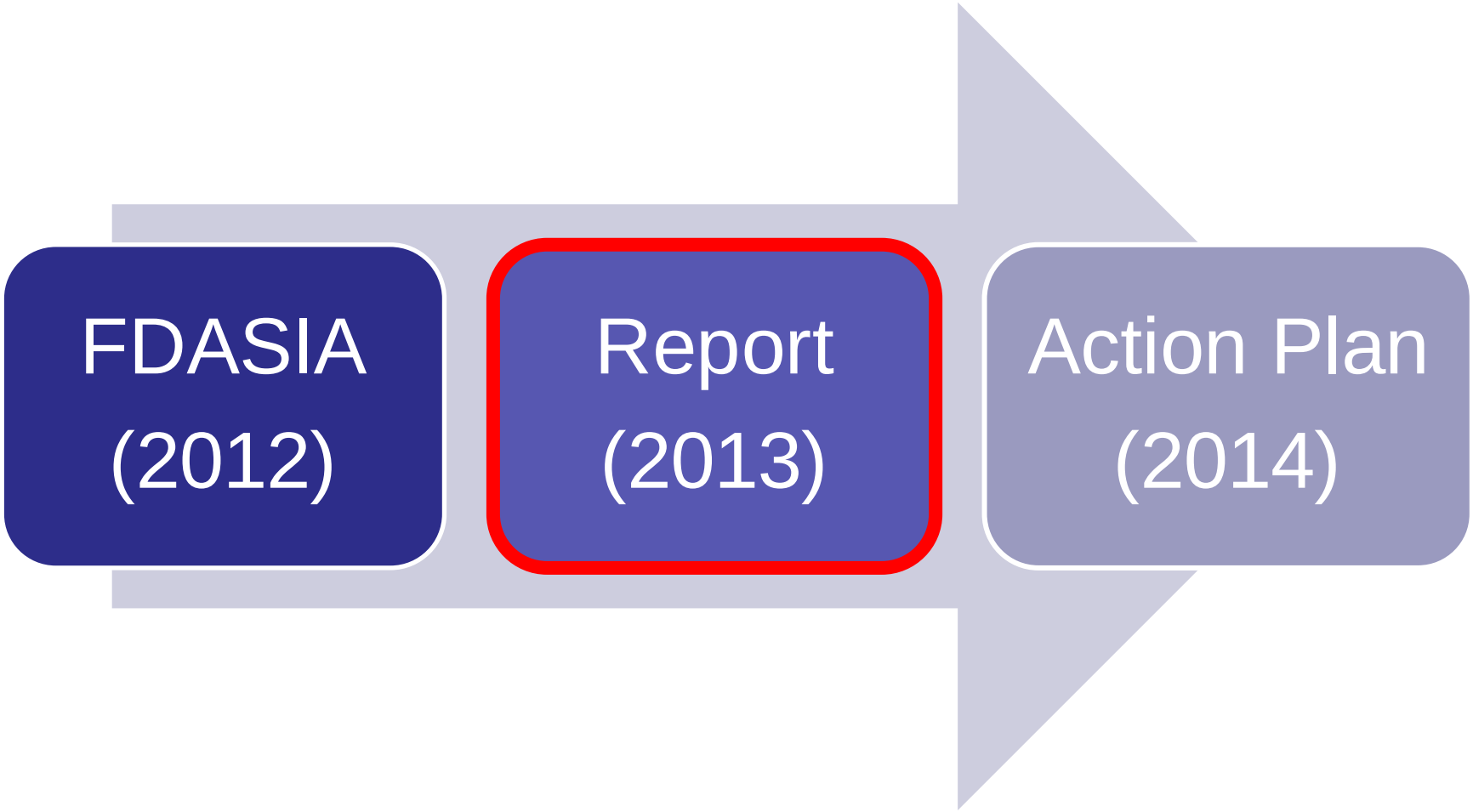
  >> *CDRH findings & identified areas for improvement*

- 2014 FDASIA 907 Action Plan:

  >> CDRH's commitments & progress

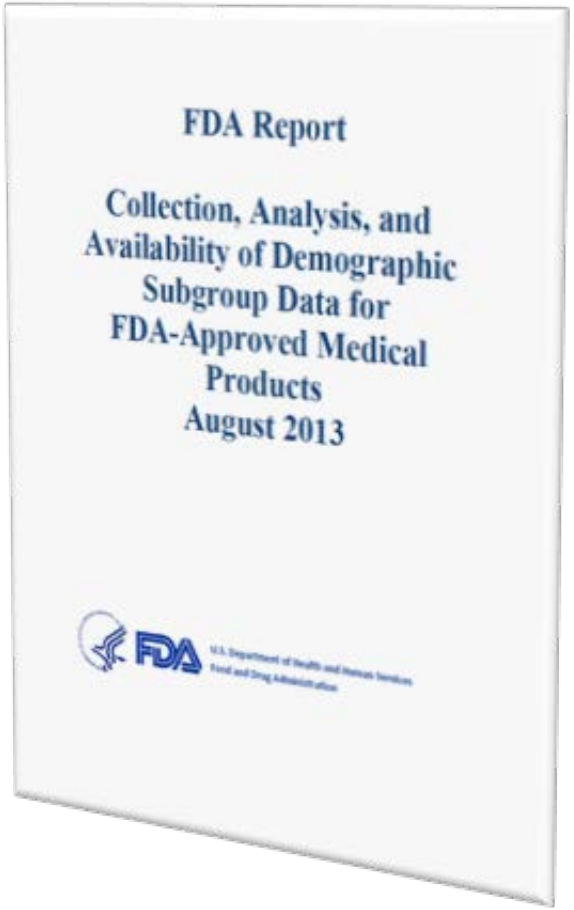
- Ongoing challenges & need for collaborative solutions

FDASIA 907 Timeline



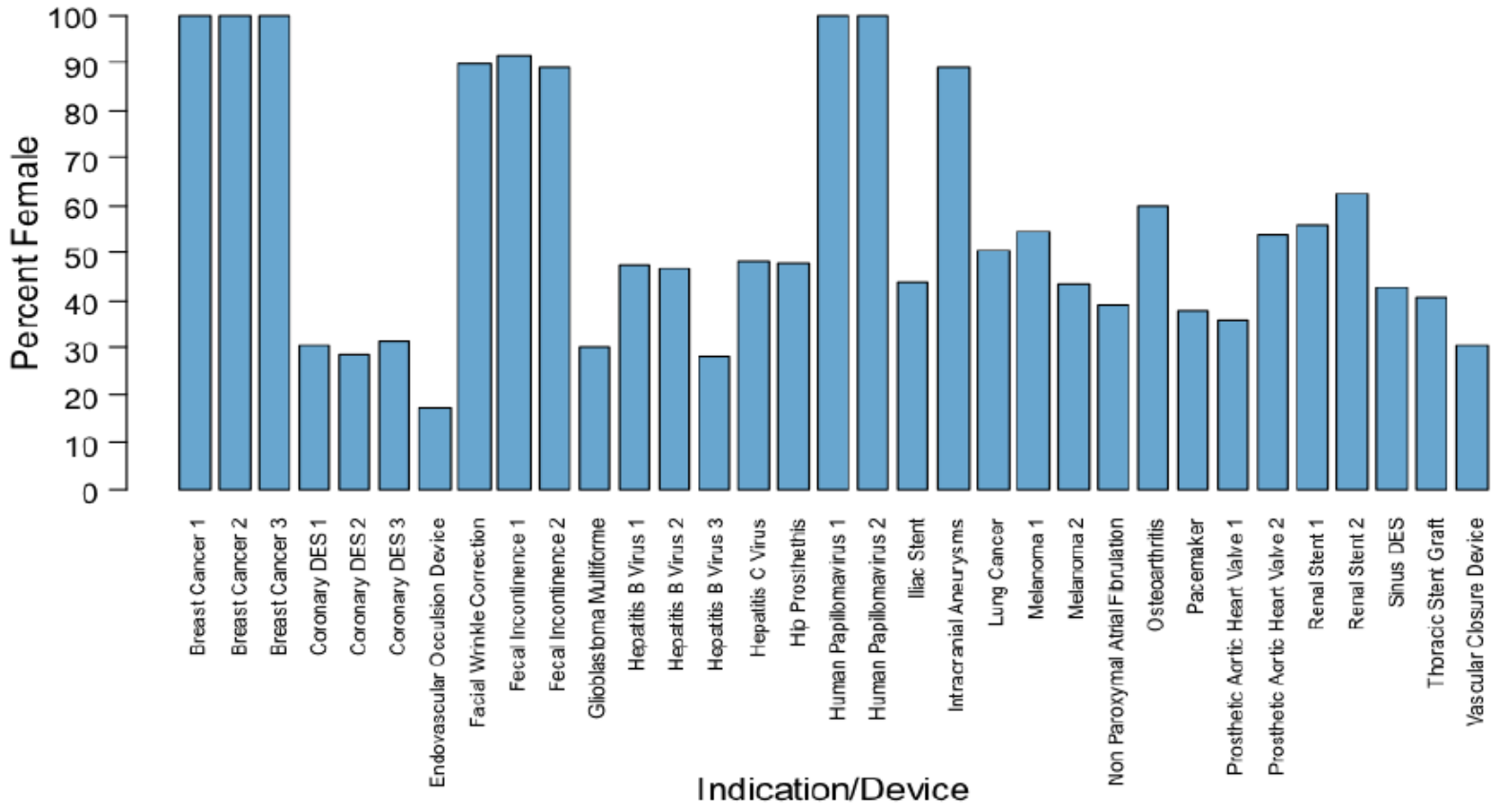
What Did We Evaluate

- 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

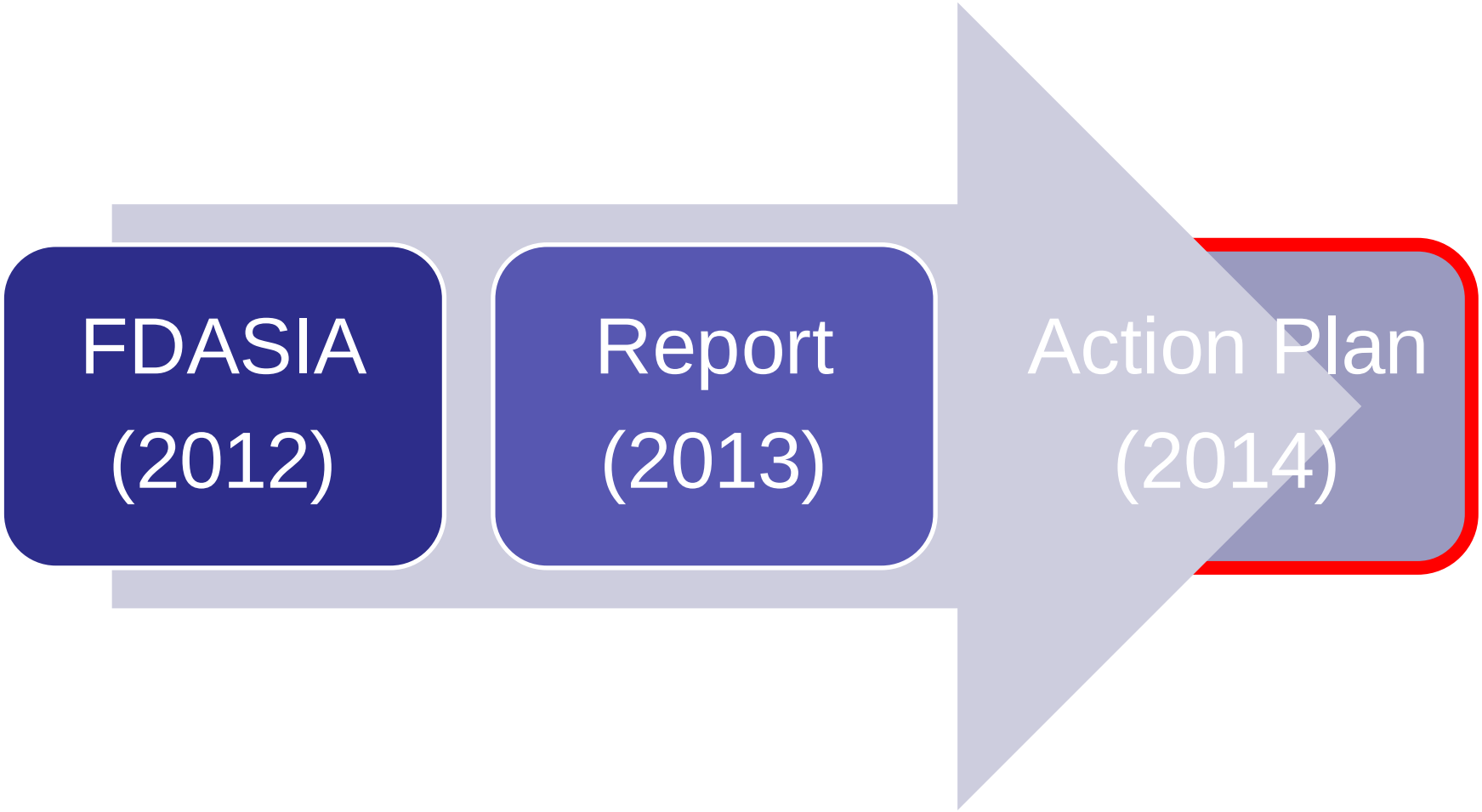
Figure 2-2: Sex Composition by Submission (CDRH)



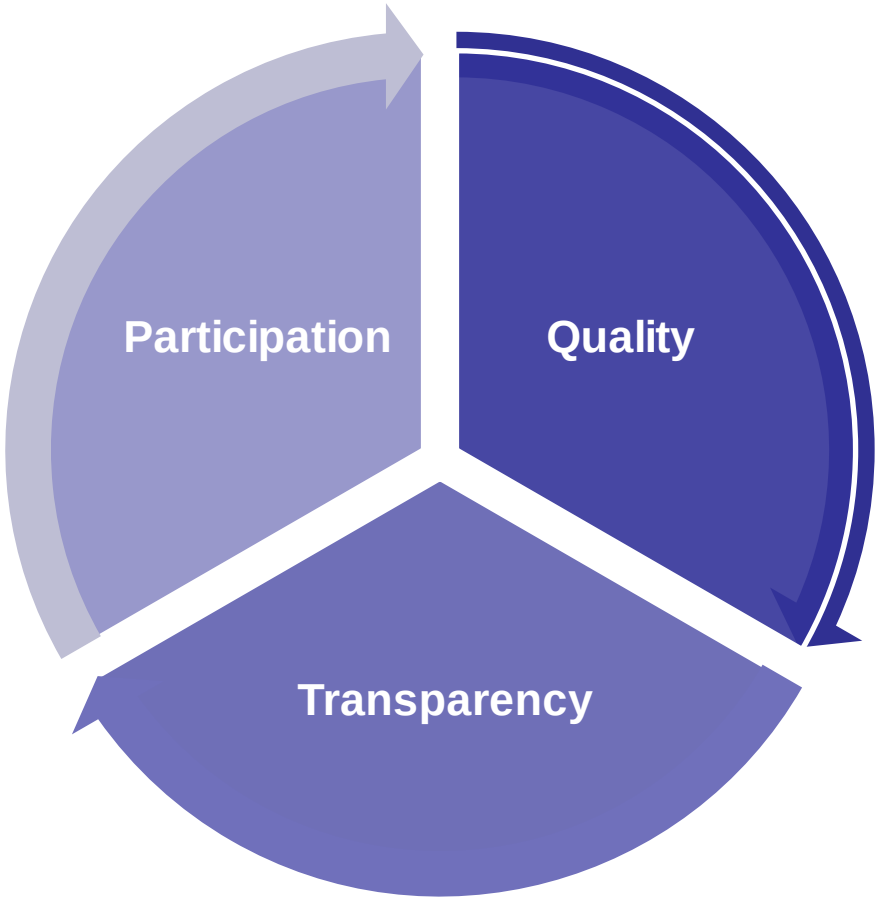
Need for Improved Consistency in Analysis and Transparency

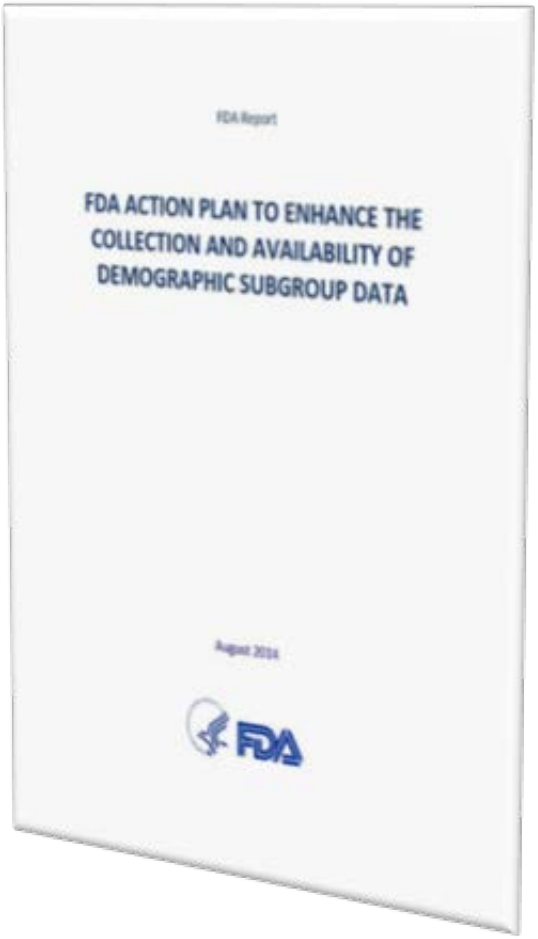
Sex	• 88% of PMAs analyzed • 63% presented publicly
Age	• 70% of PMAs analyzed • 57% presented publicly
Race & Ethnicity	• 27% of PMAs analyzed • 16% presented publicly

FDASIA 907 Timeline



Action Plan Priorities





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