



Clinical Trials: Assessing Safety and Efficacy for Diverse Populations Workshop

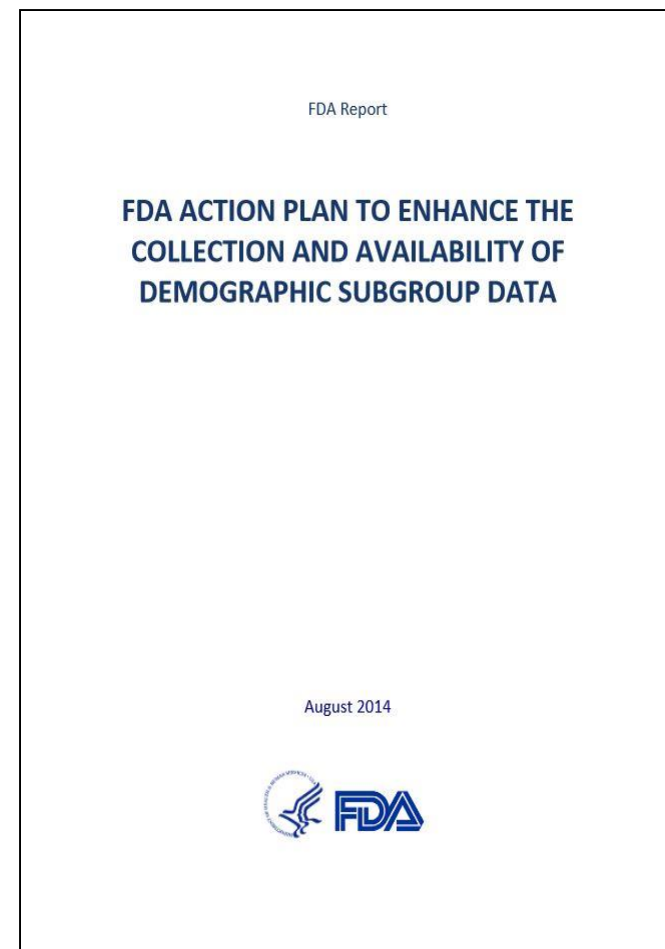
December 2, 2015



The FDASIA 907 Action Plan

Three overarching priorities:

- **Priority One:** Improve the completeness and quality of demographic subgroup data collection, reporting and analysis (**Quality**)
- **Priority Two:** Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (**Participation**)
- **Priority Three:** Make demographic subgroup data more available and transparent (**Transparency**)





Purpose of Today's Meeting*

Engage representatives from industry, academia, patients, and FDA, to discuss the importance of diversity in medical research and the incorporation of participant diversity in the design, analysis, and regulation of medical interventions.

Why?

Medical interventions may have different benefits and harms for subgroups within a population.

If clinical trials do not include an adequate number of participants who are representative of people likely to use an approved intervention, then the average results of clinical trials might not be replicated in practice.

Even if clinical trials include representative participants, important subgroup differences might not be detectable if their representation is not adequate.

For these reasons, a combination of information from clinical trials and other data sources may be helpful to address questions about heterogeneity across large and diverse populations

Today's Logistics for Attendees

- Meeting will be recorded and slides available on JHU CERSI website
 - <http://www.jhsph.edu/research/centers-and-institutes/center-of-excellence-in-regulatory-science-and-innovation/>
- Microphones are available for questions (webcast)
- Docket – for comments open
 - (**Federal Register** / Vol. 80, No. 210 / Friday, October 30, 2015, Docket No. FDA–2015–N–3805])
- **Housekeeping Details**
 - Cell Phones: please mute/turn off ringers
 - Wireless connection
 - Restrooms- outside and to the left
 - Breaks- snacks as well as options for lunch are available in the atrium