

It's Time to Deliver:

Including pregnant and lactating women in clinical research

Historic Perspective on HIV and TB Research in Pregnant Women

Dr. Lynne M. Mofenson, Elizabeth Glaser Pediatric AIDS Foundation

Ongoing and Planned IMPAACT Studies in Pregnant Women

Dr. Sharon Nachman, Chair of the IMPAACT Network

Maternal, Adolescent, and Pediatric HIV/AIDS Therapeutics Clinical Trials Network: Pregnant Women in the NIAID HIV/AIDS Clinical Trials Network Re-Competition

Dr. Carl W. Dieffenbach, Director of the Division of AIDS, NIAID

The Role Community Advocates Can Play to Advance More Inclusive Research Agendas

Dr. Liz Barr, Co-Chair of the Women's HIV Research Collaborative, Co-Chair of the ACTG Community Scientific Subcommittee

Opportunities to Advocate for Research in Pregnant Women

Lindsay McKenna, Treatment Action Group

Opportunities to advocate for research in pregnant and lactating women

Lindsay McKenna, MPH

Treatment Action Group

14 March 2018

It's Time To Deliver Webinar Series, Part II

The logo for the Treatment Action Group (TAG) features the letters 'TAG' in a bold, red, sans-serif font. The letter 'A' is stylized with a red dot above it, resembling a period or a specific character.

Treatment Action Group

PRGLAC Task Force

A Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) has been formed to advise the U.S. Secretary of Health and Human Services (HHS) on federal activities to facilitate the inclusion of pregnant and lactating women in research.

PRGLAC Task Force

The Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) has held 3/4 planned meetings:

1. August 2017 – to review existing federal initiatives and define scope of TF and report to HHS
 2. November 2017– focused on research ethics
 3. February 2018– focused on communication strategies
- ✧ Report due to HHS September 2018; HHS then has until December 2018 to act on PRGLAC recommendations
 - ✧ Opportunity for PRGLAC TF to be extended beyond 2018 by Secretary Azar

PRGLAC Task Force

The next PRGLAC meeting is **May 14–15** and will focus on recommendations to improve the development of therapies that are safe and effective in pregnant and lactating women

More info available here:

<https://www.nichd.nih.gov/About/Advisory/PRGLAC>

TAG and its partners are hoping to see recommendations that support:

- Increased funding for research in pregnant and lactating women
- Mechanisms/ incentives to fill data gaps for existing medicines
- A regulatory framework/ requirement for NDAs to include safety and other data necessary to inform use in pregnant and lactating women;
- Study or data requirements to help shift researcher mindsets from assumed exclusion to presumed inclusion; and
- Disease focused registries

NIH Request for Information (RFI)

- PRGLAC TF issued RFI to solicit input from the wider scientific community
- Responses are due April 2nd and can be submitted by e-mail to kaeserl@mail.nih.gov
- More information is available here:
<https://grants.nih.gov/grants/guide/notice-files/NOT-HD-18-003.html>

FDA Public Meeting: Evaluating Inclusion and Exclusion Criteria in Clinical Trials

- April 16th from 8:30–5:00 @ National Press Club in Washington D.C.
- Meeting will ultimately inform FDA guidance
- Registration & other info available from:
<https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials>