Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

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February 3, 2020
Recap of PRGLAC Activities Since August 2019

• Each working group met 5 times from September 2019 to January 2020 via webinar

• Additional discussion:
  • The Office for Human Research Protections
  • NIH’s All of Us Communications
  • Best Pharmaceuticals for Children Act program representatives from NIH and FDA
  • NCATS’s Clinical and Translational Science Awards program

• Main goal: Complete template of core questions for Recommendations 1-13
Today’s Presentations

• For each recommendation, working groups will summarize the following:
  • Bullet points reflecting steps from worksheets,
  • Steps needed to implement this recommendation, and whether any have been started
  • Which stakeholders/federal agencies should be involved in carrying out this recommendation, and which should have the lead
  • Potential costs to carry out the recommendation
  • Potential timeframes for each step
  • Major takeaways
Working Group 1: Research/Training

- Co-chairs: Andrew Bremer (NICHD) and Victoria Pemberton (NHLBI)
- Members: Christina Bucci-Rechtweg (Novartis), Bridgette Jones (KC School of Medicine), Jeanna Piper (NIAID), Jeanne Sheffield (JHU), Wendy Weber (NCCIH)
- Ad hoc Members: Brookie Best (UCSD), Christina Chambers (UCSD), Ahize Eke (JHU), George Saade (UTMB), Lynne Yao (FDA)
- NICHD Staff: Sarah Glavin and Elizabeth Wehr
Working Group 2: Regulatory

- Co-chairs: Shelli Avenevoli (NIMH) and Karin Bok (NIAID/VRC)
- Members: Dorothy Fink (OWH/HHS), Melissa Gorman (Shriners Hospital), Robert Ternik (Eli Lilly)
- Ad hoc Members: Michael Greene (Harvard), Rahul Gupta (March of Dimes), Susan McCune (FDA), Melissa Tassinari (Mother-to-Baby), Susan Wood (GWU), Anne Zajicek (NIH)
- NICHD Staff: Lisa Kaeser
Working Group 3: Communication

• Co-chairs: Camille Fabiyi (AHRQ) and Kaveeta Vasisht (FDA)

• Members: Kristi Lengyel (UCB, Inc.), Joan Nagel (NCATS), Diane Spatz (U Penn School of Nursing)

• Ad hoc Members: Alicia Forinash (St. Louis College of Pharmacy), Tamara Johnson (FDA), Belinda Pettiford (NC Dept of HHS), Melissa Simon (Northwestern University), Douglas Storey (JHU), Sarah Taylor (Yale)

• NICHD Staff: Lorena Kaplan
Working Group 4: Discovery

• Co-chairs: Elena Gorodetsky (ORWH) and Aaron Lopata (HRSA)

• Members: Susan Givens (March of Dimes), Linda Lipson (Retire-VA), Voula Osganian (NIDDK), Jennita Reefhuis (CDC)

• Ad hoc Members: Susan Kindig (Eli Lilly), Kelle Moley (March of Dimes), Sonja Rasmussen (Univ of Florida), Sarah Reece-Stremtan (Children’s National/Academy of Breastfeeding Medicine), Leyla Sahin (FDA)

• NICHD Staff: Christie Rogers
International Efforts Related to PRGLAC
International Efforts

• Goal: create a trusted biomedical ecosystem capable of providing evidence-based information on the safety of medications during pregnancy and breastfeeding in an efficient, systematic and ethically responsible way

• 5-year initiative; public-private partnership involving 88 organizations from 22 countries

• $28.6 million € project

• Key activities:
  • Use existing de-identified data generated during routine patient care to improve and unify data collection
  • Develop procedure and tools to collect digital data and samples from pregnant women
  • Create the first Europe-wide human milk biobank for research purposes
  • Develop tools to predict which drugs are likely to be transferred to human milk
Questions?