

# Use of Medications during Pregnancy and Breastfeeding: Maternal, Fetal, and Neonatal Impact

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## CHAIRPERSONS

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# Topics

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Pregnancy-induced changes in clinical pharmacology (Maged Constantine, MD)

Applications of pharmacometrics in pregnancy (Kevin Krudys, PhD)

Drug development in pregnancy (Christina Bucci-Rechtweg, MD)

# Goals

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Understand the pharmacoepidemiology of medication use in pregnancy and lactation.

Understand academic, regulatory, industry efforts in developing improved understanding of clinical pharmacology in pregnancy and lactation

Learn how NICHD's MFMU and OPRU have developed knowledge in these areas

Understand need for clinical trial designs to enable gathering of these data in pregnancy and lactation

# Take-Away Points

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Most pregnant and breast feeding women take medications, some prescribed and some not.

Dosing, safety and efficacy information for drugs taken during pregnancy and lactation is lacking

There is a need to develop methods to collect these data, on the pregnant women/ fetus and mother/neonate

# Speakers

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## Maged Costantine, MD

- Associate Professor, Dept of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, University of TX Medical Branch

## Kevin Krudys, PhD

- Lead Pharmacologist, Office of Translational Sciences, CDER, US FDA

## Christina Bucci-Rechtweg, MD

- Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation