

ONGOING RECRUITMENT



VACCINES & VIRUSES

Pertussis/Tdap Vaccine (Boostrix)

CHRONIC CONDITIONS

RHEUMATOLOGY

- Lupus (medication exposure only)
- Psoriatic Arthritis

DIGESTIVE

 Functional Constipation (Chronic Idiopathic Constipation or Irritable Bowel Syndrome with Constipation)

NEUROLOGICAL

Multiple Sclerosis

SKIN

- Eczema/Atopic Dermatitis
- Psoriasis

OTHER

 Non-disease controls / No exposure to disease or medication

MEDICATIONS

- Adbry® (tralokinumab-ldrm)
- Benlysta® (belimumab)
- Kesimpta® (ofatumumab) (US PATIENTS ONLY)
- Mayzent® (siponimod) (US PATIENTS ONLY)
- Motegrity® (prucalopride)
- Sotyktu ® (deucravacitinib)
- Tremfya® (guselkumab)

KEY MESSAGES FOR POTENTIAL PARTICIPANTS



Why are Pregnancy Studies important?

Pregnant people are typically excluded from clinical trials when a drug is being developed. It means a medication, once approved by the US Food & Drug Administration (FDA), can be prescribed to patients with little to no information on the safety of the drug if used during pregnancy. Yet, 9 out of 10 pregnant people in the U.S. take medication(s). MotherToBaby (MTB) studies provide critical information on the safety of medication use by enrolling pregnant people and their babies. Our findings are used by moms and health providers to make treatment decisions and may be added on drug of prescription medications.

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A mom's role in an MTB study?

MTB studies are observational. Enrolled people will not be asked to take any medications or vaccines or change any part of their routine. Here's what happens:

- People participate from the comfort of their home;
 No travel required
- People will be interviewed by phone 1-3 times during pregnancy and at least 1 interview after the baby's born. Some studies may have additional interviews.
- People will be asked to consent for a copy of medical records of the pregnancy and the baby's medical records.

Why join an MTB Pregnancy Study?

People who enroll will interact with MTB's expert staff who can provide additional support during their pregnancy and answer questions about exposures during pregnancy and breastfeeding. Participation will help us learn more about the safety of medications and/or vaccines during pregnancy; Future pregnant people and their families can benefit for the information collected.

"But I'm not taking a medication, why are you asking me to participate?"

We also encourage **pregnant people who do not have a chronic health condition or are not taking any medications** to participate in addition to the people who take medications. It helps us to determine if the medication or health condition being studied increases risks compared to a pregnancy without these exposures.

When pregnant people, living in US or Canada, qualify for one or more of our studies they are included into one of the groups below:

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Has taken the medication being studied during a current or previous pregnancy.

2

Has NOT taken the medication being studied, but has the same health condition as group 1.

3

Has NOT taken the medication being studied and does NOT have the same health condition being studied.

REFERRING CLIENTS TO OUR STUDIES

How can you bring up research studies when counseling a client?

MotherToBaby's goal is to get more pregnant people involved in our research studies. There may be different motivation needed for pregnant people to learn more about our studies. Here are some ways you may choose to introduction into our studies to your clients:

- We're working with a group of pregnant people across the U.S. and Canada who want to make a difference and help us identify exposures that may impact pregnancy health. Can I email you more information?
- We are looking for pregnant volunteers to join a national pregnancy registry to help us gather the information needed to answer questions like the one you asked. It would be great if you help improve our knowledge on this subject?
- You, too, can be part of the solution that identifies exposure-related benefits or risks for other pregnant people. What's your email so I can share more information about this unique opportunity for you?
- May I invite you to participate in a research study? You don't need to do anything differently from what you're doing now. You'll participate in 1-3 interviews from home and we ask that you share your medical records but only for the pregnancy.
- Are you interested in joining our community of pregnant parents who are sharing their pregnancy journey with MTB's pregnancy studies team?
- With more information collected through MTB research studies, pregnant people are empowered to make informed decisions about exposures. Can I let our study team know that you are interested in learning more about our studies?
- Did you know that we are looking for people just like you to join our research study? Can I connect you to our study team so they can tell you about the benefits of sharing your pregnancy experience with us?
- > Pregnancy studies help pregnant people and their doctors learn more about how medicines can be safely used during pregnancy. Can I add your name as an expecting person who would share your experience with over-the-counter and prescribed medications during pregnancy?
- > Our pregnancy studies collect information about exposures like medications, health conditions, and vaccines during pregnancy. Would you be interested in sharing your experience? You will not be asked to take anything, and participation can be done at home. You will provide information about your health and your baby's health.

HOW CAN WE SUPPORT YOUR REFERRALS TO MOTHERTOBABY PREGNANCY STUDIES?



Reach out to Robert with comments, questions, or concerns:

Robert Felix rfelix@health.ucsd.edu





Refer a client today:

MotherToBaby.org/Health-Providers mothertobaby@health.ucsd.edu 877.311.8972