

Project title	Drug safety assessment is difficult for breastfeeding mother-infant pairs		
Study level(s)	□ MSc	🗆 PhD	🛛 Postdoctorate
Principal investigator(s)	Julie Autmizguine, M.D., MHS, FRCPC		
Project duration	2-3 years		
Start date	As soon as po		

Date of posting: 2021-10-12

Research laboratory presentation

The research laboratory focuses on clinical pharmacology in pediatrics. Its research activities help reduce the number of drug prescriptions that do not comply with regulatory approval, contributing data on the efficacy and safety of drugs for children of all ages. More specifically, the research projects of Dr Autmizguine's team focus on optimizing the dose of drugs in pediatrics, based on pharmacokinetic modeling and simulation.

Research project description

There is insufficient information on drug secretion in milk due to the exclusion of lactating women from clinical trials and drug development processes. As a result, either non-compliance with the necessary drug treatment or discontinuation of breast-feeding may occur, even if the expected level of exposure of the infant is low. In contrast, accidental infant exposure to drugs in breast milk continues to occur due to a lack of rational risk assessment, resulting in severe cases of toxicity, including death. This important societal impact problem is multifactorial, but one of the key elements is the lack of pharmacokinetic (PK) information on drug secretion in milk and infant exposure, which is the first line of evidence for the Risk Assessment. To solve this maternal and child health problem, we propose to establish a study framework as a standard tool in the field, which combines a population PK approach to estimate the means and changes in drug concentration profiles in milk and physiological PK (PBPK) modeling of infants to predict profiles of their drug exposure levels.

This multicenter project co-led by Dr. Autmizguine aims to establish a new framework for the study of drugs for lactating mothers and infants in order to generate pharmacokinetic data on drugs in milk and exposed infants, which inform risk assessment both in drug development and in post-market clinical settings. For this project to be carried out, close collaboration will be necessary with Yves Théorêt (Ph.D.) and the Pharmacology Research Unit (URP) of the CHU Sainte-Justine Research Center.

Required training and profile

The candidate sought must:

- Hold an appropriate diploma for the level requested (a PhD for the postdoctoral fellowship) as well as an excellent academic record;
- Demonstrate motivation and autonomy to complete this project;



- Possess a solid knowledge of pharmacology and its experimental techniques in the development of analytical methods required to measure the concentration of various drugs and / or metabolites in human biological fluids (eg plasma, serum, whole blood, breast milk), their execution and the validation of these methods;
- Have experience in LC-MS / MS mass spectrometry (preferably with an Agilent triple quad);
- Have good communication and organizational skills;
- Speak and write in English;
- Have a good publication record.

Conditions

The student must apply for admission to the University of Montreal as a postdoctoral fellow and must comply with the eligibility conditions in effect. It should be noted that postdoctoral fellows at CR-CHUSJ have the status of postdoctoral fellowship trainees (SPB). They are considered to be researchers in training and are not employees of the CHUSJ. They are paid in the form of a scholarship, not a salary. For this reason, CR-CHUSJ postdoctoral fellows are not eligible for employment insurance benefits, parental insurance, retirement plans and other benefits reserved for employees. Federal tax deductions will be taken at source upon payment of the bimonthly scholarship. He / she will also have access to the CHU Sainte-Justine Foundation's internal merit scholarship program.

The duration of research training is conditional on:

- The availability of research funds allocated for the breast milk project;
- The progress of the project.

For international students, application to the Government of Canada work permit will be required.

Submit your application

Interested candidates are invited to submit their application to Dr. Julie Autmizguine by email at julie.autmizguine@umontreal.ca, including:

- **√** Curriculum vitæ
- ✔ Most recent transcripts
- V Cover letter
- **√** References

Julie Autmizguine , M.D. , MHS , FRCPC

Clinical Associate Professor, Départements de pharmacologie et pédiatrie, Université de Montréal, Clinician and research investigator, pediatrician infectious disease specialist, CHU Sainte-Justine



Equity, diversity and inclusion

The masculine gender is used without discrimination and for the sole purpose to facilitate reading. The CHU Sainte-Justine subscribes to the principle of equal access to opportunities and invites women, members of visible and ethnic minorities, persons with disabilities and Indigenous people to apply. We would appreciate it if you could inform us of any disabilities that would require technical and physical accommodation adapted to your situation during the selection process. Please be assured that we will treat this information as confidential.

Studies at the CHU Sainte-Justine Research Center

Pursue your <u>graduate or postdoctoral studies</u> at the **CHU Sainte-Justine Research Center**, and be one of the 500 students, fellows and interns involved in accelerating the development of knowledge in the field of maternal, child and adolescent health, whether in basic or clinical research. Under the supervision of prominent scientists, especially in leukemia, rare pediatric diseases, genetics, perinatology, obesity, neuropsychology and cognition, scoliosis and rehabilitation, you will have the opportunity to work with multidisciplinary scientific teams and collaborators from all over the world.

About the CHU Sainte-Justine Research Center

CHU Sainte-Justine Research Center is a leading mother-child research institution affiliated with Université de Montréal. It brings together more than 200 research investigators, including over 90 clinician-scientists, as well as 500 graduate and postgraduate students focused on finding innovative prevention means, faster and less invasive treatments, as well as personalized approaches to medicine. The Center is part of CHU Sainte-Justine, which is the largest mother-child center in Canada and the second most important pediatric center in North America. More on <u>research.chusj.org</u>

