

QUARTERLY RESEARCH NEWS

OFFICIAL NEWSLETTER OF THE OFFICE OF RESEARCH

In This Issue

MEET DR. VICKY FERA

CLINICAL TRIAL
SPOTLIGHT

UPCOMING TRIALS TO
MSH

MEET THE MSH
RESEARCH TEAM

CLINICAL TRIAL UPDATES FOR INVESTIGATORS

BY MICHELLE DIMAS, MANAGER, OFFICE OF RESEARCH

In honour of Clinical Trials Day 2021, the Office of Research has put forth our first newsletter to showcase exciting research happening at Markham Stouffville Hospital (MSH) and highlight our incredible team of researchers and coordinators.

We also want to highlight recent changes, partnerships and learnings that have impacted clinical trials at MSH. As of April 2021, MSH is a member of The Network of Networks (N2). Forging this partnership will benefit MSH by bringing our site together with trialists and clinical research professionals from across the country,

be a part of a common platform for sharing best practices, and access resources utilized by other hospitals and research institutes.

The Office of Research has introduced a new process for clinical trials called, Impact Assessment (IA). Impact Assessment is conducted for all human research studies that will impact the various departments at MSH. This new process is conducted before the trial proceeds with ethics and contractual approval. More information on the IA process can be found on the research Acorn page.

Lastly, the MSH Research Ethics Board (REB) has developed new guidance documents and policies that are available for researchers to support them when starting and throughout their clinical trial. New guidance documents include 'how to report protocol deviations', 'determining if a project is research or quality improvement' and 'reporting SAEs or unanticipated problems'. You can find new guidance documents and policies on the REB Acorn page.

If you have any questions please email me at: mdimas@msh.on.ca



CLINICAL TRIAL SPOTLIGHT

MSH will be participating in an exciting new COVID treatment trial called EB05. This trial is sponsored by Edesa Biotech Research Inc. and is taking place at several sites across Ontario – Toronto General Hospital, Southlake Regional Health Centre, St. Joseph’s Hospital, and North York General Hospital.

EB05 is a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of EB05 + SOC vs. placebo + SOC in adult hospitalized patients with COVID-19.

The investigational product (EB05) is given as a single infusion to eligible patients. EB05 is a monoclonal antibody with high affinity and specificity to human TLR4. Previous research has demonstrated a good preliminary safety and tolerability profile of EB05 with no safety signal identified after administration of a dose of up to 15 mg/kg.

Patients will be given either EB05 or placebo and followed for 28 days while in hospital, or up until early discharge. Follow-up will be conducted at 60 days.

Once consented and enrolled in the trial, patients will receive standard of care in addition to daily screening of COVID-19 symptoms, clinical laboratory tests and screening to assess respiratory distress and organ failure.

The trial is being supported by collaboration with lab, pharmacy and nursing staff.

Questions about EB05 can be directed to Dr. Vicky Fera and Dr. Anthony La Delfa, Co-PIs of the trial, or to the research coordinator, Mohammad Shohel.

“

I am truly excited that we are constantly looking at opportunities to provide our patients with the latest treatment options.

– LISA HARPER,
DIRECTOR, MEDICAL
ADMINISTRATION,
PLANNING AND
TRANSFORMATION

MEET THE OFFICE OF RESEARCH TEAM

Edeliza Mendoza is a clinical research coordinator who supports oncology clinical trials.

Mohammad Shohel is a clinical research intern supporting various non-oncology trials including EB05, ADDAM and CATCO.

Nyah Shah is a research volunteer supporting CATCO, CONTAIN and is essential in assisting with monitoring visits.

RESEARCH HIGHLIGHTS

- **125% increase** in new research studies from FY20/21 (increase of 15 studies)
- **118% increase** in research funds from FY20/21 (increase of \$91,914.18)
- Opened **12 COVID studies** in FY20/21

MEET DR. VICKY FERA

Principal Investigator of CATCO, CONTAIN and EB05

Dr. Vicky Fera is an Infectious Disease physician at MSH. She also serves as the Principal Investigator for several COVID-19 treatment trials: CATCO, EB05, and CONTAIN.

Her research interests include studies that focus on treatment and investigation of COVID-19. She has actively been a part of the COVID vaccine and treatment discussion. Dr. Fera has been featured in Toronto Life and The Daily Courier discussing the turbulence of COVID on ICU patients and vaccinations for children. Recently, she participated in a podcast discussing vaccination work for children with special needs.

Dr. Fera has been instrumental in bringing COVID trials to MSH patients and forging partnerships to collaborate with other sites across Canada.



Upcoming Clinical Trials at MSH

- **ADDAM** is a trial lead by Dr. Susan Kirsch in pediatric diabetes. The trial will enroll patients with T1D or diabetes of unknown type with the onset before 25 years of age. System, Women's College, and the University of British Columbia.
- **MA40** is a 3CTN oncology trial led by Dr. Vikaash Kumar. The study will compare investigator assessed progression free survival (PFS) using RECIST 1.1 in patients with ER+/HER2- advanced (metastatic or loco-regionally recurrent not amenable to curative therapy) breast cancer treated with ipatasertib and fulvestrant versus placebo and fulvestrant after progression on first line CDK 4/6 inhibitor plus AI treatment.
- **CONTAIN** is an out-patient COVID treatment trial led by Dr. Vicky Fera. Patients will be treated for 2-weeks using inhaled and nasal ciclesonide to help reduce respiratory symptoms of COVID-19. The study is conducted in collaboration with The Research Institute of McGill University, William Osler Health
- **CO.29** is a 3CTN oncology trial led by Dr. Sam Babak. This is a multi-centre biomarker-driven adjuvant treatment study to evaluate the impact of de-escalation/escalation treatment strategies post-op ctDNA-informed management. Patients will be randomized 1:1 to be treated according to ctDNA results (Arm B: ctDNA-informed), or per standard of care (Arm A: SOC).
- **HIP ATTACK-2** is led by Dr. Steve McMahon in the department of surgery. The study will investigate whether accelerated surgery for hip fracture in patients with acute myocardial injury is superior to standard care in reducing death at 90 days after randomization.

Research Accomplishments and Highlights

The ILIAD trial (PI: Dr. Vikaash Kumar) has been accepted for publication in *The Breast* (Sept 2020) and an additional manuscript will be submitted in *Supportive Care in Cancer* (March 2021). The study was supported by a research grant from the Canadian Cancer Society. An animated video has been made and can be viewed here: <http://www.ohri.ca/newsroom/story/view/1339?l=en>

MSH participated in a COVID trial investigating mental health outcomes among healthcare workers (Dr. Jeya Nadarajah & Michelle Dimas) in collaboration with UHN (Dr. Rima Styra). The study was accepted for poster presentation at the European Association of Psychosomatic Medicine 2021 conference in the *Work and Social Environment & Return to Work* category.

MSH participated in a study investigating a clinical decision instrument for 30-day death after an Emergency Department visit for atrial fibrillation in collaboration with Sunnybrook (Dr. Clare Atzema). The study published in *Annals of Emergency Medicine*. You can access the manuscript here: <https://doi.org/10.1016/j.annemergmed.2015.07.017>

A study investigating emergency department visits for hypertension in collaboration with Sunnybrook (Dr. Clare Atzema) has been published in *Annals of Emergency Medicine*. You can access the manuscript here: <https://doi.org/10.1016/j.annemergmed.2018.06.002>

The interprofessional nature of research

Interprofessional collaboration [IPC] has been defined as “an active and ongoing partnership between professionals from diverse backgrounds with distinctive professional cultures... working together in providing services for the benefit of healthcare users.” (Monavvari et al., 2020). It should come as no surprise that research at MSH would not be possible without the coordinated efforts and expertise of various professions across the hospital working together for a common goal.

Providing patient-centered research requires cohesion and teamwork from all impacted departments including laboratory, pharmacy, nursing, diagnostic imaging, pathology, decision support, and the list goes on. MSH is fortunate to have exceptional IP support where each and every member makes a substantive contribution individually and collectively to the success of the trial. As we grow research across the organization, we look forward to engaging more of our staff in this exciting endeavour.

Updates from the MSH REB

From Dr. Gail Morris, REB Chair

The REB has seen a large increase in new submissions over the last year and our Board has done an outstanding job in keeping up with the added volume. We have started to conduct an environmental scan to update our REB application forms and provide more guidance and support to researchers. This includes new templates and documents to support you in designing your study. Please keep an eye on the REB Acorn page for new material in the future.

The REB has started to send regular reminder emails to investigators about upcoming REB expiry dates. These email reminders will help investigators stay on top of their REB approval.

As a friendly reminder, The REB offers one-on-one or group ethics consultations for staff, investigators, coordinators and students prior to and throughout the ethics review process. If you require support please email ResearchAdmin@msh.on.ca to arrange a consultation.

MEET THE REB TEAM

Dr. Gail Morris is a retired family physician and serves as the Chair of the MSH REB.

Dilo Pullai is a research ethics coordinator. She manages the REB inbox, assisting with communication and approval letters, conduct ethical reviews and supports the full board.

Lauren Quero is a research ethics intern tasked with updating the REBs templates, policy and guideline development, and SOP implementation.



MSH REB Portfolio Report

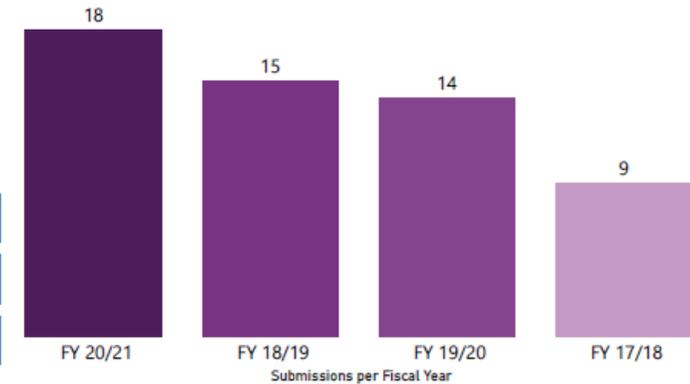
Total Number of Studies Approved by the MSH REB

122

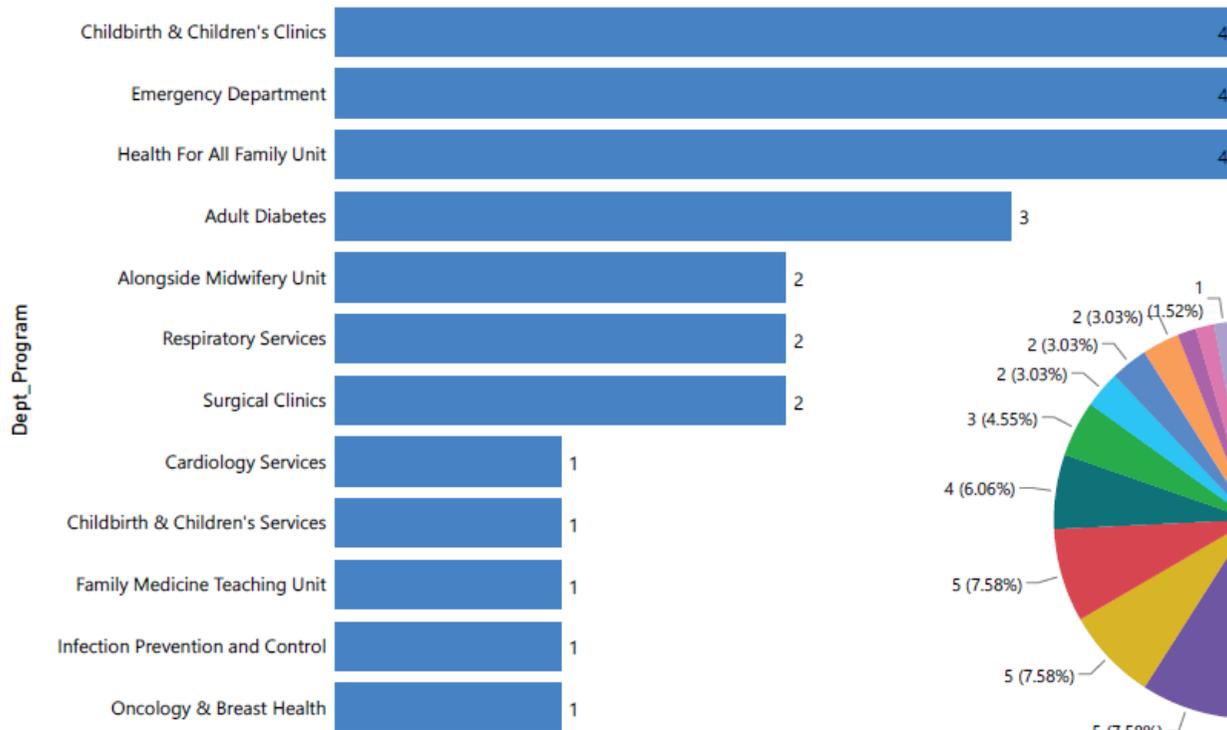
Number of Active Studies Approved by MSH REB

52

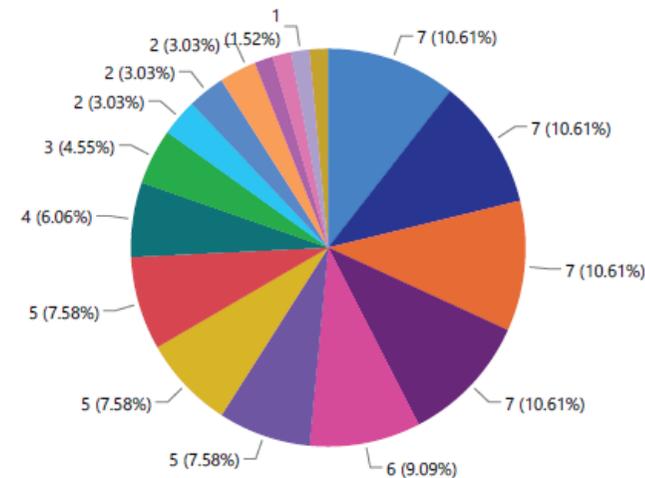
Number of New Studies by Year



Funded Studies by Department



Number of Studies by Department



Department

- Emergency Department
- Family Medicine Teaching Unit
- Health Family Unit
- Health For All Family Unit
- Adult Diabetes
- Alongside Midwifery Unit
- Childbirth & Children's Clinics
- Inpatient Medical Services
- Infection Prevention and Control
- Surgical Clinics
- Professional Practice
- Quality, Patient Safety and Experience
- Respiratory Services
- Cardiology Services
- Childbirth & Children's Services

Funded Studies by Source



Funding Source

- Grant
- Industry Sponsored

Number of MSH initiated studies



Initiated by MSH

- N
- Y