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Covid-19 Update

The COVID-19 pandemic has imposed significant strains on the world of clinical research. Nevertheless, the responses to the pandemic have introduced innovations that will strengthen the management of clinical research and the way we work. At Exactis, we continue to push forward by adapting to maintain work continuity despite the challenges we are all facing. We appreciate your continued support and the way the Exactis network has been adapting to our new reality. An example of this is the remote consenting of patients allowing for the continuous recruitment into the PMT registry. Thank you!

Future of PMT: Sustainability

The goal of the PMT registry is to be able to extract what Exactis needs out of a well-documented data landscape, determine the data quality requirements that will affect our success, then profile and analyze the data so it is useful for its purpose always keeping in mind the patients and precision oncology. During our next PICC meeting we are planning to discuss some of our reflections to optimize and ensure the sustainability of our PMT Registry and ensure success moving forward.



PMT Registry Database: Moving to ATiM

We are in the process of making significant changes to the PMT portal in the coming months by migrating our data collection system to the Advanced Tissue Management Application (ATiM). ATiM has been adopted as the software of choice for several large-scale pan-Canadian studies, and many of our network sites are already using this database for the operations of their biobanks. As a highly functional and flexible platform, we are presently working with software developers to customize ATiM to meet our project needs. Stay tuned! More information is coming your way in the months to come.

Ongoing Studies

ClinicalTrials.gov Identifier:
NCT03363217

TRAM-01:

Trametinib for Pediatric Neuro-oncology Patients with Refractory Tumor and Activation of the MAPK/ERK Pathway.

There are 93 patients out of 118 enrolled so far and 38 patients currently under treatment.

ClinicalTrials.gov Identifier:
NCT04409925

DISCONNECT-1:

DISmantling COvid iNduced Neutrophil ExtraCellular Traps

This is a pilot study to investigate the safety and feasibility of rhDNase1 and its impact on neutrophil extracellular traps (NETs) in COVID-19 infected patients.

The study is open at MUHC and McMaster. 15/15 patients have been enrolled, and 7 are still currently on follow-up.

ELAINE Trial
ClinicalTrials.gov Identifier:
NCT03781063

SERMONIX:

Exactis' collaboration with Sermonix Pharmaceuticals is in the context of a pre-screening initiative and study start up at Canadian sites for the ELAINE trial. A total of 25 blood samples from PMT participants were profiled, however, due to the low rate of ESR1 mutation (12%) reported in the first 25 blood samples profiled the Sponsor announced the termination of the pre-screening activities at the PMT sites. The Sponsor agrees to approve extra blood pre-screening on a case-by-case basis.

ClinicalTrials.gov Identifier:
NCT04566458

Knight Pharma (Exactis-05)

Real World Data Study in HER2+ Metastatic Breast Cancer Patients in Third-Line Therapy

This retrospective observational study is collecting real-world data from HER2+ metastatic breast cancer patients to describe treatment sequences of all therapies received in the metastatic setting, to measure overall survival, progression free survival, time to next active anti-cancer therapy, and to estimate the health resource utilization during third-line therapy. The study is now closed to enrollment as target recruitment has been achieved.

TRICIA

TRIPLE negative breast Cancer markers In liquid biopsies using Artificial intelligence.

The objective of the study is to develop signatures of good and poor outcome as well as tumor response to chemotherapy in TNBC by integrating multi-dimensional profiling data of tumor and liquid biopsies making use of AI tools. The ultimate objective is to be able to identify which patients will benefit from adjuvant treatment. Currently a total of 81 out of 130 TNBC patients have been enrolled at different sites across Quebec and Ontario.

Upcoming Studies

ClinicalTrials.gov Identifier:
NCT04564079

Exactis-01:

A Multi-centre Observational Study to Evaluate the Clinical Utility of Returning Genomic Aberration results from the OncoPrint Precision Assay in Advanced or Metastatic NSCLC.

Eight sites will be participating (JGH, PMH, TOH, QEII, TMH, GLD, CHUS, and SBH). This site investigator-initiated trial will enroll 200 patients under the supervision of the PI of the study, Dr. Jason Agulnik. The JGH was the first site to be initiated on April 7th, 2021.

ClinicalTrials.gov Identifier:
Not yet registered

ClinicalTrials.gov Identifier:
Not yet registered



Exactis-02:

A Prospective Observational Cohort Study to Assess the Association of Circulating Tumor DNA in Blood with Disease Recurrence after Curative Liver Resection in Metastatic Colorectal Cancer

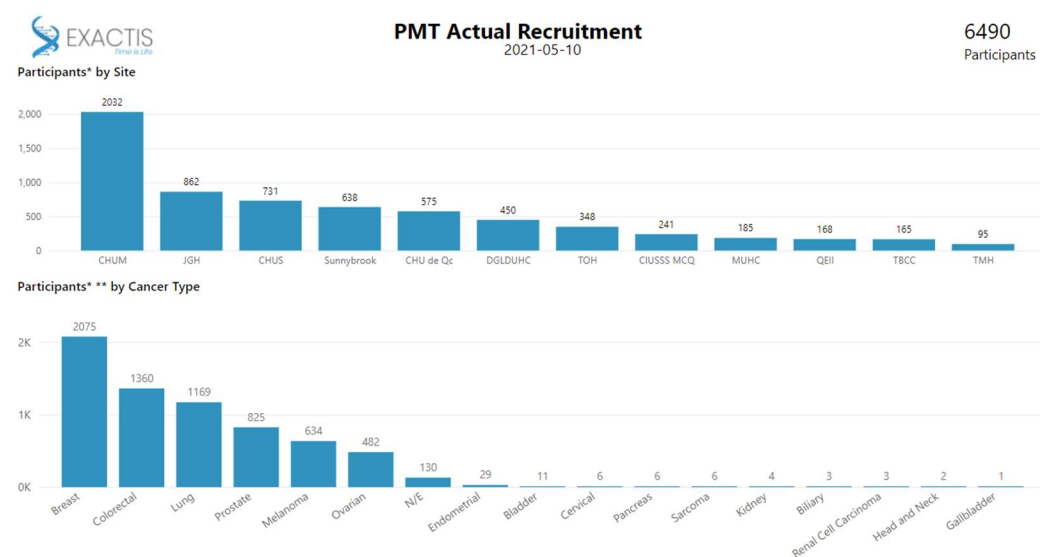
The single site investigator-initiated trial will enroll 100 patients at CHUM under the supervision of the PI of the study, Dr. Simon Turcotte. Start of study is expected for the third quarter of 2021.

Exactis-03:

A Phase I/II Basket Trial of the Combination of Olaparib and Navitoclax in Women with High Grade Serous Epithelial Ovarian Cancer and Triple Negative Breast Cancer.

The PI of this study is Dr. Helen MacKay at the Sunnybrook Cancer Center. The protocol is being finalized and Phase I, which will enroll approximately 20-36 patients, is expected to start third quarter of 2021 at SBH, PMH, and CHUM.

PMT Updates



Welcome to Exactis and Staff Changes!

We are pleased to announce that **David Bouffard, PhD** has joined Exactis Innovation as the Director of Personalize my Treatment. David brings over 20 years of research and development expertise in the pharmaceutical and contract service sectors. In his role as PMT Director, David is responsible for the operational and scientific leadership of our active, longitudinal patient registry including coordination with precision oncology research projects undertaken by Exactis and its network of 15 sites. David works within the Exactis leadership team, the PICC, and CMO to optimize the PMT registry cohorts with access to relevant trial opportunities for patients.

We are also pleased to announce the arrival and staff changes of the following key people:

Haifa Lucy Bassett recently joined Exactis as Clinical Operations Manager. Lucy brings more than 18 years' experience in the clinical research industry and her therapeutic experience includes a wide range of indications such as

oncology, neurology, hematology, infectious diseases, and neurology. Lucy is overseeing clinical operation activities at Exactis.

Touhid Rashid joined Exactis in 2019 as a CRA and recently moved to a more senior position as PMT Regional Manager. Touhid obtained his MD degree from University of Dhaka (Bangladesh) and completed his MSc in Experimental Medicine at McGill University. As the PMT Regional Manager, Touhid will work closely with the Exactis' operational team to coordinate and support PMT initiatives and clinical studies within the Exactis Network of sites. Also, in his role of Project Manager, he is responsible for the TRICIA and Exactis-02 studies as well as for the execution of other PMT sub-studies, such as Exactis-01.

Anastasia Papageorgiou joined Exactis in July 2020 as a Project Manager. Anastasia holds a BSc in Biochemistry and has over 20 years experience in the CRO industry. She is managing clinical studies from start-up to close-out.

Yasmine Madagh-Biskri joined Exactis in August 2020 as a CRA and quickly moved up to Project Manager in Nov 2020 where she is managing clinical trials. Yasmine holds a MSc in Molecular Chemistry and has previous experience working as a CRA on phases I-III studies.

Nathalie Turgeon joined the Exactis team in November 2020 as Clinical Documentation Specialist, where she will be maintaining the Trial Master Files for the different Interventional and Observational studies of Exactis. Nathalie has over 18 years of previous experience working in CROs on several phase II-IV studies.

Pascale Brisebois joined the Exactis team in November 2020 as a Clinical Research Associate (CRA) and will be monitoring interventional and observational studies. Pascale has 18 years experience as a Study Coordinator at MUHC in Phase I-III studies in different therapeutic areas such as Oncology, Radiation Oncology, Diabetes and Ophthalmology.

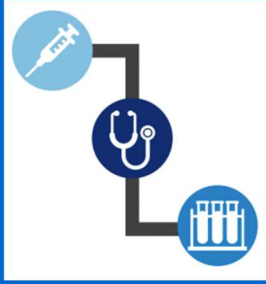
Joakem Fossung joined the Exactis team in December 2020 as a Senior Clinical Research Associate and will be monitoring interventional and observational studies. Joakem obtained his BSc in Nursing, holds an MSc in Pharmaceutical Medicine and is working on completing his Doctorate in Public Health and Medical Informatics.

Cyrielle Beaubois joined Exactis as a Clinical Data Manager in February 2021 and will take care of all the activities related to EDC Data Management. Cyrielle obtained her M.Sc in Public Health and Epidemiology. Over the past 10 years, she had the opportunity to work as a research assistant in hospital and universities as well as Data Manager for the Quebec Leukemia Cell Bank.

Syeda Irine Islam joined the Exactis team in March 2021 as a Clinical Trial Assistant where she will support the Clinical Operations team. Syeda has a MSc in Biochemistry at an Advanced Care Pharmacy, and she has experience in coordinating the treatment of cancer patients across Québec.

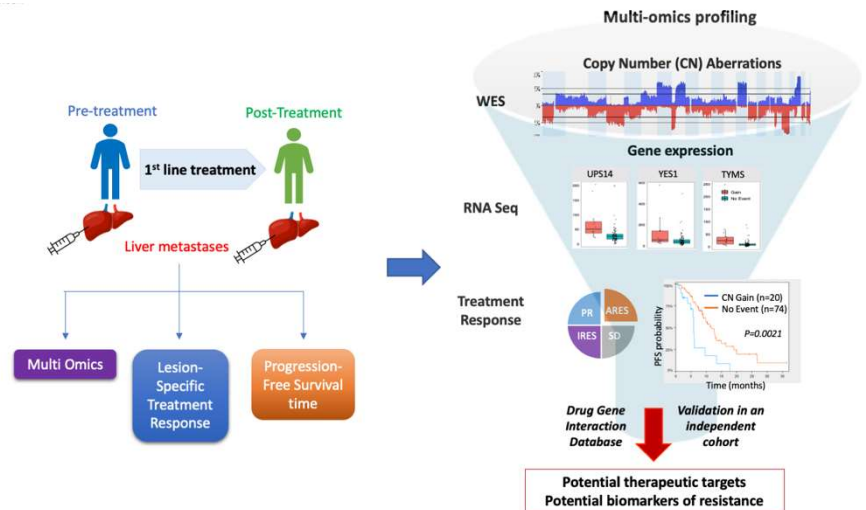
Other News

We are pleased to announce that our manuscript entitled "Copy number and transcriptome alterations associated with metastatic lesion response to



treatment in colorectal cancer” was accepted for publication in *Clinical and Translational Medicine*. Congratulations to everyone involved!

This study investigated genomic-phenotype associations in a large colorectal cancer liver metastases cohort and identified novel molecular features associated with treatment response and patient outcome.



Link to article: <https://onlinelibrary.wiley.com/doi/10.1002/ctm2.401>

How to cite this article:

Gambaro Karen, Marques Maud, McNamara Suzan, *et al.* Copy number and transcriptome alterations associated with metastatic lesion response to treatment in colorectal cancer. *Clin Transl Med.* 2021;11: e401.

We are working on a special edition of the Newsletter to update you on the different changes regarding the PMT at the different sites of the Network. We will present the new investigators and PMT coordinators to make sure that everyone is up to date. Stay tuned!

THANK YOU!

