



The Altascientist

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EARLY PHASE RESEARCH CONTINUITY IN THE ERA OF COVID-19

Business continuity, especially during times of uncertainty, is vital. Swift and decisive action to mitigate risk and support ongoing viability of activities is crucial. The COVID-19 pandemic challenges the strongest, most actionable plans, and they must be supported by consistent and clear communications.

Since the beginning of the pandemic, Altasciences has responded quickly and decisively with the goal of ensuring the safety of our teams, the animals in our care, the study participants, and business continuity for our clients. Thus far, there has been no viral outbreak at any of our five sites thanks to all staff following precautionary guidelines, both state/provincial and our own.

Using the most up-to-date medical and scientific information, we rapidly implemented new and adapted safety procedures in all areas of the business. We are proud and appreciative of the daily efforts of our teams and the resilience they showed over the past months, which allowed us to maintain our operational capabilities and continue to fulfill client deliverables.

Our corporate response team continues to assess and make decisions regularly around the following key elements:

- I. Employee health and safety
- II. Participant health and safety
- III. Animal welfare
- IV. Travel restrictions and visitor screening
- V. Communication strategy
- VI. Data and research integrity

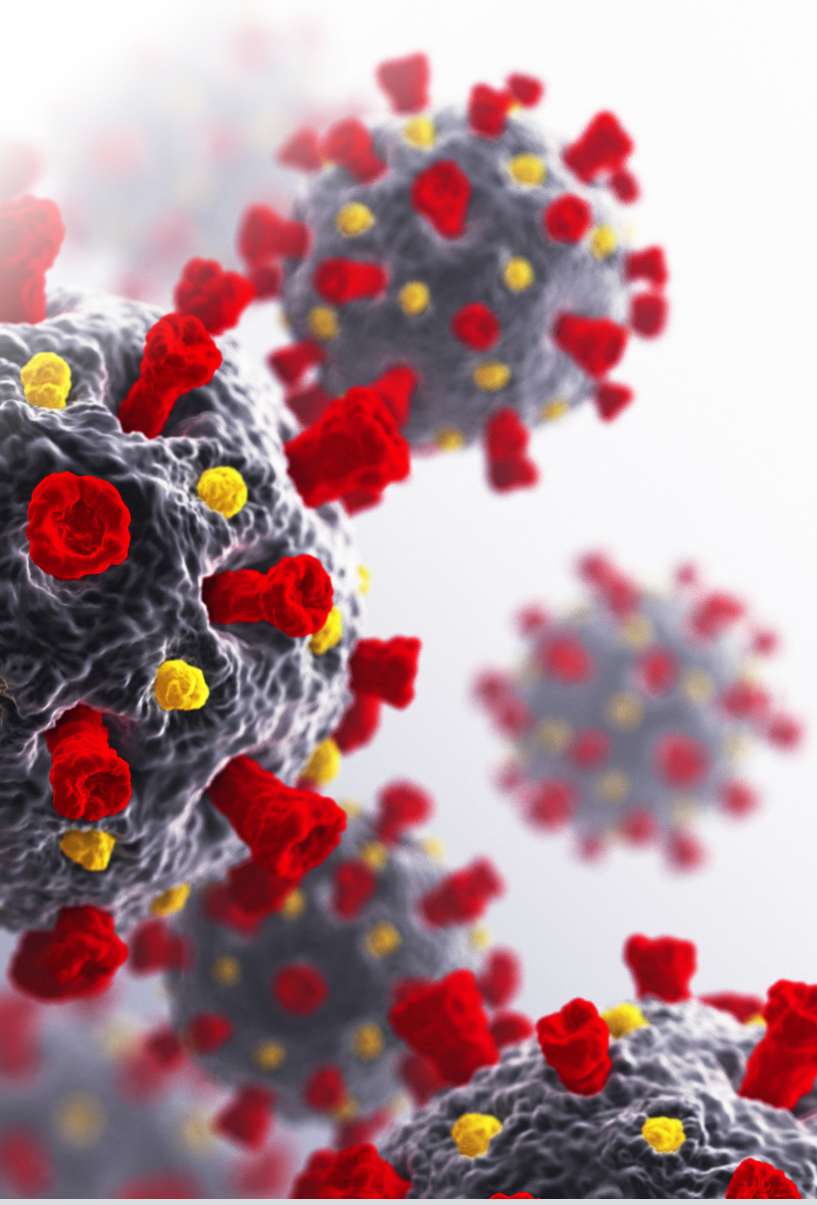
I - Employee Health and Safety

Altasciences ensures its contingency plans adhere to all health and safety recommendations set forth by the national, state, and provincial authorities incumbent to each location. These include physical distancing, sanitary measures, testing, and management of any symptomatic employees and study participants.

Employee safe return assessments and guidelines are in place at all sites, which guide our managers and employees to understand when it is appropriate to return to work should they have experienced symptoms, been tested for COVID-19, or been self-isolating. They also address how to manage a presumptive COVID-19 case or positive diagnosis.

Depending on the specific operational requirements of each site, individually designed safety protocols have been implemented. Our clinical facilities have implemented COVID-19 testing protocols, enhanced PPE, and safety procedures. Our risk assessment and mitigation program has been updated to assess each drug, protocol, and process as they relate to risks associated with COVID-19. In our bioanalytical labs, we adapted our standard operating procedures to include special precautions for handling of known COVID-positive biological samples. At our preclinical site, additional steps are taken to ensure there is no zoonotic virus transmission, and our manufacturing site has staggered their shifts and augmented cleaning and sterilization procedures in high-traffic areas.

At all our sites, measures are in place to restrict the number of people gathered in meeting rooms and offices, and all other interactions that could propagate the virus. Whenever the nature of the work allows, staff are instructed to work remotely, or stay home if they or anyone in their family present symptoms.



II - Participant Health and Safety

In an effort to further reduce risks to both our staff and study participants, Altasciences developed a COVID-19 mitigation strategy.

A combination of antibody and PCR testing has been put in place at each of Altasciences' clinical pharmacology units. Study participants are tested between one and three days prior to each check-in to the clinical unit. Results to date are presented below.

In most cases, testing does not replace the initial physical precautions, such as the use of PPE, distancing, or health and temperature screening, but it does permit the loosening of some restrictions previously required in its absence.

COVID-19 Participant Testing Results to Date

Date Range	Site	Test Type	No. of Tests	Positives*	Positive Rate
May 24-Sep 28	Kansas City, U.S.A.	PCR	565	4	0.71%
May 3-Sep 28	Montreal, Canada	PCR	3025	27	0.89%
		IgM antibody	5433	41	0.75%
		IgG antibody		63	1.16%

** Participants who test PCR and/or IgM positive are referred to public health authorities and their primary care givers for confirmation and follow-up. Altasciences' medical teams work closely with local public health authorities and diagnostic providers to ensure the swiftest and best course of action is taken. Contact tracing and notifications are initiated where appropriate. Clinical action plans have been developed for multiple scenarios in order to ensure the safety of our participants and employees.*



Participant Physical Distancing and Age Risk Mitigation

Measures are in place to restrict participant movement within our facilities. All participant areas are continuously evaluated and reconfigured to ensure adequate space allocation. Areas where this proved unfeasible are now restricted and/or closed off. We carefully evaluate whether and when to allow potentially at-risk participants (such as those over 60 years old) to take part in studies.

III - Animal Welfare

Altasciences' responsibility extends to the safety, health, and overall wellbeing of the animals in our care. As part of our animal welfare program, and in concert with employee health and safety measures, PPE use, which is always part of our process, has been augmented to prevent zoonotic transmission of the virus.

Altasciences remains in contact with the Office of Laboratory Animal Welfare, and we are maintaining all government mandated practices and recommendations towards securing animal welfare.



IV - Travel Restrictions and Visitor Screening

As national, state, and provincial governments change containment restrictions, strict travel screening procedures remain in place at Altasciences, and are applied to all visitors and staff who have been travelling. We continue to monitor government policies and apply an internal risk assessment to determine safe procedures for allowing non-essential visitors at our facilities.

Sponsor Visits and Monitoring

External visitors are presented options for remote site tours and audits. Altasciences has created a customized virtual experience which allows for virtual visits to our sites, with direct access to our scientists, clinicians, toxicologists, or quality assurance personnel. Remote monitoring procedures for source data verification and medication reconciliation have also been implemented.

Staff Travels

Our employees are currently not permitted to travel to other Altasciences sites or to visit clients. Anyone who has travelled outside of the country and/or is coming from abroad must self-isolate for at least 14 days upon arrival.

Local Visitors and Traffic

Altasciences does not allow visitors to enter our facilities unless they have been cleared through the specific site screening process.

V - Communication

A communication framework with our clients has been established through clearly defined channels.

- We implemented accelerated timeline templates to allow for quick study startups and diminished bottlenecks related to COVID-19 safety procedures
- We have communication plans in place should a project be impacted by scheduling shifts and safety processes related to COVID-19

The response team continues to ensure communication is provided in an understandable, timely, transparent, and coordinated manner.

In regards to our employees, in a recent employee survey with representation from all our sites, 86% of respondents found that there was 'enough and timely' or 'more than enough and timely' internal communication regarding the COVID-19 situation. 83% rated the information as either 'good' or 'fantastic'. Our Human Resources team continues to collect feedback on policies and procedures through various mechanisms so that necessary modifications can be made, and employee comments and suggestions are heard and addressed to ensure productivity, quality and confidence remain high.

VI - Data and Research Integrity

Each Altasciences function and service has been carefully evaluated, and we applied measures to minimize impacts on study integrity. FDA, EMA, and MHRA guidance recommendations are being followed. Measures such as remote monitoring and auditing, study-specific COVID-19 risk-assessment and mitigation, as well as screening tests, are also applied to secure integrity of the collected data.



Facilities

New operating norms were put in place with respect to cleaning schedules, facility entry, employee/client screening, maintaining social distancing, and work-from-home policies.

Workforce

As restrictions change, we adapt our processes. The pace at which changes are implemented is closely monitored to ensure we maintain our usual levels of quality, safety, and excellent science.

Essential Service Provider

As an essential services provider, Altasciences has supported many of our clients with their COVID-19 vaccine programs, as well as providing data to leverage currently marketed drugs for reducing inflammation and/or pain from chronic COVID-19 symptoms. Our bioanalytical labs have accommodated samples from Phase III trials occurring around the world, and we have been able to accelerate preclinical studies supporting COVID-19 research with a five-week reporting timeline to address the global urgency of the pandemic.

LOOKING AHEAD

Moving forward, Altasciences is constantly adapting its operations to the changing environment. Our business processes evolve to keep pace with the situation, and we are investing resources in new and different ways of staying connected with, and providing value for, our clients. Our primary goal is to ensure the continued safety of our staff, participants and research animals, so that we can deliver on our business commitments. We are in this together.



ALTASCIENCES' COVID-19 RESOURCE CENTER

Visit our [COVID-19 webpage](#).

Review our [COVID-19 therapeutic capabilities](#).

Read our press release titled [Altasciences completes a Phase I study on gimsilumab for COVID-19 related ARDS](#).

Listen to our podcasts:

- [Clinical and Regulatory Considerations for Developing COVID-19 Treatments](#)
- [Commentary on FDA Guidance on Development and Licensure of Vaccines to Prevent COVID-19](#)

ABOUT ALTASCIENCES

Altasciences is a forward-thinking, mid-size contract research organization offering pharmaceutical and biotechnology companies a proven, flexible approach to [preclinical](#) and [clinical pharmacology](#) studies, including [formulation, manufacturing, and analytical services](#). For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include [preclinical safety testing](#), [clinical pharmacology and proof of concept](#), [bioanalysis](#), program management, medical writing, clinical monitoring, biostatistics, and data management, all customizable to specific sponsor requirements.

Altasciences helps sponsors get better drugs to the people who need them, faster.