



ATMA JOURNEY CENTERS

Clinical Trial Team

March 18, 2023

18 March 2023

Dear ATMA Students,

This letter is being written to you to share ATMA's approach and protocols in assessing the utility of psychedelic medicines via clinical trials. Participation in this trial is an important but optional component of the ATMA Advanced Psychedelic-Assisted Therapy Training Program and the information below will offer insight into the processes that are necessary to bring a trial from conception to implementation.

Psychedelics, in various forms, have been used for centuries in spiritual and cultural practices, and more recently, they have been studied for their potential therapeutic benefits. While they gain popularity, it is critical that they are thoroughly assessed in clinical studies before they become available for use in a clinical setting. In order to research these drugs in an ethical and scientifically sound manner, ATMA has assembled a leading-edge Clinical Trial Team led by Dr. Ravi Bains, our psychiatrist/Principal Investigator. We have confidence that these medicines will benefit many people in a clinical setting; therefore, we believe that the hard, rigorous work that is necessary to gain approval from Health Canada (HC) is well worth the effort.

The overarching goal of ATMA's clinical trials is to investigate the potential benefits and risks of psychedelic medicines in a controlled setting, as well as to provide practical experience to clinicians who may wish to incorporate these medicines into their current or future practices. The trials we design involve meticulous testing and evaluation to assess the safety and efficacy of these substances in treating a variety of mental health conditions, such as depression, anxiety, PTSD, and addiction, while also assessing therapists' views on their utility.

After the ATMA Trials' Team completes a trial protocol, a clinical trial application (CTA) is submitted to HC. The protocol then undergoes a rigorous assessment for feasibility and scientific merit, and frequently requires revisions to ensure the mandate of HC is met with respect to clinical trials. Upon approval, HC issues a No Objection Letter (NOL).

Before a trial is opened for enrolment, we must also receive approval from a local ethics board, such as the Health Research Ethics Board of Alberta (HREBA) – a provincial agency that provides ethical review and oversight of clinical trials involving humans. Ethics review and approval is a mandatory step in the clinical trial process; this helps to ensure participant safety, and without this approval, trials cannot proceed to enrollment.

In addition to the protocol receiving approval from both HC and the ethics board, the Primary Investigator (PI) must also obtain approval from HC to store and administer a controlled substance, such as psilocybin, in the clinic. Once these approvals have been obtained, trial enrolment is permitted to open. At this stage, applicants are thoroughly assessed to ensure they meet all inclusion/exclusion criteria as outlined in the trial protocol. If these conditions are met, the participants must sign an Informed Consent Form and are officially enrolled in the trial.

There are many steps from trial conceptualization to participant enrolment. During this process, trial protocols tend to evolve; each time a change is made to a protocol, a formal amendment is required, and approval from HC and ethics must be obtained. Amendments can take up to 30 days to approve, which can delay the process. Although it can take longer than we wish, the ATMA Trials' Team understands that this process with HC and ethics boards ensures that clinical trials maintain high standards and scientific integrity, with participant safety and well-being being a top priority.

We appreciate your understanding in this process and we will continue to update you with more information as it become available to us. For now, we will be posting new details regarding enrolment. We encourage you to stay informed regarding the latest developments in ATMA's clinical trial portfolio through our website www.atmajourney.com. Working together, we can continue to explore the potential benefits of these substances and potentially develop new treatments for mental health conditions.

Sincerely,
The ATMA Clinical Trial Team