



Welcome to Usona Institute's Fall 2018 Newsletter – we're looking forward to sharing the most recent updates on our work as we transition into the next season. In this edition, we'll be discussing the following activities:

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Psilocybin Program Updates

In June, Usona received helpful comments from the U.S. Food and Drug Administration (FDA) regarding multiple aspects of our program, including the psychotherapeutic approach, qualifications for clinical facilitators participating in our trials, and our CMC (Chemistry, Manufacturing, and Controls) development work. A teleconference with the FDA has been scheduled for early October, and outcomes of this discussion will inform next steps in the opening of our IND for psilocybin as a treatment for MDD (major depressive disorder).

As important dialogue continues with the FDA, our other clinical program activities continue to progress on all fronts. These activities include the finalization of research site budgets and contracts, along with clinical facilitator training development. It is a dynamic process with many moving parts; barring any unexpected delays, we anticipate activating our first study sites in the first half of 2019. For the Phase 2 study, we expect up to seven sites within the United States.

Although enrollment won't begin until next year, we have already begun collecting contact information from potential study volunteers. Please visit our clinical trials website at www.usonaclinicaltrials.org to learn about our proposed study and to sign up for more information as our work progresses.

Usona Clinical Trials

Chemistry & Drug Development Updates

Both Usona's Madison and San Luis Obispo chemistry teams are continuously working with our pharmaceutical contract manufacturers to support the final phases of our large-scale cGMP (current Good Manufacturing Practice) psilocybin production. The completion of our bulk cGMP psilocybin is now anticipated for the end of 2018. Usona will be supplying qualified researchers with our cGMP psilocybin at no charge as it becomes available. For more information please [contact us](#).

The application for a Schedule 1 Research license at our Madison lab has been approved by the DEA, with an additional application for a Schedule 1 Manufacturing license currently underway. The Schedule 1 Research license for our San Luis Obispo lab has been successfully renewed.

Organizational Growth

As Usona's work has continued to grow and expand in recent months, so has our organization of dedicated and hardworking individuals. We're excited to welcome Kristi Kaylo as our Madison-based Laboratory Operations Manager, Tura Patterson as our Senior Director of Strategic Partnerships, and our newest team member, Tina Sauder, who is featured below.

Usona will also be incorporating a Compliance Program Manager position into our team over the next few months to assist in building Usona's quality system and ensuring compliance with regulatory obligations as a sponsor of FDA-approved studies and holder of DEA licenses.

For more information on the Usona team, please follow the link [here](#).

Tina Sauder - Clinical Trials Associate



"There is a great need for novel approaches to treating depression and anxiety - psilocybin offers a new and promising approach. I am drawn to Usona's mission of understanding the science behind psilocybin and making what is learned publicly available. With this approach, I believe we will be able to provide an effective alternative to treating depression that is well received by both the scientific community and general public."

We are pleased to welcome Tina Sauder to the Usona team! In her role as Clinical Trials Associate, Tina will support a wide range of activities on Usona's Clinical Operations team, including quality assurance activities, managing regulatory files, and ensuring compliance with regulatory standards.

Tina comes to Usona with a background in research project management at the University of Wisconsin-Madison, and is a Certified Clinical Research Coordinator through the Association of Clinical Research Professionals. She holds a BS degree in Kinesiology from the University of Wisconsin-Madison, and an MS degree in Exercise Physiology from Iowa State University.



Scientific Collaborations

Usona's dedication to advancing the field of research in psilocybin and other consciousness-expanding medicines is nourished by the connections and collaborations made with other scientists and institutions globally.

In August, Usona hosted [Dirk Hoffmeister, PhD](#) from Friedrich-Schiller University in Jena, Germany at our Madison, WI headquarters. Dr. Hoffmeister is a Professor at the Jena School for Microbial Communication and the Head of Pharmaceutical Microbiology at the Leibniz Institute for Natural Product Research and Infection Biology, with research interests in the biochemistry and genetics of natural product biosynthesis.

Other recent collaborations include those with the [D'Or Institute for Research and Education \(IDOR\)](#), a private non-profit based in Rio de Janeiro, Brazil, that engages in scientific research and promotes advancements in education and healthcare. In February and April, Usona hosted IDOR scientists at our Madison, WI campus to discuss the intersections between their research and Usona's current and future research interests.

Usona has also been assisting researchers collaborating with [PRISM \(Psychedelic Research in Science & Medicine\)](#), an Australian non-profit research association working on developing medical applications for psychedelics. The group, based in Melbourne, has recently received conditional approval to conduct the first psilocybin research on that continent.



Scholarship Program

Usona is pleased to announce the recent establishment of our Scholarship Program. Usona provides scholarship opportunities for students engaged in post-graduate academic study in North America to pursue a degree in the field of psychedelic sciences or related clinical/translational research. The aim of this program is to advance knowledge about psychedelic sciences and support students interested in pursuing a career in psychedelic research, consistent with Usona's overall mission and goals.

We would like to congratulate Usona Institute Scholar Laurel Sudgen on her award and dedication to the field of psychedelic research:

Laurel Sugden, Doctoral Student



Laurel Sugden is an Interdisciplinary Studies PhD student at the University of British Columbia (UBC) in Vancouver. Her research interests center around the anthropological and psychological study of the therapeutic effects of San Pedro, a mescaline-containing cactus that has been integrated into Andean culture, spirituality, and healing practices for millennia.

Ms. Sugden and her doctoral program advisor, [Wade Davis, PhD](#), will be giving a talk at the Liu Institute for Global Issues at UBC on October 16th, 2018 – please follow the link for more information on her presentation, [“Opening the Gates of Heaven: 4,000 Years of Mystery and Medicine in the Andes”](#).

For additional information on our Scholarship Program, please write to us at info@usonainstitute.org. Applications are reviewed in May and November of each year.



Usona to Host Training Course in October

Usona Institute will be hosting a [Clinical Research Professional Certification Preparation and GCP \(Good Clinical Practice\) Review Course](#) through the [Society of Clinical Research Associates \(SOCRA\)](#) in Madison, WI on October 29th, 2018. This program is publicly open to those interested in participating.

For more information on how to register for this course, please follow the link [here](#).



Support Psychedelic Research

As a non-profit organization, Usona depends solely on the support of donations to fund our research and clinical studies. If you would like to offer your support through a donation, please follow the link below or [contact us](#):

Support Usona



Thank You

The work that we do at Usona is one part of a collective vision to bring healing to those who are most in need – we thank you for your interest and support as we continue to move forward in all that we do.

With warmth,
The Usona Team



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