



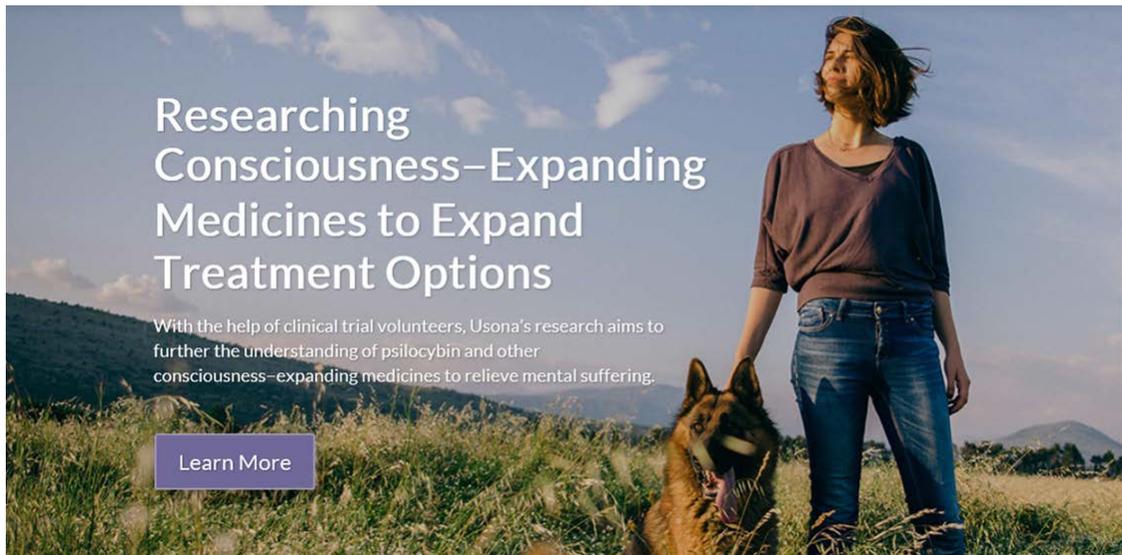
Dear Supporters,

Welcome to Usona Institute's 2018 Spring Newsletter - we're eager to share the most recent updates on our work! In this edition of our quarterly update, we'll review the following activities:

- [Usona Clinical Trials Website](#)
- [FDA Investigational New Drug \(IND\) Application Update](#)
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Usona Institute Clinical Trials Website



The Usona clinical trials website, usonaclinicaltrials.org was launched in mid-May and provides information about Usona's research, major depressive disorder (MDD), and what it's like to participate in a clinical trial. Though we are not yet actively recruiting, visitors to the site may enter an [email address and zip code](#) to receive email updates about changes to the website and forthcoming details about participating in our clinical studies. The zip code will help us identify candidates located near a planned research site, and will assist us in providing the most relevant updates to those who are interested.

For more information on Usona's clinical trials, please visit the link below:

[Usona Clinical Trials](https://usonaclinicaltrials.org)

FDA Investigational New Drug (IND) Application Update

On May 31st 2018, Usona submitted a response to FDA comments on our Investigational New Drug application for psilocybin as an intervention for MDD. This response contains new information about our CMC (Chemistry, Manufacturing, and Controls) plans and outlines the content of the preparation, dosing day, and integration sessions, as well as information regarding requisite qualifications of clinical facilitators participating in Usona-sponsored studies. Once the FDA has reviewed and accepted all responses, Usona will

move forward with applying for [Breakthrough Therapy Designation](#) and prepare to open recruitment for our upcoming Phase 2 clinical trial.



Psilocybin Clinical Program Updates

Our clinical operations team, together with our collaborators, have been very busy with all of the details necessary to launch our Phase 2 trial in the MDD population with the aim of enrolling the first subjects before the end of 2018. We anticipate five to seven sites within the U.S., and have been actively working with the anticipated sites on the qualification process, budgets, and contracts, while also building the infrastructure required for quality systems/compliance and study data management.



Chemistry Updates

Usona's chemistry team has been working in conjunction with our pharmaceutical contract manufacturer and formulation development company to complete the last phases of our initial large-scale cGMP (current Good Manufacturing Practice) psilocybin synthesis campaign. We expect our bulk cGMP psilocybin to be completed and encapsulated into our final drug product toward the end of 2018, aligning with the anticipated start time of our clinical trial in the MDD population. Usona will be supplying researchers with cGMP psilocybin at no charge; for more information, please [contact us](#).



The Madison lab; meeting at DEA Headquarters in Washington, D.C. (from left to right: Gary Tarpley, PhD - Chairman of the Scientific Advisory Board; Kelsey O'Hern - Project Manager, Drug Development; Alexander Sherwood, PhD - Medicinal Chemist; Laura McCormick - Director of Operations).

In April, members of the Usona team met with DEA officials in Washington, D.C. to discuss the acquisition of a Schedule 1 Research license for our chemistry research lab based in Madison, Wisconsin. Site inspections of the lab have been completed and approved, and an application for the Schedule 1 Research license is now moving through the approval process at DEA headquarters. The Madison lab will enhance efforts already underway at the California lab to improve synthetic processes and develop analytical methods for psilocybin and other compounds.



Usona Team Member Highlight - Charles L. Raison, M.D.



Charles “Chuck” Raison, M.D. is the Director of Clinical and Translational Research at Usona Institute, and is a member of the Usona Scientific Advisory Board. He is also the Mary Sue and Mike Shannon Chair for Healthy Minds, Children & Families and Professor in the School of Human Ecology and the Department of Psychiatry – School of Medicine and Public Health at the University of Wisconsin–Madison.

Dr. Raison’s expertise within the domains of clinical psychiatry, immunology, compassion meditation, and the

study of ancient healing practices bring a depth of scientific understanding to Usona's work in building our study designs and clinical trial protocols in accordance with rigorous FDA regulations.

Dr. Raison is internationally recognized for his studies examining novel mechanisms involved in the development and treatment of major depression and other stress-related emotional and physical conditions, as well as for his work examining the physical and behavioral effects of compassion training.

Please follow the links below to learn more about Dr. Raison's work and continued commitment to find novel treatments for those most in need:

- [Treating the Body to Treat the Mind](#)
In this segment of NPR's To the Best of Our Knowledge, Dr. Raison discusses depression, inflammation, gratitude, and his research in finding new ways to treat depression as a disease of the body as well as the brain. *NPR*
- [Running Away or Righting the Way: Is Psilocybin a Viable Psychiatric Treatment?](#)
Charles Raison, M.D. and Michael Bogenschutz, M.D. discuss the history and potential of psilocybin research. *MD Magazine*
- [Charles L. Raison, MD: A History of Psychedelics in Psychiatry](#)
Dr. Raison discusses the history of psychedelics in psychiatry in an interview for MD Magazine. *MD Magazine*



International Forum on Consciousness 2018

On May 17-18, Usona Institute assisted in sponsoring the 9th *International Forum on Consciousness*, hosted by the [BioPharmaceutical Technology Center Institute](#) in Fitchburg, Wisconsin. This year's forum focused on topics related to the "Means and Metrics for Detecting and Measuring Consciousness", with [speakers](#) (including Usona Scientific Advisory Board member [Franz X. Vollenweider](#)) from around the globe discussing the newest emerging technologies and conceptual frameworks for exploring the phenomenon of consciousness within the domains of sleep, wakefulness, altered states, focused attention, and coma.

We're honored to have had the opportunity to support the scientific exploration of consciousness and the

expansion of knowledge within the fields of neuroscience, psychiatry, and multicultural perspectives on the nature of mind.

To view recordings of the forum online, please visit the link below:

International Forum on Consciousness 2018 Videos

Psilocybin Research in the Media

Psilocybin research has seen a wave of increased media attention this season, largely supported by the publication of author Michael Pollan's newest New York Time's Best-Selling book *How to Change Your Mind: What the New Science of Psychedelics Teaches Us About Consciousness, Dying, Addiction, Depression, and Transcendence*. Please follow the links below to some of Mr. Pollan's interviews and publications on psychedelic research:

- [Consciousness, Chemically-Altered](#)
In this segment of NPR's Science Friday, Michael Pollan and Robin Carhart-Harris, PhD discuss the history of psychedelics and the neuroscience of consciousness with radio host Ira Glass. *NPR*
- [The New Science of Psychedelics](#)
Michael Pollan discusses the history of psychedelic research, as well as contemporary studies examining psilocybin for the alleviation of depression, anxiety, and addiction. *The Wall Street Journal*
- [Michael Pollan on testing psychedelics as a treatment for depression](#)
Michael Pollan and CBS news anchors discuss the potential of psychedelics to treat a variety of psychological conditions, including depression. *CBS News*

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

All of us at Usona Institute would like to express our gratitude and appreciation for your interest in our work and mission. We wish you a wonderful spring season, and look forward to connecting with you again in the summer!

Warmly,

The Usona Team