



## Usona Institute and Usona Campus Background

Investigation of new and existing psychedelic molecules are showing therapeutic potential in the treatment of mental health conditions, including depression, anxiety, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), eating disorders, cluster and migraine headaches, alcohol, nicotine and other substance abuse disorders.

This work will continue to grow from years of academic research to [a common understanding in the mainstream](#). As [new studies](#) come out, we are seeing an increased interest by the public sector as referenced by the [Director of NIH](#) and a [new law at a state policy level](#).

Usona Institute works across the spectrum from drug discovery and clinical research towards FDA approval and delivery of care.

### ABOUT USONA INSTITUTE

*“Our objective is to find new and effective methods to relieve anxiety and suffering and contribute to the understanding of neuroscience and the relationship of the mind and body. This is a frontier of research that will shape our future in important ways that we are just beginning to appreciate.”*

– Bill Linton, Co-Founder & Executive Director

- [Usona Institute](#) is a non-profit medical research organization created to serve the public good with an open science model of operation. We conduct and support pre-clinical and clinical research to further the understanding of the therapeutic effects of psilocybin and other consciousness-expanding medicines. Our focus is on alleviating depression and anxiety in people for whom current medical treatments fall short in offering relief and a better quality of life.

Usona Institute is able to accomplish its mission through collaboration with many scientists, clinicians, research centers, expert consultants, and philanthropists worldwide.

- The inspiration to establish Usona was sparked by the promising findings of prior academic research on psilocybin’s effect on anxiety and depression in people with life-threatening cancer. Usona was established with the goal of bringing these new treatments through the rigor of FDA regulatory approval to address the unmet medical needs. [FDA has granted Breakthrough Therapy designation to Usona Institute](#) in recognition of this need and the preliminary evidence of effective treatment potential.
- The [Usona team](#) includes over 25 employees with expertise in clinical research, mental health, pharmacology, medicinal chemistry and regulatory affairs, in addition to an extended network of drug development experts.
- Usona is located in Fitchburg, Wisconsin with satellite offices in California and Germany (Usona Institute Europa).
- Usona sponsors [clinical trials](#) under commercial investigational new drug (IND) applications, following the regulatory pathway toward FDA approvals. Usona’s Phase 2 clinical trial was launched in Fall 2019. It is the first randomized, double-blind, placebo-controlled study of single-dose psilocybin to treat patients with major depressive disorder (MDD). An early phase, first-in-human study in a second novel compound, 5-MeO-DMT, is planned for 2022.



## **USONA INSTITUTE CAMPUS**

- The Usona Institute Campus supports a novel blend of disciplines in psychedelic science and education. It is designed to bridge the learning across academic discovery, clinical research and integrative therapies.
- The campus serves as a global center for education, learning and developing best practices in therapy protocols and facilitation.
- The campus will support existing and novel collaboration between Usona with visiting scholars, scientists, and clinical practitioners from around the world.
- The space encompasses 93,000 square feet (8,640 square meters) on 17 acres of wooded land at a combined cost of \$60M.
- 30 employees are expected to move in when the space is completed in 2024 with capacity for additional growth and expansion.
- Medicinal chemistry and manufacturing will continue to be conducted at the laboratories located in California and Wisconsin, with further support by our contract manufacturers.

## **PREVALENCE OF DEPRESSION**

- According to the World Health Organization, depression is a global epidemic and crisis which calls for humanitarian action. It is the leading cause of disability worldwide, and is the most common mental health disorder
  - affecting over 322 million adults
  - including 17.3 million Americans
  - creating a total estimated economic burden of \$210.5 billion per year in the US alone
- Treatment options have remained essentially the same for decades. Current treatments are only effective 30% of the time and may offer only short-term relief.
- Existing treatments induce dependency, produce a range of life-impairing side effects, and often require a lifetime of use. Psilocybin has the potential to transform the current approach to the treatment of depression.

## **OPEN SCIENCE**

- Usona Institute is dedicated to working for the public good through the advancement of scientific knowledge and the alleviation of mental suffering. Usona subscribes to an open science model which accelerates scientific learning through an open and collaborative approach to discovery and development. [Usona is among the many who have committed to an open science approach.](#)
- The open science concept is an approach to scientific research and development that shares significant new discoveries quickly within the public domain to help other researchers build on and apply the latest learning to their own work.
- In both clinical trials and medicinal chemistry, Usona has been fortunate to partner with experts within the fields of psychiatry, pharmacology, biology and neuroscience. Knowledge-sharing and collaboration have been

cornerstones of the development of the many dynamic branches of Usona's work. See a full list of Usona collaborators [here](#).

- Examples of Usona practices around collaboration and support include:
  - Publishing scientific papers on discoveries related to the synthesis and characteristics of psychedelic molecules.
  - Investigational Drug Supply Program that provides qualified researchers material at no cost.
  - Educational Programs to further work in the field.
  - Hosting of scientific visioning and information-sharing events, bringing together the leading researchers in the field to share their work and learnings and enable future collaborations.
  - Support for [Porta Sophia](#), a web-based portal for accessing publications and other forms of information relevant to the filing and granting of patents.

## USONA EXPERTISE

- **Clinical Research:** Usona's clinical operations include study protocol development, clinical facilitation (guiding) protocols and training; coordinating with Contract Research Organizations for the onboarding and management of clinical research sites; developing quality control systems; and carrying out related nonclinical studies.
- **Drug Development** includes discovery, synthesis and current Good Manufacturing Practice (cGMP)
  - **Medicinal Chemistry:** Usona has DEA-licensed chemistry laboratories in Madison, WI and San Luis Obispo, CA, both with full synthetic and analytical capabilities. Usona medicinal chemists have published [numerous scientific papers](#) over the last three years including key papers on synthesis and characterization.
  - **Chemistry, Manufacturing, and Controls:** Usona's initial batch of cGMP psilocybin was completed in late 2018 and a first batch of cGMP 5-MeO-DMT was produced in 2020. Usona provides both research-grade and pharmaceutical-grade investigational compounds through its Investigational Drug Supply Program.
- **Regulatory Affairs:** The Usona Quality System spans cGMP, GLP, GCP and GVP compliance in accordance with ICH, US, EU and other relevant regulations. Usona works in step with several regulatory bodies worldwide in the development, storage and delivery of scheduled drug materials.
- **Facilitator (Guide) Training:** Usona currently offers training for facilitators participating in our Phase 2 clinical trial. This program was developed in partnership with collaborators and other experts in the field and continues to be refined in response to our growing understanding of the key skills and abilities required for successful facilitation within a clinical trial setting.

In response to increasing requests to share our expertise, and recognizing the need for adequately trained and highly skilled facilitators to advance this research broadly, Usona is exploring the expansion of this training program in continued collaboration with key strategic partners for sites whose research aligns with our mission and commitment to open science.

- **Scholarship Program:** Usona provides scholarships to qualified post-graduate students and licensed practitioners engaged in study or professional training within the field of psychedelic sciences. The goals of the

Scholarship Program are: (1) To advance knowledge within the field of psychedelic sciences, and (2) To promote the future accessibility of consciousness-expanding therapies and practices as they become approved.

- **Designing a Model for Care:** Creating a future-based delivery model is critical work today to ensure broadest access. Usona is working with experts in social sciences and clinical policy to study a pollination approach that may provide a path forward where there is continued recirculation and renewal of resources and the generation of increased community well-being.

## SCIENCE OF PSYCHEDELIC THERAPY

The driven work of researchers well over the past decade has revealed hope and potential. Here is a sampling of their study in psychedelic science:

- Classic hallucinogens, including psilocybin, have very low physiologic toxicity and have not been shown to produce organ damage or negative neuropsychological effects. <https://pubmed.ncbi.nlm.nih.gov/18593734/>
- A single dose of psilocybin lowers anxiety, depression and fear of death and increases quality-of-life in people with life-threatening cancer. <https://pubmed.ncbi.nlm.nih.gov/27909164/>
- A psilocybin-assisted psychotherapy lowers anxiety, depression, demoralization, hopelessness and fear of dying up to two years after treatment. <https://pubmed.ncbi.nlm.nih.gov/31916890/>
- A single dose of psilocybin can lead to long-term increases in the personality trait of openness in adults. <https://pubmed.ncbi.nlm.nih.gov/21956378/>
- Psilocybin with supportive therapy is associated with an 80 percent decrease in tobacco use in smokers, sustained at 6 months. <https://pubmed.ncbi.nlm.nih.gov/25213996/>
- Classic psychedelic use is associated with decreased psychological distress and suicidality in the US adult population. <https://pubmed.ncbi.nlm.nih.gov/25586402/>
- Psilocybin with supportive therapy is associated with abstinence from alcohol use up to 36 weeks after treatment. <https://pubmed.ncbi.nlm.nih.gov/25586396/>
- Recent meta-analysis shows that 1-3 doses of classic serotonergic psychedelics, including psilocybin, are safe, without significant adverse side effects, and show preliminary evidence in treating depression, anxiety, obsessive-compulsive disorder, and tobacco and alcohol use disorders with relatively long-lasting effects ranging from weeks to months. <https://pubmed.ncbi.nlm.nih.gov/33125716/>
- The FDA lists Psilocybin and MDMA as “Breakthrough” Therapies. [Psychedelics and Psychedelic-Assisted Psychotherapy \(review\). Reiff et al, 2020](#)