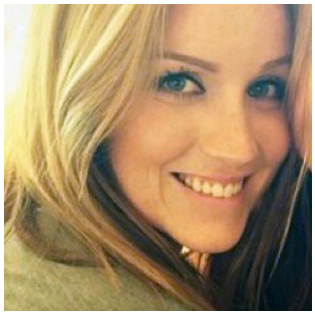
Investigator-Initiated Trials with MDMA

BY MELISSA FIELD, B.A., ALYSSA MCNAMARA, B.S., & REBECCA MATTHEWS

Melissa Field, B.A.



Alyssa McNamara

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In clinial trials sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS), such as our ongoing Phase 3 trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD), we perform protocol development, regulatory submission, funding, study monitoring, and other functions related to the responsibilities of the Sponsor role in clinical research.

In Investigator-Initiated Trials (IITs) the Investigator is also the Sponsor (or Sponsor-Investigator, SI). Therefore, the S-I has the responsibility to comply with federal regulations applicable to both the Sponsor and the Investigator. The U.S. Food and Drug Administration (FDA) defines the S-I as "an individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational drug is administered."

For an IIT, the SI must adhere to Sponsor obligations with federal regulations which include (but are not limited to) the following:

- The submission and maintenance of their regulatory authority applications and reports (i.e. an Investigational New Drug Application (IND) with the FDA, for studies conducted in the U.S.)
- Ensuring that the study is funded adequately
- Monitoring their study for adherence to their country regulations and Good Clinical Practice (GCP)

MAPS and MAPS Public Benefit Corporation (MAPS PBC) are pleased to guide and aid researchers across the globe in their IITs studying MDMA. IITs are important in growing product knowledge and providing important safety data for continual research. Data from IITs can be pivotal in establishing a pipeline for concepts with MDMA treating various indications.

The following is a partial list of MAPS-supported IITs now enrolling, or in the planning stages for new research:

POSTTRAUMATIC STRESS DISORDER

- (Preparing for initiation) The effects of MDMA on Prefrontal and Amygdala Activation in Posttraumatic Stress Disorder
    - Location: Yale University - New Haven, Connecticut, US
    - Researcher: Benjamin Kelmendi, MD
    - Anticipated Start: Q4 2019
- (Under regulatory/ethics review) Open-label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD
    - Location: VA Loma Linda Healthcare System – Loma Linda, California, US
    - Researchers: Shannon Remick, MD and Allie Kaigle, PharmD, BCPP
    - Anticipated Start: Q2 2020
- (Preparing for regulatory/ethics review) A Phase 2 Open-Label Treatment Development Study of MDMA-Assisted Psychotherapy in Conjunction with Cognitive Processing Therapy (CPT) for Chronic Posttraumatic Stress Disorder (PTSD)
    - Location: Remedy – Toronto, Ontario, Canada
    - Researcher: Anne Wagner, Ph.D., Candice Monson, Ph.D., Michael Mithoefer,

M.D., Annie Mithoefer, B.S.N., and Emma Hapke, M.D.
    - Anticipated Start: Q2/Q3 2020

ALCOHOL USE DISORDER

- (Enrolling) MDMA-Assisted Psychotherapy for the Treatment of Detoxified Patients with Alcohol Use Disorder
    - Locations: The Blackberry Centre and Colston Fort (Avon and Wiltshire Mental Health Partnership NHS Trust), Clinical Research and Imaging Centre (CRIC Bristol), University of Bristol – London, England
    - Researchers: Benjamin Sessa, M.D., Laurie Highbed, Ph.D., Professor David Nutt, Claire Durant Ph.D., and Tim Williams, M.D.

Several other MDMA research concepts have also been presented to MAPS for support across various clinical indications, including:

- PTSD (Liberia, England, US, Colombia)
- Alcohol Use Disorder (US)
- Autism Spectrum with Social Anxiety (Australia)
- Grief (Canada)
- Depression (Norway)
- Mood and Anxiety in Advanced Stage Cancer (New Zealand)
- Multiple Sclerosis (New Zealand)

These concepts are still developing, and will be reviewed by MAPS PBC once proposals are provided by the researchers.

Melissa Field, B.A. *earned a bachelor degree in Business Administration in 2010 from Baker University, while working as an In-House Clinical Research Associate for a contract research organization (CRO). After earning her degree and gaining CRO experience, Melissa moved to expand her career in a clinical research site setting. She spent several years working at an NCI-designated cancer center. Under her direction of the center's regulatory affairs department, she spear-headed successful process efficiencies, cross-department project collaborations, and team development/training initiatives while guiding the expansion of Industry, Investigator-Sponsored, and national consortium research projects. At MAPS PBC, Melissa is currently serving as Clinical Research Associate, focusing on MDMA research in both MAPS Sponsored and Investigator-Sponsored studies. She contributes a passionate drive in the common goal for the benefit of psychedelics and cannabis in our society. In her spare time, Melissa enjoys cycling, hiking, and playing with her rambunctious home crew of two daughters, a dog, and two cats.*

Alyssa McNamara, B.S. *earned a bachelor's degree in Neuroscience with a minor in Bioinformatics in 2017 from the University of California, Santa Cruz. Prior to joining the MAPS Public Benefit Corporation (MPBC), Alyssa worked as a Research Associate in the field of immuno-oncology, where she helped to research and develop therapeutics to treat ovarian cancer. Alyssa also worked in the field of Neurodevelopment, where she studied transcription factors and mechanisms of action implicated in Autism Spectrum Disorders. At MPBC, Alyssa is currently serving as a Clinical Study Assistant, supporting the Clinical Operations team. She is excited to join the dedicated and enthusiastic team at MAPS/MPBC. Alyssa joined MAPS/MPBC to help make an impact in the lives of people suffering around the world. She strives to help improve the standard of care for mental illness and neurological disorders. In Alyssa's free time, she enjoys running and Geocaching with her family.*

Rebecca Matthews *Rebecca Matthews is the Associate Director of Clinical Operations at the MAPS Public Benefit Corporation (MAPS PBC), a wholly owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit. Rebecca is leading the Clinical Operations teams in conducting clinical trials around the globe in all indications and clinical programs supported by MAPS PBC and MAPS. Rebecca began consulting with MAPS in 2009 and joined MAPS PBC full-time in 2015. Prior to her work at MAPS and MAPS PBC she worked in clinical research and development at Chiron/Novartis starting in 2001 with a focus in the indications of sepsis and vaccines. Rebecca is drawn to the field of research and drug development to support the advancement of healthcare and to provide novel and improved treatments for the benefit of humankind. She is deeply passionate about this amazing journey and honored to be on the forefront of psychedelic medicine research. Rebecca earned her B.A. from UC Berkeley in 2000. She resides in Northern California CA alongside her husband, two daughters and the family labradoodle and can be found starting impromptu dance parties, enjoying delicious tacos and playing in nature with family and friends.*