Evaluation of the Health Equity Program by Multidisciplinary Association for Psychedelic Studies (MAPS) and Lykos Therapeutics (Lykos)

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Program Description

In recent years, research by various organizations have explored the effects of the synthetic psychedelic compound, MDMA — also known as 3,4-methylenedioxymethamphetamine, or ecstasy and molly in recreational psychedelic culture. The pioneering nonprofit, Multidisciplinary Association for Psychedelic Studies (MAPS), along with their public benefit corporation, Lykos Therapeutics (Lykos), has been working closely with the U.S. Food and Drug Administration (FDA) for the approval of MDMA-assisted therapy to treat post-traumatic stress disorder (PTSD). With Lykos announcing the FDA's acceptance and priority review of their new drug application (NDA) for MDMA to be used in combination with psychotherapy,[1] their vision of a Health Equity Program, announced in 2020, continues to gain relevance and importance. This is especially the case given the fact that 13 million Americans reported having PTSD in 2020.[2]

Centered around the belief that mental health is a human right, MAPS' Health Equity Program aims to increase access to MDMA-assisted therapy, as well as the training needed for professionals to facilitate it. More specifically, their goal is to cultivate a network of MDMA therapists, supervisors, and trainers "from communities who experience high rates of trauma and insufficient access to care." [3] The 2020 announcement of the Health Equity Program stated that over the next three years, four main initiatives would be focused on after fundraising and allocating $5.5 million: "1) developing scholarships for training therapists from historically marginalized communities, 2) supporting clinics and patients in the expanded access program with a treatment access fund, 3) building inclusive and equitable community, outreach, and education, and 4) hiring new team members at MAPS and MAPS Public Benefit Corporation (MAPS PBC)," (Ginsberg,

[1] Lykos Therapeutics Announces FDA Acceptance and Priority Review of New Drug Application for MDMA-Assisted Therapy for PTSD - Feb 9, 2024 (lykospbc.com)
[2] How Common is PTSD in Adults? - PTSD: National Center for PTSD (va.gov)
[3] Health Equity - Multidisciplinary Association for Psychedelic Studies - MAPS

Ali, Aggarwal, Menapace 2020). Since this announcement, MAPS PBC has rebranded to Lykos Therapeutics, which has its own website separate from their nonprofit parent organization.[4] In addition, the application link to participate in the Health Equity Program on MAPS' designated web page redirects individuals to Lykos' home page, indicating that the program is either: 1) not yet fully operational, 2) being redeveloped, 3) on pause as Lykos focuses on their NDA for MDMA-assisted therapy, or 4) some combination of these options, while also considering hidden factors that may be in effect, such as financing or other logistics. In this sense, the purpose of the evaluation may serve flexibly as both developmental and formative.

Nonetheless, progress by MAPS and Lykos to legitimize MDMA-assisted therapy has demonstrated the need for their Health Equity Program. Although the modality of healing has not necessarily been approved by the FDA, their "NDA submission included results from numerous studies including two randomized, double-blind, placebo-controlled Phase 3 studies (MAPP1 and MAPP2) evaluating the efficacy and safety of MDMA used in combination with psychological intervention versus placebo with therapy in participants diagnosed with severe or moderate to severe PTSD, respectively. Both MAPP1 and MAPP2 studies met their primary and secondary endpoints and were published in *Nature Medicine*," [5,6] — highlighting their momentum.

The research that sets the premise of the Health Equity Program is that — for the most effective therapy to occur — racial and ethnic alignment between the individuals involved can improve trust, safety, and outcomes (Ginsberg et al. 2020). With one of the main goals being to empower communities, the program seeks to train therapists, supervisors, and trainers from

[4] Home - Lykos (lykospbc.com)
[5] Mitchell JM, Bogenschutz M, Lilienstein A, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 609 2021;27:1025–33
[6] Mitchell JM, Ot'alora MG et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med. 2023 Sept 14 doi: 10.1038/s41591-023-02565-4. Online ahead of print.

marginalized communities.[7] Moreover, these communities also experience high rates of trauma that intersect with insufficient access to care and economic development (Ginsberg et al. 2020). These prioritized communities include "therapists who represent the Indigenous, Black, Latinx, LGBTQ+, non-able bodied, refugee or immigrant communities, as well as individuals who have been formerly incarcerated, work in rural communities, and/or who are economically marginalized." [8] In addition, the program plans to expand access for patients through the treatment access fund, which would cover start-up costs of clinics, as well as subsidize the costs associated with administering MDMA-assisted therapy for patients who need financial support. Resources from the treatment access fund are also allocated for community building, education, outreach, and hiring team members to fulfill the program's objectives.[9]

The founder of MAPS and Lykos, Dr. Rick Doblin, announced their march toward a world of net-zero trauma by 2070 at the opening address of their historic conference, Psychedelic Science 2023 (PS23). For all transparency purposes, I was able to attend this conference by earning a scholarship before being hired to evaluate this Health Equity Program. Dr. Rick Doblin made his point concisely, "what we mean is not eliminating trauma — there's always going to be trauma — but we want to stop adding to the burden of suffering." [10] The goals of the Health Equity Program enables MAPS and Lykos to achieve this feat by increasing the diversity of trained professionals to administer MDMA-assisted therapy, as well as subsidizing the costs to access MDMA-assisted therapy. This indicates the significance of an iterative evaluation approach, ensuring proper function and efficacy of the program over time.

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[7] Health Equity - Multidisciplinary Association for Psychedelic Studies - MAPS

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[10] Personal notes taken from the opening address: Opening Address from Rick Doblin, Ph.D. - Psychedelic Science 2023 (mapyourshow.com)

Literature Review

In the United States, trauma rates are disproportionately high among Indigenous, Black, and Latinx Americans (Alegría et al. 2013; Roberts et al. 2011). Moreover, PTSD rates are significantly higher among transgender and gender non-conforming individuals in the U.S., indicating that sexual orientation and gender identity also play a crucial role in susceptibility to trauma (Mizock and Lewis 2008; Roberts et al. 2012). However, the lack of attention and insufficient funding over the years has resulted in restricted availability of cost-effective healthcare services, leading to deficiencies in culturally sensitive and efficient treatment (Ginsberg et al. 2020). One study revealed that Black newborns are three times more likely to die than White newborns if the caregiver is a White physician (Greenwood et al. 2020). In contrast, this outcome disparity drops significantly if Black newborns are cared for by Black physicians (Greenwood et al. 2020). This research lends itself to the need for initiatives focused on aiding the most marginalized individuals in society, which ultimately has a beneficial effect on a wider scope of people, commonly known as the "curb-cut effect," (Blackwell 2017). Ginsberg et al. (2020) emphasize that the Health Equity Program is developed to reverse outcome disparities that result from "healthcare as usual."

Research conducted by Glynos et al. (2023) demonstrated the disconnect between naturalistic use of psychedelics and conventional healthcare through an anonymous survey that sampled Canadian adults (n = 2,384). Although therapeutic goals to self-treat a health condition were often included in the naturalistic use of psychedelics, only 4.4% of participants reported using them with a therapist, and only 3.6% in a clinical setting (Glynos et al. 2023). Just as Glynos et al. (2023) note that more training and education for health care providers is needed, Black (2023) advocates for a collaborative method to maximize the potential of psychedelic-assisted therapy

(PAT) to promote population health. Specifically, Black (2023:1) highlights the need to "intentionally develop regulatory, clinical, and payment systems supporting clinical research, rigorous safety monitoring, and implementation." Furthermore, Black (2023) suggests that this can be created through mutual networks of social support, but also connected and responsible to public institutions with the duty of equitably disseminating these therapies for the advancement of social and health equity. In this sense, the Health Equity Program is in alignment by developing a system that can increase access to care *and* training. However, the need remains to improve equity within our healthcare and socioeconomic systems more generally, as the program is bound by these structures.

In an open letter addressed to racial/ethnic and sexual/gender minorities, Ching (2019) shares intersectional insights from his own therapist training trial for MDMA-assisted psychotherapy. Relevant themes that pertain to the Health Equity Program were discussed by Ching (2019), which included: cultural pride; LGBTIA+ pride; acceptance of intersectionality; set and setting; and patience, perspective, and strength in retrospection. Ching (2019) concludes by emphasizing the need for investigators of MDMA-assisted psychotherapy to concern themselves with issues regarding intersecting identities, which in turn, can support participation of minority populations through culturally attuned practices. Consequently, the amount of minority stakeholders would also be increased (Ching 2019). This coincides with a study conducted by Williams, Reed, and George (2021), which examined the experiences of three African American female therapists who were administered MDMA as part of an FDA-approved clinical trial and training. Despite the variation in experience between the three therapists, themes of strength, safety, connection, and managing oppression/racialization were found (Williams et al. 2021). Moreover, the participants found these MDMA experiences to be personally significant and

insightful for improving the accessibility and effectiveness of Western approaches to psychedelic-assisted therapy within the Black community (Williams et al. 2021). By establishing greater accessibility to both practitioners and clients from marginalized communities, the Health Equity Program is poised to implement such equitable suggestions through a collaborative approach with stakeholders (Ginsberg et al. 2020).

In a similar vein, Mintz et al. (2022) advocates for the inclusivity of individuals with physical and sensory disabilities in clinical trials regarding psychedelic therapies. Drawing from the body of research of disability studies and medical ethics, Mintz et al. (2022:4) note that the exclusion of individuals with disabilities would reinforce the structural ableism within healthcare — or the "discriminatory manifestation of lowered expectations toward people with disabilities on the part of medical providers." In alignment with this issue, Ginsberg et al. (2020) note that MAPS' Health Equity Program also aims to prioritize therapists who are not able-bodied in their trainings. Moreover, the aim of the Health Equity Program to broadly expand access for patients through the treatment access fund ultimately encompasses the inclusion of individuals with disabilities (Ginsberg et al. 2020). In this manner, inclusivity in regard to both practitioner training and patient access is focal to the Health Equity Program.

With Oregon being one of the states at the forefront of implementing psychedelic-assisted therapy, the Oregon Health Authority provides a Facilitator Training Program Curriculum Worksheet. [11] Section 2 focuses on cultural equity training in relation to psilocybin services, which is estimated to take 12 hours. In review of the curriculum, it becomes apparent that there is an effort for racially-just and culturally competent implementation of psychedelics by the state — aligning with the vision set by MAPS and Lykos.

[11] TP-Curriculum-Worksheet-6-1-2022.pdf (oregon.gov)

Stakeholders

A preliminary checklist of potential stakeholders regarding MAPS' Health Equity Program has been developed for this evaluation (See Appendix A). The key stakeholders include the program developers — MAPS and Lykos — as well as the program funders, which includes but perhaps is not limited to: Libra Foundation; Riverstyx Foundation; Open Society Foundations; Dr. Bronner's All-One; the Psychedelic Science Funders Collaborative (PSFC); and atai Impact. Program funders, who are also considered key stakeholders, range from high-donor individuals such as Gwyneth Paltrow, Bob Parsons, Craig Nerenberg, Phoebe Taubman, and Rachel Ratliff; as well as small-medium donors. The primary stakeholders of the Health Equity Program, or the midstream impactees, include the program staff and managers who operate the program to achieve the program's goals. Direct program impactees include therapists, supervisors, and trainers from BIPOC and/or LGBTQ+ communities, as well as "individuals who have been formerly incarcerated, work in rural communities, and/or who are economically marginalized." [12] Moreover, patients that seek MDMA-assisted therapy but need financial assistance, as well as clinics willing to implement the modality, are also direct program impactees — altogether, constituting the primary stakeholders of the Health Equity Program. Indirect program impactees include communities with high rates of trauma, related professionals and organizations in the field, and the broader community (in the sense that this program may improve public health more generally).

While all the stakeholders of this program are of importance, their roles in evaluation will vary. For example, the key stakeholders will help to identify the program's objectives by answering questions as suggested by general evaluation practices (Fitzpatrick, Sanders, and Worthen 2023), such as: 1) What do you perceive as the program's purpose? 2) How well do you think it works?

[12] Health Equity - Multidisciplinary Association for Psychedelic Studies - MAPS

3) What concerns do you have about it? 4) What would you like to know about it? 5) What do you hope to learn from the evaluation? This not only serves to gauge key stakeholder concerns, but helps to inform what the evaluation reports should contain. Similarly, program impactees (direct and indirect) may be asked some of these questions to help gauge the program's effectiveness, such as questions 2 and 3. In this sense, program impactees are able to provide input in regard to the program. Furthermore, program staff and program impactees will become involved in the formation of evaluation questions, data collection processes, and interpretation of results. However, program staff and other relevant team members at MAPS and Lykos will ultimately make the operational decisions that affect the program, both developmentally and formatively.

Peripheral stakeholders include the broader field concerned with psychedelics, as well as the psychedelic community that constitutes it. While programs with similar aims are cited by MAPS, [13] the ecosystem of inclusive psychedelic training and access programs are still in their early stages as MDMA (as well as psilocybin) are on track to be legitimized as having medicinal value by the FDA. Collaborative evaluations with related stakeholders, as well as the dissemination of relevant information with stakeholders across the psychedelic space and general public, would serve to increase our understanding of what is and is not working, why, and possible solutions. This approach ensures that the maximum number of stakeholders benefit from such programs. While those who identify as a White cisgender individual are technically disadvantaged by the nature of focus for these programs, it is important to note that the premise of why the Health Equity Program should exist is to support communities that have historically been socioeconomically disadvantaged, especially in healthcare. Moreover, the category of "economically marginalized" may include White cisgender-identifying individuals in and of itself. Despite the focus of inclusion

[13] Psilocybin Facilitator Training Programs in Oregon: An Inside Look at Oregon's Burgeoning Psychedelic Marketplace - Multidisciplinary Association for Psychedelic Studies - MAPS

in the Health Equity program, other factors that may disadvantage potential program participants include financial limitations of both the program and the participant, program enrollment capacity, conflicting schedules and circumstances, as well as the lack of awareness of the program itself.

Logic Model

The logic model for the Health Equity Program follows the standard input, output, and outcomes model in evaluation practices (See Appendix B). By establishing a treatment access fund with donations from the sponsoring organizations and individual donors of various amounts, the Health Equity Program is able to award scholarships and provide MDMA-assisted therapy training for therapists, supervisors, and trainers from marginalized communities. In order to do so, however, a portion of the treatment access fund is allocated for the hiring of dedicated team members, ultimately providing operational function and support for the program. Moreover, the treatment access fund also expands access to patients that need financial assistance by subsidizing clinical costs, and creating inclusive and equitable community outreach and education. Through the participation of therapists, supervisors, and trainers that represent the aforementioned populations facing marginalization, patients seeking MDMA-assisted therapy may be provided a wider array of mental health professionals to choose from in order to pursue their healing with greater efficacy. The activities of this program, as well as the participation of the populations that this program intends to serve, lead to several outcomes that contribute to health equity.

The lasting impact of an efficient Health Equity Program is a pathway and model of access to MDMA-assisted therapy training for marginalized therapists, supervisors, trainers, and patients from marginalized communities. Consequently, this counters health outcome disparities, improving overall public health. Such outcomes also support the merit and sustainability of the program and its staffing, as communities and (potential) funding organizations are able to see the

benefits of the Health Equity Program. More immediately, the feasibility of marginalized professionals to gain the skills to facilitate MDMA-assisted therapy increases, supporting the program's goal of access and equity. Efforts around inclusive education and community outreach events also supports the broader public's knowledge by covering a "broad understanding of cultural and historical trauma, psychedelic education, and harm reduction." [14]

In pursuit of empowering communities and providing access for all, it is important to note that the Health Equity Program operates according to the protocols of the larger bureaucratic structure of healthcare, as well as the legal system (on multiple levels). In brief, social, economic, and political conditions may serve as detriments to the goals of the Health Equity Program. For example, factors such as how well the economy is doing, the state of stigma on psychedelics, and how psychedelics are being framed politically (or more generally portrayed in the media), may all affect the program and its outcomes. Nonetheless, research has shown the need for such a program, and with Lykos' NDA under review by the FDA, the momentum of the psychedelic space seems to be moving in a positive direction.

Program Theory

As the Health Equity Program states on MAPS' website, "The most important element of successful therapy—especially psychedelic therapy—is establishing a safe space through a trusting relationship between providers and patients. Research has shown that racial and ethnic alignment between the giver and the receiver of therapy can improve survival, safety, and trust." [15] In this sense, the treatment access fund — along with initial program staff and a network of healthcare and industry professionals — empowers the Health Equity Program to progress towards their goal of a culturally responsive and equitable healthcare model for MDMA-assisted therapy.

[14] Health Equity - Multidisciplinary Association for Psychedelic Studies - MAPS
[15] Health Equity - Multidisciplinary Association for Psychedelic Studies - MAPS

Given the aforementioned literature, the design of the program is structured in a way that counters the health disparities experienced by (historically) marginalized communities by offering a path that alleviates socioeconomic barriers.

With a dedicated team being employed to operate the program through the treatment access fund, the distribution of scholarships to therapists, supervisors, and trainers from marginalized communities can be achieved at scale. As the demand for psychedelic-trained mental health care professionals continues to increase, the Health Equity Program plays its role by training diverse cohorts of professionals that can help fulfill the demand. Moreover, education and community outreach may mitigate the stigma surrounding psychedelics and the individuals who choose to experience them, especially in regard to communities who are not only marginalized and have high rates of trauma, but may hold intersecting stigmatized identities. In essence, increased access to MDMA-assisted therapy leads to greater likelihood of healing for all.

Primary Evaluation Questions

1. How effective is the scholarship and inclusion process to expand therapist training to therapists, supervisors, and trainers from historically marginalized communities?

   [Data will be collected through documents and focus groups with staff members]
2. What did program participants find most useful about the Health Equity program, and what do they think could be improved?

   [Data will be collected through focus groups with program-trained participants]
3. Did program participants who underwent training find it culturally competent and of quality?

   [Data will be collected through focus groups with program-trained participants]
4. What is the impact on communities that program-trained participants serve?

   [Data will be collected through surveys and focus groups with program-trained participants]

5. What is the impact of the treatment access fund to support clinics and patients, what could be improved?

   [Data will be collected through interviews with clinicians and surveys with patients]

6. What do staff think the program is doing well, and what could be improved?

   [Data will be collected through documents and focus groups with staff members]

7. Is the Health Equity program functioning as intended? Is it efficient and sustainable?

   [Data will be collected through documents and focus groups with staff members]

Description of Data Sources

The secondary data sources that will be used for this evaluation include any program documents describing the nature of the Health Equity program and its processes. For example, annual reports to discern budgetary constraints of the evaluation, as well as to help determine the effectiveness of the scholarship process and sustainability of the program; or training manuals to gauge cultural competency for targeted populations of the program. Any relevant reports of evaluations regarding similar programs in the psychedelic ecosystem may also be included.

There are several primary data sources that will be used for this evaluation, such as program participants, clinicians, patients, and staff members. To explore the effectiveness of the program training, each participant cohort will be asked for their consent to participate in a focus group once they have completed their training. Moreover, program staff will be asked to participate in focus groups, contributing to the overall efficiency and understanding of actual program practices, as well as what could be improved. In addition, clinicians and patients who utilize the treatment access fund may act as primary data sources through interviews and surveys, respectively. For example, interviews may be used with funded clinicians to gain an in-depth understanding of what they are experiencing on the ground; while anonymous surveys will be used for patients who utilize

the treatment access fund and/or have benefited from a racially/ethnically aligned therapist from the program. This will support the evaluation's inquiry into the impact of the treatment access fund. In addition, the evaluator or program staff will take pictures of the training spaces held by the program (while they're vacant) to visually portray the context of setting, and see how it aligns with efforts around cultural competency. This will help gauge the pulse of the program in its efforts to expand training access, create a more diverse network of MDMA-assisted therapists, and the overall effectiveness and quality of the training.

Primary Research Method

The primary method that will be used in this evaluation are focus groups, which will consist of each program cohort of therapists, supervisors, and trainers from historically marginalized communities; as well as a separate group consisting of program staff, such as the therapist trainers, administration, finance, education and outreach, and so on. The practicality of conducting focus groups is in the fact that it enables a space that fosters discussion of a shared experience. The cohort focus group will ultimately shed light on primary research questions 2, 3, and perhaps even 4; while the program staff focus groups will shed light on primary research questions 6 and 7. The participant focus groups will occur once at the end of program training for each cohort, contributing to an iteration of program effectiveness. In implementation of this evaluation, therapists, supervisors, and trainers who participate in the Health Equity program will be asked for their consent to participate in a focus group at the end of their training. Each focus group will aim to not exceed more than 8 participants to ensure that sonic space is shared while still leaving room for a diversity of voices. The total size of the focus group, however, may be decided on the cohort size and feasibility of splitting the cohort into separate groups. Discussion with key stakeholders in the Health Equity program may also influence whether or not to separate focus groups by

occupation (therapists, supervisors, and trainers). The focus groups will be facilitated by the lead evaluator and an assistant to record and take notes, after of which, both the lead evaluator and assisting staff will clean and code the transcripts. Moreover, the focus groups may be conducted either online via Zoom or on-site, depending on the method of training administration. If the budget for evaluation allows, interviews may also be conducted with certain focus group participants who have a lot to share in regard to the evaluation's purpose.

Focus groups with program staff will be conducted quarterly, which in turn, also contributes to the different facets that lead to program effectiveness. The size of the staff focus group will vary depending on how many staff members there are, but will generally follow best practices to not exceed 10-12 participants — ensuring sonic space can be properly shared given the timeframe. In addition, check-ins between the lead evaluator and individual staff members may occur in case something significant needs attention between focus groups.

Ethical Considerations

Ethical considerations in conducting this method with program participants include informed consent. The difficulty with proper consent lies in the fact that there is a degree of unpredictability to focus groups in regard to what will be brought up in conversation. However, this can be mitigated by disclosing the unpredictable nature of a focus group within the informed consent form, and proper facilitation. In addition, the nature of the program seems to connect therapists, trainers, and supervisors to one another, contributing to the diverse network of MDMA-assisted therapists the program aims to achieve. In this sense, rapport is built between program-trained participants, as they are of similar professions seeking the same goal. In turn, this may actually contribute to the discussions within focus groups. Overall, the methods used in this evaluation pose minimal risk to the human subjects involved.

Cultural and Political Context of Evaluation Plan

Within the United States, the psychedelic ecosystem operates within a lingering "War on Drugs" landscape. This brings the evaluation into context of ethical, legal, and cultural difficulties that call for close scrutiny as the integration of psychedelics into society takes place more broadly. Given the current understanding of the Health Equity program, there are no foreseen conflicts of evaluation inquiry from different key stakeholders. Perhaps at most, the cost-effectiveness of pursuing all 7 primary research questions may not be feasible depending on the evaluation budget. An advisory committee consisting of members from different key stakeholder groups will be constructed in an attempt to equitably reach any discrepancies regarding the inquiries and process of the evaluation as well. For example, if budgetary constraints require some primary research questions to be dropped, the advisory committee will seek consensus on the priorities of the evaluation, and how they may need to shift over time or depending on social circumstances.

Dissemination

To ensure the development of ethical and quality health equity programs within the psychedelic ecosystem, evaluation reports will be made public on MAPS and Lykos' website. In order to increase education regarding psychedelics and their uses, social media graphics, journal articles, and press releases will be produced that clearly demonstrate the mechanisms and outcomes of the Health Equity program, as well as its impact. In effect, this may also contribute to outreach efforts, informing not just the public, but relevant professionals and the patients who seek this modality of healing. Dissemination will also be focused on informing politicians, policymakers, and health insurance providers, which in turn, will coincide with lobbying efforts to pass legislation that supports MDMA-assisted therapy, as well as subsidize clinical costs.

Appendix A

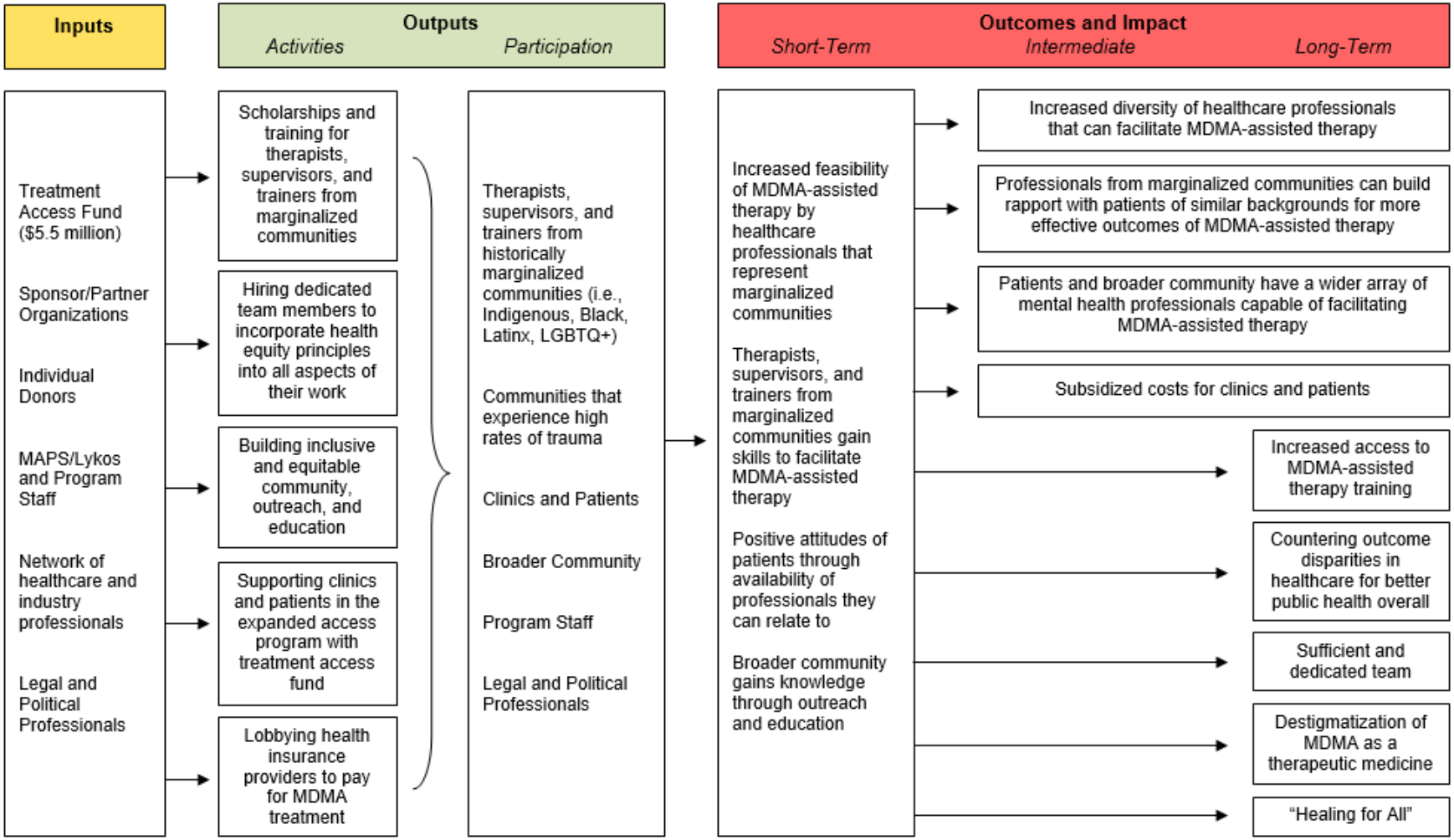
Checklist of Potential Stakeholders – MAPS Health Equity Program

Individuals, Groups, or organizations that need to know about the evaluation	To make policy affecting the program	To make operational decisions affecting the program	To provide input to evaluation	To react to evaluation plans and reports	Only for interest in the program and/or evaluation
Program developer(s): – Multidisciplinary Association for Psychedelic Studies (MAPS) – Lykos Therapeutics (Lykos, formerly MAPS PBC)	**X**	**X**	**X**	**X**	
Program funder(s): – Libra Foundation – Riverstyx Foundation – Open Society Foundations – Dr. Bronner's All-One – Psychedelic Science Funders Collaborative (PSFC) – Atai Impact – High-donor Individuals – Small-Medium Donors			**X**	**X**	
Group who identified the need for the program: – Natalie Lyla Ginsberg, M.S.W. – Ismail Lourido Ali, J.D. – Ritika Aggarwal, M.F.T. – Fede Menapace, M.B.A. – Other relevant team members at MAPS/Lykos – Relevant literature from academics	**X**	**X**	**X**	**X**	
Other providers of resources (facilities, supplies, in-kind contributions): – Unspecified	**-**	**-**	**-**	**-**	**-**
Program staff: – Training team for MDMA-assisted therapy – Education and outreach team – Legal and political team – Administrative team		**X**	**X**	**X**	
Direct program impactees: – BIPOC, LGBTQ+, and other marginalized therapists, supervisors, and trainers – Patients seeking MDMA-assisted therapy that need financial assistance – Clinics			**X**	**X**	
Indirect program impactees: – Communities with high rates of trauma – Broader community – Related professionals and organizations					**X**
Potential program adopters: – Other psychedelic organizations					**X**
Community members; the public					**X**
Health insurance providers				**X**	**X**
Politicians				**X**	**X**

Appendix B

Program Logic Model: MAPS Health Equity Program

Situation: With the recent FDA acceptance and priority review of Lykos Therapeutics' NDA for MDMA as a therapeutic medicine, the Health Equity Program by MAPS (Lykos' nonprofit parent organization) is becoming increasingly significant, calling for evaluation to ensure efficacy.



Assumptions

1. Research shows that an element of successful therapy is a safe space and trusting relationship with those involved. Racial and ethnic alignment may contribute to the fostering of a safe space and trustful relationship, leading to more positive outcomes of MDMA-assisted therapy.
2. Mental health is a human right, and "healthcare as usual" is unconscionable. Therefore, equitable and culturally competent healthcare is needed.

External Factors

1. Protocols within the bureaucratic structure of the health industry and overarching Federal legal system must be followed for the legitimate implementation of MDMA as a medicine.
2. How State laws intertwine with Federal laws also complicate the matter.
3. Funding for the program needs to be met and sustained.
4. Negative public opinion about psychedelics may serve as a detriment to outreach.

Appendix C

Management Plan and Evaluation Budget

Management Plan			
Evaluation Questions	Tasks	Time frame	Personnel time
1. How effective is the scholarship and inclusion process to expand therapist training to therapists, supervisors, and trainers from historically marginalized communities?	1a. Work with program staff to review relevant documentation to gauge the current state of the scholarship and inclusion process.	1a. First month of evaluation, then annually	Lead evaluator and program staff: 1-2 weeks
	1b. Determine which localities with historically marginalized communities are not having program applicants and/or are not receiving scholarships.	1b. First month of evaluation, then annually	Lead evaluator, assistant evaluator and program staff: 1 week
	1c. Outreach and education in communities identified with a lack of applicants and/or representation.	1c. Second month of evaluation, then annually (if applicable)	Program staff: Ongoing
	1d. Meet with key stakeholders and advisory committee to discuss scholarship restraints and solutions.	1d. Month 3-5 of evaluation, then annually (if practical)	Lead evaluator, assistant evaluator, program staff, key stakeholders, advisory committee: 1-hour meetings as necessary
2. What did program participants find most useful about the Health Equity program, and what do they think could be improved?	2a. Have each cohort of program clientele participating in the training sign an informed consent form regarding the focus groups prior to training.	2a. In accordance with the admittance of each cohort poised to undergo program training	Program staff: Ongoing per cohort

— 3. Did program participants who underwent training find it culturally competent and of quality?	2b. Take pictures of vacant training spaces (if in person).	2b. First month of evaluation	Program staff: 0.5-1 hour
— 4. What is the impact on communities that program-trained participants serve?	2c. Conduct focus groups with therapists, supervisors, and trainers who have completed the program training.	2c. In accordance with the end of each program training	Lead evaluator, assistant evaluator: Ongoing per cohort, about 1 hour each
	2d. Clean, analyze, and interpret data.	2d. 1 month after each focus group	Lead evaluator, assistant evaluator: Ongoing per cohort, about 15 hours per week
	2e. Meet with key stakeholders to discuss findings and next steps.	2e. In accordance with the completion of each cohort report (~2 months after each focus group)	Lead evaluator, assistant evaluator, program staff, key stakeholders, advisory committee: About 2 hours per meeting
5. What is the impact of the treatment access fund to support clinics and patients, what could be improved?	5a. Meet with program staff to review relevant documentation to gauge the current state of the treatment access fund.	5a. First month of evaluation	Lead evaluator and program staff: 1-2 weeks
	5b. Have each clinician that utilizes the treatment access fund sign an informed consent form to eventually participate in an interview regarding the benefits and challenges they face with expanding access.	5b. In accordance with funds being disbursed to clinics	Program staff: Ongoing per contract of funds agreement

	5c. Inform clinicians about the purpose of the evaluation, conduct interviews, and partner for patient survey recruitment.	5c. 2-4 months after funds have been disbursed	Lead evaluator and assistant evaluator: Ongoing per fund disbursement, about 1-2 hours per meeting and interview
	5d. Clean, analyze, and interpret data.	5d. 1-2 weeks after interview, ongoing with survey data	Lead evaluator and assistant evaluator: Ongoing per interview, about 8 hours per week
	5e. Meet with key stakeholders to discuss findings and next steps.	5e. Ongoing within other reports, depending on how many interviews are conducted within the evaluation	Lead evaluator, assistant evaluator, program staff, key stakeholders, advisory committee: About 30 minutes within meeting for other reports
6. What do staff think the program is doing well, and what could be improved?	6a. Meet with program staff to discuss purpose of evaluation and ask for their consent to participate in quarterly focus groups.	6a. First month of evaluation, and continually with new members of program staff	Lead evaluator and program staff: ~0.5-1 hour
— 7. Is the Health Equity Program functioning as intended? Is it efficient and sustainable?	6b. Conduct quarterly focus groups with program staff, in addition to periodic check-ins in case something comes up in between focus groups.	6b. First month of evaluation, check-ins ongoing	Lead evaluator and assistant evaluator: About 0.5-1 hour per focus group
	6c. Clean, analyze, and interpret data.	6c. Month 2-3 of evaluation	Lead evaluator and assistant evaluator: About 8 hours per week
	6d. Meet with key stakeholders to discuss findings and next steps.	6d. Month 3-5 of evaluation, then annually or as needed	Lead evaluator, assistant evaluator, program staff, key stakeholders, advisory committee: Variably between 0.5-2 hours as necessary

Evaluation Budget			
Personnel	Hourly rate	Hours	Annual Total
Lead evaluator (internal)	Salary	N/A	$88,000
Assistant evaluator (external)	$25	312 (6 hrs/wk for a year)	$7,800
Administrative assistant (external)	$20	208 (4 hrs/wk for a year)	$4,160
— (or) Lead evaluator handles administration			
TRAVEL	*BUDGET*		
Driving and flying	$5,000		$5,000
PRINTING	$200		$200
OTHER	*EXPENSE*	*USERS*	
Transcription software	$20 per user/mo	2	$480
— (and/or) Free if recorded and automatically transcribed through Zoom or similar software			
Data analysis software	$460/yr	2	$460
TOTAL			$106,100

Appendix D

[Cohort] Focus Group Interview Guide

Welcome

- Thank cohort for time and participation
- Introduction of lead evaluator, assistant evaluator, and what our roles are

Overview of the Evaluation and Topics

- State purpose of evaluation and topics
    - Introductions and backgrounds
    - Program opinions on current state and how to improve
    - Cultural competency
    - Community impact of their work

Ground Rules

- No wrong answers, all points of view are valid
    - Please feel free to share your perspective even if it disagrees with other participants
- Please respect the sonic space by letting others finish their point, while also being mindful of how much time your response is taking.
    - We encourage thorough answers, yet simply seek for the sonic space to be equitable between all participants — should all participants have something to say
- First name basis during the focus group but anonymity in reports and confidentiality

Questions and Probes

1. So, to begin, can we go around the group and have each of you introduce yourselves and how you learned about the program?
2. What were your first impressions of the program?
3. What were your experiences like during the training?

4. How does the program do in terms of culturally competent delivery?
    a. How did this affect your experience during the training?
5. What does the program do well, and what can the program do better?
    a. What did you find most useful, and what did you find ineffective?
6. How has your professional work impacted the communities you serve, and how do you think this training will affect that impact?
    a. Can you describe any instances where your clients inquired about participating in psychedelic-assisted therapy?
7. To conclude, is there anything else anyone feels is important to mention?

[Staff] Focus Group Interview Guide

Welcome

- Thank staff for time and participation
- Introduction of lead evaluator, assistant evaluator, and what our roles are

Overview of the Evaluation and Topics

- State purpose of evaluation in regard to program staff

Ground Rules

- No wrong answers, all points of view are valid
    - Please feel free to share your perspective even if it disagrees with other participants
    - No employment repercussions will result from this evaluation
- Please respect the sonic space by letting others finish their point, while also being mindful of how much time your response is taking.
    - We encourage thorough answers, yet simply seek for the sonic space to be equitable between all participants — should we all have something to say
- First name basis during the focus group but anonymity in reports and confidentiality

Questions and Probes

1. How are you all feeling about the work this program is doing?
    a. Do you feel like you're making an impact?
        i. What can be done to improve your working conditions?
2. What is the program doing efficiently, what are the strengths?
3. What is the program doing inefficiently, what are the weaknesses?
    a. What can be done to improve the program?
        i. Any ideas to enhance the processes towards our goals?

4. From what you see in your operations, is the program functioning as intended? If not, why?
    a. Any ideas to improve the function of those program aspects?
5. To conclude, is there anything else anyone feels is important to mention?

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