

# Ayahuasca research in the US: meeting FDA and DEA regulations



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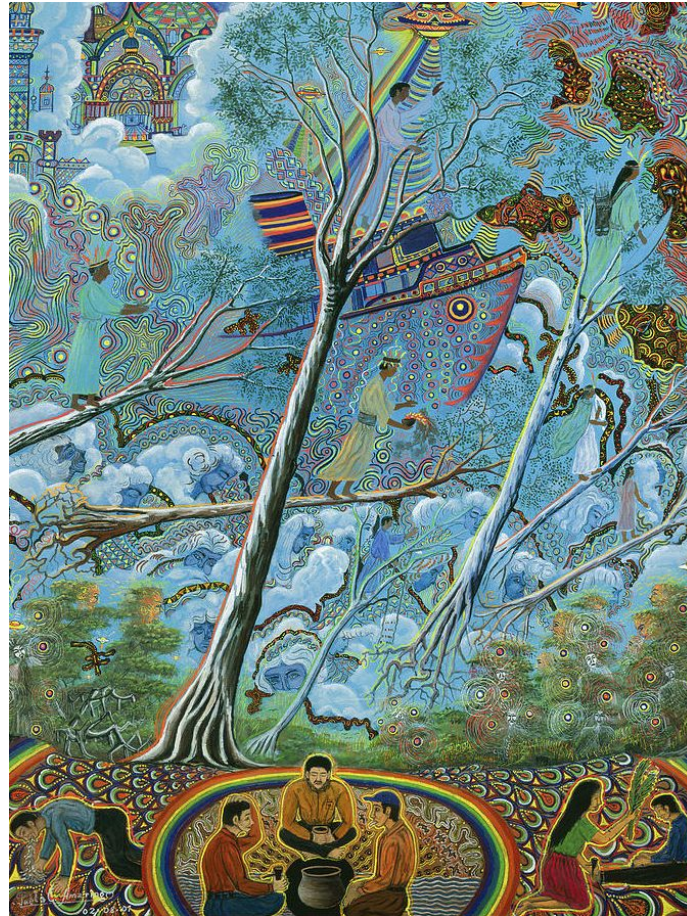
Seattle Washington

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2019 WORLD AYAHUASCA CONFERENCE

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How shall we proceed with impeccable scientific research of the sacred while respecting and honoring the indigenous healers in South America?



Pablo Amaringo

# My first ayahuasca experience in 1999 in Brazil

A direct experience of transcendence and the healing power of ayahuasca

Astonished awakening....



Dennis McKenna PhD



Luis Eduardo Luna PhD







How to bring the beauty and power of ayahuasca into a research environment while honoring and respecting the ancient wisdom and tradition.



## **GOAL since 1999**

To manufacture potent, standardized, stable ayahuasca tea suitable for a Phase I trial approved by the US Food & Drug Administration (FDA) and meets US Drug Enforcement Agency (DEA) security requirements

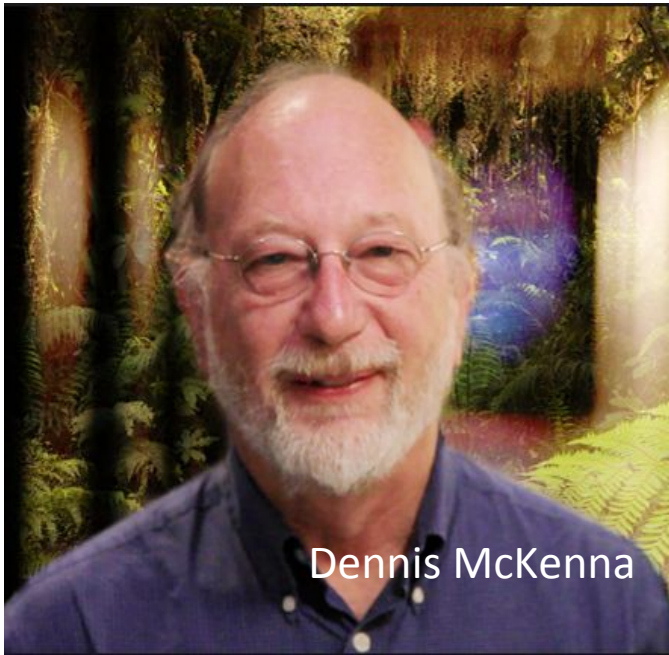
Make ayahuasca healing available to everyone who needs it.

# 12 critical steps towards the first clinical trial of ayahuasca in the United States



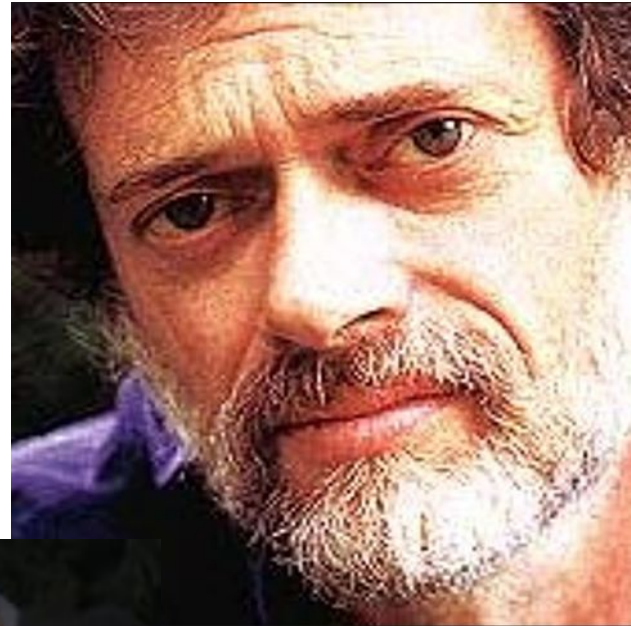
# STEP 1

Learn and study all things  
Ayahuasca....



Dennis McKenna

Terence McKenna



Kat Harrison



Ali Maya



Wayra

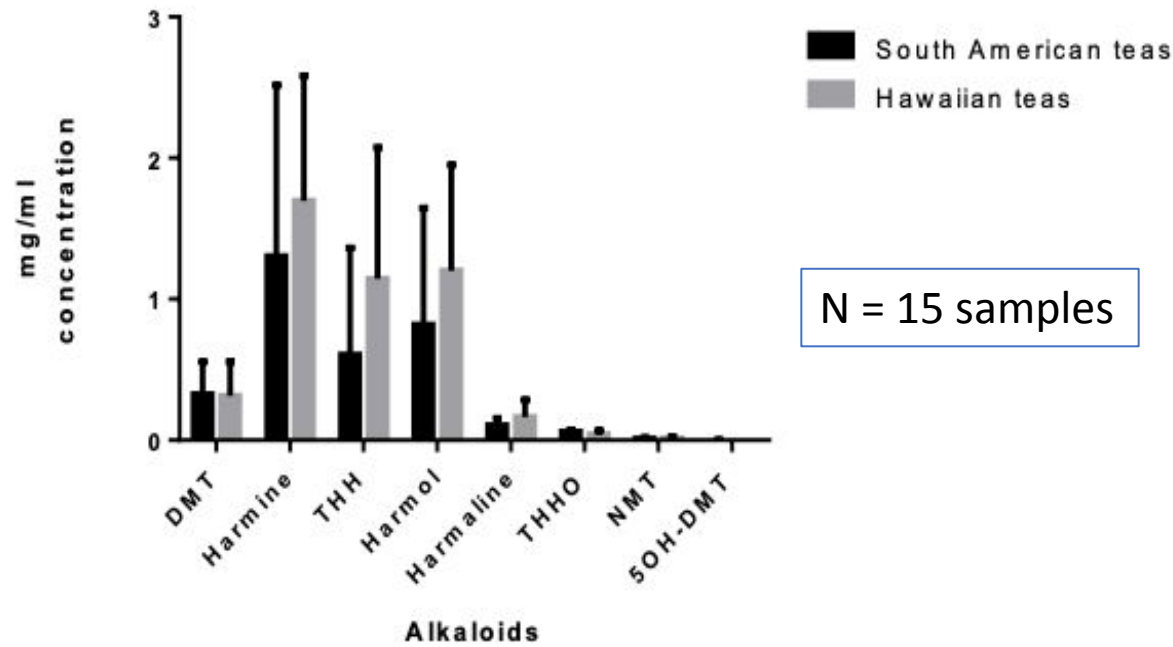


Eduardo Luna

# Collect ayahuasca tea samples from ceremonies conducted in Brazil, Peru and North America

Ayahuasca teas made in South America and Hawaii have similar DMT and Harmala alkaloid levels.

Concentration of Major Alkaloid Constituents in Ceremonial Ayahuasca Teas



DMT concentrations ranged from 0.28 – 0.78 mg/ml in concentration. There were no significant differences between the mean DMT concentration between teas made in South America (0.49 mg/ml + 0.17) and those made in Hawaii (0.48 + 0.14 mg/ml).



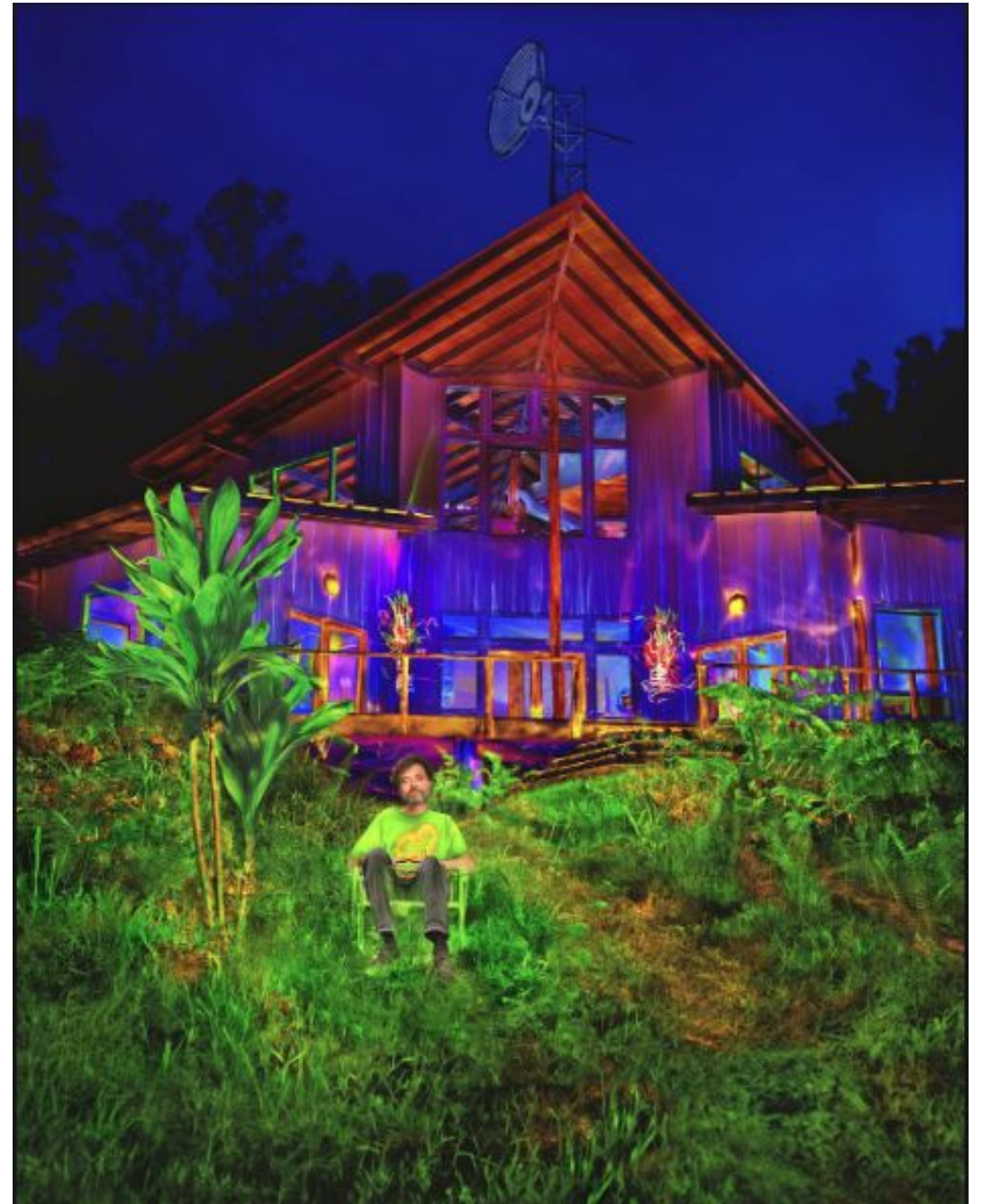
# Learn and do chemistry

Active alkaloid constituent	Callaway 1996 UDV church Ayahuasca tea single sample (mg/ml $\pm$ SD)	Mean $\pm$ SD of 15 ayahuasca tea samples made in S. America or Hawaii(mg/ml $\pm$ SD)
DMT	0.24	0.49 $\pm$ 0.14
Harmine	1.70	2.26 $\pm$ 0.83
THH	1.07	1.64 $\pm$ 0.52
Harmaline	0.20	0.21 $\pm$ 0.09

## STEP 2

Protect, grow and study  
*B. caapi* and *P. viridis*

FDA Good Agricultural  
Practices







Vines planted by Kat Harrison, Dennis and Terence McKenna in the late 1970s. Over 40 years old.





Vouchered by herbaria in Iquitos,  
British Columbia and  
Missouri Botanical Gardens





# Teach and learn from graduate students

Trevor Clark

Hayley Prescott

Leanna Standish



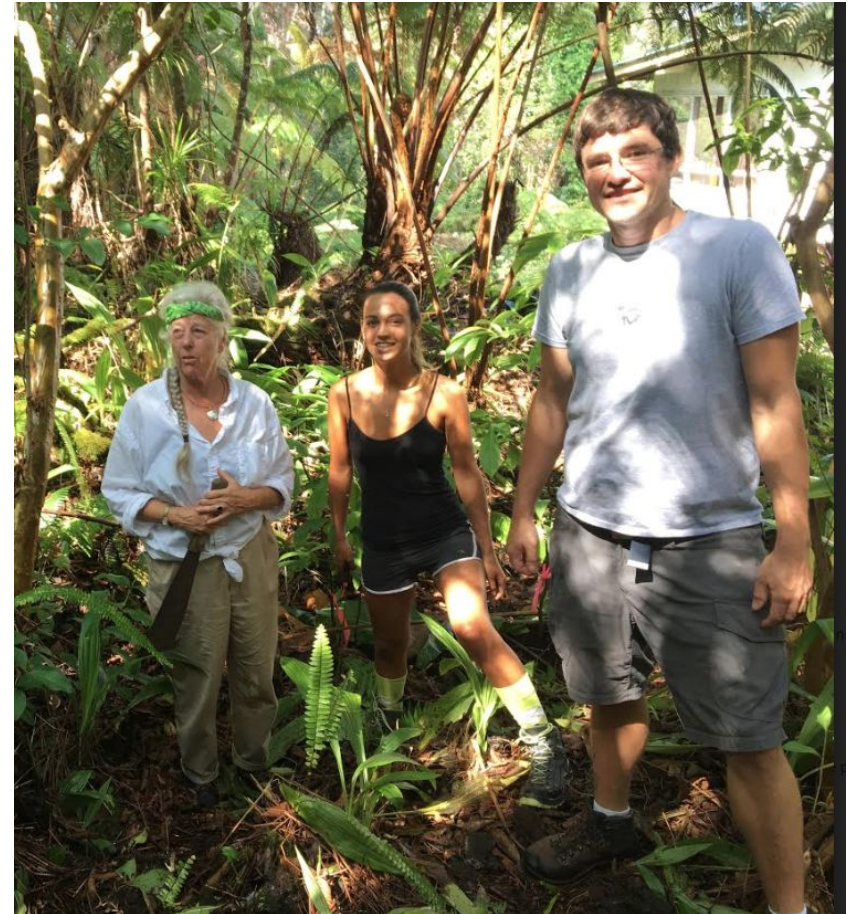
NIH T32 grant and Heffter  
Foundation grant  
for bench work at Bastyr  
University



Dr. Dawn Reardon

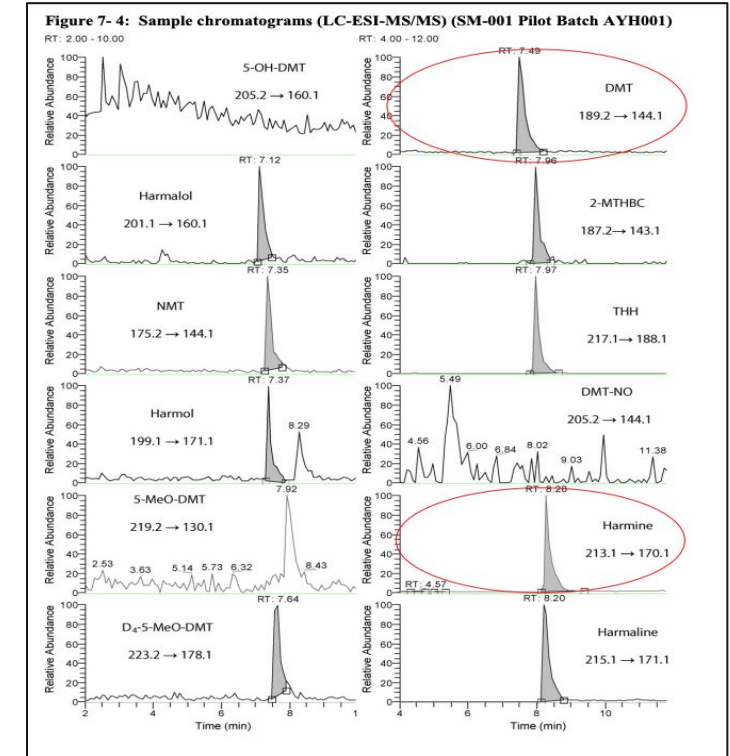


Rebecca Mains





# STEP 3 Make experimental batches of ayahuasca tea in a quantitative controlled laboratory setting with DEA oversight



100 ml autoclaved  
bottles

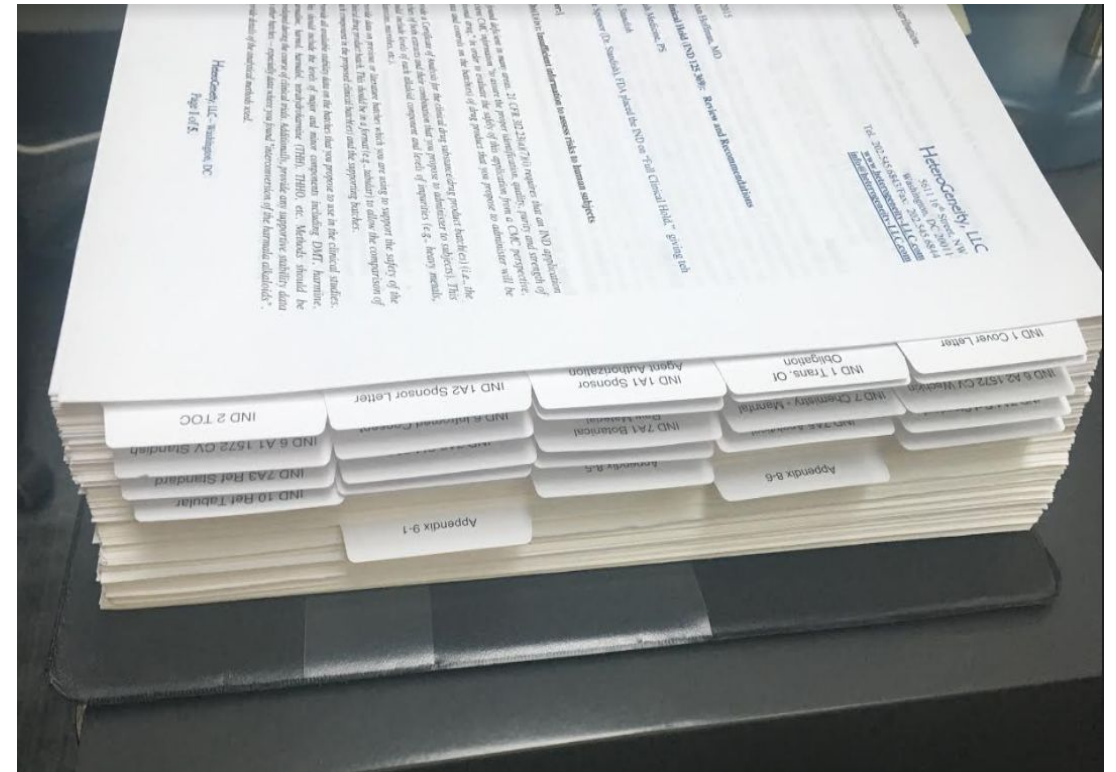




## STEP 4

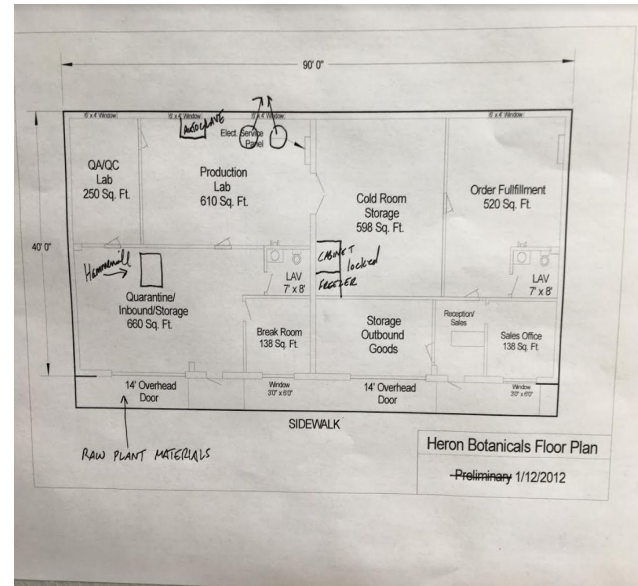
Obtain FDA approval for a Phase I trial for a specific formulation of ayahuasca tea using specific vouchered *B. caapi* and *P. viridis* cultivars

## Safety and dose finding study N = 12



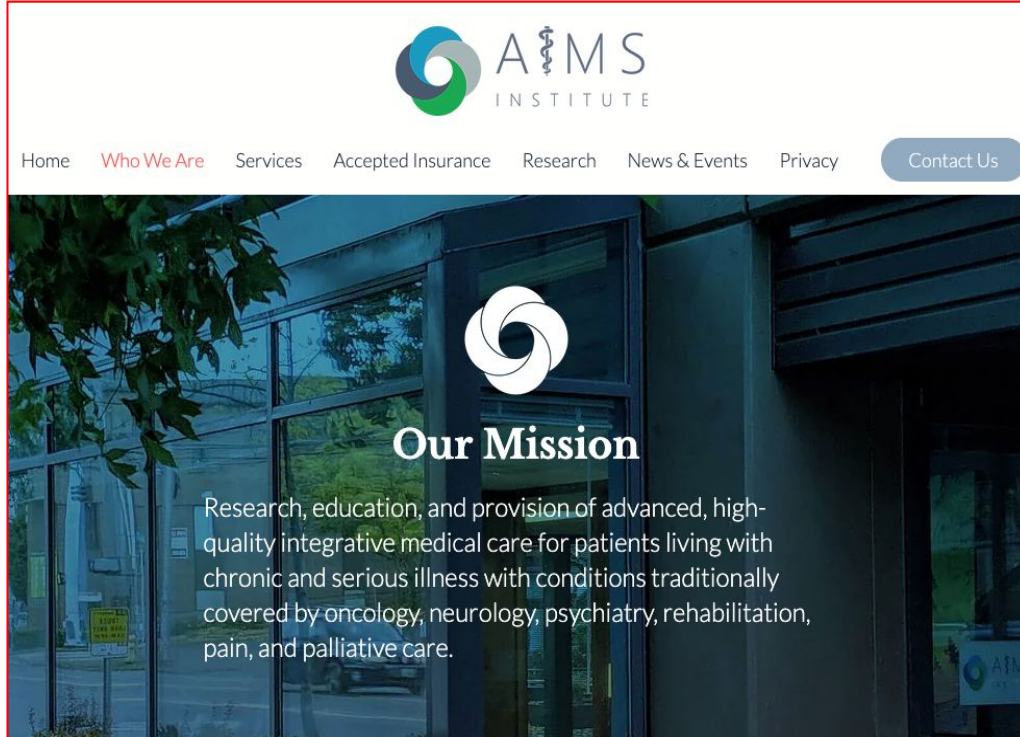
# STEP 5

Contract with a botanical manufacturing site in the US that meets FDA GMP regulations and could be modified to meet DEA security requirements (Heron Botanicals in Kingston Washington)



# STEP 6

Create a clinic where our ayahuasca trials can safely be conducted under IRB oversight with AIMS clinical staff who have been trained by MAPS (AIMS Institute in Seattle).

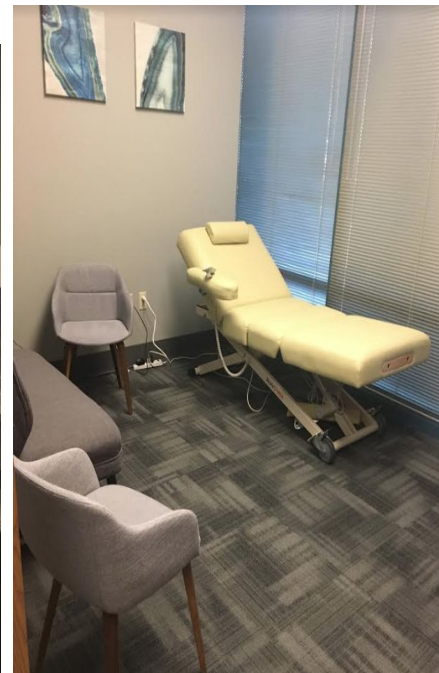
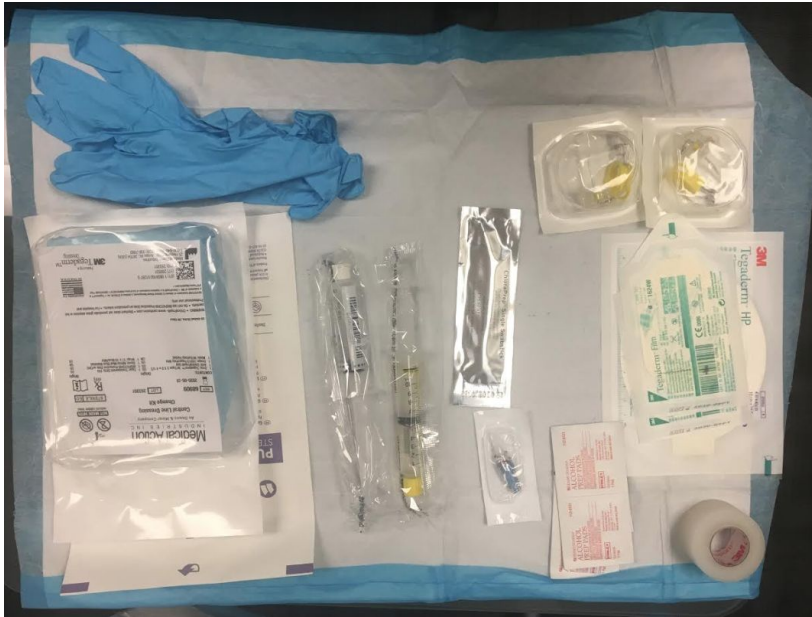


Nathan Schmidt ARNP  
Sunil Aggarwal MD, PhD

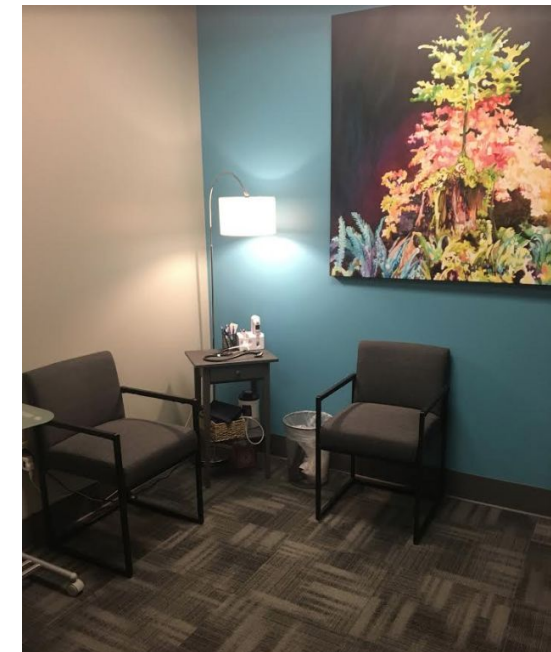
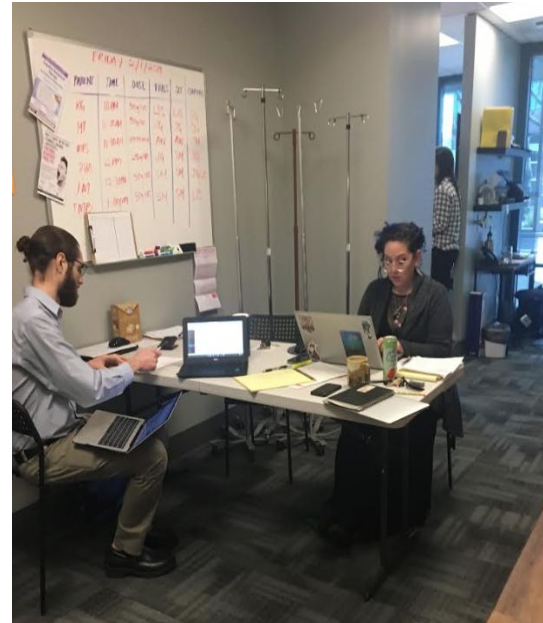


Angela Ward RN





AIMS Institute in Seattle



# First 6 steps accomplished. It only took 20 years.

1. Growing and harvesting the sacred plants in the U.S. that meet Good Agricultural Practices (Hawaii)
2. Learning from ayahuascaros how to make a potent ayahuasca tea (Brazil, Peru, Hawaii)
3. Making experimental batches of ayahuasca tea in a quantitative controlled laboratory setting with DEA oversight
4. Obtaining FDA approval for a Phase I trial for a specific formulation of ayahuasca tea using specific vouchered *B. caapi* and *P. viridis* cultivars (Standish Medicine in Seattle)
5. Contracting with a botanical manufacturing site in the US that meets FDA GMP regulations and could be modified to meet DEA security requirements (Heron Botanicals in Kingston Washington)
6. Creating a clinic where our ayahuasca trials can safely be conducted under IRB approval with AIMS clinical staff who have been trained by MAPS (AIMS Institute in Seattle).

# STEPS 7-12 are next...

7. Obtain DEA manufacturing license application, which entails modifications to the botanical drug manufacturing and laboratory site and a DEA inspection
8. Conduct R&D small-scale to large-scale production of our standardized botanical drug (Heron Botanicals)
9. Contract with FDA and DEA approved outsourced labs for pre-clinical toxicology studies
10. Submit the pre-clinical toxicology data to the FDA
11. Complete the Phase I safety and dose finding study to be conducted at AIMS Institute in Seattle
12. Publish the trial results and obtain FDA approval for the Phase II trials.



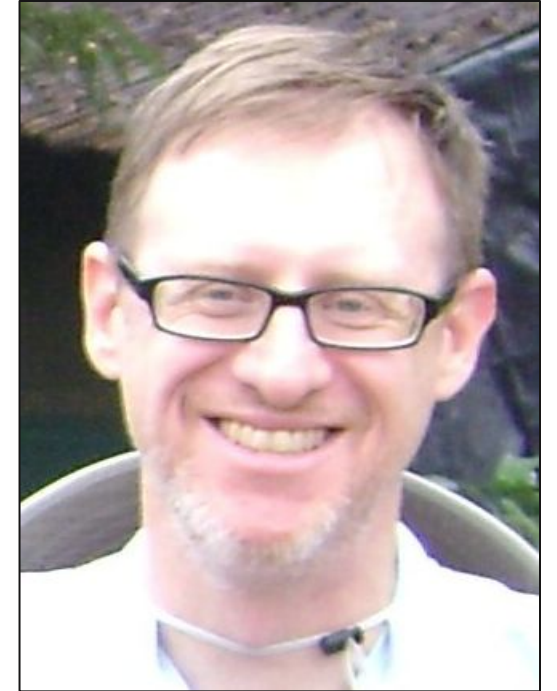
Victoria Hale, PhD



Sunil Aggarwal, MD, PhD



Eric Yarnell, ND



THE DREAM TEAM

\$50,000 grant from Seattle lawyer  
Robin Wechkin and Microsoft's Bill Bolosky to MAPS  
to support this work



We will need to raise millions of dollars to finish the Phase I trial.

Donate to MAPS to support this work!

<https://tinyurl.com/ayascience>

