

5 CONSIDERATIONS FOR IDENTIFYING PATIENTS FOR YOUR PSYCHEDELIC STUDY

So, you have a psychedelic investigational product, and now you're working on your patient entry criteria? Here are five considerations to help keep your patients safe and collect the data regulators need:

1

Has the patient previously used psychedelics? If so, was it recreational or part of a formal clinical trial? If recreational, determine if usage over the last two years would be considered consistent with substance abuse. If consistent, exclude.

2

If that prior experience was in a medical setting, was it a positive experience? If not, they may not be a good candidate for a clinical trial. We recommend excluding potential participants who experienced worsening of mood, anxiety, or development of active suicidal ideation after previous medical use.

3

Be sure to carefully diagnose the illness under study and ensure there is adequate severity and stability of symptoms in order to measure a detectable change if one occurs from use of your product.

4

Also inquire about other psychiatric history the patient may have, as well as family history. We recommend excluding patients with any current (or lifetime) history of a psychotic disorder, bipolar disorder, or personality disorder.

5

Be mindful of other concomitant medications the patient is taking. Drug-drug interactions with psychedelics and other serotonergic agents are not yet well understood.

Of course, enrolling the right patients is just one part of your program. Running psychedelic trials in psychiatric indications is one of our specialties. [Check out our website](#) to learn more about our psychedelic expertise.

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