

# A Psychedelic Experience With CDISC

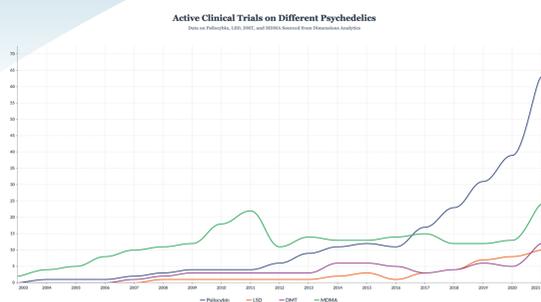


Martyn Deverell  
MAC Clinical Research

Craig Parry  
MAC Clinical Research

## 1 TIMELINES OF PSYCHEDELICS

Since the first psychedelic trial of LSD in 1943<sup>(1)</sup> the interest in what psychedelics do and how they can positively impact people's health is becoming more important. In recent years, there has been a huge increase in the number of clinical trials in psychedelic research.



Sources:  
(1) MAPS. (2014, April 15). First LSD Hallucination: April 16, 1943 - Multidisciplinary Association for Psychedelic Studies - MAPS. Multidisciplinary Association for Psychedelic Studies - MAPS. <https://maps.org/news/media/first-lsd-hallucination-april-16-1943/>  
(2) Fultrnavi@tks, U. (2022, May 27). Hope and hype: psychedelic drugs still to prove value in clinical trials. Clinical Trials Arena. <https://www.clinicaltrialsarena.com/features/psychedelic-clinical-trials/>

The majority of psychedelic trials are on Psilocybin<sup>(2)</sup>. This is mostly because of the minimal risk of toxicity and low potential for dependence or addiction. Due to the nature of psychedelics, the main benefit of their use is in treating mental health disorders such as depression.

The Drug Reform Policy released in 2021 means that psychedelic drugs are only legally permitted for psychedelic therapy within a clinical trial setting.<sup>(3)</sup>



[3] Dubley, P., & Dubley, P. (2023). United Kingdom's Psychedelic Drug Laws: How Soon Before There's Progress? - Tripsitter. In Tripsitter - Your guide to the responsible use of mind-expanding substances. <https://tripsitter.com/legal/uk/>

## 2 HOW DO PSYCHEDELICS WORK?

Most psychedelics fall into one of three families of chemical compounds: tryptamines, phenethylamines or lysergamides.

They all take action via serotonin 2A receptor agonism<sup>(4)</sup>. When these compounds interact and bind to serotonin receptors, they modulate the activity of key circuits in the brain involved with sensory perception and cognition.

To put it simply, psychedelics induce a heightened state of consciousness characterised by a hyperconnected brain state.

Sources:  
(4) Nichols, D. E. (2016). Psychedelics. Pharmacological Reviews, 68(2), 264–355. <https://doi.org/10.1124/pr.115>



## 3 DATA CAPTURE

How do we measure the effectiveness of psychedelic compounds?

One word: **Questionnaires**

The range of questionnaires to be completed in a psychedelic study is vast and the amount of information collected can be challenging to map out.

### LIST OF QUESTIONNAIRES USED ON A PSYCHEDELIC TRIAL

9. PHARMACODYNAMIC AND EFFICACY ASSESSMENTS.....	74
9.1. Binding Integrity Questionnaire (Part A Only).....	74
9.2. Pharmacodynamic Assessments.....	74
9.2.1. Spielberg's State-Trait Anxiety Inventory Trait Subscale.....	74
9.2.2. Warwick-Edinburgh Mental Well-being Scale.....	74
9.2.3. Post-treatment Changes Scale.....	74
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9.2.7. Social Connectedness Scale - Revised (Part B Only).....	75
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9.3. Acute Subjective Pharmacodynamic Assessments.....	75
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### EXAMPLE QUESTIONNAIRE CRF PAGE FROM A PSYCHEDELIC TRIAL

## 4 CONTROLLED TERMINOLOGY

A commonly seen questionnaire is the Columbia Suicide Severity Rating Scale (C-SSRS), specifically the Baseline/Screening questionnaire. CDISC defines the questions with labels and codes.

Under the current CDISC limitations, there is a 40-character limit, meaning the values must be restricted and shortened when compared with the question asked on the CRF (which is the same for most questionnaire code lists). With the addition of a prefix being required to the question, as seen on the screenshot below, this character limit is further reduced.

Due to the character limit, the question is abbreviated and as a result does not explain the original question particularly well.

This also leads to the question of "should we follow the same naming process for code lists not defined by CDISC to ensure consistency?"

A key issue in being limited to 40 characters or less is that abbreviated text can cause confusion leading to inaccuracies.

### CODED CODE LIST FOR THE COLUMBIA SUICIDE SEVERITY RATING SCALE (C-SSRS)

CSS04TC (Columbia-Suicide Severity Rating Scale Baseline/Screening Version Questionnaire Test Code)				
NCI Code: C106661, Codelist extensible: No				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C106707	CSS0401A	CSS04-Wish to be Dead-Life	Columbia-Suicide Severity Rating Scale Baseline/Screening Version - Have you wished you were dead or wished you could go to sleep and not wake up? (Lifetime).	C-SSRS Baseline/Screening Version - Wish to be Dead (Lifetime)
C106708	CSS0401B	CSS04-Wish to be Dead-P_M	Columbia-Suicide Severity Rating Scale Baseline/Screening Version - Have you wished you were dead or wished you could go to sleep and not wake up? (Past _ Months).	C-SSRS Baseline/Screening Version - Wish to be Dead (Past X Months)
C106709	CSS0401C	CSS04-Wish to be Dead, Describe	Columbia-Suicide Severity Rating Scale Baseline/Screening Version - Description of wishing to be dead.	C-SSRS Baseline/Screening Version - Description of Wish to be Dead
C106710	CSS0402A	CSS04-Non-Spec Suicid	Columbia-Suicide Severity Rating Scale	C-SSRS

## 5 CDISC QUESTIONNAIRES, RATINGS & SCALES

The CDISC Questionnaire, Ratings and Scales or QRS team are a group of volunteers who investigate how the series of questions, tasks or assessments used to provide a qualitative or quantitative assessment of a clinical concept or task-based observation is being mapped. Anyone can suggest a new QRS Supplement by filling in a QRS Supplemental Request Form.

The website provides guidance and resources to aid in the production of both Tabulation Datasets (including SDTM) and the Analysis Datasets (such as CDISC ADaM). Additionally, and specifically with the SDTM datasets there are further resources showing

an example CRF, illustrating how particular questions from a specific questionnaire are typically displayed. CDISC even includes supplemental domain (SUPP--) examples, when applicable, for those fields which may not be captured by the parent domain, i.e., QS or RS. Having further examples based on Psychedelic trials from the QRS team would be a massive help.

The creation of a psychedelic trial therapeutic area user guide (TAUG) would be a great aid to the programming community. Additionally, removing the 40-character limit would likely improve understanding.

### A SCREENSHOT OF THE CDISC QRS SUPPLEMENTAL FOR THE 10-METER WALK/RUN QUESTIONNAIRE

## 6 CONCLUSION

With recent developments in CDISC and the rise in psychedelic trials, we are likely not far from a psychedelic-specific therapeutic area user guide (TAUG).

This would result in more information around the lesser-known questionnaires thus aiding the mapping from raw data to the CDISC standards and improving the overall data mapping process and results.

Other potential risks to consider:

- > Questionnaire fatigue skewing results
- > High drop-out rates from trials