efpia
European Federation of Pharmaceutical Industries and Associations

Clinical Development of Psychedelics for Psychiatric Disorders

Author: Date:






Industry Perspective
Nanco Hefting & Guy Goodwin

EFPIA Industry Perspective

EFPIA is committed to working with all stakeholders to close the competitiveness gap with other regions of the world, while taking action now to create faster, more equitable and sustainable access to medicines.

- **The EFPIA Clinical Research Expert Group (CREG) collected input from a number of companies developing psychedelics:**
  - Compass Pathways – Guy Goodwin
  - ATAI Life Sciences
  - Cybin
  - GH Research
  - Reunion Neuroscience
  - Daniel Umbricht
  - MindMed
  - Gilgamesh

Guidance for the development of drugs producing a psychedelic experience for treatment of psychiatric disorders

- Definition of an acceptable comparator for all stages of drug development
- Definition of the **minimum** individual support necessary to provide for safety during drug administration
- The collection of adverse effects in trials with different psychedelics

Definition of an acceptable comparator for all stages of drug development

- **The psychedelic experience is inherently unblinding and impossible to match by an "inert" drug**
  - Especially if patients have previous psychedelic experience
- **Likelihood of functional unblinding may bias interpretation of efficacy, which could potentially be mitigated by the inclusion of alternate or additional control conditions**
  - Comparison across multiple dose levels may provide a convincing argument for efficacy
- **If, as appears in multiple studies, the subjective effects of the acute experience are predictive of outcome, such a finding is supportive of an additional dose-related effect**

Definition of the individual support necessary to provide for safety during drug administration

- The psychedelic experience is inimical to interactive psychotherapy
- Most drug development programs do not include structured psychotherapy
- Ensure consent to treatment includes adequate pre-administration information about the psychedelic experience
- Define (manualize) the minimum support model for the trials and train support staff accordingly
- Recognize a wide range of backgrounds for support staff compatible with the core competence to provide individual support of the acute experience
- Do not include psychotherapeutic efforts in the sessions that follow drug administration

The collection of adverse effects during trials with psychedelics

- **The ICH definition of an adverse event as untoward medical occurrence**
  - Psychedelic experiences are not necessarily untoward
- **Document acute experience with either a suitable scale (though no single scale is yet available), or capture by verbatim and report. Untoward events should be captured as Adverse Events**
  - Sponsors may define and report Adverse Events of Special Interest (AESIs) related to psychedelic experiences
  - Follow-up on psychedelic experiences is advised to ensure safety
- **A few patients have terrifying psychedelic experiences which may be, or lead to untoward occurrences**
  - These should be recorded as (S)AEs and followed-up as per standard safety monitoring

efpia

European Federation of Pharmaceutical Industries and Associations

Thank you