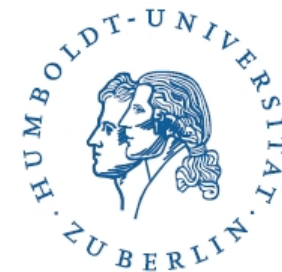


# What can patient and public involvement in research contribute to safe and effective use?

Prof. Dr. Isabel Dziobek



Deutsches Zentrum für  
Psychische Gesundheit



## **Conflict of Interest**

Researchs Funding: BMBF, BMWK, DFG, TBDF

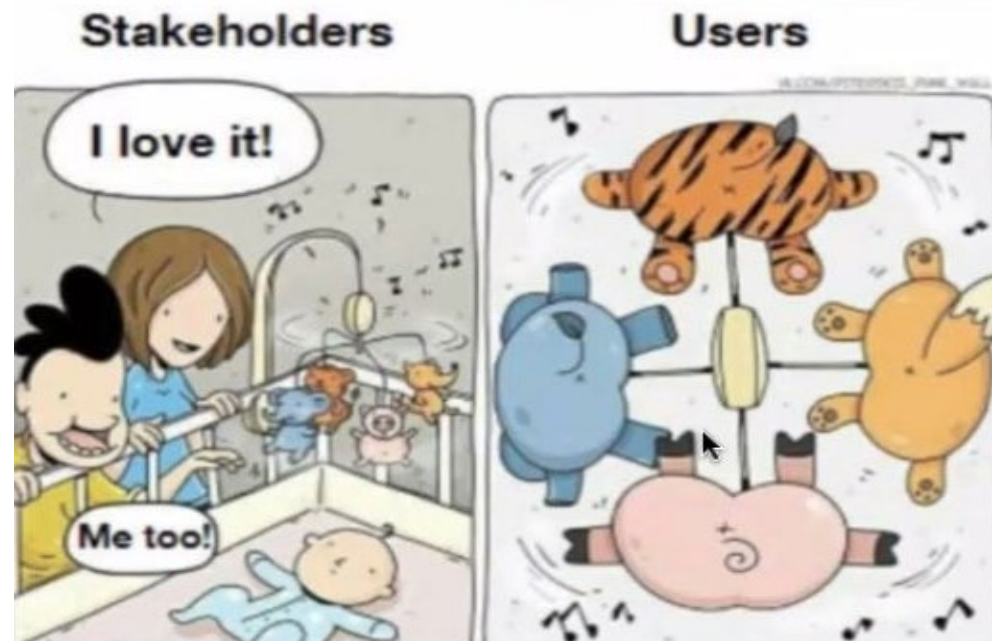
Lectures: no industry honoraria

Consultancy: none

Shares: none

## Patient and Public Involvement (PPI)

- Academic research typically conducted with no/very little involvement of patients and the public
- Lost opportunity to improve validity, quality and accountability of clinical research
- Rising ethical standards are changing power imbalance between researchers and experts by experience



# Patient and Public Involvement (PPI)

What is PPI?

- Research that is done WITH or FROM people with lived experience and not just about or for them. INVOLVE, 2012
- Study participation  $\neq$  participatory research



**Stage Model of Participation**

Level 9	Community-Owned Initiatives	<b>goes beyond participation</b>
Level 8	Decision-making Authority	<b>Participation</b>
Level 7	Partial Delegation of Decision-making Authority	
Level 6	Shared Decision-Making	
Level 5	Inclusion	<b>Preliminary Stages of Participation</b>
Level 4	Consultation	
Level 3	Information	
Level 2	Instruction	<b>Non-Participation</b>
Level 1	Instrumentalization	

**Figure 2: stage model of participation by M. T. WRIGHT [16]**  
Following the levels of participation of WRIGHT, real

## Reasons for PPI

- **Because it is ethically and legally indicated**

→ UN Convention of Rights of Persons with Disabilities, 2008

- **Because it makes science better**

→ identify topics of relevance  
→ better outcome measures  
→ Better recruitment, greater diversity  
→ fewer drop-out  
→ lower costs  
→ results reach communities  
→ better acceptance and accountability of research



- **Because it has positive effects on researchers and experts of experience**  
→ mutual respect through perspective taking  
→ new knowledge and skills  
→ self-confidence and empowerment

- **And also...**  
Recent calls and journal guidelines

- PPI has become new standard
- Essential criteria for research funding bodies
- Duty in governing organizations

## PPI in Psychedelic Research

- Almost no realizations of PPI in clinical trials on psychedelics
- Few exceptions: e.g. trials on psilocybin - ICL pilot study (AN), EPIsoDE trial (TRD), research on MDMA


Although application here especially appropriate...

- Safety, acceptance and accountability of research of utmost importance (abuse of power in early studies)
- Diversity low in clinical research on psychedelics
- Difficult access for minority groups
- Expectancy bias
- Patient reported outcomes especially appropriate (heterogeneity of experiences and adverse events)



# Guidance for PPI in psychedelic research

- Numerous Frameworks/tools to support PPI in general research
- However, psychedelic research needs tailored approach given special context/history:
  - complex socio-political landscape
  - rapidly changing drug policy
  - knowledge from traditions pre-dating modern research
  - social stigma associated with recreational use
  - 20-year hiatus in research

 **frontiers**  
in Psychiatry

ORIGINAL RESEARCH  
published: 30 September 2021  
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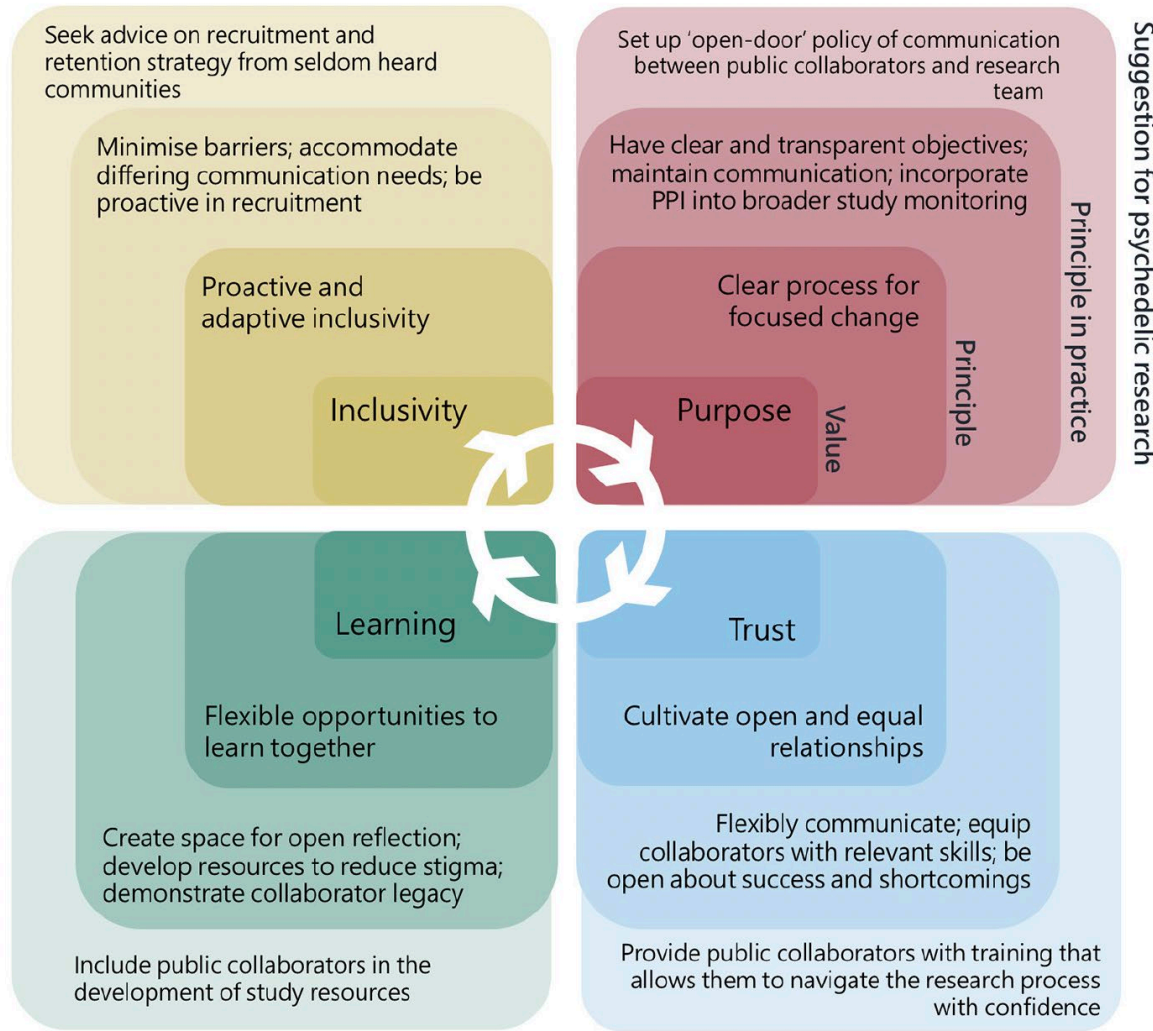
## Co-design of Guidance for Patient and Public Involvement in Psychedelic Research

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# PPI Framework for psychedelic research



*„Trust has long been placed at the center of guidance related to psychedelic research, in which participants are encouraged to “trust, open, and let go”.*

*In this context, the responsibility lies with the researcher to be trustworthy, rather than a participant to be trusting.*



**Thank you for your attention!**