

Improving support for neuropsychiatric clinical trial participants

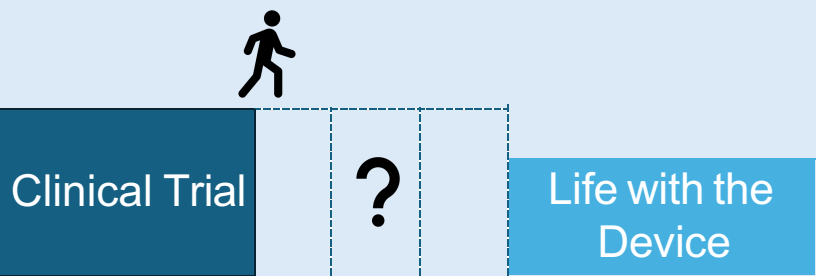
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BACKGROUND

Clinical trials for targeted brain stimulation devices are rapidly expanding for psychiatric and neurological indications such as Tourette Syndrome, traumatic brain injury, depression, and PTSD.

There has been increasing concern regarding patients' investigational device support needs after the trial ends, the issue of **post-trial support**.



AIM

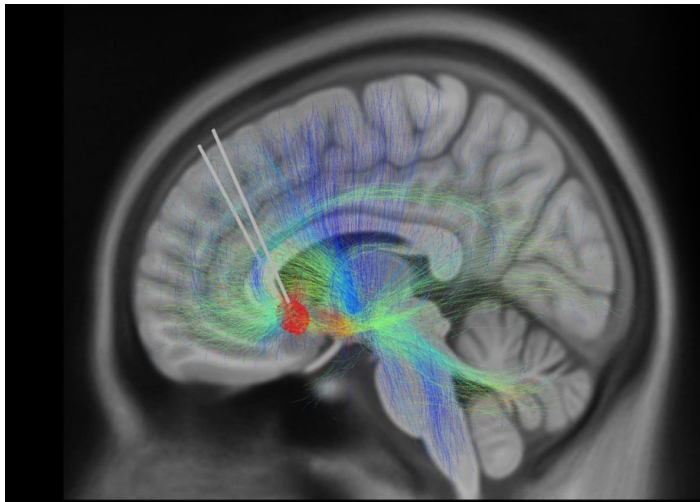
We are **engaging a wide range of stakeholders** involved in neural device research:

- Patients
- Support partners
- Researchers
- Regulatory experts
- Device companies
- Insurers

In order to:

- (1) **map the scope and impact of post-trial support gaps;**
- (2) **identify pragmatic strategies and policy suggestion** to improve long-term support for patients after the trial.

Neurostimulation like **deep brain stimulation** can offer significant relief to trial participants and their family members.



I've had over 95 percent reduction in my tics. So, I'm doing things that I never could have done before.

Trial participant · Tourette syndrome

Counting her tics has gone from how many per minute to how many she's had in the last month.

Support partner · Tourette syndrome

23 years of agony stopped on a dime.

Trial participant · depression

I have switched from barely surviving to living.

Trial participant · brain injury

"Anything I can do to get this approved and available to the world, I would do it. I will give time, I will give money. I'll do whatever needs to be done.

Support partner · brain injury

Gaps in **post-trial planning** across these trials that can lead to harms and burdens on those who participate in these trials after the trials end.

If I had some guidance or some help or something like that, I wouldn't feel so alone. I felt really alone in this. I was on my own in this.

Trial participant

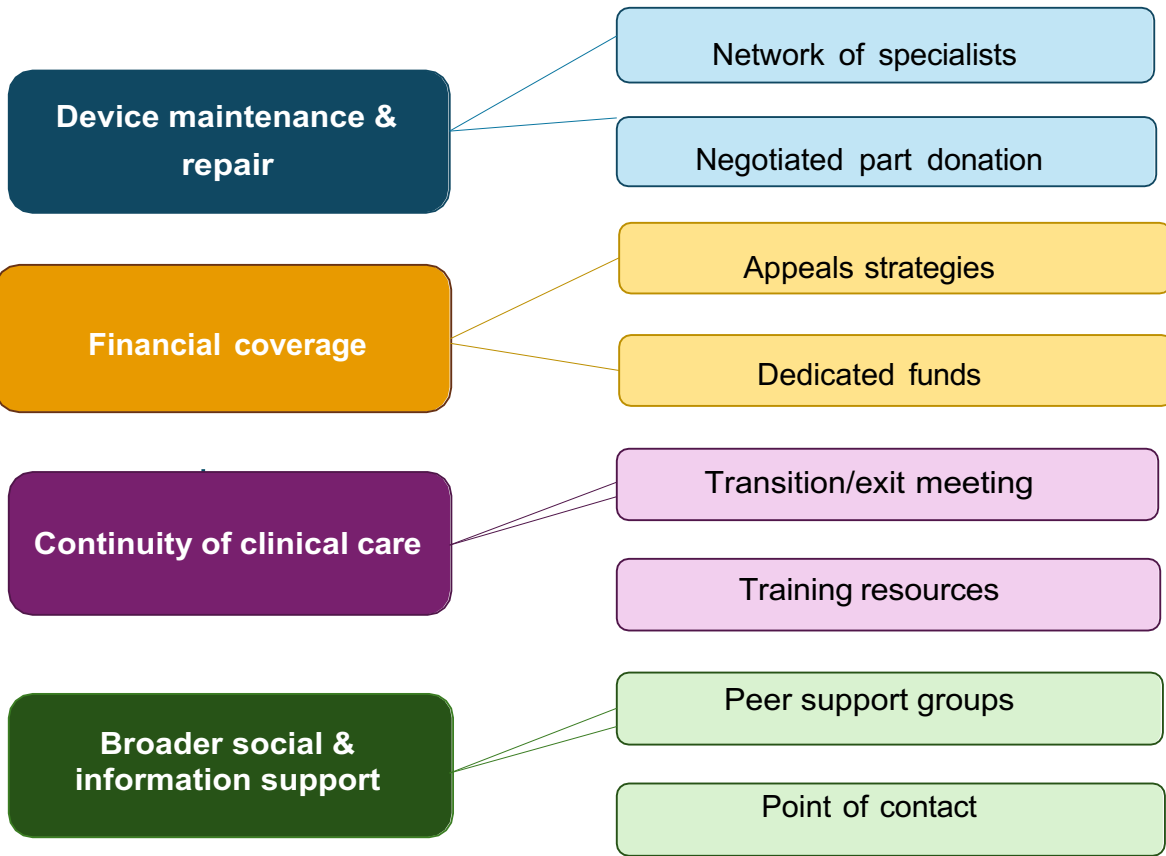
They almost need a navigator to help them. 'Okay, this is how it's going to be.'

Care partner

The company dissolved, and there was no device support, and the company actually told some of the subjects that they had to come in and be explanted. There's a trial, the company is financially unstable, if it dissolves, there's no money set aside, there's no support for patients who benefit."

Deep brain stimulation researcher

Interviews with >100 stakeholders across the neural device research ecosystem to map transitional support needs.



Invitations to Collaborate

- ▶ Seeking regulatory, patient advocacy, industry, & insurer **input to guide pragmatic policy & best practice suggestions.**
- ▶ Identifying potential **funding pockets that could help support patients' travel costs** to access specialized care.
- ▶ Brainstorming how we could **improve peer support avenues** for patients who participate in these trials & support partners.



Contact info here!



Find our lab website here!