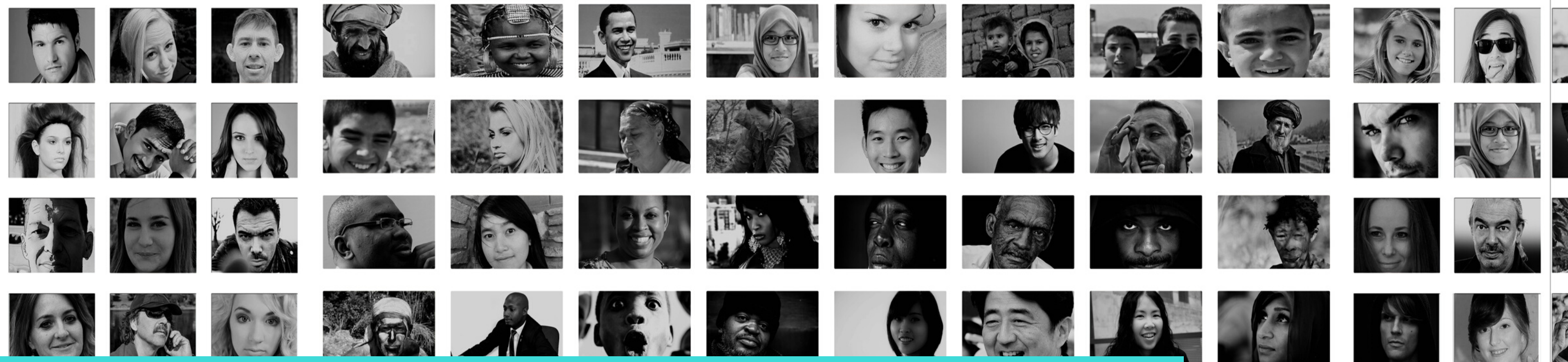




Many Happy Returns

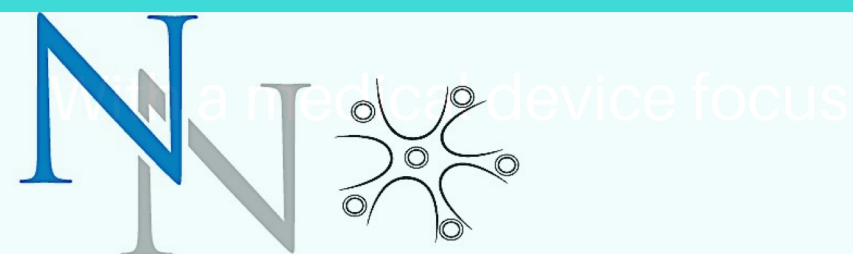
How engaging with patients/end-users can improve clinical execution and economics in neuromodulation development

April 22, 2020 @ 3pm EDT.



End-user Engagement

JENNIFER FRENCH



with a medical device focus

NEUROTECH NETWORK



WHY DOES IT MATTER?

Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations

FDA/CDRH Draft Guidance
September 2019.



Why Does It Matter?

FDA/CDRH Definitions Draft

D

Draft Guidance

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations>

Patient Engagement

E

"Intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations"

S

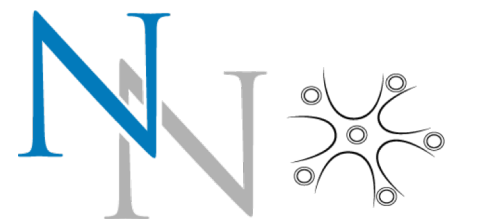
Subject/Research Participant

"Individuals who are or become a participant in research, either as a recipient of the test article or as a control."

Patient Advisor

A

"Individuals who have experience living with a disease or condition, and can serve in an advisory or consultative capacity to improve clinical investigation design and conduct, but who are **not** study/research participants themselves."



Why Does It Matter?

FDA/CDRH Pilot Program

C

CDRH Patient and Caregiver Connection Program - PCCP

Launched in 2019, this pilot program involves 14 condition-based organizations including caregivers

Program Direction

<https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-and-caregiver-connection>

D

P

Program Purpose

“...enhances CDRH’s ability to hear, understand, and integrate their perspectives in the course of its work.”

Patient Preference Information

<https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-preference-information-ppi-medical-device-decision-making>

I



Patient Science and Engagement Program Goals

Understand the patients' perspectives and proactively incorporate them into all our decisions and regulatory activities where appropriate		
Consistent Regulatory Review	Patient Engagement	Optimize Research Roadmap



Key Opinion Leaders

In-Depth Interviews with Program Leaders

F

Fredriech's Ataxia

C

**Creaky Joints
Global Healthy Living
Foundation**

P

**Parkinson's Foundation
Michael J. Fox
Foundation**

S

**North American Spinal
Cord injury Consortium**

Success Factors

Common Success Factors from Programs

E

Empowerment

Participants were prepared and empowered to participate

C

Clarity

Collaborators had a clear discussion about expectations, goals, roles & responsibilities on both sides.

T

Thoughtful

Careful consideration of when to engage the end-user perspective including language and timing.

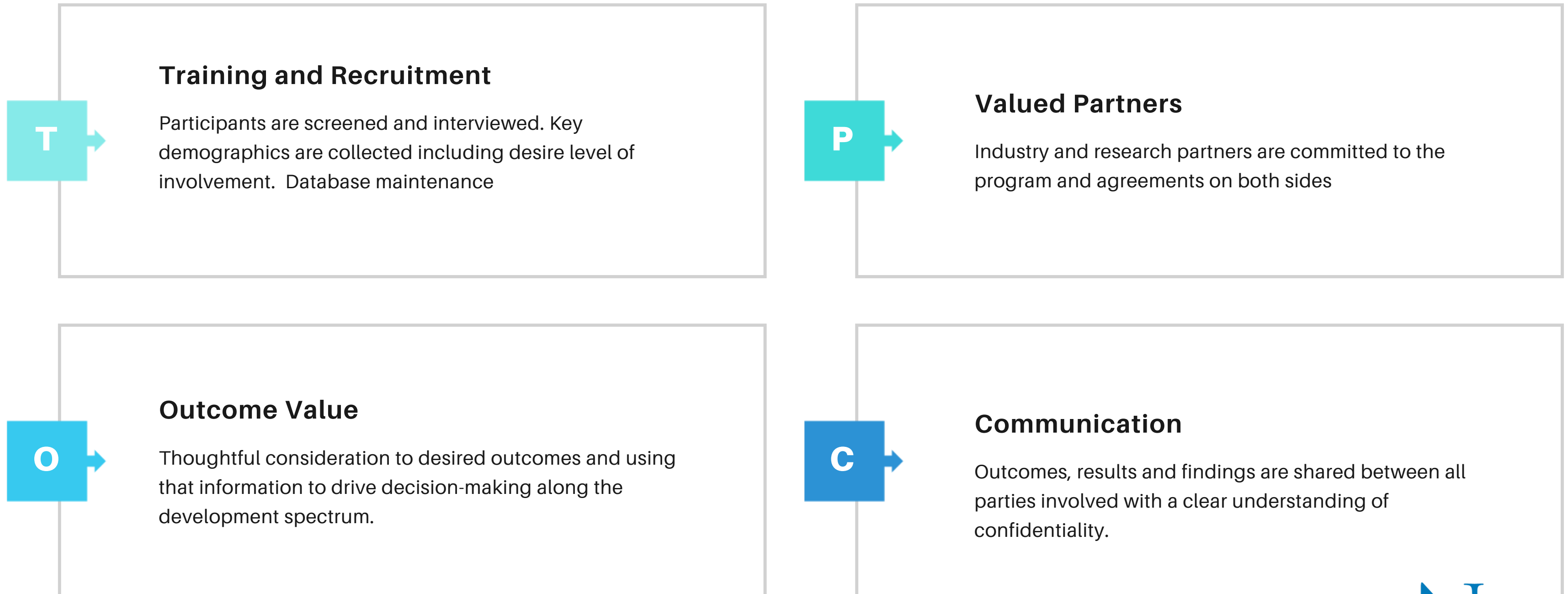
C

Communication

Timely communication of results to the end-user collaborators and feedback from the collaborators.

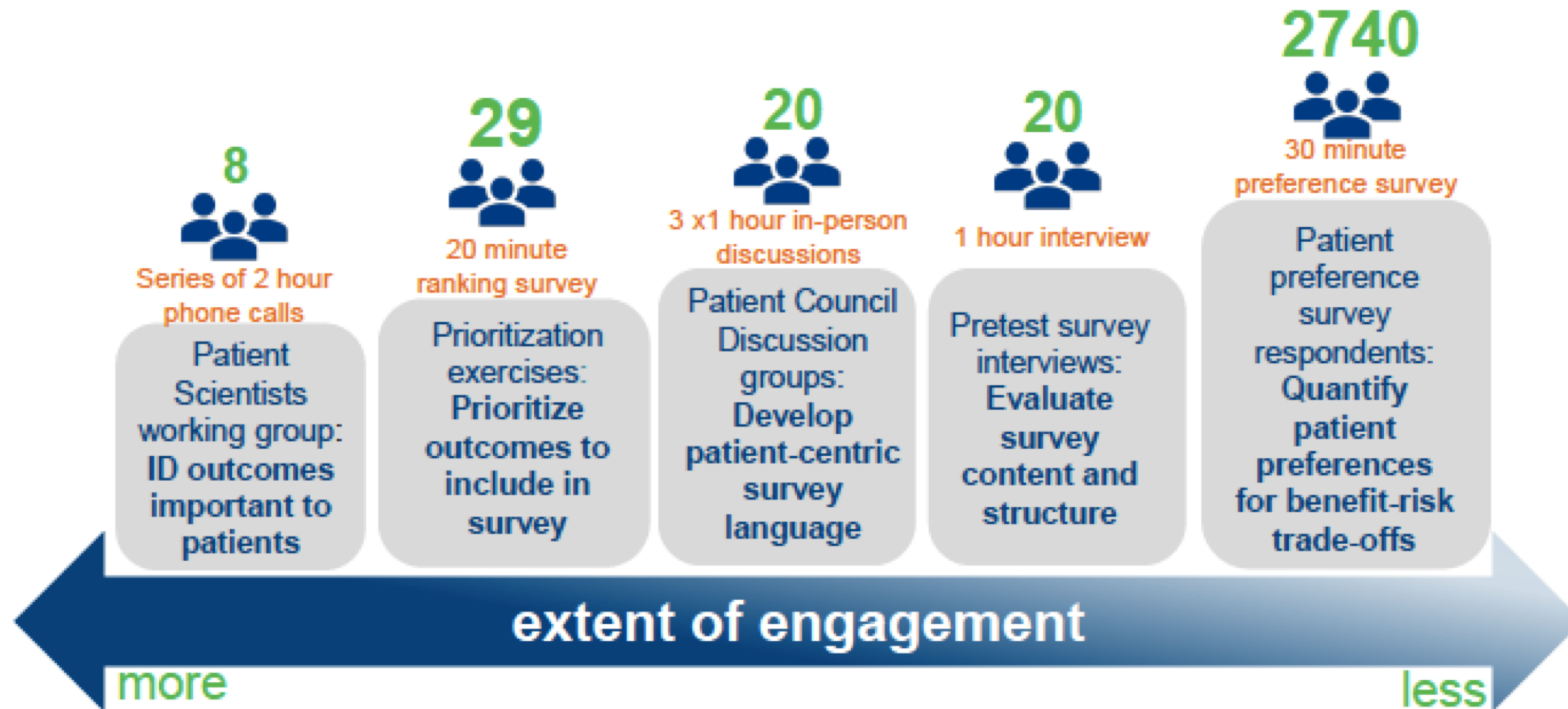
Key Components

For a good working relationship



Spectrum of Participation

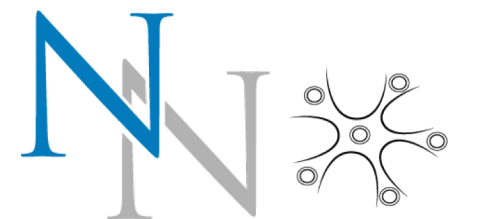
Courtesy of FDA/CDRH and MJFF





Engagement is Teamwork

Designing
Neuromodulation with the
End-user involved



Discussion Panelists



Blythe Karow

CEO, Evren Technologies



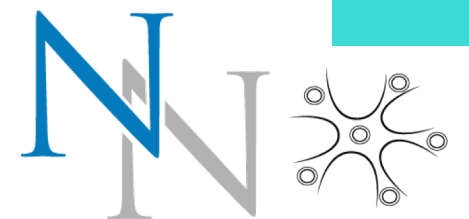
Yagna Pathak

Sr. Research Scientist, Abbott
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Learn More

**Helping the
Neuromodulation
Community embrace
Patient Engagement**

<https://www.patients-academy.org/>

<https://neurotechnetwork.org/>