

Patient Engagement in Clinical Trials: Key Considerations

January 9-10, 2018

CTTI Multi-Stakeholder Expert Meeting

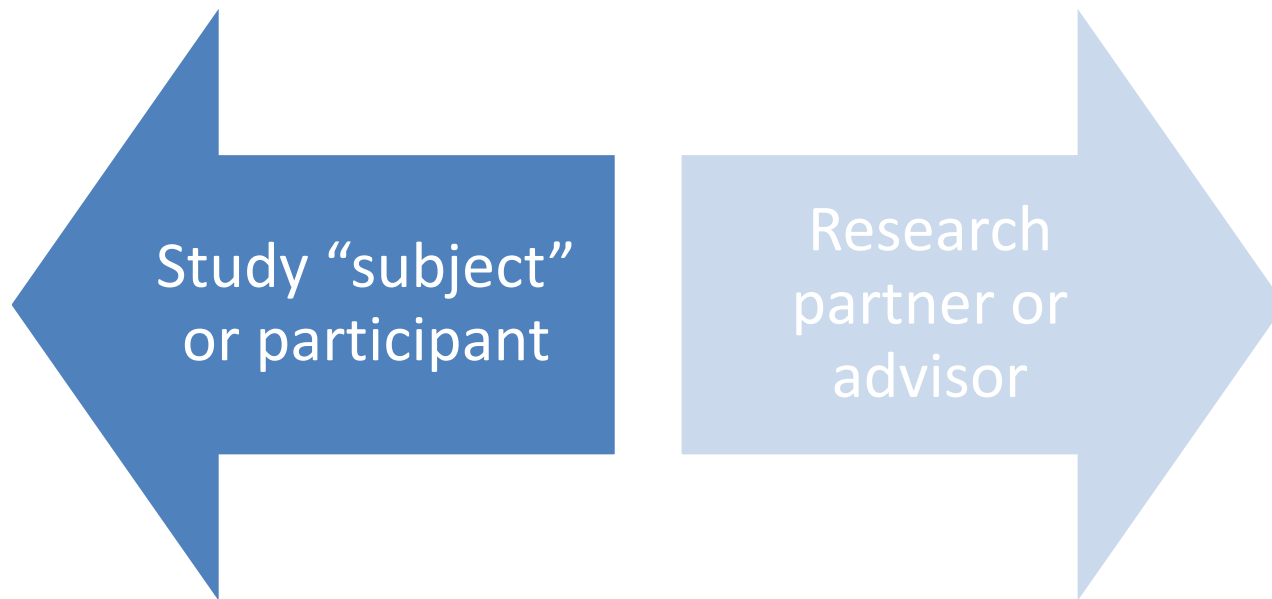
Bethesda, MD



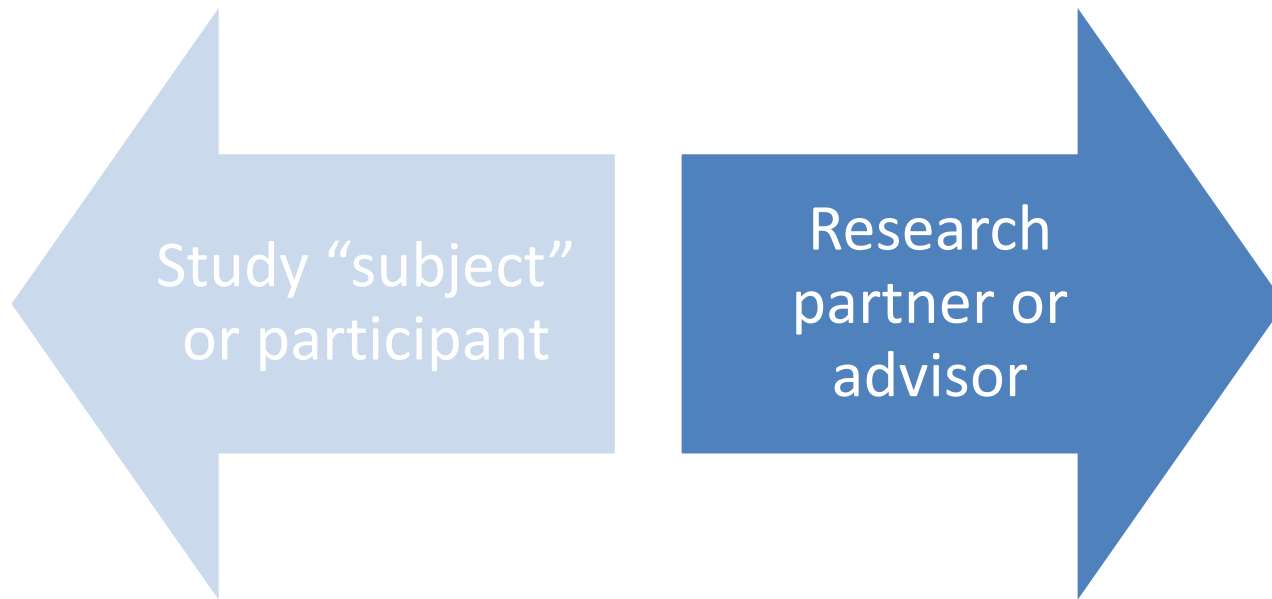
For our discussion

- Definitions
- Emerging promising practices
- Lessons from the field

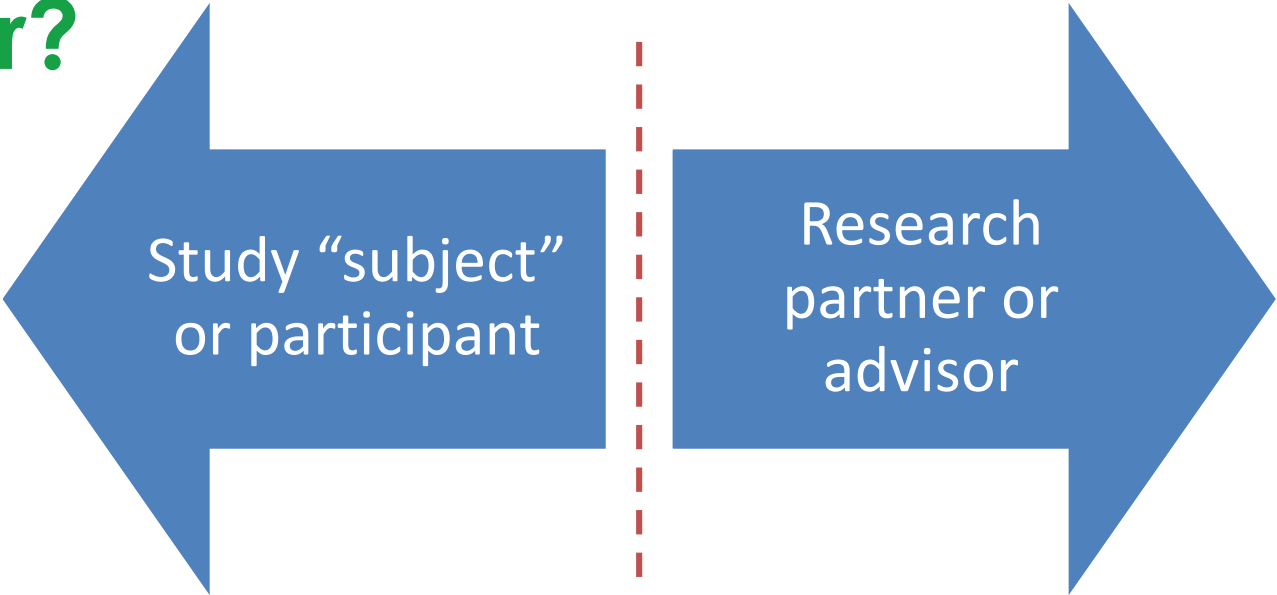
“Engagement” of *participants* in clinical trials



“Engagement” of *partners* in clinical trials



How do these types of engagement differ?



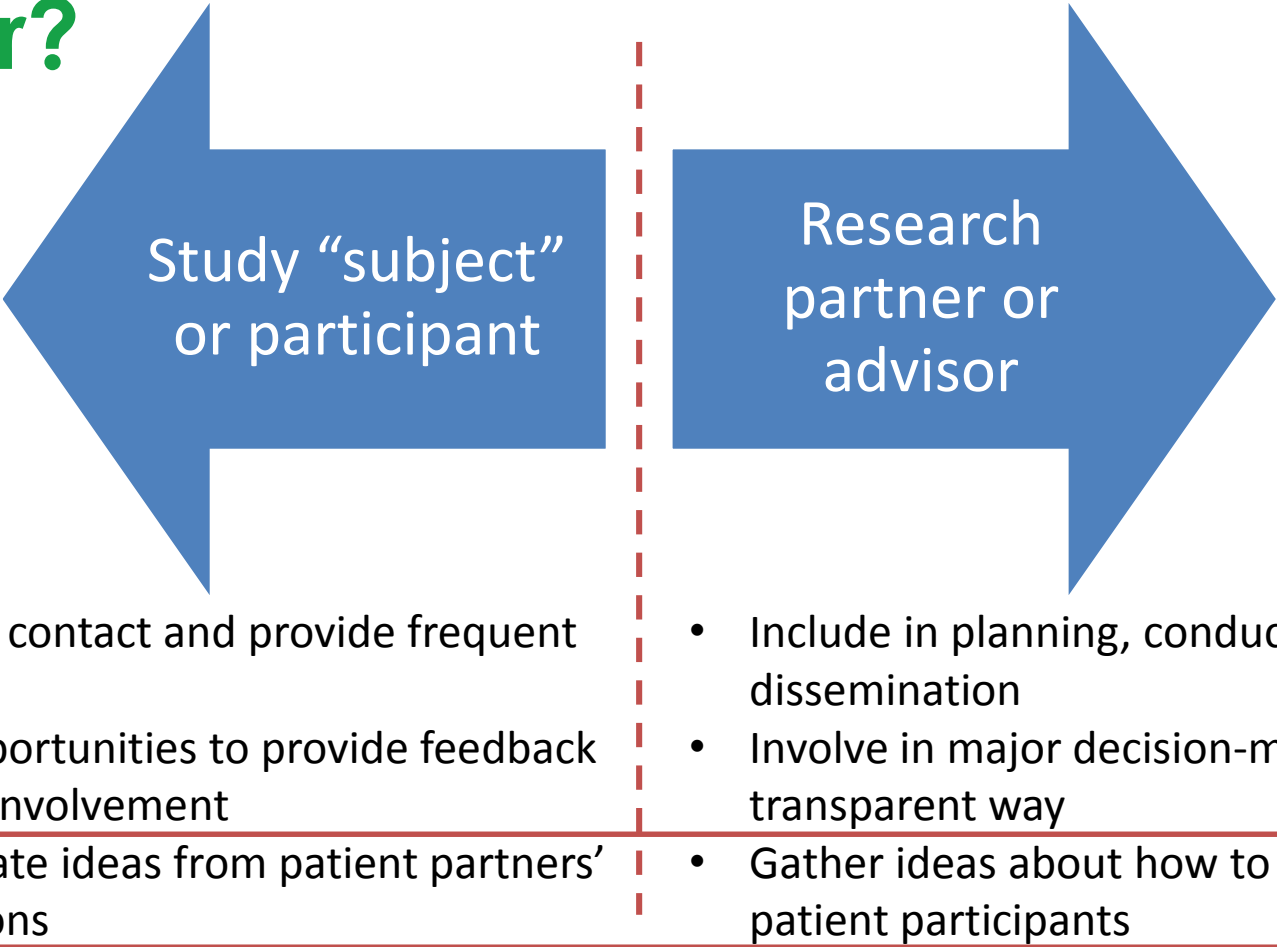
Study “subject”
or participant

- Maintain contact and provide frequent support
- Offer opportunities to provide feedback on their involvement
- Incorporate ideas from patient partners’ suggestions

Research
partner or
advisor

- Include in planning, conduct, and dissemination
- Involve in major decision-making in a transparent way
- Gather ideas about how to engage patient participants

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From theory to practice

- Start at the beginning—or before
- Engagement can happen in many ways
- Aim for iterative

Need a
survey

Key patient advisors suggest a broader mechanism for input

Draft

With the survey with the key patient advisors

Test

With patient committee

Revise

As relevant/warranted

Field

Looking through the
microscope: a cross-section of
engagement

Lessons from the field

- Start with the goal, not the rule
- Seek diversity
- Allow the right of first refusal
- “Train” bi-directionally
 - Patients: translate to be actionable information
 - Researchers/clinicians: translate to be understandable
 - Both: recognize and appreciate each other’s viewpoints



Turning to technology...

- Visual ability
- Dexterity/mobility/pain
- Empathy
- Access to my own data
- Profitability vs. privacy

Resources for promising practices in engagement

- PCORI/Patient-Centered Outcomes Research Institute (rubric, literature tool, results tool)
- PFMD/Patient Focused Medicines Development (<http://patientfocusedmedicine.org/wg-intro/>)
- NHC/National Health Council (rubric, guidances)
- FasterCures (<http://www.fastercures.org/programs/patients-count/science-of-patient-input-resources/>)

Mobile technology-specific engagement insights

- Mobile Apps (MAPPS): Patient and Caregiver Attitudes, Behaviors, and Knowledge
(<https://www.pcori.org/research-results/2012/pilot-project-creating-app-helps-stroke-survivors-and-their-caregivers#toc-abstract>)
- The DiabetesMine and #wearenotwaiting
(<https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting>)
- Development testing of mobile health interventions for cancer patient self-management: A review
(<https://www.ncbi.nlm.nih.gov/pubmed/25916831>)



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