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

Study “subject” or participant

Research partner or advisor
“Engagement” of partners in clinical trials

Study “subject” or participant

Research partner or advisor
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
Looking through the microscope: a cross-section of engagement

- **Need a survey**
- **Draft**
  - Key patient advisors suggest a broader mechanism for input
  - With the survey with the key patient advisors
- **Test**
  - With patient committee
- **Revise**
  - As relevant/warranted
- **Field**
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)
- NHC/National Health Council (rubric, guidances)
Mobile technology-specific engagement insights

- The DiabetesMine and #wearenotwaiting (https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting)