Decision Support Tool: Real Time Data Sharing with Study Participants

This decision tool is intended to support trial designers, working in partnership with patients, determine whether outcomes data collected should be shared with study participants in real time via the mobile technology. The questions are organized hierarchically to reflect the impact these issues may have on the safety, quality and feasibility of a typical study. However, this tool is not intended to be applicable to every trial, nor to be all-inclusive. CTTI recognizes that relative ranking of questions may vary according to the nature of the study and recommends that users freely adapt this tool to best meet their needs. For additional considerations pertaining to sharing data in real time, please reference Section IV-1 of the recommendations.

Is sharing and/or displaying data in real time part of standard care?

*Example: Use of a CGM in T1D*

- **NO**

Can participants, without clinician support or contextualizing information, understand the data?

*Example: An EKG wave vs. step count*

- **YES**

Are there clear instructions for and support available to participants who may notice nontypical or unexpected data?

*Example: An elevated heart rate*

- **NO**

Can this threat to internal validity be mitigated through study design?

*Example: Double-blind design to equalize any impact of behavior modifications across arms*

- **NO**

Are participants able and likely to modify their behaviors as a result of viewing snapshots or data in real time?

*Example: Low activity data motivating increased movement*

- **NO**

Does the target participant population expect that the data be shared with them in real time?

- **YES**

It is unlikely that it would be valuable to share data in real time with participants.

As long as trial integrity can be preserved, it is likely appropriate that data be shared in real-time with participants.