Case Study: Returning Value to Participants without Compromising Study Integrity

When mobile technologies are used in clinical trials, participants may bring expectations for being able to see their data in real-time. Yet in many regulatory-submission trials, providing real-time access to outcomes data can pose significant risks to study integrity.

While individual health data should often be shared in other ways—such as at pre-determined times during the trial while meeting with study staff—there may also be substantial value in sharing other types of information throughout the trial, as discussed in Recommendation II.8. The mPower study, launched in March 2015, provides one example.

This observational, smartphone-based study enrolled more than 15,000 participants in the first nine months. However, there was also a substantial drop-off in participation after seven weeks, and participants were submitting comments such as, "If you depend on us to partner with you in research, it would be good to give us feedback." In response, an infographic was prepared summarizing general information about the participant population and their responses to a feedback survey.
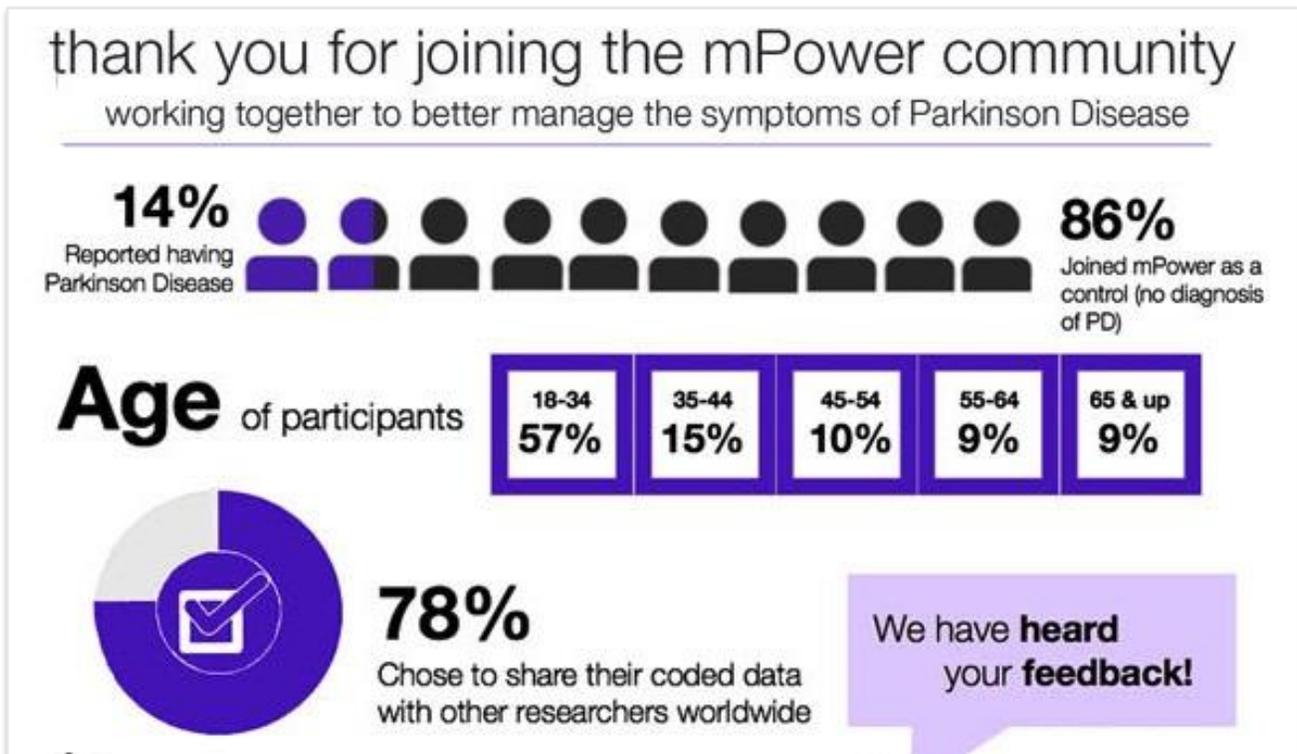

Image courtesy of Sage Bionetworks

A representative for the study noted that, after sending the summary, "We received love notes. It really doesn't take much to give back to people."

Other approaches that the study sponsor has taken to return value to participants include:

- ► After feedback is requested from study participants, returning a summary of that feedback.

- ► Implementing technology updates based on user requests (e.g., allowing more entries in a medication reminder calendar) and informing participants that changes were implemented in response to their suggestions.

- ► Using gamification to make required study activities engaging and fun for participants. As one mPower study participant noted, "Even though kids are the ones supposed to be playing games to learn, it makes it easier for adults too. It also makes it fun and makes me want to come back to finish the task every day..." Gamification may not be appropriate in all cases.

- ► Making it easy for participants to share their data (if they so desire) with other researchers.

The best options for returning value and health data may vary, and some approaches may not be appropriate for registrational trials. CTTI recommends engaging patient and site perspectives early and often during the planning process.