

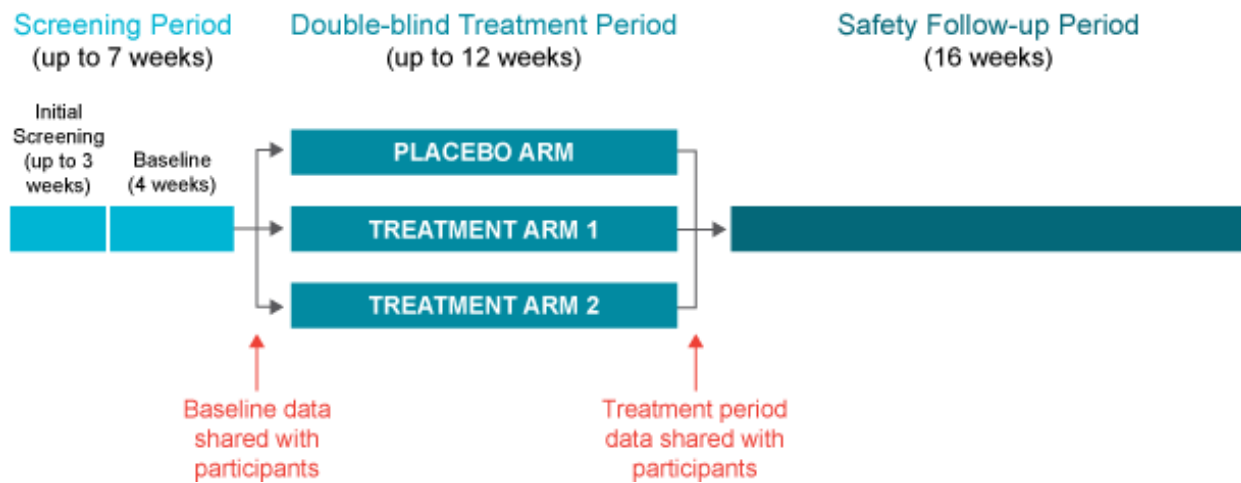
Case Example: Sharing Data to Promote Patient Engagement

During a Phase 2a study using a provisioned handheld technology for data capture, periodic sharing of data with study participants promoted engagement while maintaining trial integrity. Drug development experts, the product team, and patient representatives, collaborated to develop this strategy.

In this trial, each study participant used the handheld diary technology to capture all efficacy-related data, from baseline through the safety follow-up period (see Figure A). Study investigators reviewed participants' data with them during study center visits, at the discretion of the investigators. The time points typically included the end of the baseline period and the end of the double-blind treatment period. Participants did not have access to data from the technology itself.

Sharing data with participants aimed to promote participant engagement, demonstrate that all data are important for the study, and promote participant adherence with the use of the technology. To date, participant adherence rates are excellent. As a future step, the sponsor plans to develop tools to help study participants view certain data on their own.

Figure A



Reference: Relevant CTTI Recommendation

- Safety and trial integrity should be paramount when considering sharing data with study participants in real-time. (Click [here](#) for more)