

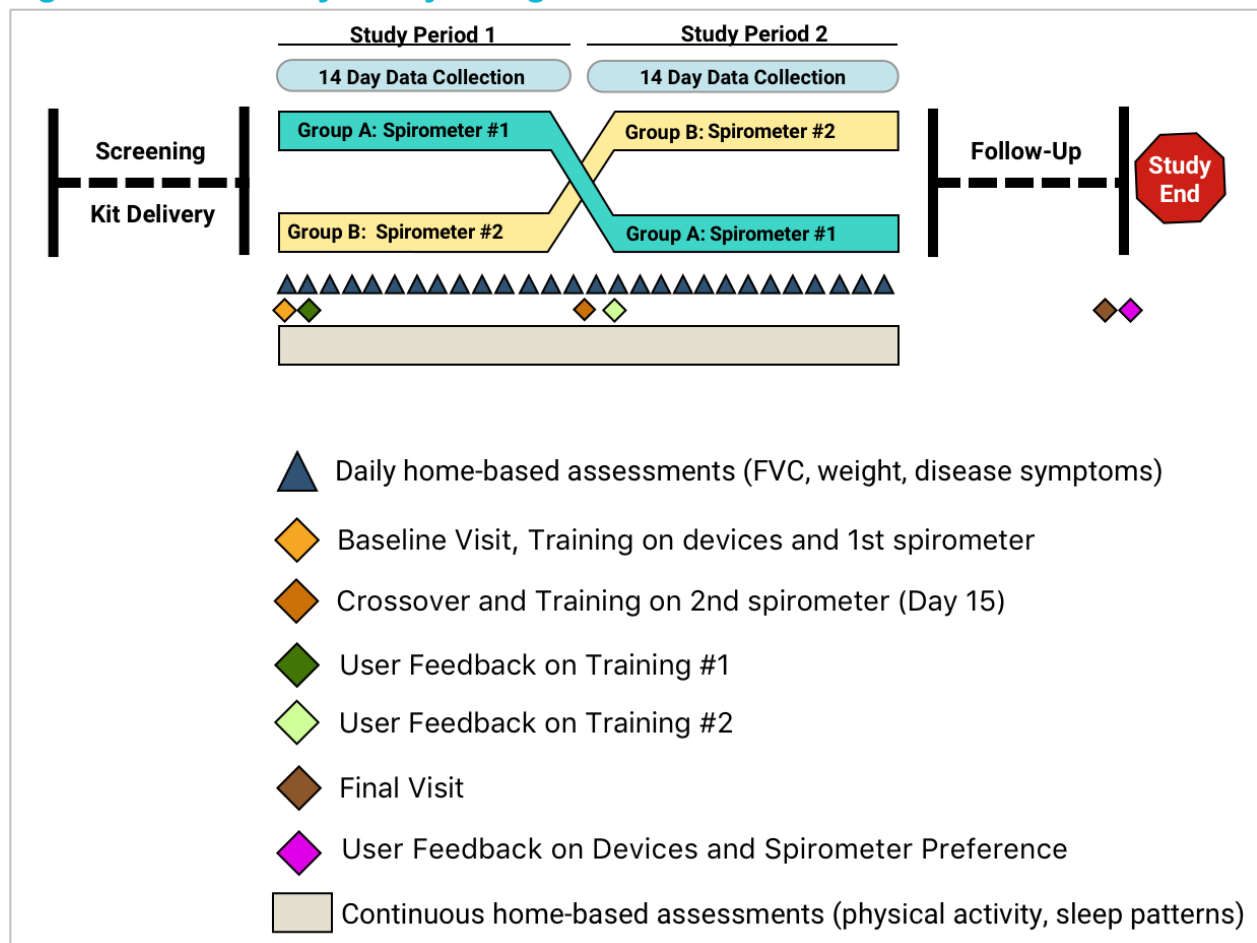
## Case Example: Feasibility Testing to Promote Successful Inclusion of Digital Health Technologies for Data Capture

One sponsor conducted a feasibility study with a cross-over design to 1) support the appropriate selection of digital technologies for data capture, and 2) inform the design and conduct of future virtual clinical trials in Idiopathic Pulmonary Fibrosis (IPF) with feedback from study participants. Ten participants who met the inclusion/exclusion criteria typically applied to IPF trials were enrolled to evaluate the use and adherence of several home-based digital technologies to collect clinically-relevant data from IPF patients, including:

- Two spirometers,
- A wearable activity and sleep monitor (watch containing an accelerometer),
- A wireless body weight scale, and
- A smartphone with an application to assess common disease symptoms.

The design of the feasibility study is summarized in Figure A, and the key findings highlighted in Table A.

**Figure A: Feasibility Study Design**



**Table A: Key Study Findings**

Study Aim	Approach(es)	Findings to Inform the Development of Future Virtual IPF Studies
Evaluate use of and adherence to a suite of home-based digital technologies.	<ul style="list-style-type: none"> <li>▶ Evaluate completeness of data collected.</li> <li>▶ Collect subjective feedback from participants through a series of phone interviews.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Adherence across all activities was <math>90.18\% \pm 11.69</math> (SD)</li> <li>▶ High adherence rates demonstrates that it is feasible to use digital tools for home based collection of clinically-relevant data from patients with IPF over a 30 day period.</li> <li>▶ Most participants found the process of recording their symptoms in a digital app to be easy, quick, and straightforward.</li> <li>▶ For a few patients, sleeping with the watch was difficult, making it a difficult factor to use for long periods of time.</li> </ul>
Inform the selection of a home spirometer technology from a short-list of two identified by the study team.	<ul style="list-style-type: none"> <li>▶ Use a cross-over design to allow all participants to use, test and provide feedback on both technologies.</li> <li>▶ At the end of the study, ask participants to rate their spirometer technology preference and provide reasons for their preference.</li> <li>▶ Assess accuracy, precision and consistency of measures in each technology.</li> <li>▶ Assess performance of each technology against last in-clinic measurement.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Precision and consistency of repeated measurements within a single IPF patient using in home spirometry was similar across both spirometers and similar coefficient of variation was reported by previous studies in daily home based spirometry for healthy subjects, COPD patients, and IPF patients.</li> <li>▶ Accuracy of home spirometry underestimated the FVC Value compared to historical in-clinic FVC measurements. This decrease could be due to different tools or disease progression.</li> </ul>
Evaluate the effectiveness of participant training on the technology.	<ul style="list-style-type: none"> <li>▶ Collect user feedback on each technology training.</li> <li>▶ Evaluate participant adherence.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Adherence across all activities was <math>90.18\% \pm 11.69</math> (SD).</li> </ul>

Explore participant preferences on the frequency of active data collection <sup>1</sup> .	<ul style="list-style-type: none"> <li>▶ Collect user feedback at the end of the study.</li> <li>▶ Evaluate participant adherence.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Participants preferred daily single-blow spirometry over daily multiple blow spirometry.</li> </ul>
Explore participant preferences regarding sharing technology-data.	<ul style="list-style-type: none"> <li>▶ Collect user feedback at the end of the study.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Participants prefer to receive output results following each spirometry test.</li> </ul>
Evaluate the ability to enroll participants in future virtual studies using similar technologies and protocol.	<ul style="list-style-type: none"> <li>▶ Collect user feedback at the end of the study.</li> </ul>	<ul style="list-style-type: none"> <li>▶ 9 out of 10 participants reported they would be interested in participating in a future study of longer duration.</li> </ul>

### Reference: Relevant CTTI Considerations

For additional considerations pertaining to feasibility studies, please reference [CTTI Recommendations for Testing a Digital Health Technology](#).

- Sponsors should consider conducting feasibility (or pilot) studies prior to launching the trial.
  - To assess the suitability of the technology and any unanticipated consequences. (Click [here](#) for more)
  - To ensure familiarity with the nature of the data outputs from the digital technology(ies) and the correct analytical approach. (Click [here](#) for more)
  - To inform the development of a robust technology management plan. (Click [here](#) for more)

<sup>1</sup> Note – passive data collection was continuous