

Schedule of Assessments: Example for a Decentralized Clinical Study

Study Phase	Screening and Enrollment	Onboarding	Study Course	End of Study	Follow-up	Notes
Schedule	Days -14 to 1	Day 1	Day 2-14	Day 14	8 Weeks from end of study.	After the initial 14-day study period, follow up will be conducted 8 weeks from the end of study.
Window (days) of Study Task Availability	N/A	+1	+1	+7	+7	
Study Tasks and Activities						
Confirmation of Eligibility Criteria and Diagnosis	X					Participants should have a local report confirming disease diagnosis.
Informed Consent	X					Participants will review the eConsent language, take a short consent comprehension quiz and proceed to complete a CFR Part 11 compliant e-signature process. A copy of the signed consent will be emailed to participants upon completion of enrollment.
Medical history and demographics		X				Medical history includes concomitant comorbidities, surgical history and social history. Demographics includes age, sex, gender identity and race/ethnicity.
Prior and concomitant medications		X	X	X	X	Concomitant medications include any prescription and over-the-counter medications. During Onboarding, all drugs used by the participant within 28 days of the start of study will be recorded. Participants will also have the opportunity to report any medications changes during the study course, end of study and follow up periods.
Height, weight and BMI		X				Completed in the Smart Omix app using the Smart Selfie module.
ePRO survey(s)		X	X	X	X	Completed on an iOS or Android smartphone using the Smart Omix app. Participants will receive

Schedule of Assessments

Sharecare Example

Smart Omix

						reminders when new ePROs are available, and when they are due to expire.
Patient-Generated Health Data (PGHD)		X	X	X		Includes passive data collection for sleep, physical activity, and heart rate. Data collected via smartwatch.
Medical or Adverse Events		X	X	X	X	Any changes to medications or procedures, hospitalizations or other medical events occurring during the study period or at follow up will also be collected.