

Participant Time Commitment Model

Audience: Sites/investigators

Purpose: To provide a model for a participant-centered study calendar, wherein the participant's time commitment for study participation is clearly structured and outlined in detail. The Participant Time Commitment model offers calendars and associated tables as an example for a theoretical study (Study X) investigating a treatment for Alzheimer's.

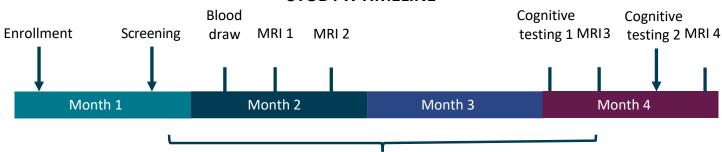
Considerations for use

- Adaptability the Participant Time Commitment Model offers an example of how to integrate a
 participant's schedule with a study schedule to proactively plan for study visits, specimen and
 data collection points. Because study timelines and requirements vary significantly, this tool
 serves as a reference guide to be adapted further by study staff and implementation partners.
- *Unique* each study calendar will be unique for each study participant, dependent on the commitments required by their personal life, workplace, enrollment date (the exemplar study assumes an enrollment date of September 1 for a hypothetical participant).



STUDY X: a phase 2 trial for an oral self-administered Alzheimer's drug

STUDY X TIMELINE



Oral self-administration of drug X

STUDY X REQUIREMENTS								
Month Appointment Purpose		Number of Appointments	Timing	Total Time	Transport Included			
Month 1	Screening	2	Non-consecutive	8 hours (4hrs/appt)	Yes			
Month 2	Blood draw	1		2 hours	Yes			
	MRIs	2	14 days apart	6 hours (3hrs/appt)	Yes			
Month 3								
Month 4	Cognitive testing	2		16 hours (8hr/appt)	Yes			
	MRIs	2	14 days apart	6 hours (3hrs/appt)	Yes			



STUDY X – Month 1

SEPTEMBER

Filled by site staff	Appointment Purpose	Number of Appointments	Timing	Total Time	Transport Included
Filled by	Screening	2	Non- consecutive	8 hours (4hrs/appt)	Yes

participant

Sur day	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						Appointment 1: preferred
Appointment 1: possible						Appointment 2: preferred
Appointment 2: possible						



STUDY X – Month 2

STUDY X - OCTOBER

Appointment Purpose	Number of Appointments	Timing	Total Time	Transport Included
Blood draw	1		2 hours	Yes
MRIs	2	14 days apart	6 hours (3hrs/appt)	Yes

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					Blood draw appointment: possible, after 4pm	Blood draw appointment: preferred, any time
					MRI appointment 1: possible, after 4pm	MRI appointment 1: preferred, anytime
					MRI appointment 2: possible, after 6p	MRI appointment 2: preferred, after 1pm



STUDY X - Month 3 STUDY X - NOVEMBER

Continue drug or placebo (no in-person appointments this month!)

Appointment Purpose	Number of Appointments	Timing	Total Time	Transport Included

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday



STUDY X – Month 4

STUDY X - DECEMBER

Appointment Purpose	Number of Appointments	Timing	Total Time	Transport Included
Cognitive testing	2		16 hours (8hr/appt)	Yes
MRIs	2	14 days apart	6 hours (3hrs/appt)	Yes

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					MRI appointment 1: possible, after 4pm	Cognitive testing appointment 1: possible, any time
					MRI appointment 1: preferred, after 4pm	Cognitive testing appointment 1: preferred, any time
					MRI appointment 1: possible, after 4pm	Cognitive testing appointment 2: possible, any time
					MRI appointment 2: preferred, after 4pm	Cognitive testing appointment 2: preferred, any time