Persona Participant Profile:

Participant Name:
Jenny Jorge

Age:
72, Married

Sex:
Female

Location:
USA, Lives 6 months in Montana in Summer and 6 months in Florida in Winter

Occupation:
Retired School Teacher, Active Lifestyle, Provides child care to grandchildren 3 days a week.

Key Considerations from interviews with healthy volunteers:

Aperature:

What motivates her to join the trial?

Health conscious and prevention.

Tech:

Has smart phone, on Facebook, not so tech savvy

Participant background:

- Walking 2 miles 3xs a week
- Controls monitors health so she doesn't attract RSV.
- Understands the importance of vaccine.
- Others in her age group or friend had covid and not doing well with breathing.
- Underlying stable COPD/lung disease (susceptible to RSV)

Clinical Trial Detail (Fictional Example)

Study Title:

Vaccine trial to prevent Respiratory Syncytial Virus (RSV)

Duration:
2 Years- 2 RSV seasons

8 Visits Total:
Enrolment visit
2 site visits
2 hybrid visits (onsite or at home)
2 telehealth Check in's
Post-study close-out visit
Additional visits if RSV episode

Number of Participants:
20,000 including 15% Diverse Population

Number of Countries:
12 across northern/southern hemisphere with rotational seasonal enrollment schedules

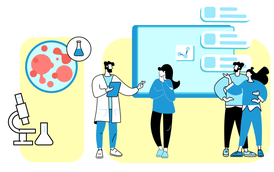
Exclusion Criteria:

- Participant has an acute illness
- Participant has a severe or potentially life-threatening chronic disorder
- Participant has a know allergy to vaccines

Inclusion Criteria:

- 60 and older
- Elderly and otherwise healthy, with or without stable chronic medical conditions (e.g., Cardiovascular, respiratory, lung)
- Participants will be included on the basis of physical examination, medical history, and vital signs
- Participant must be able to read, understand, and complete questionnaires and diaries
- Participant must be willing to provide verifiable identification, have means to be contacted and to contact the investigator during the study.

ePRO App
Diary
Home health nurse visit
eConsent portal
Participant engagement App
Telehealth visit
Study-related technology portal



Journey Stage

Recruitment / Prescreening	Enrollment/Consent	Study Participation - Schedule of Activities					Study Closeout - Schedule of Activities
	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4-5-6	If RSV episode	Close-out visit
Key considerations							
1. Potential participants identified through direct-to-participant multi-tactic outreach (digital/traditional awareness and advertisements) or referral from friend, family, treating physician 2. Potential participants are directed to a Recruitment Portal to learn more about the study and invited to complete a screening questionnaire to determine their pre-eligibility 3. Potential participants are referred to study site and contacted by site staff.	Informed consent discussions with study team and screening Inc/Excl activities at study site Participants trained on study related technology, portals and apps	**Randomization and Vaccination RSV Season 1** Lab collected at study site Vaccine Dairy RSV Surveillance (eDairy) during season and Quality of Life (ePRO) throughout trial Participant engagement through app	**Follow-up after vaccination** Lab collected at study site or at participants home RSV Surveillance (eDairy) during season and Quality of Life (ePRO) throughout trial Participant engagement through app	**Follow-up at end of RSV Season 1** Telehealth check-in including AE review RSV Surveillance (eDairy) during season and Quality of Life (ePRO) throughout trial Experience survey via portal Participant engagement through app	Visit 4: **Re-vaccination RSV Season 2** ~Visit 1 Visit 5 and 6: **Follow-up till end of RSV Season 2** ~Visit 2-3	**If RSV-like symtoms detected during Surveillance** Assessments at study site, at participants home or at the clinic (if hospitalised). Quality of Life (ePRO) and eDairy for episode	**Post-study closeout:** 1. 'Share Thank you for participating' messaging 2. Collect Experience survey 3. Request consent to share results of study via email or through Participant Engagement App or portal. 4. Offer transparency whether participant received active vaccine or placebo vaccine. 5. Return personal health data obtained through study. 6. Data reuse options to participants (anonymized use for future studies) 7. Obtain consent for outreach for future studies, tissue samples, labs etc.
Key Participants	Participant, Care Team, PI, Sub-PI, CRC	Participant, PI, Sub-PI, CRC	Participant, PI, Sub-PI, CRC	Participant, PI, Sub-PI, CRC, Home health nurse	Participant, PI, Sub-PI, CRC	~Visit 1, 2, 3	Participant, Care team, PI/Sub-PI, CRC, Home health nurse	Participant, PI, Sub-PI, CRC
Healthcare Team	Primary care physician, Nurse practitioner, CRC	Visit 0 to 6 →	PI, Sub-PI, CRC, Home health nurse (if option)		Visit 6 →		Primary care physician, Nurse practitioner, Infectious Disease specialist (if hospitalized) PI/Sub-PI, CRC, Home health nurse	Primary care physician, Nurse practitioner, PI/Sub-PI, CRC
Empathy Mapping: Thinking/feeling/doing	Will this vaccine help me? What impact might my participation have on my family, my grandchildren? Is it safe? Is there a someone that I can speak to if I have complications? Will my participation make a difference for future patients?	Concerns about technologies used in the trial? Will the technology work? eConsent? ePROs? Schedule of Assessment Tracking - What comes next? Virtual visits?	Will technology help connect participant when not on site? Will participants feel connected/engaged throughout the trial? What is needed to make sure participants feels supported? What happens if participant loses connection during telehealth visit?		How is team notified? Want to check with regular physician for endorsement? Concerns about employed technologies? (eConsent, portals, etc) Nervous about if they are they going to get active vaccine or placebo? "Wanting" the experimental vaccine or vice versa		What comes next? Are there long term side effects I need to be aware of? What is the normal follow up for something like this?
Pain Points Barriers retention and engagement blockers	Awareness of clinical research, find a vaccine trial	**What could prevent participation:** - Lack of understanding (RSV, Vaccine)? - Concerns about risk and long term safety data. Will it help me? - What are the long term effects? - Trial commitment and time to participate in the trial? - Scheduling & Transportation? **What could motivate:** - More healthcare? - Access to new vaccines? - Greater good and help others? - Financial compensation?	Length of trial - How will I feel after the vaccine? Will I be able to exercise and care for my family? Lifestyle impact (elderly are retired) Transportation/Travel time Technology - Tech savvy? Access to smartphones/computers?		Internet access in remote areas? Compensation for internet? Expectations of the caregivers Underlying health issues Regional Barriers: Confidentiality, Regulations Country wide Time restrictions, Transportation Loss of interest		While study results are rarely shared, will this trial be an exception? Will my data be returned? Where do I go next? What's next?
DCT Components	Technology such as recruitment and referral portal/apps to identify potential participants.	**E-Consent** Review ICF before onsite consent process: Read from home before coming to the center Use eConsent to allow for multi modal engagement, video/audio learning options Engage with participant to gauge literacy/understanding of information Multiple modalities for information sharing Knowledge checks Opportunities to ask questions	**Trial is hybrid, with onsite, home health and telehealth options:** - On Site visits for screening, enrolment, vaccination and training - Home Health visit for blood sampling and training during follow-up visits - Telehealth Visits for follow-up at end of season - If RSV-episode, additional assessements conducted on-site or via Home Health (if the assessment allows) or at the clinic (if hospitalised).		**Technology used throughout the trial:** - eDiary for RVS surveillance during seasons. - Electronic capture of questionnaires and participant reported outcomes (ePRO) throughout trial - Portal for feedback survey at selected visits - App to engage participants during season and in-between seasons		Information is collected digitally and should be shared with care teams. App to share study results and 'Thank you messaging'.
What do sponsors, sites, and tech providers need to run a trial like this?	Access to participant recruitment and referral portal/apps Collateral: participant brochures in waiting rooms, etc, for this population to explain the trial.	Access to software to support eConsent Training options on-demand for site staff	Access to technology for collecting data electronically (eCOA, ePRO, edairy, portal). Sites need ability to connect with participant via Telehealth and ability to engage via App. Sites need home healthcare nurses (own staff or offered by study sponsor).		Sites need training options on-demand, Tech specialists for problem solving, transparency on privacy and security concerns (tech safeguards for hacking networks). Sponsors need transparency on regulatory landscape		Participants needs support for long term access to trial information. Site needs to support participants long term access.