

1572 Annotation Example

1. Vaccine Study Based on RSV Patient Journey Map:

Protocol Title: **Vaccine trial to prevent Respiratory Syncytial Virus (RSV)**

Study Execution Plan:

Hybrid model with Traditional Brick and mortar site and Pharmacy based adjunct site

Direct to patient outreach, as well as site to patient outreach and referral

Visit 0: eConsent. Informed consent conversation with site staff. Screening.

Visit 1: Initial Visit in clinic, with initial RSV Vaccine dose, labs collected at site.

Visit 2: Follow up lab at pharmacy site. Labs collected at pharmacy.

Visit 3: Telehealth AE Follow up with Study Coordinator

Visit 4: RSV Vaccine Dose at Pharmacy Based Research Site (Year 2)

Visit 5: Follow up lab at pharmacy site. Labs collected at pharmacy.

Visit 6: Telehealth follow up with Study Coordinator (pharmacy)

RSV event: HCP involvement - SOC PE / Labs and RX

For this annotation example:

Traditional research site: Perfection Clinical Research Inc.

123 Main Street, Sunrise FL 33351

PI Name: Dr. Tom Pretty

Research Coordinator: Lena Love, RN (DOA Log)

SubInvestigator: : Dr. Steve Ferrone, MD

Sub-investigator Pharmacy location:

Walgreens

6401 W Commercial Blvd, Tamarac, FL,

Pharmacist: Michael Campbell

Study Nurse: Marilyn Martin, RN

Patient's Primary Care Physician: Dr Stevie Nicks,

12651 W Sunrise Blvd Suite 202, Sunrise, FL 33323

(Not part of the study staff)

IRB: Advarra

6100 Merriweather Drive, Suite 600, Columbia, Maryland 21044

Central Labs: LabCorp

Labcorp Central Laboratory Services Limited Partnership

8211 SciCor Drive

Indianapolis, IN

2. Rare disease Example - based on Rare Disease Patient Journey Map

Wolfram-like syndrome is a rare endocrine disease characterized by the triad of adult-onset diabetes mellitus, progressive hearing loss (usually presenting in the first decade of life and principally of low to moderate frequencies), and/or juvenile-onset optic atrophy. Psychiatric (i.e. anxiety, depression, hallucinations) and sleep disorders, the only neurologic abnormalities observed in this disease, have been reported in rare cases. Unlike Wolfram syndrome, patients with Wolfram-like syndrome do not report endocrine or cardiac findings.

This clinical trial will assess a new oral medication that may slow the progressive loss of vision. Standard visual assessment tests will be used as the primary outcome measure.

15 patient study at one research site only, at Washington University in St. Louis, MO
Initial visit in clinic in MO; Follow up visits thru telehealth and local HCP, Visits 3, 5 and 7
Home care for visits 2, 4 and 6 (Labs drawn, PE, etc)

PI : Charles Berry, Washington University Dept of Ophthalmology, St Louis, MO,
Christina Turner (Sub-Inv)
Michael McDonald (Study Coordinator, St. Louis)

HCP for visits Visits 3, 5 and 7

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Nina Simone, HCP Center Nurse

Jo Baker Home health care nurse (PCM Trials, HQ Address: PCM Trials, 709 N/ Clarkson Street,
Denver, CO 80218 USA)
Study nurse in Durham

IRB:
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Washington, 98374, United States

DTP Pharmacy: Pharmacist: Ronnie Milsap - Pharmacist (NC)
Marken
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Central Pharmacy Distribution direct to patient: Almac Inc
Almac Group
25 Fretz Road
Souderton PA18964
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