

Study Product Administration Activity

Scenario 1: Incorrect Participant

Two Participants Anna (PID 781623) and Annie (PID 462341) came for their final vaccination visit 5. The protocol requires a blinded nurse to collect injections from pharmacy, which was one block away. Injections are placed in cooler bags with a temperature logger for temperature control during transfer to the clinic.

Its summertime hence Research Nurse (RN) rushes to complete IP administration to avoid IP loss due to temperature excursion. The first participant to come to the clinic, Anna, is called in and the injection administration procedures are completed. Next, the 2nd participant, Annie, is called in for IP administration. The RN notices that the PTID on the injection label does not match the PTID listed on the source documentation in Annie's chart. Later that day, they discovered they had administered Anna the IP prepared for Annie.

PID = Participant Identifier

Questions to Ponder

Scenario 1: Incorrect Participant

What should you do about this error?

Is a temperature logger required for this situation?
How do you know?

Who should you communicate to about the error?

How should you report the error?

What can be done at your site to prevent this
from happening?