Recording FluSNIFF-toddler Study Data in the Child's NHS Electronic Health Record (EHR)

Purpose

This guidance outlines what information may be added to a participant's NHS Electronic Health Record (EHR) during the FluSNIFF-toddler trial, with specific consideration for:
- Maintaining study blinding

- Ensuring data integrity

- Respecting parental access via the NHS App

- Complying with GCP and sponsor guidance

Background

Parents/guardians of trial participants may access portions of their child's EHR via the NHS App. It is therefore essential to ensure that any entries made during the study:

- Do not disclose randomisation or unblind allocation

- Do not cause unnecessary concern or misinterpretation

- Are consistent across study sites

Standard Operating Procedure (SOP): Recording Trial Data in EMR

Purpose:

To maintain the scientific integrity of the FluSNIFF-toddler trial by minimising risk of bias in the primary outcome (medically attended wheeze), while ensuring appropriate clinical documentation standards are upheld.

Procedure:

1. **During trial visits (Day 0 and Day 28):**

    - *Do not* enter any information into the child's NHS EMR contemporaneously.

    - All visit details (consent confirmation, eligibility, IMP/placebo administration) must instead be documented on the Patient Specific

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Direction (PSD) form or equivalent paper source notes. This paper record serves as the source document for the visit.

2. **At end of participation (Day 57 or later, following completion of the final remote follow-up visit [Visit 3]) :**

    - The IMP administration and trial participation record should be uploaded into the child's NHS EMR retrospectively.

    - Entries must use the following wording:

      "Added in retrospect as per FluSNIFF protocol. Intranasal influenza vaccine (Fluenz Tetra) administered on [date] and/or intranasal placebo administered on [date]."

    - Backdate the entry to the original visit date to maintain chronological accuracy.

    - Upload a copy of the PSD to the record at this stage.

3. **Adverse Events (AEs/SAEs):**

    - Clinically significant AEs/SAEs that require routine care must still be documented in the EMR contemporaneously, as per normal NHS practice.

4. **Rationale:**

    - Entering trial participation contemporaneously may bias GP/clinician behaviour if the child re-attends during the follow-up period, potentially altering the primary outcome. Retrospective entry ensures trial integrity while preserving a complete clinical record.

Responsibilities:

- Site PI to ensure compliance with this SOP.
- Delegated staff to follow documentation instructions exactly.
- Monitoring will check for adherence.

FluSNIFF toddler

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What to Record in the EHR

Study participation and immunisation record should only be entered in the EHR on (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]) to avoid potential study bias.

Item	Record in EHR?	Notes
Study participation	Delayed	Record at (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]). Recording at enrollment may bias the primary outcome assessment (may make clinical staff more likely to record medically attended wheeze)
Intranasal vaccine administration	Delayed	Record at (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]) only as parents may be able to see EHR online
Placebo administration	Delayed	Record at (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]) only as parents may be able to see EHR online
Adverse Events/SAEs	Yes, if clinically significant	If assessed/treated in routine care, it will be captured.
Randomisation group	Never	Clinical information (vaccine and placebo administered dates)

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		recorded on EHR at (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]).

Suggested EHR Entry – LAIV Administration
When LAIV (Fluenz Tetra) is administered as part of the study, use the following entry in the EHR on or after (**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]) from enrollment:

> ***"Intranasal influenza vaccine (Fluenz Tetra) administered as per approved FluSNIFF clinical study protocol on X date. Intranasal placebo was adminstered on X date.***

- Avoid naming "FluSNIFF" or stating the child is in a clinical trial in the EPR.
- Do not enter any data that could indicate when placebo or vaccine was given.

When to Record
The date of LAIV and placebo administration should be entered into the NHS record at the end of patient participation ((**Day 57 or later**, following completion of the final remote follow-up visit [Visit 3]))

Parental Access to NHS App: Suggested Message for Sites
If a parent queries missing data in the NHS App, staff may use this explanation:

> ***"Some parts of the study are blinded so we don't add all information to the medical record straight away. Once the study is completed, any relevant information—such as the flu vaccine given—will be added to the record."***

Contacts for Clarification
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