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FluSNIFF Toddler S2 Refresher Training

Ensuring Success in Season 2

University Hospital Southampton

NIHR

RCGP RSC

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FluSNIFF-toddler Study

Season 2 Refresher Training

Part 1 — For Everyone (30 mins)

- Season 1 recap
- What's new for Season 2
- Protocol amendment & consent update
- Season 1 learnings: SAE reporting, placebo data entry, treatment cost

Part 2 — New Sites Only (30 mins)

- Full study overview, roles, LAIV & placebo, blinding, IMP management
- Platform walkthrough, GCP training, informed consent & delegation
- Q&A and key contacts

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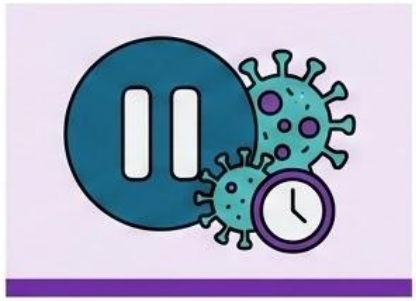
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Season 1 Recap



Study Timeline & Recruitment

Ran over roughly 2–3 months, with approximately 1,193 participants randomised across sites.



Early Flu Season Operational Pause

Paused due to flu/RSV season starting earlier than anticipated — this was operational pause, not a safety pause.



Clinical Downgrade of SAEs

All Grade 4 SAEs (4) were downgraded to Grade 3 on clinical review.



DSMB Approval to Restart

DSMB accepted all reclassifications on 1 June 2026 and gave the go-ahead to restart for Season 2.

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What's New for Season 2

1. 

Protocol Amendment & PIS (V4.0) submitted 1 July 2026. Refined SAE reporting and PIS updates based on feedback.

2. 

New GP-as-PIC model for Season 2 sites.

3. 

Site Guide Rewritten (V3). Builds on Season 1 learnings, updated SoECAT costs, clearer SAE/placebo guidance.

4. 

Targeting ~250 sites for Season 2. Aiming for vaccine delivery in early September 2026.

5. 

Once **HRA/MHRA approval** is in place, **recruitment will begin.**

6. 

Expected date for first vaccinations week commencing 7th September.

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Protocol Amendment & Consent Update

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1. Status & Approvals

Substantial Amendment
Submitted on 1 July 2026, updating Protocol V4.0 and PIS (dated 24 June 2026).

HRA Decision
Expected late early August 2026.

CAG Approval
Letter has been received and submitted.

2. Site Readiness

Capacity & Capability
Once approved, sites must issue local Capacity and Capability before vaccinations can commence.

Further Guidance
Specific details and timing will follow shortly via the study team and Site Guide V3.

3. Current Protocol

Important Notice

Please refer to the current approved versions until you are officially notified that the new amendment is live at your specific site.

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Platform Update: eISF

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1. Options & Access

Season 2 Options
Sites struggled with the Florence Electronic Investigator Site File (eISF) so we have different options for Season 2.

Access & Guidance
Full access and how-to guidance will be provided separately.

2. Florence & Support

Continue with Florence
You still have the option of using Florence so please continue to do so if there are no issues.

Ongoing Support
Questions in the meantime — contact the study team as usual.

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Season 1 Learning: SAE Reporting Pathway Fix

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1. Season 1 Issue

Direct Entry Bypass
Some sites entered SAE data directly into the platform, which bypassed the automated eSurvey uMed Sponsor alert chain.

Unreported Events
This meant a small number of SAEs went unreported through the intended route.

2. Season 2 Fix

Clear Pathway & Definitions
This is fixed for Season 2. The correct pathway and severity definitions are set out clearly in Site Guide V3 and the amended protocol.

Mandatory Action
Always follow the eSurvey uMed Sponsor alert chain for SAEs do not rely on direct platform entry alone.

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Season 1 Learning: Placebo Data-Entry Reminder

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S1 Data Entry Issue



In Season 1, some sites recorded "No" in the "administered" field when giving placebo rather than LAIV — this looked like a missed dose when it wasn't.



Site Guide V3 now includes explicit warning boxes at Visit 1 (step 8) and Visit 2 (step 4) to prevent this.

Season 2 Process & Reminders



The platform has also been updated to help with that data field.



Reminder: whether LAIV or placebo was given is reliably confirmed by the lot number and expiry date on the record — not the "administered" field alone.

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That's Part 1 done — over to new sites for Part 2



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PART 2: FULL STUDY & GCP TRAINING (NEW SITES)

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Main Study Overview

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Phase 2 randomised single blinded placebo-controlled crossover trial assessing LAIV safety in children aged 12–23 months

- Early Vaccine Group - Fluenz at Day 0
- Late Vaccine Group - Fluenz at Day 28
- Placebo at other visits
- Parents / legal guardians blinded

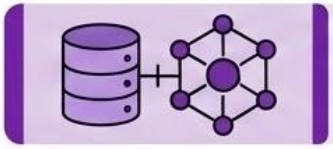
- Sponsored by University Hospital Southampton, funded and supported by NIHR and RCGP RSC
- Delivery supported by uMed, a clinical research technology platform
- **Primary outcome:** Medically attended wheeze within 28 days

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uMed Responsibilities



Patient identification via EHR and outreach (site approves patients for outreach)



Digital pre-screening and eConsent (obtaining parent signature prior to 1st Site Visit)



Follow-up surveys (Day 7, 14 post-vaccine & Day 28 & 56)



EHR data collection



SAE alerting

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Site Responsibilities

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Arranging of 2 appointments

Conduct Visit 1 / Day 0

- Review and countersign eConsent
- Randomise
- First administration - Fluenz or placebo
- Provide instructions for surveys – parent reminder card!

A Site Guide will be provided!

Conduct Visit 2 / Day 28 (-3/+7)

- Re-confirm consent
- Second administration - opposite of first visit
- Provide instructions for surveys

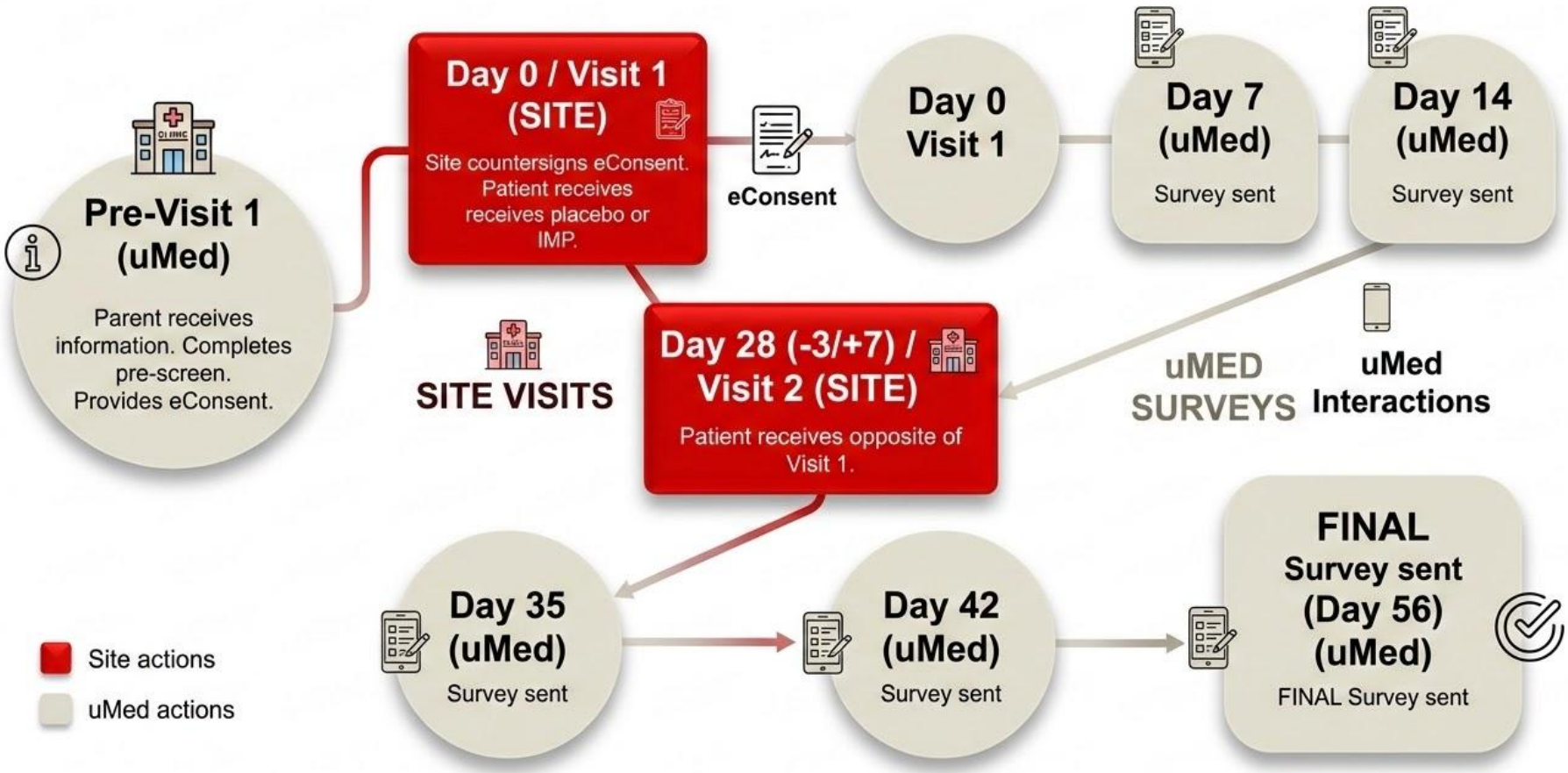
Complete visit data in uMed platform including recording IMP administration, batch, expiry

Confirm and record any SAE alerts received from uMed

Complete delegation log

Overview of journey

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LAIV & PLACEBO

An Overview of the Invesigational Medicinal Products used in FluSNIFF.

What is LAIV?

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LAIV (Live Attenuated Influenza Vaccine), specifically **Fluenz**, is delivered **intranasally** — as a **nasal spray**.

LAIV (Fluenz)



Dose: 0.2 mL total (0.1 mL per nostril) via prefilled single-use applicator.



Breathing: Child breathes normally; no inhalation required.



Action: Weakened virus stimulates immune response in nasal passages.



Ordering: Ordered via UKHSA — free of charge.

Placebo

0.9% saline administered intranasally using a 1ml syringe with nasal atomiser. The total dose is 0.2 ml — 0.1 ml per nostril, the same volume and technique as the LAIV (Fluenz) spray.

What do these look like?

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Atomiser



Syringe 1ml



Fluenz



Importance of Maintaining Parent Blinding

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Trial Context

In the **FluSNIFF-toddler** trial, the child's parent/guardian must remain blinded.

They must not know whether their child receives the live attenuated influenza vaccine (LAIV) or saline placebo at each visit.

Why Blinding Matters

Essential for Trial Validity

Maintaining blinding ensures the results can be trusted to inform national vaccine policy.

What sites must do:

Prevent Product Visibility

Always administer the spray in a way that prevents the parent from seeing which product is used.

Direct Parent's Attention

Ask parents to look away or focus only on holding their child during administration.

Maintain Neutral Delivery

Use identical wording and tone regardless of whether vaccine or placebo is given.

Delayed EHR Documentation

Do not record active vaccine or placebo type immediately in the EHR to prevent parental web portal leaks.

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

FluSNIFF-Toddler • Site Initiation Visit

Key principle: Study participation and immunisation should only be entered in the EHR on Day 57 or after — to avoid biasing assessment of the primary outcome.

Item	Record in EHR?	Notes
Study participation	Delayed	Record at Day 60. Recording at enrolment may bias outcome assessment (may make staff more likely to record medically attended wheeze).
Intranasal vaccine administration	Delayed	Record at Day 60 only, as parents may be able to see the EHR online.
Placebo administration	Delayed	Record at Day 60 only, as parents may be able to see the EHR online.
Adverse Events / SAEs	Yes, if clinically significant	If assessed or treated in routine care, it will be captured as normal.
Randomisation group	Never	Vaccine/placebo administration dates are recorded on the EHR at Day 60; the group itself is never disclosed.
PSD (Patient Specific Direction)	Delayed	Uploaded to the EHR at Day 60.

Suggested EHR entry — LAIV administration

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

- Do not name "FluSNIFF" or state the child is in a clinical trial in the record.
- Do not enter anything that could indicate when placebo vs. vaccine was given.
- Enter on or after Day 57 from enrolment.

If a parent asks about missing data in the NHS App: *"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."*

IMP Management

Parameter	Fluenz (LAIV)	0.9% Saline Nasal Spray
Source	NHS supply via UKHSA (ImmForm)	Routine stock vials/ampoules
IMP Status	Not IMP until removed from fridge for use	Not applicable
Storage	2–8°C, NHS cold chain protocols	Room temperature
Cold Chain Monitoring	NHS fridge logs until point of use	Not applicable
Accountability Log	Batch/expiry recorded at administration only	Not applicable
Transport	Handled via NHS processes	Not applicable
Packaging	Original NHS packaging	Original NHS packaging
Disposal/Return	Record used doses; discard per NHS SOP	Dispose per normal NHS procedures

WHAT IS AN MAAE / SAE

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MAAE – Medically Attended Adverse Event

🩺

- New or worsening symptom requiring healthcare contact
- Includes GP, urgent care, A&E, or telephone consultation
- **Primary Outcome** = wheeze within 28 days

SAE – Serious Adverse Event

❌

- Death or life-threatening event
- Hospitalisation or prolonged stay
- Significant disability/incapacity
- **Must be reported within 24 hours** of site awareness

📌 **In FluSNIFF:** Parents report via uMed surveys → Sites are alerted to confirm and complete reporting.

💻 Let's take a look at the platform…

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…and walk through a **patient's data entry journey** at site.

We'll cover:

- How to log a Visit Date when booked and change
- How eConsent is countersigned at site
- How to randomise
- What data is entered at each site visit
- Where sites can view and update study information
- How Serious Adverse Events (SAEs) are reported

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Archiving and Data Retention

Consent and identifiable data to be stored securely for 25 years

Data Protection – Your Role Under GDPR

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🛡️ **Data Protection Responsibilities**

- Handle all participant data in accordance with GDPR
- Only access data you're authorised to see
- Never share login credentials to uMed or any platform

🔐 **eConsent & eCRF Data**

- Personal data collected by uMed must be securely stored
- Any paper backup must be securely locked and uploaded as needed

💡 **Always report data breaches or concerns immediately to the PI or study team.**

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GCP Guidance

- Targeted GCP included in this SIV for those without formal training
- NIHR certification encouraged [NIHR Learn]
- PI must ensure all staff are trained and supervised
- Training records must be filed in the eISF
- Contact study team for additional training resources

What is GCP?



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Good Clinical Practice (GCP) is an internationally recognised standard that ensures the **rights, safety, and well-being of clinical trial participants** are protected, and that the **data collected are credible and accurate**.

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Informed Consent

- Parent/guardian completes eConsent via uMed prior to Visit 1
- Site must confirm consent at first visit and countersign
- Allow time for questions; ensure understanding and voluntariness
- Consent must be documented before any procedures
- Nurses/AHPs may confirm and countersign eConsent **only if trained and delegated**.
- Paper ICF available as backup if needed

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Delegation of Duties

- Only delegated staff (on log signed by PI) can perform study tasks
- Roles must match training and be recorded in the Delegation Log
- Log must be kept current and stored in Investigator Site File (ISF)
- PI remains ultimately responsible for oversight and compliance

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Why GCP Matters: Patient Safety First

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- GCP is not just about compliance – it's about protection.
- Children aged 12–23 months are a vulnerable group.
- GCP ensures:

- Informed parental consent is valid and voluntary
- Safe vaccine handling and dosing
- Proper reporting of any adverse events
- Accurate records for every visit

Every action taken under GCP protects the child's rights, well-being, and safety.

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Questions & Key Contacts

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Study team and uMed contact details provided in Site Guide

Any further queries?

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