FluSNIFF toddler

Site Support Handbook

Frequently Asked Questions & Common Scenarios

Companion to the FluSNIFF-Toddler Site Guide (V3)

Season 2 (S2) Restart — V1.0, 3 AUG 2026

Built from real Season 1 site queries, so this handbook covers what actually comes up in clinic — for full step-by-step procedures, refer to the Site Guide.

How to Use This Handbook

This handbook is a quick-reference companion to the FluSNIFF-Toddler Site Guide (V3). Where the Site Guide sets out the full step-by-step procedures, this handbook answers the specific questions and situations that came up most often at sites during Season 1 — so you can find a fast answer without calling uMed for routine queries.

Each answer includes a pointer back to the relevant Site Guide section for the full procedure. If your question isn't covered here, or you're unsure, contact sitesupport@umed.io — that's always the right first step.

Quick Escalation Directory

Query type	Contact
All routine site queries (first port of call)	sitesupport@umed.io / 0800 055 4288
SAE escalation confirmation	sitesupport@umed.io — confirm for every SAE, don't assume the platform alert alone is enough
Protocol deviations	protocoldeviation@umed.io
LPMS / ETC / RDN access queries	Your local RDN contact (rdn.nihr.ac.uk/about-us/delivery-organisations)
Fluenz ordering issues (ImmForm/UKHSA)	sitesupport@umed.io — will liaise with UKHSA on your behalf
eISF / delegation log / training	sitesupport@umed.io

1. Recruitment & Consent

Q: A parent doesn't seem to realise they're taking part in a clinical trial — they think it's their child's routine flu vaccination.

A: Clarify gently before proceeding: explain this is a research study comparing two nasal sprays, that their child was randomly assigned one of them, and that the PIS they were given at consent covers this. If they no longer wish to continue, treat this as a withdrawal, not a deviation — do not proceed with the visit until they confirm they understand and wish to continue.

↳ Site Guide: Visit 1, step 4 (Consent tab) — confirm/countersign ongoing consent.

Q: A child meets the NHS Green Book criteria for the injectable flu vaccine (e.g. sickle cell disease, other clinical risk group) — can they still take part in FluSNIFF?

A: No. Children who meet Green Book clinical-risk indications for the NHS injectable vaccine should be receiving that via the routine NHS autumn programme and should not be invited into FluSNIFF — LAIV is not contraindicated for them clinically, but they should already be offered the injectable route by their GP. If this is identified after consent, screen the child out and do not randomise. Flag to sitesupport@umed.io so we can review how they were invited.

Q: Can I invite my own patients directly, outside the uMed digital outreach?

A: Sites should not run independent recruitment outside the uMed-managed pathway (screening survey, eConsent, and approval in the uMed platform). If a parent approaches you directly and is interested, ask uMed sitesupport to add them to the outreach list rather than consenting them ad hoc.

Q: A sibling of an existing participant wants to take part too — is that a problem?

A: No — siblings can take part as separate, independent participants provided each meets the eligibility criteria in their own right and is separately consented and randomised. There's no restriction on multiple children from the same household.

Q: A parent has consented but hasn't booked, or hasn't attended, their Visit 1 appointment.

A: This was one of the most common drop-off points in Season 1. Encourage the parent to book promptly — uMed sends automated reminders, but a site call can help. If they ultimately don't attend, the site should opt the patient out on the platfom.

2. Visits & Randomisation

Q: The platform won't let me randomise a child — it's flagging an age error.

A: The system checks the child is 12–23 months old on the day of Visit 1. Double-check the date of birth entered matches records exactly. If the child is genuinely eligible and the system still blocks randomisation, contact sitesupport@umed.io with the participant ID rather than attempting a workaround.

Q: We administered the product before randomising the child in the platform.

A: This is a protocol deviation. Complete the Protocol Deviation Form as soon as you notice, and email it to protocoldeviation@umed.io. Always randomise first, then administer — consider adding this as a checklist step at your site before every Visit 1.

↳ Site Guide: Visit 1 steps 5–6 (Randomisation, then Administer) and Protocol Deviation Reporting section.

Q: A parent is asking which product (Fluenz or placebo) their child received.

A: Staff must remain blinded-appropriate in how they respond — do not reveal or imply which product was given. Per the PIS, parents can be told which spray their child received after the study ends, if they wish. Use this line if asked during the study.

↳ Site Guide: Importance of Maintaining Parent Blinding.

Q: Visit 2 falls outside the -3/+7 day window — can we still carry it out?

A: Contact sitesupport@umed.io before the visit if you can see it will fall outside window, so we can advise. If it has already happened out-of-window, complete it as normal in the platform and also raise a Protocol Deviation Form — recording the deviation doesn't prevent the visit data being used, but it needs to be documented.

3. IMP Administration

> **⚠ Most common Season 1 data error**
>
> Sites recorded “No” in the administration field when placebo (rather than Fluenz) was given. This field records whether an intervention happened at all — always record “administration occurred = Yes” whenever either product was given, including placebo.

Q: We forgot to record the Fluenz lot number and expiry date at the time of the visit.

A: Check the physical vial/box used that day, or your site's vaccine fridge log, to retrieve the batch and expiry, and enter it retrospectively as soon as possible. If you genuinely cannot identify which batch was used, contact sitesupport@umed.io — do not guess or leave it blank without flagging it.

Q: The wrong product was administered in error (e.g. Fluenz given instead of placebo, or vice versa).

A: Report this immediately as a protocol deviation using the standard form, and notify sitesupport@umed.io directly (in addition to the form) given the safety and blinding implications. Do not attempt to correct the platform record to disguise which product was actually given — record what happened.

Q: Our atomiser stock is running low.

A: Check remaining atomiser stock ahead of each clinic session — atomisers are Sponsor-provided and costs are covered, but lead time is needed to reorder. Contact sitesupport@umed.io to arrange a top-up before you run out.

Q: There's been a vaccine fridge temperature excursion.

A: Do not administer any Fluenz from the affected stock. Record the excursion per your site's normal cold-chain SOP and contact sitesupport@umed.io before using the stock — we'll confirm with the Sponsor/manufacturer whether it remains usable.

4. Safety Reporting

> **⚠ Season 2 safety pathway — confirm every time**
> Entering an SAE into the uMed platform does not, by itself, confirm that uMed and the Sponsor/CI have been notified. Actively confirm escalation with sitesupport@umed.io for every SAE, regardless of how it came to your attention.

Q: What's the difference between an MAAE and an SAE?

A: An MAAE (Medically Attended Adverse Event) is any event where the child receives medical attention — these are recorded but need no further site action beyond documentation. An SAE (Serious Adverse Event) meets specific seriousness criteria (e.g. hospitalisation, life-threatening event) and must be reported within 24 hours via the uMed platform, with escalation confirmed as above.

Q: Does an overnight hospital stay always count as an SAE?

A: Yes — any overnight hospital admission should be reported as an SAE, with one exception: a planned hospitalisation for a pre-existing condition that has not worsened is not reportable as an SAE.

Q: A child attended A&E — do we need to report this as an SAE?

A: Not automatically. A&E attendance should only be reported as an SAE if it meets the SAE seriousness criteria (e.g. admission, life-threatening event) — routine A&E attendance that doesn't meet these criteria doesn't need SAE reporting, though it may still be an MAAE.

Q: How do I decide the severity grade on the SAE form?

A: Use the CTCAE v6.0 (2025, paediatric-amended) grading table in the Site Guide — Grade 3 requires marked limitation and medical intervention; Grade 4 requires A&E assessment or hospitalisation. If in doubt, grade conservatively and let uMed/CI review.

↳ Site Guide: Safety Reporting — Severity grading table.

5. Data Queries & Corrections

Q: I've noticed I entered the wrong date, or against the wrong participant.

A: Correct it directly in the uMed platform.

Q: A participant is withdrawing — what do I need to do?

A: Record the withdrawal in the platform with the date and reason if given (parents aren't obliged to give a reason). No further visits or IMP administration should take place once withdrawal is recorded.

Q: uMed has raised a data query against one of my entries — how quickly do I need to respond?

A: Please respond as promptly as possible, ideally within a few working days — timely responses keep the trial dataset clean for DSMB and regulatory reporting. If you're unsure how to resolve a query, contact sitesupport@umed.io rather than guessing at a correction.

6. EHR, LPMS & Payments — Quick Pointers

These areas are covered in full in the Site Guide; the quick answers below cover the most common points of confusion.

Q: When do I add FluSNIFF data to the child's NHS record?

A: Not before Day 57. Recording earlier can bias the primary outcome and may unblind parents via the NHS App. Never record the randomisation group.

↳ Site Guide: Recording Study Data in the Child's NHS EHR.

Q: Which visit carries the Excess Treatment Cost (ETC) in LPMS?

A: Whichever visit administers Fluenz — Visit 1 for the Early Vaccine group, Visit 2 for the Late Vaccine group. Both visits should still be logged in LPMS regardless of arm, but the ETC flag follows the Fluenz-administration visit specifically.

↳ Site Guide: Instructions for Reporting via LPMS.

Q: I don't have LPMS/EDGE access at my site — who do I contact?

A: Your local RDN (Research Delivery Network) support team sets up LPMS access — see rdn.nihr.ac.uk/about-us/delivery-organisations. This isn't something uMed or the Sponsor can set up directly.

7. Common Scenarios at a Glance

A fast reference for situations that come up in clinic. For anything not listed, contact sitesupport@umed.io.

Situation	Action Required	Who to Notify
Parent has consented but child now has an acute illness (e.g. fever, bronchiolitis) at Visit 1	Do not randomise or dose today. Complete consent as usual; rebook within the recruitment window and repeat Visit 1 in full on return.	No escalation needed — reschedule
Child attended A&E the day before their visit	Assess against SAE criteria before the visit; if it meets criteria, report as an SAE. If not, proceed with the visit as planned unless clinically inappropriate.	sitesupport@umed.io if SAE criteria met
Parent asks which vaccine allocation their child received	Do not disclose. Use the approved PIS line about finding out after the study ends.	No escalation needed
Site forgot to record the LOT number at Visit 1	Retrieve from fridge log/stock records and enter retrospectively.	sitesupport@umed.io if it cannot be identified
Wrong vaccine given in error (Fluenz vs placebo swapped)	Complete Protocol Deviation Form; do not alter the record to obscure what was given.	protocoldeviation@umed.io and sitesupport@umed.io
Child already received NHS (non-trial) Fluenz separately	Should have screened out at eligibility — flag for review; do not proceed with trial dosing.	sitesupport@umed.io
Parent withdraws after Visit 1	Record withdrawal and date in platform; no further visits.	No escalation needed beyond platform entry
Site cannot access the uMed platform	Check login/password reset in the first instance.	sitesupport@umed.io
Vaccine fridge failure / temperature excursion	Quarantine affected stock; do not administer.	sitesupport@umed.io before using stock
Visit completed outside the protocol window	Complete the visit as normal in the platform; also file a Protocol Deviation Form.	protocoldeviation@umed.io
Overnight hospital stay reported by parent via eDiary	uMed will notify you; confirm SAE reporting and escalation on the platform within 24h.	Confirm with sitesupport@umed.io
Sibling of existing participant wants to join	Treat as an independent new participant through the normal pathway.	No escalation needed

8. What Changed for Season 2, and Why

These changes were made directly in response to Season 1 site feedback and DSMB review — flagged here so returning site staff understand the reasoning, not just the new rule.

SAE reporting pathway

Some SAEs entered directly into the platform in Season 1 didn't trigger the automated alert to uMed and the Sponsor, so they went unreported through the intended chain. For Season 2, sites must actively confirm escalation with uMed for every SAE — this is now a safety net alongside the automated alerts.

Placebo administration field

Sites frequently recorded “No” in the administration field when placebo was given, since it wasn't the “real” vaccine. This field tracks whether any intervention occurred, not which one — always “Yes” if either product was given.

ETC / LPMS attribution

Previous guidance said the Treatment Cost applied uniformly to Day 0. This was corrected: it follows whichever visit administers Fluenz specifically, which differs between the Early and Late Vaccine groups.

Login and account setup

Season 1 saw heavy support demand from expiring login links and manual account setup. If you experience repeated login issues in Season 2, contact sitesupport@umed.io promptly