APR 19, 2023

Protocol status: Working

Created: Jan 11, 2023

Last Modified: Apr 19, 2023

PROTOCOL integer ID: 75098

Keywords: Single-cell sequencing, lymph node, influenza vaccine, ancestry

LEGACY01: ADVERSE EVENTS

In 1 collection

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ABSTRACT

This protocol details about adverse events in an experimental medicine study of seasonal influenza vaccination responses in Lymph nodE single-cell Genomics in AnCestrY (LEGACY01).

ATTACHMENTS

602-1266.docx

GUIDELINES

DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

Results in death

Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe

Requires hospitalisation, or prolongation of existing inpatients' hospitalisation

Results in persistent or significant disability or incapacity

Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

REPORTING PROCEDURES

Adverse events should be reported depending on the nature of the event and the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance. Events should be graded according to the FDA: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials, taking account of local laboratory reference ranges.
https://www.fda.gov/media/73679/download

NON-SERIOUS AES

These will be recorded in the following instances:

- Those occurring in the 5 days following lymph node tissue sampling
- Those occurring in the 28 days following influenza vaccination

SERIOUS AES

SAEs must be recorded during the entire study.

An SAE form should be completed and emailed to the Chief Investigator within 24:00:00. However, hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the REC which gave favourable opinion of the study, where in the opinion of the Chief Investigator the event was:
'related', i.e. resulted from the administration of any of the research procedures; and
'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

The aQIV is subject to additional monitoring. At the Chief Investigator's discretion, side effects of vaccination that are suspected adverse reactions will be reported to the MHRA via its Yellow Card Scheme: www.mhra.gov/yellowcard

Note

CONTACT DETAILS FOR REPORTING SAES

Please send SAE forms to the Chief Investigator:
katrina.pollock@nhs.net
Tel: +44(0)203 313 8073 (Mon to Fri 09.00 – 17.00)

The Chief Investigator is responsible for onward reporting of SAEs to the REC and Sponsor (RGIT@imperial.ac.uk)