Scottish Government
Riaghaltas na h-Alba
gov.scot

E: vaccinationsdelivery@gov.scot

Dear Colleague(s)

COVID-19 VACCINATION PROGRAMME: JCVI ADVICE ON CLINICAL TRIAL PARTICIPANTS

This letter provides details of the Joint Committee on Vaccination and Immunisation (JCVI) recommendations relating to additional vaccination of those individuals involved in COVID-19 vaccine clinical trials.

Key Objectives

1) To update on the Joint Committee on Vaccination and Immunisation's (JCVI) recommendations in relation to the vaccination of individuals who have taken part in clinical trials of COVID-19 vaccinations.
2) To clarify operational guidance on:
   - Offering individuals who have previously participated or are currently participating in clinical trials for vaccines that have not yet been authorised for use in the UK:
     (a) additional primary vaccination doses; and
     (b) for those eligible, access to the COVID-19 vaccination programme for booster doses; and
   - Offering eligible individuals who previously participated in clinical trials for vaccines that have subsequently been authorised for use in the UK access to the COVID-19 vaccination booster programme.

Background

3) There are around 3,000 participants in COVID-19 vaccine trials in Scotland. Without these volunteers in previous, on-going and future trials, we would not be in a position to have an evidence-based vaccination programme against COVID-19.

4) However, there are concerns that participants in vaccine trials without routine access to their vaccination status for international travel via vaccine certification could be disadvantaged.

From the Chief Medical Officer
Dr Gregor Smith

11 November 2021

SGHD(2021)32

Addresses

For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Primary Care Leads, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
Chief Officers of Integration Authorities
Chief Executives,
Local Authorities
Directors of Pharmacy
Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
Operational Leads

For information
Chairs, NHS Boards
Infectious Disease Consultants
Consultant Physicians
Chief Executive, Public Health Scotland
NHS 24

Further Enquiries

Policy Issues
COVID Vaccination Policy
TeamVaccinationsDelivery@gov.scot

Medical Issues
Dr Syed Ahmed
Syed.ahmed@gov.scot

Pharmaceutical and Vaccine Supply Issues
NHS NSS National Procurement:
NSS.fluvaccineenquiries@nhs.scot

5) This has been a particular issue for vaccine trials involving vaccines not currently authorised for use in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), and where destination countries are unwilling to accept a letter of participation within a clinical trial as proof of equivalent vaccination status. This is thought to affect around 1,500 clinical trial participants.

6) Participants in clinical trials were initially issued with a letter of comfort from their trial's Principal Investigator (PI). This letter outlined that the holder of the letter should be given equivalent status to someone who can demonstrate their full vaccination status via their record of vaccination.

7) In Scotland, participants in vaccine trials involving vaccines which have subsequently been authorised for use, namely Oxford-AstraZeneca (Spikevax), should now be able to access their record of vaccination through standard channels.

8) Participants in trials with vaccines not currently authorised for use in the UK, for example Novavax, Medicago or Valneva, have been sent a paper certificate containing a 1D barcode, as opposed to certificates for routine vaccination (i.e. a vaccination authorised for use in the UK) which contain a 2D QR code.

9) However, despite clinical trial participants being treated as if they are fully vaccinated for domestic purposes, there is a continued inability for some trial participants for vaccines not authorised for use in the UK to travel internationally which has resulted in some withdrawing from clinical trials.

10) As a result of this, the integrity and sustainability of our current COVID-19 vaccine programme is now a concern. Moreover, there is the possibility that this issue could negatively impact individuals being willing to volunteer for future vaccine trials.

JCVI Advice

11) The Scottish Government is guided by the clinical and scientific advice on vaccination provided by the Joint Committee on Vaccination and Immunisation (JCVI).

12) The Green Book has been updated and states that individuals who have participated in a clinical trial of COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial PIs on whether any individual should receive additional doses for the purposes of vaccine certification.
Greenbook chapter 14a

Additional Primary Course

13) The JCVI has advised that additional doses of UK authorised vaccines are not necessarily clinically required for individuals who have participated in a vaccine trial which is expected to have produced a partial immunological response.

14) However, the JCVI has recommended that, if desired, trial participants may request an additional primary course of UK authorised vaccine following appropriate advice from their PIs (or delegated members of the trial team).

15) Once vaccinated with an additional primary course, individuals would be able to travel internationally in so far as their record of vaccination will now show them as fully vaccinated with a UK authorised vaccine.

Booster dose

16) The JCVI has also agreed that trial participants who are eligible for boosters should be offered booster vaccination in accordance with the eligibility criteria for the wider booster programme, and in line with the guidance contained in the Green Book. Greenbook chapter 14a

Operational Deployment

Additional primary course of UK authorised vaccine for individuals participating in clinical trials for vaccines that have not yet been authorised for use in the UK

17) If a clinical trial participant wants to have an additional UK authorised COVID-19 vaccine primary course in addition to their clinical trial vaccine, then they should discuss this firstly with their PI. Informed consent is an important part of this process due to the lack of published data on safety in this situation. If the individual still wishes to continue and the PI is content, then the PI can issue a Patient Specific Direction (PSD). This will allow the participant to receive a full primary course of an authorised MHRA vaccine through the national vaccination programme.

18) All PIs have agreed to write a PSD for their trial participants as a means of authorising a full primary course for research participants who have received a currently non-authorised trial COVID-19 vaccine, thereby providing evidence of the discussion and consent process. Vaccinators administering the vaccine on this basis should, as with other vaccination events, be covered by local indemnity arrangements.

19) A standard pathway for this route is highlighted in Annex A and a sample Patient Specific Direction is held in Annex B.

20) If an individual was previously part of a clinical trial but has opted out of the trial, and wishes to have an additional primary course of UK authorised vaccine, then they should have received advice from their previous PI on which additional vaccines they require, if any. They can make themselves known to the services and make arrangements through NHS Inform and/or the helpline. Further information about booking appointments can be found on NHS Inform. These citizens should select “No, I have not had a first dose” at the following online registration link. Registering coronavirus vaccine

Boosters for eligible individuals participating in clinical trials for vaccines that have not yet been authorised for use in the UK

21) COVID-19 boosters for eligible trial participants should be given in accordance with the eligibility criteria for the wider booster programme, and in line with the guidance contained in the Green Book.

22) If an individual is still participating in a clinical trial and is eligible for a booster, then the PI of their trial can issue a PSD. This will allow the participant to receive a booster through the national vaccine programme under existing arrangements. A PSD is

required in these circumstances to provide evidence of the discussion and consent process.

23) A standard pathway for this route is highlighted in Annex C.

Boosters for eligible individuals who have previously been part of a clinical trial for vaccines

24) If an individual was previously part of a clinical trial that has completed, or has opted out of the clinical trial, they will be called for their booster through the normal route and they will not require a PSD. If an individual has not been called forward, and thinks they are eligible for a booster, they should make themselves known to the services by using the self-booking portal for boosters that is open from the 15th of November, via this information page: boosters or by calling the national phone line.

25) A draft letter from PIs to trial participants is available in Annex D. This letter will inform the participant of their routes to vaccination and booster.

26) At the end of a clinical trial all participants should be able to speak to their PI about the type of vaccine they have had and discuss with the PI any next steps they would like to take. After discussion, the PI can issue a PSD for additional doses and/or a booster using an MHRA authorised vaccine.

Communications

27) Messaging will emphasise that additional doses of UK authorised vaccine are not necessarily clinically required for individuals who have participated in a vaccine clinical trial which is expected to have produced a partial immunological response.

28) A proactive news release will be issued, and direct communication with clinical trial teams and participants on next steps is planned.

29) Messaging will be shared with Health Boards for distribution through their channels, and we will ensure that this is also shared with the vaccination helpline to respond to any enquiries from members of the public.

Action

30) Health Boards should accept a PSD issued by PIs for clinical trial participants and vaccinate individuals in accordance with such PSDs.

31) Local Vaccination Planning Leads should work with PIs to agree a process locally to facilitate the attendance and vaccination of clinical trial participants, where required.

32) Health Boards should cascade a briefing to all clinical vaccination centres, teams and individual vaccinators to ensure all elements of this letter are clearly understood. For those coming for boosters who are eligible and completed a primary course in a trial with a vaccine not yet authorised in the UK – they may not have a record on the national Vaccine Management Tool (VMT). Trial participants have been advised to discuss this with the trial PIs and obtain a written recommendation in the form of a PSD. If individuals do not have a PSD, vaccinators should take a vaccination history from the individual and offer a booster as appropriate.

33) Vaccines given to clinical trial participants via PSD should be recorded by vaccinators in VMT in line with the national programme.

I remain very grateful for your continued support and ongoing efforts in relation to the national COVID-19 vaccination programme.

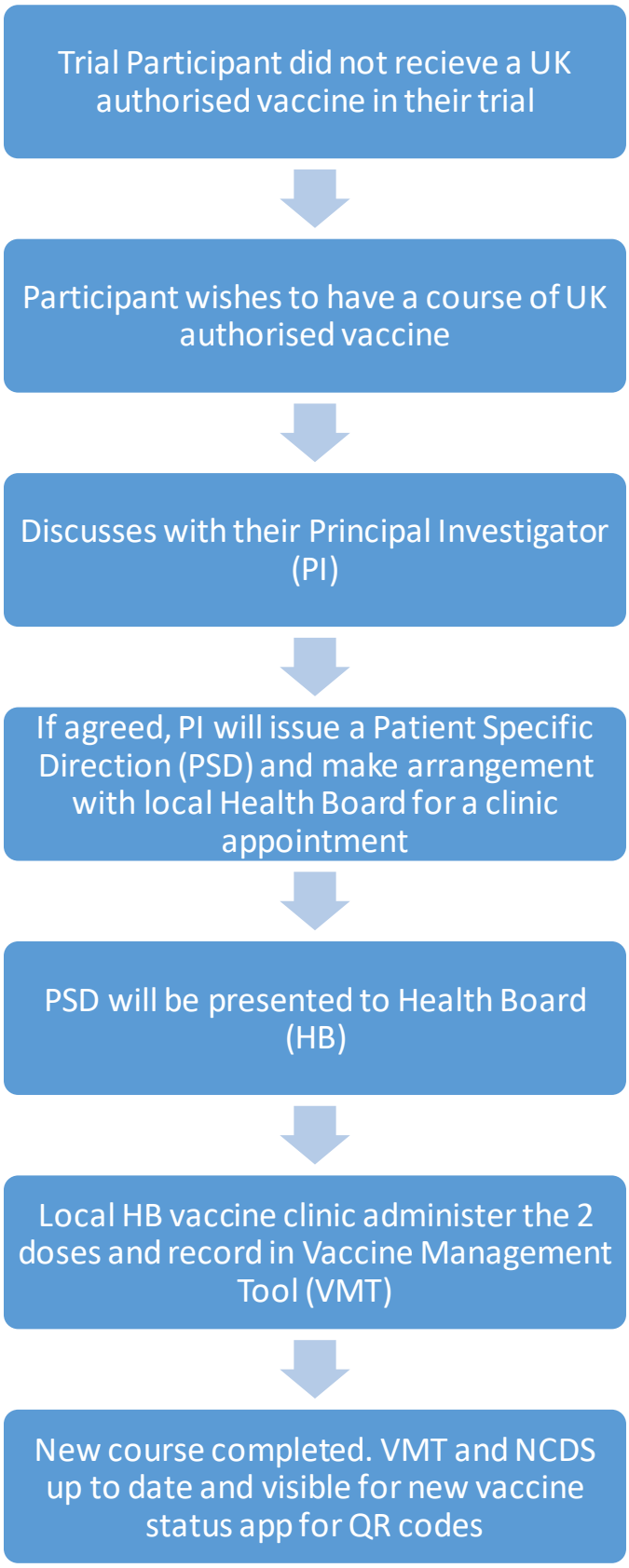
Yours sincerely

Gregor Smith

Dr Gregor Smith
Chief Medical Officer

ANNEX A

Additional vaccine primary doses for the purpose of international travel for current clinical trial participants who have not received a UK authorised vaccine



Annex B
Sample Patient Specific Direction (PSD)

Glasgow Clinical Research Facility
5th Floor, Neurosciences Building,
Queen Elizabeth University
Glasgow
G51 4TF

Email: covidresearch@ggc.scot.nhs.uk
Tel: 0141 232 7600

Date:

PATIENT-SPECIFIC DIRECTION FOR DEPLOYED VACCINATION

Dear colleague

PATIENT DETAILS

CHI:

Name:

Address:

I enclose a Patient Specific Direction (PSD) for deployed vaccination for this participant in the NOVAVAX / VALNEVA / OTHER _____ (DELETE AS NECESSARY OR ENTER TRIAL NAME) clinical trial who has elected to receive deployed vaccination at your centre.

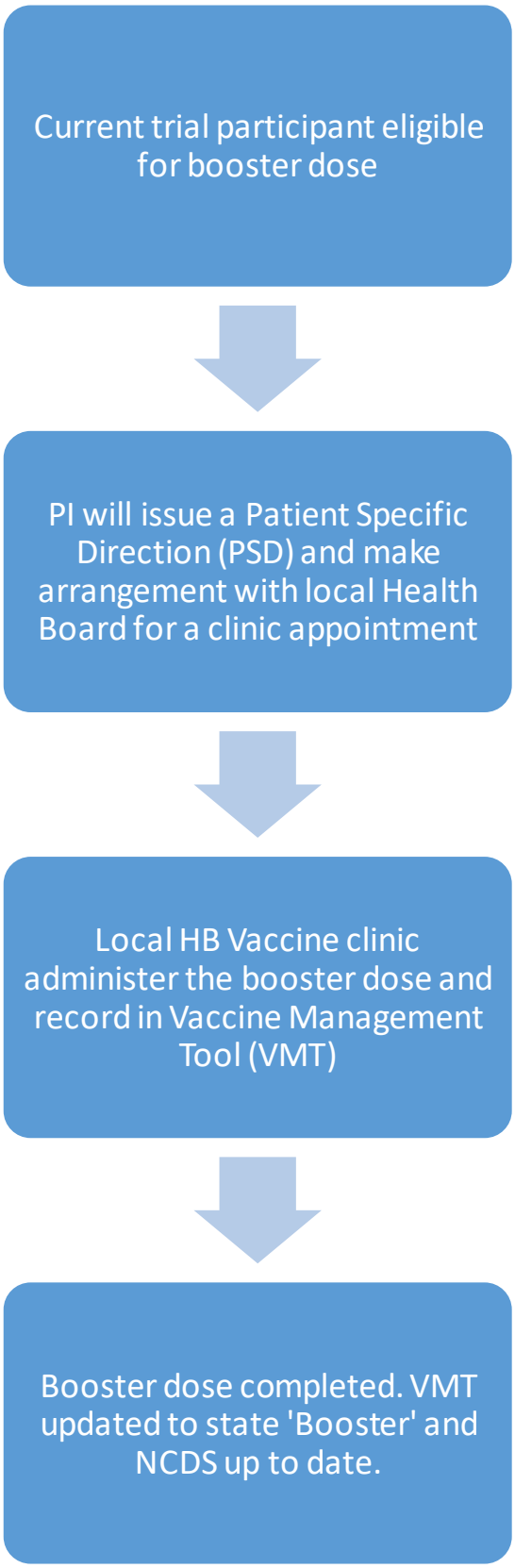
This is for (DELETE AS NECESSARY)
Primary vaccination (two doses) / Booster vaccination (single dose)
with the currently deployed vaccine appropriate for their age. The vaccine can be given from …../../…..

I can confirm that the participant has been counselled regarding vaccination and has elected to proceed with deployed vaccination following an individual assessment of circumstances.

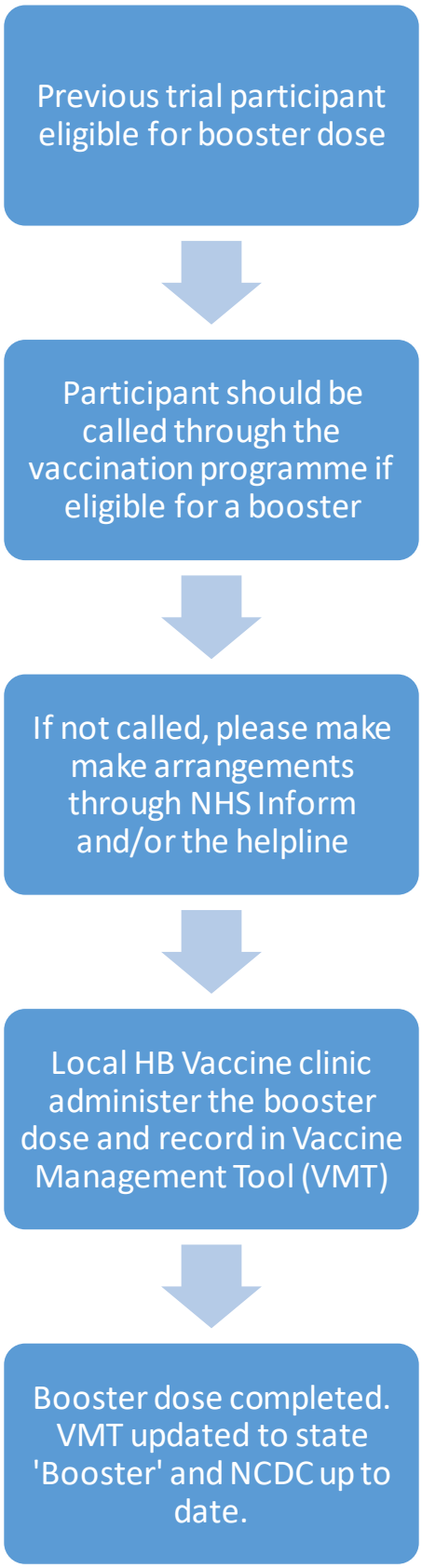
Yours faithfully
PI NAME:
SIGNATURE:

Annex C
Booster Pathway for current and previous clinical trial participants who have not received a UK authorised vaccine

Individuals who are currently a participant in a clinical trial



Individuals who have previously been a participant in a clinical trial



Annex D
Letter from PI to clinical trial participant

Dear Vaccine Trial Participant,

NHS Scotland is extremely grateful to everyone who has volunteered for coronavirus (COVID-19) vaccine trials in Scotland. You have made an important contribution in tackling the coronavirus pandemic and we thank all who have been involved.

This letter sets out important information relating to additional vaccinations and boosters.

1. How can I obtain an additional primary course of UK authorised vaccine?

We recognise that some trial participants who are currently still involved in a vaccine clinical trial and have been vaccinated with a vaccine candidate that has not yet been authorised in the UK, such as Novavax, Medicago or Valneva, have been unable to take advantage of some of the benefits (including international travel) which are currently offered to people who had received a full course of a UK authorised vaccine.

Please note, that participants who have received a full course of trial vaccines can access venues in Scotland with their existing clinical trial letters. An additional course of UK authorised vaccine is not needed for this purpose.

- The UK and Scottish Governments have been working with international partners to agree recognition for COVID-19 clinical trial participants. However, there is currently no internationally agreed policy or consensus on treatment of trial participants, despite these efforts.

- We want to do everything we can for COVID-19 clinical trial participants. As a result, in consultation with the Joint Committee on Vaccination and Immunisation (JCVI) and in partnership with Chief Investigators of these trials, participants in Scotland can discuss with their Principal Investigator the possibility of receiving an additional primary vaccination course using vaccines which have been authorised for use in the UK in addition to their trial vaccines for the purposes of facilitating international travel.

- Therefore, COVID-19 clinical trial participants who have had a complete course of an unauthorised trial vaccine (e.g. Novavax, Medicago or Valneva) may be eligible to receive a full course of a UK authorised vaccine to enable international travel. You should be aware that agreeing to an additional primary course of vaccination with a UK authorised vaccine may result in your withdrawal from the study.

- If you are currently a trial participant and would like to discuss the possibility of receiving a primary course of a UK authorised vaccine, please contact your Principal Investigator in the first instance, who will be able to provide you with more information, including any clinical risks involved. Principal Investigators can be contacted via the usual trial team contact details with which you have previously been provided.

- If you are unable to contact your Principal Investigator, you can contact NHS Research Scotland Central Management Team on communications@nrs.org.uk, who will be able to assist.

- If, after discussion with your Principal Investigator, you still wish to receive a primary course of UK authorised vaccine your Principal Investigator can issue a Patient Specific Direction (PSD). This will enable access to a full primary course of UK authorised vaccine through your local Health Board vaccination arrangements.

- Once received, this course of UK authorised vaccine will be added to your digital record of vaccination which will allow for, among others, international travel and use of digital tools to display vaccination status (such as the COVID status app).

- It is important to check the requirements of the country you wish to travel to as the rules change frequently. Some countries may recognise certain trial vaccines, or allow entry with swab tests, so there may be no need for an additional vaccine. On return to the UK, UK vaccine trial participants have already been given the equivalent status of travellers entering the UK who have received authorised vaccines.

- If you were previously part of a clinical trial for a non-UK authorised vaccine but have opted out of the clinical trial, and want to have an additional primary course of UK authorised vaccine, then you should make yourself known to the services and make arrangements through NHS Inform and/or the helpline. You should select "No, I have not had a first dose" at the following online registration link Registering coronavirus vaccine

- For further information please go to https://www.nhsinform.scot/covid-19-vaccine/after-your-vaccine/coronavirus-covid-19-vaccination-status-for-clinical-trial-participants

2. Will I receive a booster vaccination?

Participants who have taken part in a trial of a COVID-19 vaccine may now be eligible for a booster dose.

The JCVI has agreed that those who have participated, or are participating, in clinical trials will be offered a booster vaccination in accordance with the criteria set for the wider booster programme, in line with Green Book guidance on timing between the end of the primary course and a booster.

The purpose of a booster vaccination is to combat potential waning immunity. If you are in a priority group as recommended by the JCVI, you will be eligible to receive a booster dose of a UK authorised COVID-19 vaccine. The booster invitation process will be rolled out automatically to those eligible.

- If your **clinical trial has completed or you have opted out of your clinical trial** and are invited by the NHS to attend for a booster, you may go ahead and have a booster dose. If you feel you are eligible for a booster dose and have not been invited by the NHS, please make yourself known to the vaccination services and make arrangements through NHS Inform and/or the helpline (0800 030 8013). Further information about booking appointments can be found on NHS Inform. Registering for a coronavirus vaccine | The coronavirus (COVID-19) vaccine (nhsinform.scot)

- If your **clinical trial is ongoing**, your Principal Investigator and study team can advise on receiving a booster and make the appropriate arrangements with the local Health Board for a vaccine clinic appointment. Please speak to your Principal Investigator and study team to discuss, whether you have received an invitation from the NHS for a booster, or feel that you are eligible for a booster and have not been invited.

You should also be aware that boosters will be provided to clinical trial participants in line with the main eligibility criteria and in line with priority groupings.

For more information on the eligible priority groups please see https://www.nhsinform.scot/covid-19-vaccine/the-vaccines/coronavirus-covid-19-booster-vaccination/

For more information on boosters please see https://www.nhsinform.scot/covid-19-vaccine/the-vaccines/coronavirus-covid-19-booster-vaccination

Every participant makes an important contribution to the collection of data about the safety and effectiveness of trial vaccines. We are very grateful of your willingness to help and the time you have given to help identify effective vaccines.

Kind regards,

Principal Investigator