COMMISSION ON HUMAN MEDICINES (CHM)
COVID-19 VACCINES BENEFIT RISK EXPERT WORKING GROUP

Minutes of the meeting held on **Friday 23rd April 2021** at **14:00** via videoconference

Participants Present

Members

Professor Sir M Pirmohamed (Chair)
Professor J Breuer
Professor G Dougan
Mr VI G Fenton-May
Professor N French
Professor D Goldblatt
Ms S Hunneyball
Professor K Hyrich[1]
Sir M Jacobs
Professor H J Lachmann[2]
Professor P J Lehner
Mr R Lowe
Dr S Misbah
Professor Y Perrie
Professor S Price
Professor C Robertson[3]
Professor T Solomon[4]
Professor K M G Taylor
Dr R Thorpe
Professor M Turner[3]
Dr S Walsh
Mrs M Wang
Professor C Weir

Apologies

Dr A Riordan

Invited Experts[5]

[redacted]

Observers

[redacted]
Professor W S Lim
[redacted]

Secretariat

[redacted]

Professional Staff of MHRA Present

Principal Assessors

Dr J Bonnerjea - LD
[redacted] - VRMM

Presenter supporting specific item[6]

[redacted] - VRMM
[redacted] - LD
[redacted] - VRMM
[redacted] - VRMM
[redacted] - LD

MHRA Observers

[redacted] - VRMM
[redacted] - LD
[redacted] - LD
Dr S Branch - VRMM
[redacted] - LD
[redacted] - VRMM
[redacted] - VRMM
[redacted] - MHRA-Policy
[redacted] - VRMM
[redacted] - LD
[redacted] - VRMM
[redacted] - MHRA-Comms
[redacted] - LD
[redacted] - VRMM
[redacted] - LD
Dr J Raine - MHRA CEO
Ms N Rose - MHRA-NIBSC
[redacted] - LD
[redacted] - VRMM
Mr P Tregunno - VRMM
Dr K Wydenbach - LD

1 Joined at item 5
2 Joined during item 3
3 Left during item 7
4 Joined during item 2
5 Left after item 3
6 Supported Specific items

Key
LD = Licensing Division
VRMM = Vigilance & Risk Management of Medicines
Comms = MHRA Communications
NIBSC = National Institute for Biological Standards & Control
MHRA CEO = Chief Executive

1. Introduction and Announcement

1.1 The Chair reminded Members, invited Experts and observers that the content of papers and proceeding of the meeting are strictly confidential and should be treated as 'Official – sensitive commercial' and should not be disclosed. There is no consent for members / participants to record the meeting, take screenshots or photographs of presentations. The meeting was recorded by the MHRA Secretariat for minute taking purposes only. The Chair & Members including all participants gave full consent to the recording prior to the start of the meeting.

1.2 Conflict of Interest Policy (Annex I to the minutes)

The Chair reminded members and participants that, in accordance with the CHM Code of Practice, they should declare any financial interests (personal or non-personal, specific or non-specific) which they have, or which an immediate family member has, in any of the agenda items. Members were also reminded to declare any other matter which could reasonably be perceived as affecting their impartiality.

1.3 Participants declared interests and other relevant interests for this meeting listed at **Annex II** to the minutes.

1.4 Apologies were received from Professor Hyrich and Dr Riordan for this meeting.

1.5 The Chair welcomed the following Invited Experts, who participated for Item 3 only:

Ms [redacted]
Breastfeeding Network

Dr [redacted] Taunton and Somerset NHS Foundation Trust

Dr [redacted] BM BCh PhD
[redacted] Imperial College London
[redacted]

1.6 The Chair welcomed the following observers, who left after Item 5:

Mr [redacted]

Dr [redacted] Public Health England

Professor Wei Shen Lim
Chair of JCVI

Dr [redacted]
Public Health Scotland

Dr [redacted] Public Health Wales

Dr [redacted] National COVID-19 Vaccination Programme

2. COVID-19 Vaccines and Pregnancy/Breastfeeding

2.1 The EWG was informed of the latest Yellow Card reports received in connection with COVID-19 vaccines in pregnancy. A further 48 reports for the Pfizer-BioNTech vaccine and a further 96 reports for the Oxford-AZ vaccine have been received between 26th March and 15th April, resulting in 137 and 210 total reports respectively for these 2 vaccines. The types of exposure and suspected ADRs were similar to those reviewed previously and did not change the previous conclusions.

2.2 The EWG was informed that the advice to preferentially offer the Pfizer-BioNTech vaccine to women known to be pregnant was based on the larger amount of safety data available from use in the USA rather than any specific safety concerns with the Oxford-AZ vaccine.

2.3 The EWG noted that there are currently no restrictions on the use of COVID-19 vaccines specifically in relation to breastfeeding, since no harm is expected for breastfed infants from non-live vaccines. However sparse information is available for use of COVID-19 vaccines during breastfeeding, so the Yellow Card reports in association with breastfeeding have been monitored closely since the rollout began.

2.4 Yellow Card reports related to exposures in association with breastfeeding have been received for the Pfizer-BioNTech (n= 162), Oxford-AZ (n=778) and Moderna (n=1) vaccines from product launch up to 15/4/21. The number of women who have received the vaccine whilst breastfeeding is not currently known.

2.5 The majority of reports reported reactogenic ADRs that are seen in the general population and did not report any adverse effects either on breastfeeding or in their breastfed child (70% of Pfizer-BioNTech and 77% of Oxford-AZ vaccine).

2.6 There were a small number of reports of mastitis or mastitis-like symptoms, breast pain or breast tenderness for both Pfizer (n=6) and OxfordAZ (n=16); although some reports highlighted that these could make breastfeeding more uncomfortable, they did not appear to affect recipients' ability to breastfeed. The EWG considered these might be related to vaccine use, based on temporal association, but did not raise any particular concerns regarding breastfeeding.

2.7 There were a small number of reports of decreased lactation for both Pfizer (n=2) and OxfordAZ vaccines (n=14). The reported reductions varied from temporary complete inability to breastfeed (for 1 -2 days) to 10-20% that was sustained up to the time of report or follow up (max 5 weeks) was received.

2.8 About 20% of reports for Pfizer-BioNTech and 10% of the Oxford-AZ vaccine reported suspected ADRs in their breastfed children. The EWG considered that the reported symptoms are common conditions which occur in children of this age and may be coincidental rather than causally related to maternal vaccination.

2.9 The EWG noted that a number of factors can affect milk supply and infant behaviour, including general maternal health, amount of sleep, and anxiety. Whilst the EWG considered that some of the individual reports might be related to vaccine use, based on the information provided and temporal association, the low number of reports suggest that at most, a small number of women may experience a reduction in breast milk production.

2.10 Overall, the EWG were reassured by the reports related to breastfeeding, particularly the low number of reports and types of symptoms reported for breastfed children. The EWG recommended that no regulatory action was warranted by these data.

2.11 The EWG noted that there is a lot of uncertainty and anxiety amongst potential vaccine recipients over whether to have the vaccine or not due to lack of safety data during breastfeeding. The EWG therefore recommended communicating on the findings from these Yellow Card reports. The EWG considered that the data would not be sufficiently robust for inclusion in product information but noted that the communication via other routes, such as information on the MHRA website and/or through PHE leaflets, would be appropriate.

2.12 The breastfeeding experts highlighted that, although still limited, there is some emerging evidence on protective effects of vaccines by transfer of immunoglobulins via breastmilk, and that conveying this information from Yellow Card reports might also present an opportunity to convey this positive health benefit message.

2.13 The EWG also supported that communicating on the reports would allow messages to support contingency planning regarding having help on hand to assist with childcare if needed.

3. COVID-19 vaccine AstraZeneca post authorisation safety study protocol- C-VIPER pregnancy registry

3.1 The EWG heard an overview of the protocol for AstraZeneca's planned post authorisation safety study to look at use in pregnancy. The study is an international, prospective, observational cohort study of pregnant women which includes follow-up of liveborn infants up to one year of age.

3.2 The EWG discussed the length of follow up of babies born to mothers who received the AstraZeneca vaccine during pregnancy and whether it would be advisable to extend the follow up period beyond a year in order to detect neurodevelopmental problems. The EWG considered the difficult balance with extending follow up for gaining information on neurodevelopmental problems and reduce maintenance of participants to lengthy follow up. The EWG proposed requesting that the study organisers consider an additional questionnaire at 24 months to assess cognitive abilities. The EWG did however, comment that this could produce bias as parents of babies with a neurodevelopmental issue may be more motivated to continue to engage with the study up to 24 months.

3.3 The EWG commented that analysis on a country-by-country basis would be valuable as there may be very different prevalence rates of certain conditions in pregnancy and in babies born between countries participating in the study. The EWG acknowledged that this could raise issues with sample size, and also that some balance would be provided in the matching of cases and controls by country. The EWG also suggested that matching by region within country could also be valuable.

3.4 The EWG commented that while the study will take 5 years, major congenital malformations and other deficits will become evident early on, and so early data could provide reassurance and less significant changes can be picked up as the study continues.

3.5 Overall, the EWG was content with the proposed study.

4. Update on potential risk of GBS with COVID-19 vaccine AstraZeneca

4.1 The EWG was provided with an update on Yellow Card reports and epidemiological analyses of Guillain-Barré syndrome (GBS) up to and including 11 April 21 with the AstraZeneca vaccine. Clinical trial data and company data from the Summary Monthly Safety Review were also provided. Yellow Card reports were assessed against Brighton Collaboration Criteria for diagnosis of GBS.

4.2 The EWG commented that case numbers were increasing but there was difficulty in assessing cases using the Brighton Collaboration criteria due to a lack of information remained. Nevertheless, the EWG considered that the evidence did not require any product information updates currently and a more dedicated epidemiological study was required.

5. Updated review of COVID-19 Vaccines and the potential risk of immune thrombocytopenia

5.1 The EWG was presented with a summary of the Yellow Card reporting, company data and epidemiological evidence for Immune Thrombocytopenia (ITP) and other thrombocytopenia disorders reported following COVID-19 vaccination. This was an update to a previous assessment which had been reviewed by the EWG in February 2021.

5.2 The EWG were informed that there was very limited data on this topic for the Moderna COVID-19 vaccine due to low levels of usage in the UK. There were several UK Yellow Card reports of ITP and other thrombocytopenia events with the Pfizer COVID-19 vaccine, and it was noted that the number of fatal events was low. The company had also reported relatively low reporting of ITP events considering the global usage of the vaccine. There had been more frequent Yellow Card reporting of ITP and thrombocytopenia events with the AstraZeneca COVID-19 vaccine; however, it was noted that the data overlapped with reporting of Thrombosis with Thrombocytopenia Syndrome (TTS).

5.3 The EWG were presented with the MHRA's epidemiological analysis which did not show a signal in the observed vs expected analysis with the Pfizer COVID-19 vaccine and ITP. Similarly, in analysis by the company, the Pfizer COVID-19 vaccine did not demonstrate a signal for ITP in the global observed vs expected analysis. However, there was stronger evidence of a signal with the AstraZeneca vaccine in the MHRA's observed vs expected analysis. There was also a signal observed in the Rapid Cycle Analysis with ITP and the AstraZeneca vaccine which it was reported has been strengthening over time. A pre-print publication of an epidemiological study seen by the MHRA did not show strong evidence of an association of thrombocytopenia and bleeding events with the AstraZeneca vaccine, although some limitations to the study was noted to the EWG.

5.4 The EWG was also presented with data supporting the proposal by AstraZeneca to include thrombocytopenia as a common adverse event in the product information for the Conditional Marketing Authorisation application that is currently being reviewed by the MHRA. The limitations of the laboratory data used to support the frequency of common was described.

5.5 The EWG members highlighted the complexities of diagnosis of ITP and the range of different thrombocytopenic disorders there were with varying mechanisms. The EWG recommended that an expert haematology panel be formed to support the MHRA in reviewing reports of thrombocytopenia events following COVID-19 vaccination to underpin further review of this signal.

5.6 The EWG also noted that there appeared to be a strengthening signal of ITP with the AstraZeneca vaccine, but the experts cautioned that stimulated reporting may be impacting this signal.

5.7 The EWG supported the inclusion of thrombocytopenia in the Regulation 174 authorisation of the AstraZeneca COVID-19 vaccine with the frequency unknown and stated that the product information for the Conditional Marketing Authorisation will be discussed at the Commission on Human Medicines in due course.

6. Janssen Vaccine EU reliance Conditional Marketing Authorisation Application

6.1 The EWG noted that this is the first COVID-19 vaccine application with a single dose regimen; that this vaccine has already been approved for use by the US FDA and the EMA; and that no Regulation 174 request has been received from the DHSC.

6.2 The EWG were informed that this application was via the EU decision reliance procedure and that, in-line with the licensing division SOP, the assessment therefore focuses on 'GB specific considerations' with points raised only if considered 'decision critical'.

6.3 The EWG heard that at the time of submission, no GB specific concerns were identified that would impact the positive benefit/risk balance. However, two points were highlighted in the product information in relation to 1) inclusion of a recommendation regarding anaphylaxis for close observation for 15 minutes post vaccination and 2) that no advice is included in the product information regarding use of paracetamol for symptomatic relief of adverse events. It was noted that advice on paracetamol use is included in the PHE leaflet 'Covid-19 vaccination A guide for adults' given to all vaccine recipients.

6.4 The EWG were informed of the temporary pause in use of the Janssen vaccine in the US, EU and clinical trials whilst the FDA/CDC and EMA completed a review of US post-marketing reports of CVST with thrombocytopenia. The EWG noted the outcome of the PRAC review on 20 April 2021 that the overall benefit/risk remained positive; however, updates to the product information were required; and that these cases were considered to be very similar to those reported with COVID-19 vaccine AstraZeneca.

6.5 The EWG noted that the updates to the Janssen vaccine EU product information requested by the PRAC were very similar to those already included in the EU product information for the AstraZeneca vaccine. However, that there were some differences compared to the wording included in the UK product information for AstraZeneca. In particular, in the EU PI there is no contraindication in patients with previous HITT or HIT type 2, and no warning about administration in patients with a previous history of CVST or antiphospholipid syndrome.

6.6 The EWG agreed that the benefit risk for the Janssen vaccine was positive.

6.7 The EWG commented that if the UK are considering diverging from the EU PIL and SmPC, the 15minute observation window should be considered for removal given that a clear signal of anaphylaxis, beyond that expected for any vaccine, has not been detected. It was noted that a requirement for a 15-minute observation window might cause operational difficulties for the mass vaccination campaign.

6.8 The EWG heard that there is limited scope to change the product information in the reliance procedure, except where there are clear reasons to do so that can be justified, generally this is interpreted to be a serious issue that alters the overall benefit-risk or poses a potential risk to patient safety. With regards to removal of the 15-minute observation window it was

considered that these criteria are not met but that legal advice could be sought as to whether this could still be possible.

6.9 The EWG noted that, to lower the risk of patient harm through administration errors, the negative statement in the product information *not* to give intravascularly, intravenously, subcutaneously or intradermally should be removed. This was considered to be a clear patient safety concern.

6.10 The EWG noted that the data on the events of thrombosis with concurrent thrombocytopenia with the Janssen vaccine are based on more limited usage in the US compared with much higher usage of the AZ vaccine in the UK and EU. It was also noted that, whilst both vaccines are adenovirus vaccines, there are clear differences between the two including the type of adenovirus and DNA construct. Therefore, justifying full alignment of the product information may be difficult. It was noted that the clinical syndrome being reported for the 2 vaccines was similar and that the presence of anti-PF4 antibodies was common to cases with either vaccine. Therefore, it was considered reasonable to assume that a common form of pathophysiology is underlying the thromboembolic clinical syndromes in both the Janssen vaccine and AZ vaccine. Taking this all into consideration and that this procedure was via the EU reliance route, the EWG agreed that the updates to the proposed GB product information for Covid-19 Vaccine Janssen should be in-line with those recommended by the PRAC.

7. NVX-CoV2373 – Cycle 1 Clinical AR (immunogenicity & safety)

7.1 The EWG was presented with an assessment of the Phase I/II study of NVX-CoV2373, which enrolled about 1,500 adults up to 84 years in total. The trial evaluated adjuvanted and unadjuvanted vaccine, 2 antigen dose levels with the same dose of adjuvant, and a 1 vs 2-dose regimen.

7.2 The EWG heard the conclusions of the immunogenicity assessment, as follows. There is a need for the adjuvant and a booster dose to get a humoral response of similar magnitude to that of human convalescent sera. The adjuvant shows a significant [redacted] The antibody response in the ≥60-year olds is about half that in younger adults, but the SCR after 2 doses is >96% regardless of age. After the peak, IgG levels tend to decrease slowly up to 6 months, but more rapidly so for neutralising antibodies; nevertheless, the GMTs of neutralising antibodies at 6 months are still above 100 with SCRs around 70%. Consistent with the antibody response, adjuvant is crucial for induction of an antigen specific T cell response and a second dose of vaccine is needed to achieve a robust response. Overall, a mixed [redacted] response.

7.3 As far as reactogenicity is concerned, [redacted] especially after the second dose, when reactions increase in frequency and severity compared to the first dose. In addition, [redacted] for further development.

7.4 It is noteworthy that after a first adjuvanted dose, mild local reactions of pain and tenderness are more frequent than with placebo, but the frequencies of systemic reactions do not differ from placebo, except for myalgia. After the second dose, the most frequent reactions, which are fatigue, myalgia and headache, are each reported in about one third of the participants receiving the lower dose. These are generally short-lived (median 1 day, none after 7 days). The frequency of fever is low (4%) with only one case of Grade 3 fever (< 1%; between 39 and 40°). As expected, reactions are more frequent/severe in younger adults compared to

older subjects ≥ 60 years, but the frequency of systemic reactions after the second [redacted] dose is still lower than 50% in younger adults.

7.5 Regarding unsolicited events, their frequency appeared to be marginally increased in the adjuvanted vaccine arms compared to placebo; the difference appeared to be mostly driven by local and systemic reactions. There is no SAE of concern except for one case of acute colitis of unclear aetiology (considered as possibly vaccine related). Laboratory tests have only been provided for Part 1 of the trial and show occasional individual decreases in haemoglobin, increases in transaminases or urea across all arms without a clear pattern.

7.6 Finally, the level of vaccination discontinuation is very low, 1% overall and even lower in the vaccinated arms than in the placebo arm.

7.7 In conclusion, the [redacted] dose [redacted] selected for the Phase III trial is considered to have a very favourable reactogenicity profile, even in the younger adult population. Based on this limited safety database, unsolicited and laboratory tests do not raise any major concern. The only questions raised relate to the bioanalytical assays.

7.8 The EWG supported the findings and conclusions of the analytical procedure assessments undertaken by NIBSC assessors.

7.9 The EWG noted that the cellular response data included a prominent [redacted] which appears novel in the context of the vaccines evaluated thus far. The data broadly indicate a [redacted] profile the implications of which are not known, although hypothetically it could lead to a greater likelihood of vaccine exacerbated disease. The EWG noted the [redacted] vaccines have not been associated with a [redacted] response. Therefore, the EWG thought it to be plausible that the [redacted] response may be caused by the adjuvant included in NVX-CoV2373. The EWG noted this adjuvant is not entirely novel to vaccines, in particular recent studies of the malaria vaccine did not raise any concerns specific to this adjuvant.

7.10 The EWG was reassured by the immunogenicity data, however, should adverse events (AE) become apparent once the vaccine is marketed, the potential role of the [redacted] response in the development of AEs will need to be evaluated.

7.11 The EWG heard that the production of validation batches has been delayed. Also, the company have opted to include a different potency assay which includes [redacted] resulting in an assay that should quantify the amount of antigen. However, still outstanding is an explanation of the clinical implications of the [redacted] which will still be present in the product. The company intend to replicate the quality development of the DS process of the product used in the Phase III trial in US, in order that the quality profile at the new site is clinically qualified.

7.12 The EWG heard of inaccurate reports in the media stating that NVX-CoV2373 is expected to be authorised in the UK in the next few weeks.

8. Any Other Business

None.

9. Date and time of next meeting

The next Ad Hoc meeting on Thromboembolic events with COVID-19 Vaccines is scheduled to take place on **Monday 26th April** at **5.15pm**.

The next scheduled meeting is to take place **on Friday 30th April** at **10.00am**

The Meeting today started at 14:13 and ended at 16:50.

[redacted]

16th February 2023

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Annex I

Conflict of Interest Policy for CHM COVID-19 Vaccine Benefit Risk EWG

Chair and Members

- May not hold current personal interests in one or more companies associated with the development of COVID-19 vaccines
- May not currently be or have previously been involved in the development of COVID-19 vaccines

Invited to all meetings, receives all papers and presentations and is permitted full participation in discussion, including drawing up conclusions and recommendations

Invited experts

- May hold current personal interests in one or more companies associated with the development of COVID-19 vaccines
- May currently be or have previously been involved in the development of COVID-19 vaccines

May be invited to all relevant meetings, receives all papers and presentations and is permitted to participate in discussions when invited by the Chair. Does not contribute to conclusions and recommendations

Observers

Are invited to attend all meetings. Will not participate in drawing up conclusions and recommendations.

Annex II

Professor Sir Munir Pirmohamed - NPNS AstraZeneca - Research grant to UOL to support PhD in drug interactions.
Other relevant interests in Pfizer, Janssen, Sanofi – Sir Munir is part of an EU-funded IMI consortium on gene therapy, and these companies are partners in the project. The University of Liverpool will get funding from the EU (but not from the partners), this IMI project commences on 3rd November 2020.
AGILE – this is a Liverpool early phase trial platform (between University of Liverpool and Liverpool School of Tropical Medicine). It is funded by the Wellcome Trust and UKRI/DHSC/NIHR. It is NOT evaluating vaccines, but only drugs to treat COVID-19. Sir Munir is not on the trial management group, and he is not directly involved in choosing the compounds for the study. Sir Munir has no involvement with any of the developers of the compounds to be studied (academic or industrial).
Sir Munir is a member of the UK COVID Therapeutics Advisory Panel (UK-CTAP), which is advising the CMO on which compounds need to be prioritised for the RECOVERY+ trial (RECOVERY is funded via NIHR/DHSC).

Professor Breuer – NPNS – Professor Breuer is on the data safety monitoring committee, DSMB, a study looking at combining vaccines being run by Matthew Snape in Oxford. There does not appear to be any involvement of the vaccine manufacturers and is for already licensed vaccines. The study is funded by the NIHR (Dec 2020).

Professor French - Other relevant interest **-** Provides clinical care when in covering the acute medical wards where patients with COVID-19 are cared. NPNS in GSK - In September 2020 a sub-contract was signed with the Liverpool School of Tropical Medicine to undertake work evaluating the safety and effectiveness of GSK's RTS's malaria vaccine in Malawi. GSK are the primary funders to the LSTM.

Ms Hunneyball - Other relevant interest – writes articles published in the Chemist and Druggist magazine, a trade magazine for pharmacists, but receives no payment for these articles. The information referred to in the articles is in the public domain. Ms Hunneyball makes it clear that these are her personal views and reflections and references all sources of information used.

Professor Hyrich – NPNS - Professor Hyrich was co-I on an investigator-initiated research grant exploring predictors of outcome in rheumatoid arthritis. NPNS Pfizer- she is a Co-I on a grant exploring adherence to JAK inhibitors in rheumatoid arthritis. NPNS in Abbvie, Professor Hyrich gave some lectures at an education conference on effectiveness of treatment for rheumatoid arthritis.

Sir Michael Jacobs - Other relevant interest - As part of the academic role at the Liverpool School of Tropical Medicine, Sir Michael is a member of the Study Management Team and antiviral drug prioritisation group for the AGILE proof of concept (phase I/II) platform study. Sir Michael is also part of the team that submits new antiviral compounds against SARS-CoV2 for consideration by NIHR for testing on this platform. No commercial or financial interest in the trial or any of the compounds, or any pharmaceutical or biotechnology company.

Professor Lachmann – Other relevant interest as a volunteer participant in the Oxford vaccine study and no other involvement in the study.

Professor Lehner - Other relevant interest – Professor Lehner previously held a DPAC (Discovery Partnership with Academia) agreement with GSK, but this has been completed. Professor Lehner's participation in his local hospital D and T governance committee

deliberations would form the normal activity and professional responsibility in his post and does not interfere with the EWG considerations (Sept 2020).

Dr Misbah - NPNS - Holds honorary Senior Lectureship with University of Oxford & Oxford University Hospitals NHS Foundation Trust.

Professor Perrie - NPNS in Pfizer & AstraZeneca arising from a contract for a grant (March 2018), which includes contributions from these companies to the University of Strathclyde, Janssen in writing a grant for a PhD (now funded), GSK – arising from an EU grant to University of Strathclyde (Jan 2019-Dec 2019).

Professor Price - NPNS in GSK and AstraZeneca – which relates to donations provided by both companies to the British Toxicology Society (BTS) to support their Annual Congress and Education and Training of which Professor Price is currently President of the Society (2020-2022).

Professor Solomon - Other relevant interests – Professor Solomon provides clinical care for patients with Covid-19; chaired the MRC/NIHR committee which awarded funding for development of the Oxford Vaccine.

Mrs Wang – Other relevant interests arising from being highly sensitive to insect stings, and plant products such as Hyacinth bulbs, as recorded on Mrs Wang's medical records. The family of Mrs Wang lives with several rare diseases and conditions, some of which result in epileptic fits.

Professor Weir - NPNS - Imperial College and Other relevant interest arising from his department collaborates with Imperial College on a number of clinical trials.

Invited Experts & Observers

Dr [redacted]

Dr [redacted]

Professor Wei Shen Lim - NPNS arises from the institution (Nottingham University Hospitals NHS Trust) where Professor Lim works has received unrestricted investigator-initiated research funding from Pfizer for an unrelated prospective population-based cohort study of pneumococcal pneumonia in which Professor Lim is the Chief Investigator.

Dr [redacted]