COIs Considered by the COI Sub-Group in 2020

#	Issue	Potential COI	Proposed mitigating action	CET COI subgroup decision (including any required mitigating action)
1	UKSCB - Grant application to conduct cell therapy-relevant research on the reproducibility of stromal cell differentiation, expansion, transfection, cryostorage and recovery protocols.	The generated cell products would not be of clinical grade and therefore not suitable for direct clinical use; however, the generated pre-clinical data will be used in the development of a biological medicine and may be used at a later stage to support a future clinical trial application.	If research results are to be submitted in future regulatory approval e.g. Clinical Trial Authorisation (CTA) or Marketing Authorisation (MAA) MHRA divisions will be alerted; alternative agency may need to review the relevant data. Specifically: **Licensing** - Alternative European agency to process Licensing application required if UKSCB is providing operational management. **IES -** alternate European agency to inspect study if UKSCB is required to provide/demonstrate operational management. **VRMM** – VRMM's Sponsor and UKSCB to be notified if safety issues arise throughout course of study.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.
2	Contract testing gradation studies on vaccine candidate.	Providing assay data which could potentially be used in a regulatory submission at a later date, although this is not currently stated as an intended use of the data. Working with a single manufacturer, albeit as part of a consortia which could be perceived as bias.	Working in a consortium for this work rather than just engaging directly with the manufacturer. The materials we are testing are developmental materials which are potential early vaccine candidates.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.
3	Contract Testing - Testing of a candidate inactivated COVID-19 vaccine.	Providing assay data that may be used in a regulatory submission at a later date.	A contractual agreement to be established to define the use of data generated by NIBSC. The manufacturer stated that the data would not be used in a regulatory submission as the sole data set, rather as corroborating information, if it is to be included at all.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.

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			If the NIBSC data set is found to be used in a regulatory submission that is later sent to the MHRA, the MHRA may choose to have the data reviewed by an independent regulator (to be reflected in the contract)	
4	Provision of centralised laboratory at NIBSC for clinical trials testing of candidate vaccines for emerging viruses.	The results of this work are likely to be included in dossiers submitted to regulators to seek a licence for the candidate vaccines in global markets. The perceived COI is from MHRA regulators evaluating a licence application containing data produced by scientists at NIBSC	NIBSC not directly involved in development of vaccines. Samples to be provided to NIBSC blinded. Review by Clinical Trial Advisory Group and Commission on Human Medicines. If application goes to MHRA at a later stage it is proposed to seek review by another regulator of: 1) NIBSC's analytical test methodology and test conduct derived data and 2) The role of the test data in deciding whether to approve the application	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.
5	NIHR funded Phase IV Clinical Trial Asymptomatic	CPRD would be involved in this Phase IV clinical effectiveness trial which is subject to clinical trial regulation and may at some point require regulatory inspection. Also potential for the clinical guidelines in the use of the IMP in the UK and worldwide to change as a result of the outcome of the trial.	• A full CTA submission to be completed by the Sponsor for MHRA assessment, (as opposed to the potential submission under the notification scheme). • The CHM Expert Advisory Group would be asked to verify the decision on the CTA approval. • The MHRA would organise a process for the HPRA (Health Products Regulatory Agency) or an equivalent third party to undertake the inspection activities. If this was not possible, it may be appropriate for the MHRA to undertake an inspection and have any findings reviewed by an expert committee such as the CHM Expert Advisory Group to review and assess any findings.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.

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6	NIHR funded Phase IV Clinical Trial DaRe2THINK	CPRD would be involved in this Phase IV clinical effectiveness trial which is subject to clinical trial regulation and may at some point require regulatory inspection. Also potential for the clinical guidelines in the use of the IMP in the UK and worldwide to change as a result of the outcome of the trial.	• A full CTA submission would be completed by the Sponsor for MHRA assessment, (as opposed to the potential submission under the notification scheme). • The CHM Expert Advisory Group would be asked to verify the decision on the CTA approval. • The MHRA would organise a process for the HPRA (Health Products Regulatory Agency) or an equivalent third party to undertake the inspection activities. If this was not possible, it may be appropriate for the MHRA to undertake an inspection and have any findings reviewed by an expert committee such as the CHM Expert Advisory Group to review and assess any findings.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.
7	Testing by NIBSC of SARS-COV-2 product	Potential for NISBC to be testing a SARS-CoV-2 product and for NIBSC efficacy data to be included in a regulatory submission as an adjunct to a series of other results.	• Samples to be sent to NIBSC with minimal information • The data would be published in a peer reviewed journal • The NIBSC data would not be primary data but an adjunct to a whole series of in vivo experiments in different models being undertaken in Brazil, India and the US.	**Agreed** that application to do this work could proceed, managing the potential COIs as proposed.