Research at UCL and UCLH: Planning for Brexit

Below is a summary of the key likely impacts and **actions which should be taken by UCL and UCLH investigators to prepare** for a no deal Brexit. This guidance should be read in conjunction with the Research and Brexit FAQs document and applicable UCLH/UCL guidance.

Principal Investigators for Clinical Trials of IMPs (CTIMPs) at UCLH (all sponsors)

The JRO and UCLH Pharmacy have been working closely with the UCLH Brexit Committee to plan for a no-deal Brexit.

The Department of Health and Social Care (DHSC) has released guidance on planning for the supply of drugs, including Investigational Medicinal Products (IMPs) for clinical trials, in the event that Brexit negotiations conclude in a 'no deal'.

The JRO and UCLH wrote to all researchers in last year to share this information and advised that Principal Investigators (PIs) make contact with Sponsors as soon as possible to request IMP supply strategies and mitigation plans.

- IMP supply is managed by the study Sponsor, and it is the Sponsor who takes responsibility for ensuring the continuation of this supply in the event there is a no deal Brexit. UCLH Pharmacy will work with the DHSC to ensure continuity of supply where they have contractually agreed to source the supportive / standard of care medicines on behalf of a sponsor..

- As part of Brexit preparations, UCLH Pharmacy have made contact with all Commercial Sponsors for research studies requesting they share their IMP mitigation plans in the event of no deal

- UCLH Pharmacy and the JRO also contacted non-commercial sponsors to gauge the above

- In addition, it is vital that all PIs request confirmation that supplies for their specific study will continue - for those patients who are currently receiving treatment as part of the trial and for those likely to be recruited in the weeks following 1st January 2021

You should contact the JRO immediately if:

- The sponsor has no mitigation strategy and cannot continue supply – for current patients and for those planned to be recruited in the months following the end of the transition period

- The sponsors has a mitigation strategy but continued supply runs out as an emergency

Should you have any queries please email UCLH Pharmacy (Chi Chung – Principal Pharmacist for R&D: chiyee.chung@nhs.net) or the JRO at uclh.JRO-Communications@nhs.net.

Principal Investigators for all other study types at UCLH (all sponsors)

The supply of devices or specific equipment on research studies may be affected by a no-deal Brexit. Contingency plans are in place for supply of medical products.

PIs who rely upon imports of medical devices or other equipment/supplies for their research studies should contact the study sponsor to request assurances over the continuation of these supplies in the event of a no-deal Brexit.

Some research studies require the movement of tissue or data from the UK into Europe, and in some cases, from Europe into the UK. PIs should contact their sponsor immediately to discuss their plans for ensuring this movement is secured in the event of a no-deal Brexit.

The JRO are asking PIs and CIs to confirm their arrangements as part of the COVID-19 restarting studies risk assessments, and to ensure this information is reflected in their study documents.

Any concerns should be sent to the JRO on uclh.jro-communications@nhs.net.

Chief Investigators for Clinical Trials of IMPs (CTIMPs) Sponsored by UCL

The JRO has been working closely with the UCL Brexit Committee to plan for a no deal Brexit.

Trials in the EU require an EU representative (sponsor or legal representative). If there is a no deal scenario, the UK can no longer (as it has been in the past) be considered as this legal base.

As a result, UCL has established a legal base within the EU (in Ireland).

IMP trials with an EU site have already been contacted by the JRO or UCL Clinical Trials Unit to discuss the transition of the legal entity to the new UCL base in Ireland.

IMP trials with only UK sites should not need to change their legal basis. However there may be a need to provide additional information to the MHRA and the HRA. The JRO or the Clinical Trials Unit managing the study will be in touch to advise on these requirements (as needed).

Batch testing and Qualified Person (QP) release will not be affected and the current process will remain for IMP supplies coming into the UK from the EU. However, IMP supplies being exported from the UK to the EU will require an EU QP certification.

Any concerns should be sent to the JRO on uclh.jro-communications@nhs.net.

Chief Investigators on all other research studies sponsored by UCL or UCLH

For non-drug studies which have an EU site and are sponsored by UCL or UCLH – there is no requirement to alter the sponsor.

There may be different requirements for the transfer of data, tissue and blood to and from Europe. Researchers whose studies contain transferrals of this type, should expect delays in transfer as new arrangements are made. Affected researchers who have not yet been contacted by the JRO should make contact as soon as possible via uclh.jro-communications@nhs.net.