Planning for a possible No-Deal Brexit.

Research Studies Sponsored by UCL or UCLH and/or hosted at UCLH

FAQs (Version 1 11.02.2019) UCLH/UCL Joint Research Office.

The decision regarding Brexit is fast approaching. As you will be aware, there are a number of possible outcomes. A possible outcome will be a no-deal.

Should a no-deal be reached, there will be implications upon research studies – both sponsored by UCL or UCLH or hosted by UCLH.

Below, key FAQs to support researchers whilst they consider the actions required for their research programmes.

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Q1: Do I need to do anything?

All researchers on clinical research studies at UCL and UCLH should ensure they consider the implications upon their research in the event of a no-deal. Those most likely to be affected are studies with a supply of drugs, devices, and medicinal and medical products from the EU into the UK.

Those studies involving regular movement of materials, samples or data from the EU into the UK or the UK into the EU may also be affected. UCL or UCLH sponsored studies which have EU sites may also be affected.

Q2: My study maybe affected in a no-deal Brexit scenario. What should I do next?

The first port of call for all researchers is to speak to the study sponsor. Sponsors are responsible for continuing the study as per the requirements of the protocol. This includes supplies, transfers and any regulatory changes which may come into effect. Once you have spoken to the sponsor, let the JRO know immediately of the outcome.

If your study is UCL sponsored and supported by a UCL Clinical Trials Unit (CTU), the CTU should be your first port of call. The CTU will provide support and direction.

Q3: What should I do if a sponsor does not respond?

You should contact the JRO immediately, particularly if there will be consequences to participants or to the quality of samples collected on the study. Every effort should be made to ensure participants and their data are safe and so any issues should be raised immediately.

Q4: I am a researcher in receipt of EU funding. What should I do?

Check to see if you have had any communications from your funder. If not, and you are receiving Horizon 2020 funding, you should contact the JRO finance team asap. The team will be inform the UK Research and Innovations. Researchers should contact the JRO finance team on uclh.enquiry.rd.finance@nhs.net

Q5: I am a Chief Investigator on a Clinical Trial of an Investigational Medicinal Product (Ctimp) sponsored by UCL or UCLH. What do I need to be aware of?

You will need to speak to the JRO or the UCL Clinical Trials Unit managing your study asap. These teams will be looking into which changes will affect your study.

If you have supplies of IMP coming into the UK from the EU, plans will need to be made to ensure their continued supply. You may also need to consider supply to any EU sites if the IMP is released from the UK. The JRO or the Clinical Trials Unit (CTU) supporting your study will advise you on this.

If you have sites in the EU, then there will need to be a legal representative in the EU. The UK is no longer able to act in this role. UCL do however, have a subsidiary in Ireland. The JRO or the CTU supporting your trial will advise.

Sites in the UK may also require assurance from the CI on the continuation of supplies. Should this be the case, you should contact the CTU managing your study or the JRO.

Q6: I am a Principal Investigator on a Clinical Trial of an Investigational Medicinal Product (Ctimp) running at UCLH. What do I need to be aware of?

Supplies of drugs, devices or other medical equipment (specifically provided for research studies) from the EU maybe affected. The Sponsor should provide you with their mitigation plan to ensure the continuity of these supplies post Brexit. If they have yet to do so, you should request this as a matter of urgency.

In the event that a sponsor cannot provide any assurance that supplies are managed you should immediately contact the JRO to discuss.

UCLH Pharmacy department are also contacting all major sponsors to request assurances of their drug supply.

Q7: I am a Chief Investigator on a UCL or UCLH sponsored study which has EU sites. What will happen?

For studies which are not Clinical Trials of Medicinal Products (Ctimps), you will need to consider any implications upon the flow of medicines, tracers, dyes or other supplies as well as data and samples.

You should contact the JRO asap if your study has EU sites or is in receipt of samples or data from an EU entity.

Q8: Are there any issues relating to GDPR that I need to think about?

For some UCL or UCLH sponsored studies there will be. To comply with GDPR, different contract terms will need to apply for the transfer of data from the EU to the UK. If you are the CI for a UCL or UCLH sponsored study which is receiving data from sites in the EU, the site may refuse to transfer data until a Data Transfer Agreement with the UK is in place (the UK will be considered a third country).

A compatible Data Transfer Agreement will be made available. Researchers will need to provide details of the types of data being transferred.

Should your study involve transfer of data from the EU to the UK, please inform the JRO.

Q9: Should we stop recruiting new participants to research studies affected by supply issues?

The Department of Health advises we should continue to recruit participants unless you receive information to the contrary from the study sponsor. The engagement with sponsors now is therefore important.

Should you receive such information or you consider there will be a need to halt or delay recruitment, you should make contact with the JRO immediately.

Q10: The government appear to be planning for stockpiling of medicines. Does this apply to IMPs?

The Department of Health have indicated that licensed and unlicensed medicines fall within the scope of the programme which will stockpile some medicines. IMPs do not fall within the scope of this programme. Pharmaceutical companies are being encouraged to consider supply chain arrangements prior to the 29th March 2019. UCLH will not be stockpiling IMP.

Q11: What are MHRA and DOH advising?

- UCL and UCLH are working in line with the guidance provided by the MHRA, DOH and other relevant bodies. The MHRA have published a statement which encourages organisations to consider supply chains. The statement can be found at: https://www.gov.uk/government/news/supply-of-investigational-medicinal-products-for-clinical-trials-in-the-event-of-a-no-deal

- Other advice and guidance of note include: : https://www.gov.uk/government/collections/how-to-prepare-if-the-uk-leaves-the-eu-with-no-deal#regulating-medicines-and-medical-equipment

- The Department of Health have also released information relating to the planning of the supply of drugs – including to Clinical Trials: https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal

- Clinical Trials regulations in the UK may alter. The MHRA have advised that they are developing new systems to allow trail information to be shared with them in time for March 2019: https://www.gov.uk/government/publications/submitting-regulatory-information-on-medical-products-if-theres-no-brexit-deal/submitting-regulatory-information-on-medical-products-if-theres-no-brexit-deal

- The MHRA and HRA are piloting a combined regulatory approval process. 1 UCL sponsored trials has been involved in the pilot so far. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/how-combined-ways-working-pilot-already-making-impact/

Q12: What's are UCL and UCLH doing to prepare?

Both organisations have Brexit planning groups or Committees in place. Research is represented on both.