**UoB Brexit transition guidance for clinical research**

**Background**

The UK has left the EU, and the transition period after Brexit comes to an end on the 31.12.20.

General UoB Brexit guidance is available on the UoB website

<https://www.birmingham.ac.uk/international/eu-referendum/index.aspx>

This guidance provides information about the transition arrangements and processes for clinical research from 1 January 2021.

Currently all UoB-led CTIMPs are supported by one of the Clinical Trial Units (CTU). CTU colleagues have worked in close collaboration with colleagues from Legal Services, the Sponsor Representative, the Department of Health and Social Care (DHSC), international Co-ordinating Centres and UK/EU regulators to put into place transition and post-Brexit arrangements. A Brexit risk assessment is in place and is reviewed regularly. Researchers should continue to work with CTU colleagues in the usual way.

In addition, members of the Research Governance Team can be contacted for guidance via [researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)

**Key changes for the set-up and conduct of CTIMPs**

UK researchers should note that there are some changes to processes and systems currently in use.

*Submitting for HRA Approval*

The process for HRA Approval has not changed and researchers should continue to prepare the application using the Integrated Research Application System (IRAS).

[*https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/*](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/)

*Submitting information via the MHRA Submissions Portal*

From 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) will be the UK’s standalone medicines and medical devices regulator.

The MHRA Submissions portal was put into place by the MHRA to facilitate any submissions that are currently made via the Common European Submission Portal (CESP). Clinical Trial Authorisation (CTA) applications (completed in the IRAS system), substantial amendments, end of trial declaration and DSURs should now be submitted via the MHRA Submissions portal.

Members of the Research Governance Team and CTU colleagues have access to the portal and will be able to support researchers in the same way as they supported the submissions via CESP.

*Registering a CTIMP and uploading results*

Researchers are encouraged to continue to use an existing and established international register such as [ISRCTN](http://www.isrctn.com/) or [ClinicalTrials.gov](https://clinicaltrials.gov/) to ensure that the public is aware of a trial before recruitment of the first participant. Trials involving sites specifically in EU countries must be registered in the [EU Clinical Trials Register](https://en.wikipedia.org/wiki/EudraCT) (except adult Phase 1 studies).

The time frame for publishing the summary of results remains the same e.g. within 6 months of the end of trial for paediatric clinical trials or within one year of the end of trial for clinical trials in adults. Researchers must publish summary results within these timeframes in the public register(s) where the trials was registered. Use of more than one registry is not recommended. In addition, please send a confirmatory email to [CT.Submission@mhra.gov.uk](mailto:CT.Submission@mhra.gov.uk) once the result-related information has been uploaded to the public registry and provide a link.

Researchers should continue to submit a final report to the Research Ethics Committee within the same timeframe for reporting the summary of results.

<https://www.gov.uk/guidance/registration-of-clinical-trials-for-investigational-medicinal-products-and-publication-of-summary-results-from-1-january-2021>

*Amendment to an existing CTIMP*

The process for a*mendments relevant to the Research Ethics Committee (REC) has not changed and continues to be managed in line with HRA guidance.*

[*https://www.hra.nhs.uk/approvals-amendments/*](https://www.hra.nhs.uk/approvals-amendments/)

*Amendments that need to be submitted to the MHRA should be submitted via the MHRA Submissions portal.*

*IMP management*

CTU colleagues have worked closely with the Sponsor Representative and colleagues from the DHSC to assure the IMP supply for UoB sponsored studies. In line with DHSC guidance, UoB has registered for the Government Secured Freight Capacity. This will provide a route for support in a scenario where the IMP supply is disrupted. Please contact members of the Research Governance Team if you need assistance.

As a Sponsor of UK clinical trials that import investigational medicinal products (IMPs) into Great Britain from outside the UK, we will need to review the existing supply chains.

Where the product is sourced from a country on the ‘approved country for import list’, this will require a UK Manufacturing and Import Authorisation (MIA(IMP)) holder putting in place an assurance system to check that these IMPs have been certified by a Qualified Person (QP) in a listed country, before release to trial sites. The list of approved countries will initially include all EU and EEA countries. QP recertification will not be required. <https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries-from-1-january-2021>

Under the Northern Ireland Protocol IMPs being shipped from the UK to Northern Ireland will require review and approval via an QP based within the EU.

*Safety reporting*

The eSUSAR web reporting tool will remain accessible. As an academic Sponsor UoB will continue to use this platform. SUSAR reporting can also take place via the ICSR submission portal or the MHRA Gateway but these are for use by manufacturers of products

<https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021>

*Sponsor / Legal Representative requirements*

The UK will require the sponsor or legal representative of a clinical trial to be in the UK or country on an approved country list which initially includes EU/European Economic Area (EEA) countries. No amendment to the UK Clinical Trials Authorisation (CTA) is required where the sponsor or legal representative for an ongoing trial is established in the EU/EEA.

For UK international trials being conducted in the EU/EEA a legal representative must be appointed. The University of Birmingham has contracted with a company in Ireland to provide this service. Inclusion of the legal representative requires an amendment to the CTA in each member state but not in the UK.

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial-from-1-january-2021--2>

*Data management*

The General Data Protection Act (GDPR) restricts the transfer of personal data to countries outside the EEA. These so called “restricted transfers” will continue to apply in the UK after the end of the transition period.

The UK government has stated that with regards to sending personal data to the EEA this will be permitted but it will keep this under review. The UK government will however allow transfers to Gibraltar to continue.

The EEA does not offer the UK a reciprocal arrangement. Hence any transfer of personal data from the EMA to the UK will be regarded as a “restricted transfer”. Restricted transfer of data is allowed to a country with an “adequacy status”, but the UK will not have adequacy status on the 1st Jan 2021, in which case transfer needs to be covered by implementing appropriate safeguards. The simplest means of achieving this is to include “standard contractual clauses” adopted by the European Commission, which safeguard the rights for the individuals whose personal data is transferred.

**Key changes for the set-up and conduct of device trials**

It is expected that the UK will not implement the Medical Device Regulations and the following legislation will remain in place in the UK from the 1 January 2021

• Directive 90/385/EEC on active implantable medical devices (EU AIMDD)

• Directive 93/42/EEC on medical devices (EU MDD)

• Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

These directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). <https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021>

**This guidance is based on the following information**

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/guidance-health-and-social-care-researchers-end-transition-period/>

[*https://www.gov.uk/government/collections/mhra-post-transition-period-information*](https://www.gov.uk/government/collections/mhra-post-transition-period-information)

<https://ico.org.uk/for-organisations/data-protection-at-the-end-of-the-transition-period/>