**End of EU Exit Transition Period: Summary of Changes**

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| **Legislative background**Great Britain (England, Scotland and Wales) continues to operate under the Medicines for Human Use (Clinical Trials) Regulations 2004. The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 allows for the MHRA to be able to take on regulatory processes for human medicines and devices that are currently undertaken by the European Medicines Agency and other bodies.Northern Ireland continues to be aligned to EU legislation and regulations. The Ireland/Northern Ireland Protocol came into effect on 1 January 2021 and results in changes to regulations on importation requirements for medicines. |
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| **Registration of clinical trials**As of 1st January 2021, all new trials must be registered on an established international register, such as ISRCTN or clinicaltrials.gov. UHBW’s preferred registry is ISRCTN, in line with the NIHR’s policy on clinical trials registration and disclosure of results.Trials with sites based in the EU/EEA or Northern Ireland will need to be registered in the EU Clinical Trials Registry (via EudraCT). |
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| **EudraCT number**In the short term, the MHRA requires a EudraCT reference number for clinical trial applications. |
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| **Clinical trial applications, amendments and DSURs**As of 1st January 2021 the MHRA Submissions portal replaced CESP as the route for submitting clinical trial applications, amendments and DSURs to the MHRA. UHBW is a registered ‘company’ on the portal and the R&D Department is the main administrator for the account. As administrator, the R&D Department can set up user accounts for UHBW staff and individuals working on its behalf (e.g. clinical trials unit staff) and give them permission to upload submissions. |
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| **Sponsor Legal Representative**The sponsor or sponsor legal representative of a UK clinical trial must be in the UK or in a country on an approved country list, which initially includes EU/EEA countries.A sponsor established in the UK and conducting a clinical trial in the EU/EEA must ensure that a sponsor or a legal representative is established in the EU/EEA.An amendment to the MHRA is not required where a UK based sponsor is adding an EU legal representative to cover EU/EEA sites.Where the UK is a sponsor legal representative for a sponsor outside the EU/EEA, the sponsor will need to identify another legal representative for any sites based in the EU/EEA. |
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| **Publication of trial results**Trial results should be published on the public database where the trial has been registered. For CTIMPs, an email should be sent to CT.Submission@mhra.gov.uk with a link to the database where the final results have been published. This replaces EudraCT as the reporting mechanism for CTIMP final reports to the MHRA. |
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| **SUSARs**UHBW will continue to submit SUSARs via the MHRA’s e-SUSAR reporting system.Clinical trials with sites in both the UK and in the EU will need dual reporting ie via the MHRA’s e-susar website (or via the MHRA Gateway or ICSR Submissions) and to the EMA’s Eudravigilance clinical trial module (EVCTM). |
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| **Devices**UK law for medical devices will remain as Medical Devices Regulations 2002 (SI 2002 No. 618 as amended). These regulations (in the form in which they exist on 1st January 2021) will continue to have effect in Britain after the transition period.From 1st January 2021, the route to going to market for Britain and United Kingdom Conformity Assessment (UKCA) marking requirements will continue to be based on the requirements derived from current EU legislation. |
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| **Qualified Person (QP)**Qualified Person certification arrangements for IMPs manufactured in the UK remain unchanged. |
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| **Import and export of goods**From 1 January 2021 an import and an export declaration is required for all goods moving between the Great Britain and the EU/EEA and between Great Britain and Northern Ireland. This includes human tissue and medicinal products.Up until 31 December 2021, there will be a pragmatic approach to applying EU rules on importation requirements to Northern Ireland. IMP QP certified in the EU/EEA may be imported to Northern Ireland via Great Britain.An EORI number is required to move goods. The import declaration for goods being imported into the UK and the export declaration for goods being exported from the UK must have an EORI number beginning with ‘GB’. The same organisation can make both the import and the export declaration. UHBW holds a GB EORI number. Contact R&D for further details if required.Finished packs of IMPs can continue to be supplied from an approved country directly to sites in Great Britain if QP certified in an approved country. QP re-certification is therefore not required. However, From 1 January 2022, sponsors are required to have in place arrangements for UK based QP oversight of the supply chain i.e. assurance that IMP imported to the UK from an approved country has appropriate EU QP certification.QP oversight must be provided by a UK holder of Manufacturing and Import Authorisation (MIA(IMP)) and can be provided as a service across all sites. The QP providing the oversight role may be based in the UK or an EEA country. |

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| **Human Tissue**Human tissue, referred to as ‘relevant material’ under the Human Tissue Act (2004) is regulated by the Human Tissue Authority. The Act covers England, Wales and Northern Ireland. There is separate legislation for Scotland (The Human Tissue (Scotland) Act (2006). For the purposes of the Human Tissue Act (2004) . Where import and export are taking place, these are not licensable activities under the Human Tissue Act (2004). However, the storage of the material once it is imported may be licensable if this is for a scheduled purpose, such as research within the scope of the Act. |
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| **GDPR**UK GDPR came into effect in UK law on 1st January 2021. It is based on the EU GDPR  (General Data Protection Regulation (EU) 2016/679 which applied in the UK before that date, with some changes to make it work more effective in a UK context.At the end of the transition period, the UK became a third country for data protection purposes.Data flows between the UK and the EU/EEA and data sent to the EU/EEA and stored by EU/EEA processors will need to be compliant with UK GDPR and EU GDPR. The EU is currently conducting an adequacy assessment of the UK and a temporary grace period of up to six months (June 2021) has been agreed between the UK and the EU which will allow the free flow of data. As a precaution, contracts should be checked to ensure that they include clauses which will allow for the free flow of data from the EU/EEA to the UK. |

**References**

SUSAR reporting - <https://www.gov.uk/guidance/guidance-on-submitting-clinical-trial-safety-reports>

Northern Ireland - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

Human Tissue - <https://www.hta.gov.uk/faqs-hta-licensing-requirements-human-tissues-and-cells-used-clinical-trials-and-medicines-0>

GDPR - <https://ico.org.uk/for-organisations/guide-to-data-protection/introduction-to-data-protection/about-the-dpa-2018/#:~:text=The%20UK%20GDPR%20is%20the,effect%20on%2001%20January%202021.&text=The%20EU%20GDPR%20is%20regulated,advice%20on%20your%20EU%20obligations>

Clinical trials registration - <https://www.nihr.ac.uk/documents/nihr-policy-on-clinical-trial-registration-and-disclosure-of-results/12252>