END OF THE EU EXIT TRANSITION PERIOD – QUICK FACTS FOR RESEARCH

(VERSION 1.0)

Newcastle Joint Research Office

SPONSORS/UK REPS

The UK will require the sponsor or legal representative to be in the UK or country on an approved country list which
would initially include EU/European Economic Area (EEA) countries

Where the sponsor is from outside the EU/EEA and the legal representative is established in the UK; with
sites elsewhere in the EU/EEA, the sponsor will need to assign an EU/EEA legal representative for these sites

REGISTRATION

From January 1st 2021 trials will be required to use
ISCRTN or clinicaltrials.gov. The Newcastle upon Tyne Hospitals NHS Foundation Trust expects registration on
ISCRTN. However; when a trial meets certain criteria (please see Sponsorship
Policy) it may be registered on clinicaltrials.gov. Where a trial has EU or
Northern Ireland sites an entry will also be made in the EU Clinical Trials Registry

EUDRACT REFERENCE

At this time a EudraCT reference is still required by the MHRA

CLINICAL TRIALS

SUSPECTED UNEXEPCTED SERIOUS ADVERSE EVENTS

Reporting will now be completed via the MHRA gateway, eSUSAR system or ICSR Submissions (Eudravigilance replacements). The Trust as a
Sponsor is registered with the appropriate system. Clinical trials with sites
in the EU require dual reporting

NORTHERN IRELAND (NI)

Under the NI Agreement, NI will continue to follow EU regulation in many cases. The references to Great Britain refer to England, Scotland and Wales

DRUG SAFETY UPDATE REPORTS (DSUR)

As Sponsor we will be required to register for the MHRA submissions system. It allows us to upload DSURs as required. The Trust will
act as the main administrator and is able to add other organisations (for example: Clinical Trials Units) that manage studies on our behalf

LEGISLATION

Great Britain will follow the Medicines for Human use (Clinical Trials) Regulations 2004

DEVICES

LEGISLATION

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 1 January 2021)
will continue to have effect in Britain after the transition period

From 1 January 2021, the route 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

CE MARKS

CE marking and certificates by EU-recognised Notified
Bodies will continue to be recognised in Britain until 30 June 2023. After the transition period, the EU will no longer recognise UK Notified Bodies

UK Notified Bodies will not be able to issue CE certificates (other than for the purposes of the "CE UKNI" marking, which will be valid in Northern Ireland) - and will become UK Approved
Bodies from 1 January 2021

MHRA REGISTRATION IN GREAT BRITIAN

Class IIIs and Class IIb implantables, and all active implantable medical devices and IVD List A
products must be registered from 1 May 2021

Other Class IIb and all Class IIa devices and IVD List B products and Self-Test IVDs must
be registered from 1 September 2021

Class I devices, custom-made devices and general IVDs (that do not currently need to be registered) must be registered from 1 January 2022

UK CONFORMITY ASSESSMENT (UKCA)

The UKCA mark is a new UK product marking that will be used for certain goods, including medical devices,
being placed on the British market after the transition period. The UKCA mark will not be recognised in the EU, EEA
or Northern Ireland markets, and products currently requiring a CE marking will
still need a CE marking for sale in these markets

OUTSIDE THE UK

A manufacturer based outside the UK wanting to place a device on the British market, will need to
appoint a single UK Responsible Person who will take responsibility for the
product in Britain

QUALIFIED PERSON (QP)

Qualified Person certification will continue to
be required to use an IMP in UK, NI or Great Britain
clinical trials

QP certification done in the EU/European Economic Area (EEA) will also enable supply of IMP to Northern Ireland via Britain until 31 December 2021

INVESTIGATIONAL MEDCINIAL PRODUCTS (IMP)

SUPPLY TO NORTHERN IRELAND

IMPs can be supplied from Great Britain to Northern Ireland with a pragmatic approach to applying EU rules on importation requirements until 31 December 2021

From 1 January 2021 UK Customs require more detail on customs documentation for IMP being sent in to NI. For individual patient deliveries this may require further consent from trial participants in order to share their personal data for this purpose. Verbal consent should be received and documented in the patient's notes

IMPORT FROM EU/EEA

From 1 January
2022 a QP resident in the UK or an approved listed country (initially all EU and EEA) will be required to provide oversight of the supply chain of an IMP on
entry to the UK where the product is being imported from an approved listed
country. This must be performed in collaboration with a facility holding a UK Manufacturing and Import Authorisation(MIA(IMP))

Importation of
QP certified non-IMPs or unmodified comparators from listed countries will require a wholesale dealers authorisation with a named Responsible Person for
Import (RPI). Existing holders must notify authorities within 6 months and name a RPI within 2 years from leaving the EU

Sponsors are formally responsible for ensuring
appropriate measures area put in place to enable continued supplies of their IMPs to host sites

SUPPLY, AMENDMENTS & PAEDIATRIC INVESTIGATIONAL PLANS

SUPPLIER & CENTRAL LABORATORIES

Any change in supplier or central laboratory may be implemented as a non-notifiable amendment, if it does not affect participant-facing information. The amendment should be recorded at sites with the updated version
numbers of any documents, and implemented at sites.

The updated documents should be referenced in the next amendment submmitted to the Research Ethics Committee (REC)

Sponsors will be permitted to submit one amendment
that affects multiple studies

IMP, DEVICE & RADIOISOTOPES

Any changes, not within scope of the original or amended approval, to IMPs, drugs, devices or radioisotopes used in research should be notified as substantial amendments requiring submission to both MHRA and REC

PAEDIATRIC INVESTIGATIONAL PLAN (PIP)

The PIP application
process will be simplified, offering an expedited assessment where possible. MHRA
will mirror the submission format and terminology of
the EU-PIP system. The scientific content and assessment will be kept in line with European Medicines Agency (EMA)

PIP & NORTHERN IRELAND

Northern Ireland
will continue to be part of the EU's system for paediatric medicines development including agreement of EU PIPS or waivers

LEGISLATION

If operating inside the UK, you will need to comply with UK data protection law. The government intends to incorporate GDPR into law from the end of the transition period. The Data Protection Act 2018 within the UK will continue to apply

The EU version of the GDPR will still apply when operating in Europe, if offering goods or services to individuals in Europe, or monitoring the behaviour of individuals in Europe. GDPR applies to organisations in Europe who send data to the UK

DATA

TERMINOLOGY

For data protection legislation the Sponsor is the Controller and sites are the Processors. Shared Controllers are permitted

AMENDMENTS

For changes to collection of personal data for UK participants that will be transferred outside the UK, information to participants will need to be updated. A substantial amendment will be required

DATA PROTECTION IMPACT ASSESSMENTS (DPIA)

MHRA has confirmed that a DPIA should be conducted for a study by the Sponsor. There is no requirement of each site hosting that study to conduct an additional DPIA

PUBLIC ORGANISATIONS

At this time public organisations, including the NHS will have no changes enforced in processing and transferring data to the EU. It is suspected this will last for at least 6 months. Further information will follow once available

AGREEMENTS

Data sharing agreements should already be in place for data sharing partnerships. They are an appropriate safeguard and their need will continue to exist in all Brexit scenarios

DEFINITION

Human
tissue, referred to as “relevant material” under the Human Tissue Act (2004) is regulated by the Human Tissue Authority. For the purposes of the Act, import and export is considered as into and out of England, Wales and Northern
Ireland. This definition will be unchanged following the end of the transition period

HUMAN APPLICATION LICENCES

The Human Application sector must update their HTA licences from 1 January 2021 if they wish to continue to receive tissues/cells from countries within the EU (import) or, send tissues/cells to countries within the EU for human application (export). This includes establishments using these materials for the manufacture of an Advanced Therapy Medicinal Product (ATMP)

Importers - must be able to demonstrate tissue/cells meet equivalent quality and safety standards to those set out in the Human Tissue (Quality and Safety for Human Application) Regulations, 2007 (as amended)

Exporters – Must additionally ensure the release process includes confirmation by a suitably trained and experienced person that the material meets the regulatory requirements.
Changes are not required to other sector licences

BUSINESS CONTINUTY

In order to ensure continuity of supply, you will need to ensure the integrity of your supply chain via written agreements with your suppliers, risk assessments and have contingency measures in place. The agreements with your recipient organisation(s) in the third country must set out the responsibilities of each party throughout the tissue or cell pathway, including transportation and Serious Adverse Events and Reactions (SAEARs) reporting arrangements

NORTHERN IRELAND

The HTA will continue to be the ‘Competent Authority’ in NI for the regulation of tissues and cells for human application.
From 1 January 2021, establishments in NI will need to treat suppliers in Great Britain in accordance with the relevant EU regulations on non-EU suppliers

There are no additional requirements to send tissues or cells to Great Britain

TREATING PATIENTS FROM THE REPUBLIC OF IRELAND

PATIENTS

All participants will be classified as non-private
with all-inclusive fixed packages and with no professional costs. A definition of which can be found in The Newcastle upon Tyne Hospitals NHS Foundation Trust
Private Patients Policy, section 2.2 ii

CLINCIAL TRIAL COSTS

All
trial specific treatment costs will be covered as per the study specific costing tool. The NHS provides standard non-negligent harm insurance for
treatments required as a direct result of a study procedure and as an NHS patient

COMMON TRAVEL AGREEMENT

The Common Travel Area (CTA) is an agreement
between the UK and Ireland that is non-dependent on membership of the EU. British citizens in Ireland
and Irish citizens in the UK hold a unique status under each country's national
law. You do not need permission to enter or remain in the UK, including a visa,
any form of residence permit or employment permit