UNIVERSITY OF LEEDS

The Leeds Teaching Hospitals NHS Trust

EU Exit Transition – Changes to MHRA Clinical Trial Submission Systems

1) What is Changing?

As you will be aware, the United Kingdom (UK) has now left the European Union (EU), with the current transition period due to end on the 31st December 2020.

From the 1st January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) will be the UK's standalone medicines and medical devices regulator, and access to all common European submission portals will be lost.

The MHRA have therefore made some changes to their systems to allow documentation to be submitted to the regulator following this date.

This document summarises the key changes and steps required to continue managing regulatory documentation for your Leeds Teaching Hospitals NHS Trust (LTHT) and University of Leeds (UoL) Sponsored CTIMP clinical trials following this date.

2) The "MHRA Submissions" Portal

From 1st January 2021, **the Common European Submission Portal "CESP" will no longer be in use for the UK and users will need to submit all applications and clinical trial paperwork via the new "MHRA Submissions" portal**. The new system is due to go live in January 2021 and works in a similar way to CESP.

All staff responsible for submitting any form of documentation to the MHRA (e.g. initial applications, amendments, Developmental Safety Update Reports (DSURs) & End of Trial Declarations) must register on the "MHRA Submissions" portal.

Both the UoL and LTHT are registered organisations on the new system and the QA team are acting as central administrators for account access. Research teams should contact the QA Portfolio Coordinator to arrange access as soon as required.

3) Submitting Clinical Trial Applications to the MHRA:

As of 1st January 2021, Clinical Trial Application forms will need to be completed within the Integrated Research Application System (IRAS), downloaded as a PDF copy and then submitted to the MHRA via the "MHRA Submissions" portal.

It remains a condition of approval to register Clinical Trials on a publically accessible database. The register you choose (and the registry number if available), must be specified on the Clinical Trial Application Form as part of your initial submission.

The MHRA have advised that new trials in set-up **must continue to apply for a EudraCT number as per the existing process until further notice.**

4) Reference Safety Information (RSI)

From 1st January 2021, Summary of Product Characteristics (SmPC's) can continue to be submitted in place of an Investigator Brochure (IB) for Investigational Medicinal Products (IMPs) that have a Marketing Authorisation from a country on the "Approved Country List".

The current list of approved countries can be found at the following link:- List of approved countries from 1 January 2021 - GOV.UK (www.gov.uk) (subject to change – see current version on MHRA website).

As per current processes for trials with UK sites only, the MHRA must approve the RSI before implementation. For trials with both UK and EU sites, the RSI implementation date will be the date the RSI was approved in all EU member states and the UK, therefore it is suggested that the RSI is submitted to both approval bodies in tandem to prevent any delay.

5) Reporting SUSAR's to the MHRA

Access to the MHRA's eSUSAR portal will continue as normal, but access to the EU SUSAR platforms (EVWEB and EudraVigilance) will be lost.

The MHRA will **no longer perform onward reporting of SUSARs to the EU portals**, therefore if this is required you will need to submit to the EU separately.

Post transition period, new systems "ICSR Submissions Portal" and the "MHRA Gateway" will be made active to facilitate EU reporting where needed. More information on how to register for these systems can be found at this link- Registering to make submissions to the MHRA from 1 January 2021 - GOV.UK (www.gov.uk)

6) End of Trial Processes:

For active trials that are already registered on the EudraCT database, Sponsors can continue to submit results to EudraCT after the end of the transition period.

For new trials registered after the end of the transition period, you must publish trial results in the public register you've registered with.

7) What's Next?

The QA team are continuing to monitor all updates and communications from the MHRA. With new legislation coming into effect and the new systems going live in the new year, it is likely changes to our researcher facing Standard Operating Procedures (SOPs) will be required.

These will be communicated through the usual channels of communication, and further bulletins will follow as soon as additional guidance is required.

Key Resources & Further Reading:

Sponsor CTIMP SOPs and Bulletins	Sponsor QA office	http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents/
MHRA Submissions Webinars	MHRA	Webinars: preparing to make submissions to the MHRA from 1 January 2021 - GOV.UK (www.gov.uk)
MHRA EU Exit Guidance/Post transition period info	MHRA	MHRA post-transition period information - GOV.UK (www.gov.uk)

*** Should you have any queries or concerns, or would like further information regarding the content of this bulletin, * then please do not hesitate to contact the Sponsor Quality Assurance Office on Tel: 0113 30 60465**