# Guidance on registration of clinical trials for investigational medicinal products and publication of summary results if there is a no-deal Brexit

This guidance contains information about registration of clinical trials, publishing trial results and future requirements if there is a no-deal Brexit

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## Registration of your clinical trial

The UK's intention is to align transparency provisions with those currently operating in the EU, in order to eliminate the need for companies to duplicate efforts.

### Actions for those involved in registering clinical trials

In the short term, you should continue to use existing and established international registers such as EudraCT (EU), ISRCTN (International Standard Randomised Controlled Trial Number) register (UK), and ClinicalTrials.gov (USA) to ensure that UK patients are aware of your trial.

In the UK, any approval by a research ethics committee is subject to the condition that all clinical trials must be registered on a publicly accessible database. This must be done within 6 weeks from the recruitment of the first participant.

If a sponsor wishes to request a deferral for study registration within the required timeframe, in accordance with current transparency rules operating in the EU (e.g. for adult phase 1 studies), they should contact hra.studyregistration@nhs.net.

The expectation is that all clinical trials must be registered. However, in exceptional circumstances non-registration may be permissible with prior agreement from the Health Research Authority (HRA).

The UK will continue to make information about trials being conducted in the UK available to the public, patients, researchers and clinicians via the HRAwebsite and UK Clinical Trials Gateway.

# Publishing trial results

The time frame for posting the summary of results is within 6 months of the end of trial for paediatric clinical trials or within one year of the end of trial for non-paediatric clinical trials.

### Actions for those publishing results

You should publish your summary results within these timeframes in the public register (or registers) where you have registered your clinical trial.

You do not need to submit this clinical trial summary report to the MHRA as well; however, you must send a short confirmatory email to CT.Submission@mhra.gov.uk once the result-related information has been uploaded to the public register.

## Future requirements

Transparency measures will be strengthened under the new EU Clinical Trials Regulation (CTR) 536/2014. If this Regulation is not in force in the EU on exit day, it will not be incorporated into UK law under current terms of the EUWithdrawal Act. However, we will align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals.

By the time the EU's new portal goes live (as part of the new CTR), the UK will have its own equivalent hub that would give UK public, patients, clinicians and researchers a single reference point for all UK trials.

This guidance will apply from exit day in line with the the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019.