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Lowest-Risk Clinical Trials Will Benefit from a New Notification Scheme and a Shorter Period for Application Processing

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On 12 October 2023, the Medicines and Healthcare products Regulatory Agency (the MHRA) announced that the healthcare and life sciences sector will benefit from a new streamlined notification scheme for lowest-risk clinical trials (the Scheme). The Scheme will see the lowest-risk clinical trials processed by the MHRA in less than 14 days.

The current legislation that governs the regulation of clinical trials in the UK is the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is based on the EU Clinical Trials Directive. Following Brexit, the UK is in the process of overhauling its clinical trials regulatory regime to deliver a world-class regulatory environment for clinical trials to support the safe development of innovative medicines for the benefit of patients and public health.

As discussed in our previous updates, to this end, the MHRA consulted on various proposals for legislative change, which would be made using powers set out in the Medicines and Medical Devices Act 2021 (the Consultation). The MHRA designed the proposals to:

- Ensure patients safety and bring the benefits of clinical trials to everyone;
- Create a proportionate and flexible regulatory environment;
- Cement the UK as a destination for international trials; and
- Enable innovation.

The consultation closed in March 2022, and the new regulations have not yet been published.

The Scheme

Under the Scheme, the MHRA will process initial clinical trial authorization (CTA) applications for eligible clinical trials much quicker – within 14 days instead of the usual 30 days. About 20% of UK initial clinical trial applications are expected to be eligible.

The Scheme currently only applies to CTA applications for Phase 4 and certain Phase 3 clinical trials deemed to be of lower risk; it does not include CTA applications for first in human (FIH), Phase 1 or Phase 2, or amendments at this time. Additional MHRA’s criteria apply as well.

Phase 4 trials (post-marketing or surveillance trials of licensed medicines) must meet both of the following criteria:

- All investigational medicinal products (IMPs) are licensed and used according to the relevant UK, USA, or EU marketing authorisation (except for placebo); and
- There are no ongoing safety concerns with the IMP(s).

Phase 3 (pivotal pre-marketing trials and evaluate the efficacy and safety of the drug) must meet at least one of the following criteria:

- The trial is already approved in the USA or EU based on the same documentation (the same protocol and/or investigator's brochure and/or IMP dossier).
- The MHRA have approved in the last 2 years a previous phase 3 clinical trial of the IMP(s) at the same dose (or a higher dose), dosing frequency (or a higher frequency) and route of administration, and for the same indication (even if the trial was with a different sponsor) and utilising the same manufacturing process.
- IMPs are licensed and used according to the relevant UK, USA, or EU marketing authorisation (except for placebo).
- In addition, to be eligible for the scheme a Phase 3 trial must not include any of the following:
    - Complex, innovative trial design (*e.g.* basket, umbrella and platform) that allows for prospective major adaptations such as the addition of indications or IMPs via future amendments;
    - Includes paediatric participants;
    - Includes pregnant or breastfeeding participants;
    - IMP is first in class;
    - IMP is an advanced therapy medicinal product (ATMP).

The MHRA has said that it will keep the criteria for notification of clinical trials under continual review.

A favourable opinion from a Research Ethics Committee (REC) is still required for eligible trials, and although applications under the Scheme are submitted via the combined review process using the Integrated Research Application System (IRAS); the REC opinion is not part of the Scheme, and therefore the 14-day timeframe does not apply to the REC although the HRA said, at the time of the announcement, that the HRA are keen to explore how the fast-track Research Ethics Service can complement the Scheme.

The Scheme is meant to support the UK government's ambition to be one of the best countries in the world to conduct clinical research for patients and researchers by introducing more flexibility and making decisions based on an assessment of risk will help streamline processes for those running trials. The government plans to move away from 'one size fits all' legislation and introduce measures to enshrine proportionality.

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