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MHRA ANNOUNCES STREAMLINED CLINICAL TRIAL REVIEW PROCESS

In a post-pandemic world, we are seeing a number of developments manifesting around the immediate need for patients to access medicines at an expedited rate. In the recently released, UK Life Sciences Vision, the Government and regulators have identified and emphasised the importance of the speed and efficiency at which medicinal products travel through the pipeline in order to reach those who will benefit most from these novel therapies.

Indicative of the UK's 'vision' and following on from the Recovery, Resilience and Growth programme, comes the recent announcement by the MHRA of their intention to streamline the clinical trial review process.

From January 2022, the MHRA and the UK Research Ethics Services – in collaboration with the UK's Health Research Authority – will review new Clinical Trials of Investigational Medicinal Products (CTIMPs) concomitantly. It will also be the only route to clinical trial authorisation beyond January 2022.

Single Unified Request

The revised process will mean applicants only have to submit a single application, which will be put in front of the research ethics committee as well as being reviewed for authorisation of the clinical trial. The ethics sign-off and authorisation are then issued in one notification. This process will not only help to reduce the paperwork and notification encumbrance for beginning a clinical trial, but also it may also be utilised when any change or clarification is requested.

The combined review process is available now and the MHRA encourages applicants to start using the new process straight away. Existing users of the new procedure have reported a 30% improvement of overall clinical trial set-up times.

Coupled with novel marketing authorisation routes such as the Innovative Licensing and Access Pathway (ILAP), we are really seeing the MHRA take a pro-active and collaborative approach to its role in the industry. To see regulators, the Government and devolved administrations communicating and working together in order to provide a harmonised approach to improvements to these sorts of initiatives is a bright new path in the UK's post-Brexit future.

Read the MHRA's statement **here**.

Guidance and access to the combined review here can be found **here**.

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