

Pharmacists lead the way in streamlining experimental cancer trials

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A new way of conducting technical pharmacy reviews that cuts down on the bureaucracy of setting up clinical trials is being pioneered by pharmacists across the Experimental Cancer Medicine Centres (ECMCs) network, a joint initiative between Cancer Research UK and the four health departments of the UK.

The new process is coordinated by the Health Research Authority (HRA) and involves a single technical pharmacy review being carried

out once by a designated pharmacist and shared with participating sites instead of each site conducting their own separate review.

This new way of working is now being rolled out to all [clinical trials](#) across the ECMC network as part of an early implementation phase of the pharmacy review element of the new HRA Approval process.

When fully implemented, HRA Approval will remove the requirement for permission for research from individual NHS organisations, who will instead simply confirm whether they can and will deliver a research study. An integrated assessment by staff, along with the favourable ethical opinion from the research ethics committee, will provide the HRA Approval - one application, one assessment and one approval - for research in the NHS in England. Scotland currently delivers a single approval for generic R&D issues through NHS Research Scotland. The joint aim of the HRA and the devolved administrations is to deliver a co-ordinated approval throughout the UK.

For pharmacy, it is hoped the new single technical review will help speed up multicentre trials by reducing duplication of work across participating sites and allowing sponsors to respond to queries from one source without having to talk to multiple pharmacists at different sites. The reduced bureaucracy will help free up pharmacists' time to focus on supporting the set up and delivery of studies and local study set-up.

Dr Richard Baird ([link is external](#)), a clinical researcher based at the Cambridge ECMC , who is leading a new trial for patients with lung and breast cancer that has spread to the brain, said: "This is an important step in improving clinical trial set-up that has huge potential benefits for both hospital staff and ultimately patients, who we hope will be able to benefit from new experimental cancer treatments sooner.

"It has allowed us to carry out a single pharmacy review for our trial

rather than twelve separate ones, which has significantly cut down on paper work and saved hospital pharmacists' valuable time. I'm delighted that this new initiative is now being rolled out across all our trials."

Tim Root, honorary secretary of the National Pharmacy Clinical Trials Advisory Group, a Partnership Group of the Royal Pharmaceutical Society, said: "We welcome this new initiative, which is the result of many months of hard work and consultation with NHS pharmacists working across the ECMC network and builds on local initiatives already underway. Pharmacists' continued input will be vital to ensure that this new approach can work on a national scale and we look forward to supporting wider implementation."

Janet Messer, Programme Director for the HRA Approval Programme, said: "We have been delighted to work in close collaboration with Cancer Research UK and the pharmacists in the ECMC Network to develop and refine this new process. This will provide benefits for experimental cancer treatments now and it is an important step in the process of implementing HRA Approval in a controlled and collaborative way."

Professor Peter Johnson, Cancer Research UK's chief clinician, said: "We're delighted that our Experimental Cancer Medicine Centres network has been able to support this important initiative to streamline the regulation of clinical research, so patients can continue to reap the benefits from the world-class research taking place throughout the UK."

More on the HRA Approval

- Researchers will benefit from HRA Approval through the elimination of duplicate application routes and paperwork, enabling them to work on establishing research sites, recruiting participants and completing studies on time.

- Patients will benefit from HRA Approval through earlier opportunities to participate in studies and through more efficient and effective research leading to improved treatments and care.
- Industry will benefit from more joined-up access to NHS sites for research, making the UK a more attractive place for health research.
- HRA Approval will provide the platform for delivering the EU clinical trials regulations, ensuring the UK is ready and prepared and Industry can plan to place studies in the UK with continued confidence in UK readiness
- HRA Approval applies for all study types in England in the NHS.
- Health research falling under other specific legislation will still need approvals from other Regulators, these will continue to be coordinated within an overall UK wide framework for research in the UK

More information: Further details of the HRA Assessment and Approval can be found at: www.hra.nhs.uk/about-the-hra/our-approach-to-assessment-and-approval/

Provided by Cancer Research UK

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