MHRA’s new guidance on using real-world data to support clinical trials could get medicines to patients sooner

Press release

This new guidance follows consultation with stakeholders from the pharmaceutical industry, academic research, trade associations, patient organisations/charities, healthcare providers and regulatory organisations.

New guidance that outlines how greater use of real-world data for clinical trials could help expedite the availability of cost-effective treatments has today been published by the Medicines and Healthcare products Regulatory Agency (MHRA). When conducting clinical trials, the UK regulator has said that using data generated during routine healthcare to improve recruitment and aid regulatory decision-making could help bring life-changing new medicines more quickly to those who need them.

Vast amounts of ‘real-world’ data are routinely collected from patients using the healthcare system. This includes electronic patient health records, and disease and patient registries.

While information generated from real-world data is frequently used to monitor the safety of medicines and medical devices after they have gained approval, it is rarely used to demonstrate the effectiveness of an intervention before it is approved.

This new guidance follows a consultation with stakeholders from the pharmaceutical industry, academic research, trade associations, patient organisations/charities, healthcare providers and regulatory organisations.

Dr June Raine, MHRA Chief Executive said:

“When used in this innovative way, real-world data has the potential to make a huge difference when it comes to bringing medicines through clinical trials to patients.

“With fewer or even no trial-specific visits, consenting trial participants don’t have to travel long distances to get to their appointments. And with fewer logistical hurdles, real world data could make it more feasible for trial sponsors to repurpose existing medicines for new conditions.

“Because of this, and the growing need to find more cost-effective ways of conducting clinical trials, our new series of guidelines focuses on how to use real-world evidence to aid regulatory approval, helping to bring medicines to the patients who need them, sooner.”

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