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EDITORIAL

UK Centre of Excellence in Regulatory Science and Innovation in Pharmacogenomics

Since the completion of the human genome project, there has been increasing evidence of how pharmacogenomic variation can affect drug dosing, drug efficacy and safety.[1] However, the implementation of pharmacogenomics into clinical practice has been slow—many papers have highlighted the reasons for the slow uptake, and this has led to a greater emphasis on implementation projects.[2] Of note is the PREPARE study, an open-label, multicentre, controlled, cluster-randomized cross-over implementation study, which showed that a 12-gene pharmacogenetic panel was able to reduce adverse drug reactions by 30%.[3]

An important issue to consider for implementation is the regulatory landscape. This can be done through regulatory science, which the FDA defines as 'the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all regulated products'.[4] In order to advance regulatory science, in the United States, there are currently five Centres of Excellence in Regulatory Science and Innovation (CERSI) focusing on a number of different areas.

In the United Kingdom, the Pro-Innovation Regulation of Technologies Review in Life Sciences by the UK Government in May 2023[5] also recommended that CERSIs should be set up as a network across the country to ensure that knowledge is up to date, upskill the workforce and ensure research and assessment support in key areas. Funding was made available through an open competitive process, coordinated by UK Research and Innovation (UKRI) with strategic input from the Medicines and Healthcare products Regulatory Agency (MHRA).

In February 2025, seven CERSIs were set up in the United Kingdom.[6] One of these is the CERSI in Pharmacogenomics (CERSI-PGx), led by the University of Liverpool, with three academic partners, two companies, the Office of Health Economics and the British Pharmacological Society. The focus of CERSI-PGx is to work with regulators and map the most important modifiable issues which currently hamper innovation and uptake of pharmacogenomics in UK NHS. Our aim is to foster proportionate, forward-looking, inclusive and responsive regulatory decision making across pharmacogenomic development and implementation pathways. In order to undertake its work, the CERSI-PGx has four main work packages together with a cross-cutting fifth work package which will focus on patient and public involvement (Figure 1).

Work package 1 is developing guidelines on individual drug-gene pairs and guidelines relevant for industry including on genetic test development and regulatory requirements for pharmacogenomics. In this issue of the Journal,[7] we publish our first guideline focusing on *CYP2C19* genotyping in patients prescribed clopidogrel, an antiplatelet agent licensed in the UK for use in coronary artery disease, cerebrovascular disease and peripheral arterial disease.

Pharmacogenomic guidelines are available via the Clinical Pharmacogenetics Implementation Consortium (CPIC)[8] and the Dutch Pharmacogenetics Working Group (DPWG).[9] These consortia have provided pharmacogenetic prescribing recommendations for several gene-drug pairs based on systematic literature reviews carried out over the last 15–20 years. Our purpose is not to duplicate these

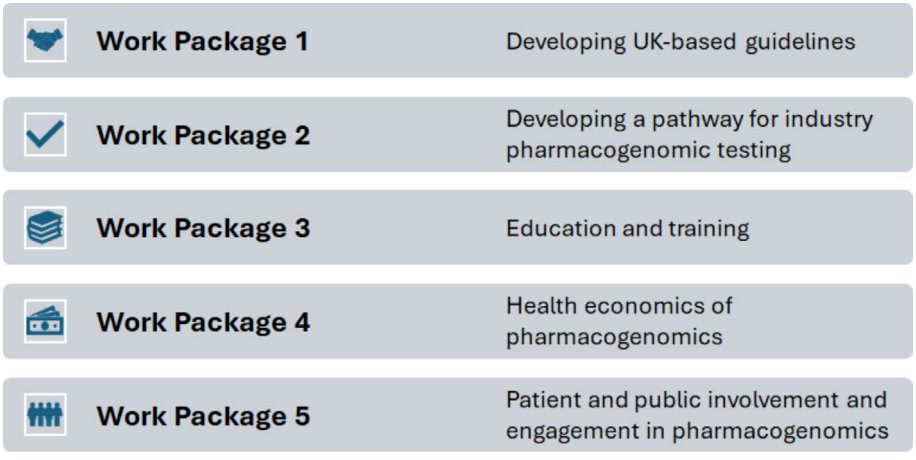

FIGURE 1 The five work packages of the UK Centre of Excellence in Regulatory Science and Innovation in Pharmacogenomics (CERSI-PGx).

guidelines, but to complement them by having a more clinical focus. To this end, we have developed a specific template, which includes sections on eligibility for testing, how the test can fit in with current clinical pathways, what variants should be tested together with turnaround times, what actions to take in individuals with different genotypes and the health economic considerations. We also highlight the evidence gaps and suggest areas for further research.

Each guideline committee will comprise a representative group of individuals from different backgrounds including clinicians from different specialities, who are the main prescribers of the specific drugs. Each guideline will be based on a comprehensive literature review, integrating the evidence provided by the CPIC and the DPWG when available. In addition, recommendations will be developed with expert input from committee members who are also able to highlight nuances in clinical practice. This is important because our aim with these guidelines, in order to facilitate uptake, is to ensure that they fit in seamlessly with the current clinical practice with as little disruption as possible. When the guideline is complete, before publication, it will be sent for consultation to different organizations including specialist societies and regulators. The responses to the consultation will be discussed with the committee, and amendments made to the guideline where appropriate. In order to ensure openness and transparency of the whole process, all information on the consultation will be published as a supplement to the guideline.

We are working on other guidelines including *ACKR1* in patients on clozapine, *HLA* typing for carbamazepine therapy, *UGT1A1* and irinotecan therapy and *MT-RNR1* and aminoglycoside use. Other guidelines will follow. Our aim is to have complete suite of guidelines, which will be updated, to serve as an enabler for implementation of pharmacogenomics. Although focused on the UK health system, these guidelines can easily be adapted to other healthcare systems around the world.

FUNDING INFORMATION

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CONFLICT OF INTEREST STATEMENT

MP currently receives partnership funding, paid to the University of Liverpool, for the MRC Medicines Development Fellowship Scheme (co-funded by MRC and GSK, AZ, Optum and Hammersmith Medicines Research). He has developed an HLA genotyping panel with MC Diagnostics but does not benefit financially from this. He is part of the IMI Consortium ARDAT (www.ardat.org); none of these funding sources have been used for the current article.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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