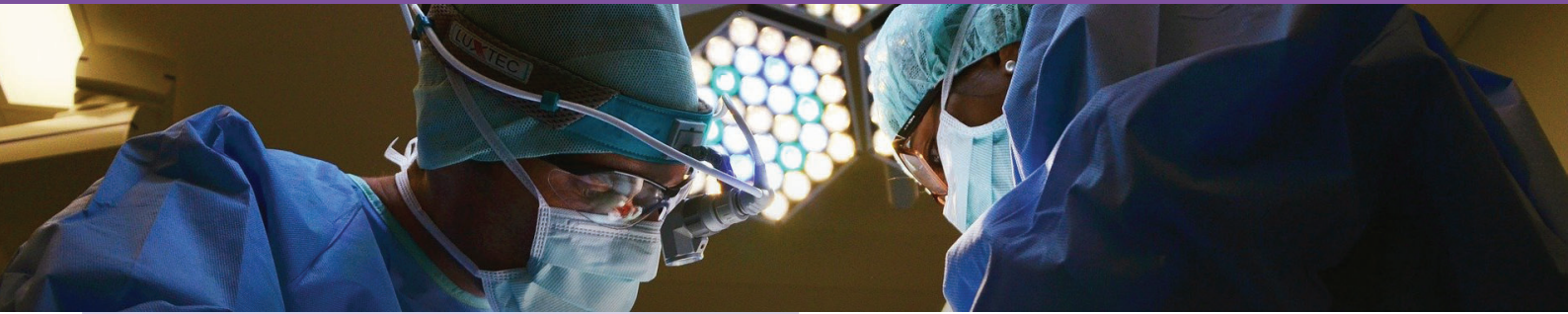


# MIDLANDS ENGINE HEALTH

## Focus on MedTech - BHP Centre for Regulatory Science & Innovation (CRSI)

MIDLANDS  
ENGINE



The Birmingham Health Partners Centre for Regulatory Science and Innovation (CRSI) was established in 2020 to support the development and delivery of novel therapeutics and medical devices in the UK, through advanced regulatory standards and tools. A truly multidisciplinary initiative, CRSI brings together experts in medicinal science, health policy and management, clinical trial design, medical law and patient-reported outcomes research, from across BHP member organisations.

The Centre's activity is broadly grouped into three pillars: policy development; research and innovation; and capacity building and education. In line with these pillars, CRSI generates evidence to support advances in regulation, convenes national and international debate between key stakeholders, develops training and support initiatives in regulatory science in partnership with local and national organisations, and leads international consensus-based guidance for healthcare in cutting-edge technologies.

In July 2020, the Centre released its first report, 'Advancing Regulatory Science and Innovation in Healthcare', calling for a coherent and specific national strategy for regulatory science - including training, funding and cross-disciplinary working. The report was endorsed by the Government's Regulatory Horizons Council, Association of British Pharmaceutical Industries (ABPI), Association of British HealthTech Industries (ABHI), patient partners and a range of national bodies.

More recently, the CRSI has been commissioned by the Regulatory Horizons Council (RHC) to inform future UK Government policy. This will address the question of how can the UK encourage international investment, innovation and improve safety in the medical devices area through regulatory and non-regulatory changes. This question is posed with particular reference to the move to the UKCA mark in 2023; learning around in-vitro diagnostic (IVD) regulation from Covid-19; and potential international routes to market for medical devices. Working with a huge range of national and international stakeholders from industry, policy, regulatory bodies, academia and patients and



public representatives, the CRSI has undertaken an extensive cross-sector review, with formal reports due to be submitted shortly to inform RHC's official recommendations to Government.

The CRSI also launched its own call to action around safe and effective medicines for use in pregnancy. The official report highlights that causes relating to pregnancy and death kill 2.7million women and children each year, but only one new drug has been developed specifically for use in pregnancy in more than 30 years, and 73% of drugs used in pregnancy come with no safety information relating to their use by pregnant women. CRSI is urging politicians, clinicians, academia, industry, patients and research funders to end this 'drug drought' through the developing and testing of new and existing medicines in pregnancy. This will help achieve the UK Government's aim to halve maternal and infant deaths by 2025, and CRSI will be developing a formal 'policy commission' in 2021 to tackle this.