REVITALISING MEDICAL RESEARCH TO IMPROVE PUBLIC HEALTH

How regulatory engagement and strategic funding for human relevant research can improve health, wealth and productivity

Public health crisis

Despite animals and humans having different genetics, biochemistry and anatomy, medical research continues to rely on the use of animals to investigate disease and develop new therapies. As a result, drug development is time consuming, costly and has limited relevance to humans, leading to a global public health crisis.

Human relevant methods

Transitioning to human-relevant **new approach methodologies (NAMs)** in drug research and development can:

- provide new insights into human biology and disease
- avoid the problem of animal-human species differences that results in misleading data
- improve prediction of the toxicity of new drugs to humans
- ultimately deliver safer, cheaper and more effective medicines to patients.

The challenge

Despite the potential of new approach methodologies, there remain significant barriers that prevent their wide-spread uptake, including lack of funding and regulatory engagement.

Key statistics

- Developing a new drug costs around £2 billion and regulatory approval can take up to 10 years.[1,2]
- Only 5 in 5,000 new drugs enter clinical testing, and just 1 in 5,000 are eventually approved.[3]
- Adverse drug reactions kill over 10,000 people in the UK,[4] account for 6.5% of hospital admissions[5] and cost NHS England up to £1.6 billion each year.[6]

Strategic funding

The process for securing funding for academic medical research takes up to a year, and the chances of success are approximately 1 in 10.[7] Securing funding for human relevant research has further challenges because researchers are competing against a more established methodology, many peer reviewers who influence funding decisions are not familiar with human relevant research methods, and there is limited funding available.

Just 0.036% of science R&D expenditure in the EU was invested in non-animal methods in 2013.[8]

Providing dedicated strategic funding for human relevant research could close the gap and enable scientists to embrace new approach methodologies and the higher rates of translation to humans, as indicated.

Regulatory engagement

Current regulatory guidance generates an expectation that new drugs must be tested in two species of animals – often mice or rats, followed by pigs, dogs or monkeys.[9]

Such regulations are outdated, resulting in wasted time and money. Drugs that work well in animals may not work or have adverse side effects in people. And potentially useful drugs that do not work in animals will not progress to human trials.

We urgently need a regulatory system fit for the 21st century which enables human relevant methodologies to support regulatory decisions on the progression of drugs into clinical trials. These cutting-edge techniques are rapidly developing, so agencies should regularly review and update their guidance to ensure it remains fit for purpose. This will ensure that the most effective new approach methodologies can support drug safety evaluation and enable innovative drugs based on human specific R&D to progress to clinical trials.

What we are calling for

A boost in strategic funding for human relevant research, and a regulatory system that is fit for purpose can help ensure new approach methodologies deliver their promise of safer and more effective medicines, more quickly and at less cost. The US and Netherlands have recognised the potential of NAMs and have ambitious programmes underway to implement these. It is time for a fresh approach in the UK.

Investment in human relevant research offers a golden opportunity for the UK to save money, create wealth and improve public health.

What you can do

1. Join the APPG on Human Relevant Science – contact **Kerry.Postlewhite@crueltyfreeinternational.org**
2. Ask the government to commit to strategic funding and regulatory engagement with human relevant new approach methodologies to support the UK to become a science superpower.
3. If you are able to and have not already done so, **sign EDM 256 on Accelerating Human Relevant Life Sciences in the UK**
4. Contact the **Alliance for Human Relevant Science** for more information

[1] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics. 2016; 47:20-33.

[2] Phrma. Biopharmaceutical research and development: the process behind new medicines. 2015. Available at: https://www.phrma.org/en/Report/Biopharmaceutical-R-and-D-The-Process-Behind-New-Medicines

[3] Harries, L. State of the art: current regulatory requirements for drug discovery, presented at virtual meeting of All-Party Parliamentary Group on Human Relevant Science in February 2021.

[4] Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004;329(7456):15-9.

[5] Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. Drug Safety. 2015; 38(5):437-53.

[6] Elliott RA, Camacho E, Campbell F, Jankovic D, Martyn St James M, Kaltenthaler E et al. Prevalence and economic burden of medication errors in the NHS in England: Rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK. Policy Research Unit in Economic Evaluation of Health & Care Interventions (EEPRU). 2018. Available at: http://www.eepru.org.uk/wp-content/uploads/2020/03/medication-error-report-edited-27032020.pdf

[7] Harries, L. State of the art for funding Human Relevant Research, presented at virtual meeting of All-Party Parliamentary Group on Human Relevant Science in November 2020.

[8] Taylor, K. EU member state government contribution to alternative methods. ALTEX - Alternatives to animal experimentation. 2014 31(2), pp. 215-218.

[9] ICH harmonised tripartite guideline. Guidance on nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals M3(R2) Available at: https://database.ich.org/sites/default/files/M3_R2__Guideline.pdf

Alliance for Human Relevant Science

The Alliance for Human Relevant Science is a collaboration of like-minded companies, charities, organisations and individuals who work together to accelerate awareness and use of human relevant approaches within industry and the scientific research community.

Visit **www.HumanRelevantScience.org** Contact **info@HumanRelevantScience.org**