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Species differences play a major role in holding back medical progress, there is problematic translation of animal results to humans. It is proven that 92% of drugs that show promise in animal tests fail to reach the clinic and benefit patients. (Ref 1) The majority of these failures are cited as 'due to adverse effects' and 'lack of efficacy in humans'. A clear example would be in predicting liver toxicity.

The likelihood of a cancer drug being approved and progressing from small Phase 1 trials to larger clinical trials is less than 6 per cent (Ref 1).
Alzheimer's disease has seen clinical trial failures of more than 99 per cent (Ref 2).

The latest human liver-on-a-chip technology alone is estimated to be worth $3 billion annually to the pharmaceutical sector due to increased R&D productivity. We are told testing requires a whole biological system; however, this is perpetuating the use of animals while completely ignoring the differences between species systems. We must do something else entirely. A laboratory environment, in itself, causes significant stress, making data even less translatable to humans.

A 2015 investigation concluded that between 50 and 89% of all preclinical research, is not reproducible, animal experimentation is implicated as a serious problem area. (Ref 3) US, EPA government scientists recently carried out vast analyses of huge datasets of animal studies on thousands of chemicals. The findings pointed clearly to both poor reproducibility and predicative value for humans. Furthermore, genetically modified (GM) animals have also failed to translate to human biology or to reflect the human situation being researched in many areas including Multiple Sclerosis, Oncological studies, Muscular Dystrophy, Diabetes, and many neurodegenerative diseases including Alzheimer's and Parkinson's. In fact, major scientific breakthroughs in disease areas such as diabetes and breast cancer have relied on studies of human patients; they would not have been possible if the scientists had used animals for their research.

Global Regulator expectation is that two animal species (rodent and non-rodent), be used for safety/toxicity testing, before progression to human clinical trials. Use of dogs and non-human primates (NHPs) have been shown to add just 2% and 0.4% respectively to the weight of evidence of existing probabilities that new drugs might be safe. (Ref 4) This negligible

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contribution is statistically insignificant to safety assurances, and causes massive needless animal suffering and death, increased monetary costs and time delays to product development.

In the USA the FDA Modernization Act 2.0 has now been enacted into law, this removes the 83 year old mandate to use animals and gives the option to use NAMs. Scientific development will be accelerated overseas whilst the UK delays in making change. There is formidable and irrefutable published evidence to immediately stop using animals in scientifically bogus tests.

References:

1. New Clinical Development Success Rates 2011-2020 Report Link

2. Are some animal models more equal than others? A case study on the translational value of animal models of efficacy for Alzheimer's disease. Link

3. Freedman LP, Cockburn IM, Simcoe TS. The economics of reproducibility in preclinical research. PLoS Biol. 2015;13(6):e1002165). Link

4. Bailey J, Thew M, Balls M. An analysis of the use of dogs in predicting human toxicology and drug safety. Altern Lab Anim. 2013;41:335–50. Link