

**POSTnote 756**

By Lucy Unwin,  
Clare Lally

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# Technology alternatives to animals in life sciences research



## Summary

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- 2 Scientific readiness of alternative technologies
- 3 Validating and standardising alternative methods
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## Contributors

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## Summary

Animals are used in scientific research for a range of purposes, including to study biological processes (discovery research), develop treatments, and assess the safety of substances to comply with regulations. In 2024, there were 2.64 million regulated scientific procedures with animals in the UK; around half were for discovery research and 22% for regulatory purposes.

Ethical, scientific and practical challenges have driven interest in alternatives to animals in research. UK policy reflects ongoing efforts to replace, reduce and refine the use of animals ('the 3Rs'). In November 2025, the government published a strategy for replacing animals in science.

Advancements in 'human-specific' technologies, including organoids, organ-on-a-chip, and artificial intelligence, are providing opportunities to implement the 3Rs. Alternative technologies vary in maturity. They show promise for specific applications, including predicting liver toxicity or studying rare genetic diseases, but currently lack capability in other areas of research, such as whole-body interactions, ageing, and behaviour. Alternative technologies may be used alongside animal models to reduce the number of animal tests.

For UK regulators to accept a process using a new technology, it must be validated (with proven reliability and reproducibility) and standardised (with consistent methods), and it must provide adequate evidence of safety and efficacy. Few technology alternatives are validated for regulatory use, which researchers say is because testing requirements are unclear, and the evidence base is limited. As scientific research operates within a global market, international frameworks strongly influence UK regulation.

The National Centre for the 3Rs (funded by the UK Government) has invested over £100 million in technology alternatives to animals since 2004. The 2025 government strategy for animals in science commits further funding and infrastructure support. The UK also plans to establish a national validation centre to replace access to EU facilities, which it lost after Brexit. The Centre for Economics and Business Research predicts that the UK's alternative technology sector could reach £2.5 billion by 2026, with global markets projected at \$29.4 billion by 2030. International trade opportunities may depend on whether countries amend their animal testing requirements.

Stakeholders have said the main barrier to wider use of alternative technologies is their scientific readiness to replace animal models. Other barriers include regulatory uncertainty, limited funding, infrastructure costs, workforce skills, and limited access to high quality human samples and datasets. Researchers have reported challenges including stigmatisation around animal use in research, but also reluctance from funders and publishers to consider methods that are less established than those used in animal models.

## Background

Animals are used in life sciences research, with the aim of:

- understanding biological systems and processes
- researching diseases and developing treatments
- assessing the safety of materials and chemicals<sup>1-3</sup>

In 2024, 2.64 million scientific procedures involving live animals were carried out in the UK,<sup>4</sup> which was 0.4% lower than 2023.<sup>a 6</sup>

Animals are used to model complex biological processes that are not studied in humans because it would not be safe or ethical to do so. Research using animals has led to breakthroughs relating to human health, animal health, and environmental protection.<sup>3,7-11</sup>

In 2024, 22% of experimental procedures using animals in the UK were conducted to comply with regulations, such as approval for health treatments.<sup>4</sup> About half were conducted for discovery research, which aims to discover new biological mechanisms rather than test existing knowledge.<sup>4</sup>

There are ethical concerns, scientific limitations, and practical considerations with using animals in research. These concerns have contributed to debate among policymakers, scientists, industry and the public about the potential to adopt alternatives.<sup>12-14</sup>

### Regulation of animal research and 'the 3Rs'

In the UK, the use of protected animals<sup>b</sup> in scientific procedures that could cause suffering, pain, distress, or lasting harm is regulated by the Animals (Scientific Procedures) Act 1986 (ASPA), later amended in 2012.<sup>c 15</sup>

Procedures using animals are controlled by the Home Office with a triple-licensing structure, and permitted only if it is not possible to use non-animal

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<sup>a</sup> Animals used in research include rodents, fish, birds, ungulates (horses, goats, pig, sheep, cattle) amphibians, reptiles, carnivores (cats, dogs, and ferrets), primates and other mammals.<sup>5</sup>

<sup>b</sup> Animals protected under ASPA include all living vertebrates and cephalopods (such as octopus). There are special protections for horses, cats, dogs and non-human primates.<sup>15</sup>

<sup>c</sup> Animal research was first regulated in the UK under the Cruelty to Animals Act 1876.<sup>16</sup>

methods.<sup>d</sup> In the UK, animal testing is prohibited for tobacco products and finished cosmetic products and their ingredients is prohibited.<sup>e</sup><sup>15</sup>

The replacement, refinement and reduction in the use of animals in research (box 1) is legally embedded into Section 2A of ASPA 1986 (amended in 2012).<sup>15</sup>

### Box 1: The 3Rs

The 3Rs is an internationally recognised framework for improving the welfare of animals used in research. It was first proposed in 1959, and is embedded in UK legislation, research policy, and funding requirements:<sup>15,21</sup>

- Replacement: avoiding or replacing animals where they otherwise would have been used.
- Reduction: minimising the number of animals used consistent with scientific aims.
- Refinement: minimising the pain, suffering, distress or lasting harm that animals might experience.<sup>22–25</sup>

The UK has replaced the use of thousands of animals in research per year through funding of the 3Rs.<sup>23,26,27</sup> In 2024, regulated animal procedures were at their lowest level since 2001.<sup>4</sup> Researchers have cautioned that this may in part reflect research moving overseas.<sup>28</sup>

In 2023, the National Centre for the 3Rs (NC3Rs)<sup>f</sup> commissioned a review of UK regulatory and ethical review processes support the 3Rs in animal research. It showed that replacement opportunities were often missed, since funding reviewers rarely suggested existing alternatives to using animals.<sup>30</sup>

<sup>d</sup> The triple licensing structure set out in ASPA requires a personal licence for the scientific investigator, a licence for the establishment in which the procedures will take place, and a licence for the project, containing details of which animals will be used and what procedures will be performed.<sup>15</sup>

<sup>e</sup> The use of animals to test tobacco products was banned in the UK in 1997.<sup>17</sup> A ban on testing finished cosmetics on animals has been in place since 1997, and for cosmetic ingredients since 2009, under policy measures aligned with EU Cosmetics Directive 76/768/EEC.<sup>18</sup> The EU fully banned the marketing and import of animal-tested cosmetics in 2013 via EU Cosmetics Regulation 1223/2009.<sup>19</sup> After Brexit, the UK confirmed that no licenses would be granted for animal testing of chemicals used exclusively as cosmetic ingredients.<sup>20</sup>

<sup>f</sup> The NC3Rs is a UK-based scientific organisation that helps the research community worldwide to identify, develop and use 3Rs technologies and approaches. It was founded in 2004, following a House of Lords recommendation to increase UK investment and activity in the 3Rs.<sup>29</sup>

## **The 2025 strategy for replacing animals in science**

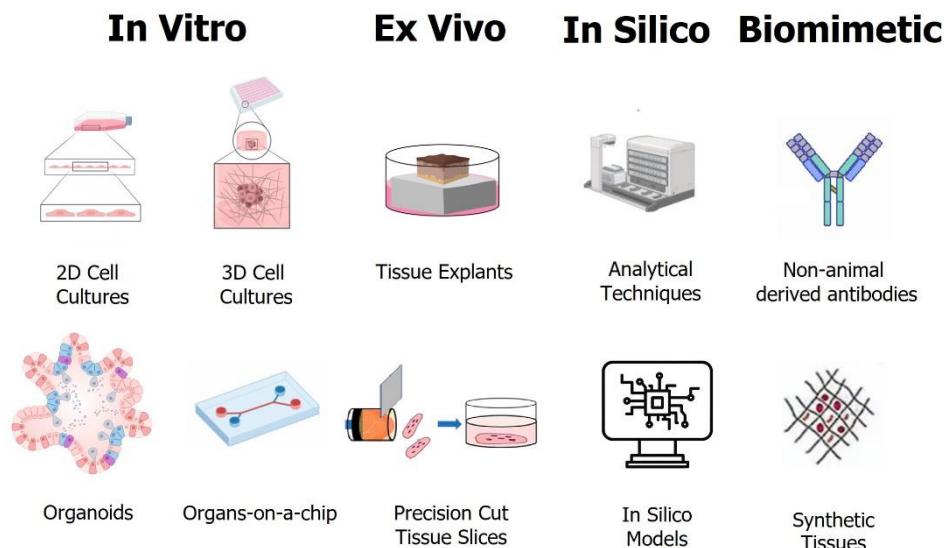
In November 2025, the government published a strategy for replacing animals in science. The strategy focuses on animal replacement but supports the appropriate use of animals where reliable alternatives are not available. It aims to drive private investment, regulatory confidence and acceptance in alternative methods, and create infrastructure and partnerships.<sup>31</sup>

## 1

# Human-specific technology alternatives to animals

Advancements in 'human-specific' technologies are providing opportunities to implement the 3Rs (figure 1).<sup>32</sup> These technologies are designed to replicate aspects of healthy and diseased human biology.<sup>33-39</sup>

**Figure 1: Examples of human-specific technology alternatives to animals**



Source: faCellitate (2025), Zhao *et al.* (2022), Shannon *et al.* (2022), Liu *et al.* (2022), Creative Bioarray (2025), Alsumidaie (2024), GeeksforGeeks (2025), Benwood *et al.* (2021).<sup>40-47</sup> These examples are not an exhaustive list of technology alternatives to animals.

## Laboratory approaches using cells and tissue

'In vitro' (meaning 'in glass') approaches are laboratory-based techniques conducted outside a living organism using isolated tissues, cells, or molecules.<sup>48</sup> Human cells or tissues are obtained from donor or patient tissue, derived from induced pluripotent stem cells (iPSCs), and/or grown under laboratory conditions:<sup>49 51</sup>

<sup>49</sup> Induced pluripotent stem cells (iPSCs) are reprogrammed cells that can form many cell types, enabling lab-grown tissues for studying diseases and testing medicines.<sup>49</sup> More

- 2D and 3D cell and tissue cultures are used to study responses to chemical signals and physical conditions, for example, testing toxicity of compounds on liver cells or modelling cancer cell behaviour.<sup>52,53,54</sup>
- Organoids are complex 3D cell cultures that replicate structural and functional qualities of human organs, used to study aspects of organ development, diseases, and drug responses.<sup>55–59</sup>
- Organs-on-a-chip are small plastic chips which combine human cells and tissues with microfluidic technology (tiny channels that carry liquids or gases) and mechanical forces to replicate functional units of living organs.<sup>33,60,61</sup> These channels simulate processes like blood flow, nutrient flow, tissue movement, and interactions between cell types.<sup>62–64</sup>

Cell and tissue approaches may be combined with *in vitro* analytical techniques:

- Omics technologies analyse molecular changes in response to stimuli, such as understanding drug mechanisms and detecting toxic effects.<sup>65–68</sup>
- High-throughput screening (HTS) provides automated, rapid testing of large numbers of compounds on *in vitro* models, applied in early-stage chemical or drug discovery and chemical safety assessment.<sup>69</sup>

## Ex vivo approaches

'Ex vivo' approaches are conducted outside of the body, usually with more complex structures, such as whole tissues or organs.<sup>70</sup>

- Human tissue explants are surgically removed fresh human tissues (such as skin, tumours, lungs, and lymph nodes) maintained in a lab.<sup>71–73</sup> They offer patient-specific treatment insights and support disease research.<sup>72,74</sup>
- Precision-cut tissue slices are uniform slices of fresh human tissues maintained in a lab, used for regulatory testing, drug screening, and comparing responses across donors.<sup>75–77</sup>

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information about stem cells, how they are regulated and used in research, and the wider ethical and societal implications can be found in the POSTnote on [Human stem cell-based embryo models](#).<sup>50</sup>

## In silico approaches

'In silico' (meaning 'in silicone', the material used in computer chips) approaches use computer modelling:<sup>78</sup>

- Computational and mathematical modelling is based on rules and statistical equations that use large datasets (such as in vitro test results) to simulate and predict biological processes, and understand disease without experiments.<sup>79-82</sup>
- Artificial intelligence (AI) and machine learning (ML) aim to learn patterns from large datasets to predict toxicity, prioritise compounds for testing or optimise experimental design.<sup>83-87</sup> These systems can refine their algorithms without additional reprogramming.<sup>87</sup>
- Digital twins are virtual models of organs, systems, or processes, based on real-time data.<sup>88,89</sup> Virtual organs can predict drug effects, understand disease, and assess chemical toxicity.<sup>89,90</sup>

## Biomimetic approaches

Biomimetic approaches involve designing materials or technologies that imitate biological structures:<sup>91</sup>

- Non-animal-derived antibodies are laboratory-produced proteins that identify and bind to target molecules.<sup>92</sup> They can identify molecules that indicate disease, drug targets and measure treatment effects.<sup>93</sup>
- Synthetic tissue models are engineered materials that physically and mechanically mimic animal or human tissues without containing living cells.<sup>94</sup> They are used to study structural and mechanical features relevant to tissue function, to test devices and drugs, and can be combined with living cell cultures to model organ microenvironments.<sup>91,95,96</sup>

## Other approaches

Other approaches include non-invasive screening technologies, such as functional magnetic resonance imaging (fMRI) and electroencephalography (EEG). These allow the study of human brain functions at a lower resolution than some invasive techniques used in animal research.<sup>97-100</sup>

Research can use organisms that fall outside current regulations, such as invertebrates and animal foetuses, eggs or larvae.<sup>101-110</sup> For example, single-celled slime moulds have been used in pre-clinical research to develop a

dietary treatment for epilepsy, later validated in animal models, and now in clinical use.<sup>111</sup>

## Use of animals in alternative technologies

Some alternative technologies still use animal-derived components. For example, Matrigel, a material that supports cell and tissue cultures, is extracted from purpose-bred mouse tumours.<sup>112</sup> Foetal bovine serum, obtained from the blood of cow foetuses, is used in cell cultures to support cell growth.<sup>113</sup> Researchers are developing alternatives, such as animal-free hydrogels.<sup>h</sup> <sup>113,115–118</sup>

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<sup>h</sup> A hydrogel is a soft, structured material that can hold large amounts of water. It can mimic aspects of biological tissues and is used in research, medical applications and drug testing.<sup>114</sup>

## 2

# Scientific readiness of alternative technologies

The suitability of alternative technologies depends on the research question and field of study.<sup>119</sup>

There are differences in how mature alternative technologies are, as well as differences in how widely they can be applied to support the 3Rs (scientific readiness).<sup>120</sup> Some alternative technologies have not yet been accepted by regulators. This is partly due to a lack of agreed criteria for assessing the maturity and reliability of the technology (see Validating and standardising alternative methods).<sup>121</sup>

Researchers, regulators, and industry representatives have said that policy changes which restrict the use of animals in research should be driven by scientific readiness, to avoid slowing scientific progress and to maintain public confidence in the safety of procedures and therapies.<sup>122,123</sup>

## Effectiveness of replicating human biology

Neither animal models nor alternative technologies perfectly replicate human biology. In certain contexts, alternative methods can generate data that may be more relevant to humans than traditional animal models.<sup>33,63,124</sup>

While these models demonstrate significant potential, researchers caution that these methods are suited to specific applications, and require further development and validation before they can fully replace animal studies.<sup>121</sup>

Promising applications include:

- Human heart cells may reveal arrhythmias that animal hearts do not always exhibit.<sup>125–128</sup>
- Brain organoids may improve understanding of human neural development and neurodegenerative disease, as certain aspects may be difficult to study in animals due to differences in brain complexity and structure.<sup>35,129,130</sup>
- Organoids and other models based on patient-derived cells may be used to investigate rare genetic conditions with no equivalent in animals.<sup>131–133</sup>
- Liver-on-chip systems may predict drug-induced liver injury where animal models may be less reliable.<sup>134,135</sup>

- Lung-on-chip and immune-cell-based systems may predict responses to inhaled chemicals, drugs and pathogens, by addressing differences in immune reactions and airway structures between humans and animals.<sup>136–138</sup>

Broader areas of research where alternative technologies are not yet suitable include:

- Understanding how organs and body-wide systems interact over time, including disease progression, ageing, neurodegeneration, obesity, immune function, circulation, and the movements and processing of hormones, nutrients, and waste products.<sup>59,139–143</sup>
- Side effects of taking one or multiple medications, such as internal bleeding and seizures.<sup>130,144</sup>
- Reproduction and developmental biology including pregnancy, embryo development and interactions between foetal and maternal systems.<sup>145–147</sup>
- Understanding behavioural changes associated with neurodevelopmental or neurodegenerative disorders and/or treatments to target them.<sup>148,149</sup>

Researchers highlighted that replacing animals in discovery research is challenging, since processes that are not fully understood cannot be modelled with confidence.<sup>150,151</sup>

## Integrated and complementary approaches

Combinations of different non-animal methods and approaches may, in the future, replicate multiple organs or systems. This could replace studies that would otherwise involve whole animals.<sup>123,152</sup>

Integrated approaches have been used in some areas of regulatory research.<sup>153</sup> Next generation risk assessments (NGRAs) combine in vitro tests with computational models and other human-relevant methods, which can assess risks associated with chemicals or substances.<sup>154</sup>

With increasing amounts of human health data, combining datasets and AI could enable more accurate predictions of drug safety.<sup>31</sup>

## Reducing the number of animals used in research

Where full replacement of animals is not yet possible, alternative technologies may be used in combination with animal models to reduce the number of animal tests.<sup>22,31,32,155</sup>

According to the Innovative Health Initiative, virtual control groups could reduce animal use in studies of toxicity by up to 25%.<sup>156,157</sup>

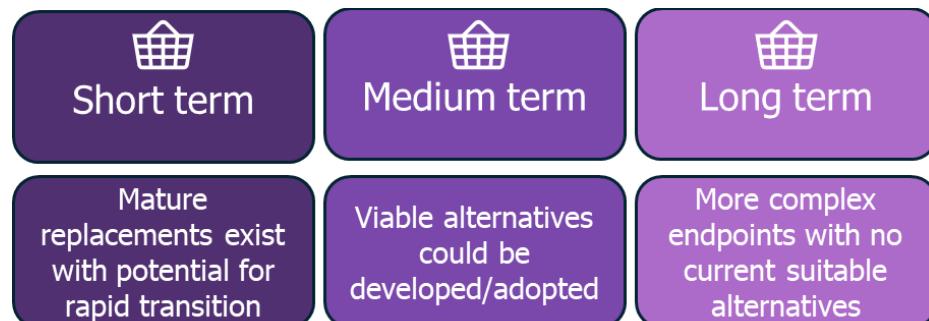
AI-based screening could help prioritise which compounds should advance through the drug development pipeline.<sup>84,87</sup> Physiologically-based pharmacokinetic (PBPK) modelling is a computational approach which predicts how a substance will behave in humans or animals.<sup>158</sup> PBPK models can estimate appropriate testing doses and potential toxicity levels, reducing the number of animals needed.<sup>159-162</sup>

## Implementing technology alternatives

The [2025 government strategy](#) uses a ‘three baskets approach’ which categorises animal tests by whether technology alternatives will be ready in the short term, medium term or long term (figure 2).<sup>i</sup>

The animal tests in each category have been agreed with regulators and include targets and timelines for replacing them.<sup>j 31</sup> As technology improves, animal tests will move between categories, or ‘baskets’, for example from long-term to medium-term.

**Figure 2. Three baskets approach to technology readiness**



Source: Department for Science, Innovation and Technology (2025). [Replacing animals in science: A strategy to support the development, validation and uptake of alternative methods](#).

<sup>i</sup> The ‘three baskets approach’ was recommended by the European Federation of Pharmaceutical Industries and Associations.<sup>163</sup>

<sup>j</sup> An example of an animal test placed in the ‘short term’ basket in the government’s 2025 strategy is skin irritation testing. This typically involves applying chemicals to the skin of animals, usually rabbits, and observing for signs of irritation or damage. Due to the maturity of alternatives that mimic human skin, the government aim to only use animal alternatives for skin irritation testing by the end of 2026.<sup>31</sup>

## 3

# Validating and standardising alternative methods

Validation demonstrates that a method is reliable, reproducible and fit for its intended purpose.<sup>152</sup>

Standardisation establishes agreed protocols to ensure methods will be used consistently in different settings.<sup>164</sup>

These processes are required for the regulatory acceptance and application of new methods.<sup>k 31,123</sup> Methods must be validated before protocols can be standardised.<sup>24</sup> A method may be validated for one purpose but not another.<sup>24,152,166</sup>

The 2025 government strategy notes that very few alternative methods to animals are validated for regulatory use, limiting broader adoption.<sup>31</sup> Validation can take a lot of time and resources, requiring collaboration across sectors.<sup>123,167–169</sup> Technology developers say that the lack of clear evaluation standards slows the uptake of alternatives.<sup>170</sup>

Confidence in research methods can be low until they are validated against effects measured in humans.<sup>171,172</sup> Limited data, and insufficient understanding of the method and how to interpret the data obtained, can slow regulatory acceptance of alternatives.<sup>30</sup>

Researchers, government officials and industry professionals have suggested a tiered approach to validation, where evidence required is based on potential exposure and risks.<sup>173,174</sup> As single technologies are rarely direct replacements for animal studies, validation must consider how different data sources and approaches can be integrated and interpreted, which may require new ways of thinking about evidence, risk and safety.<sup>153,174,175</sup>

The UK lost access to the European Union Reference Laboratory Centre for the Validation of Alternative Methods (EURL ECVAM)<sup>l</sup> after Brexit. The government's 2025 strategy plans to create a UK Centre for Validation of Alternative Methods.<sup>31</sup>

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<sup>k</sup> There are no formal requirements for validating and standardising technology alternatives in discovery research, although researchers emphasise that validation and standardisation should still be considered best practice in such contexts.<sup>165</sup>

<sup>l</sup> EURL ECVAM coordinate or support the validation of alternative technologies, often through formal studies across multiple laboratories.<sup>171</sup> Other examples include the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) in the United States, and the International Coalition of Medicines Regulatory Authorities (ICMRA).<sup>176,177</sup>

## 4

# Regulating alternative technologies

Regulatory agencies, such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Environment Agency, protect the safety of humans, animals and the environment.<sup>31,174</sup>

UK regulatory frameworks require safety testing before products, such as medicines or chemicals, are approved.<sup>m</sup> <sup>180</sup> For example, the Human Medicines Regulation Act 2012 requires that pre-clinical and toxicological data are submitted before clinical trials for new medicines can begin (figure 3).<sup>178</sup>

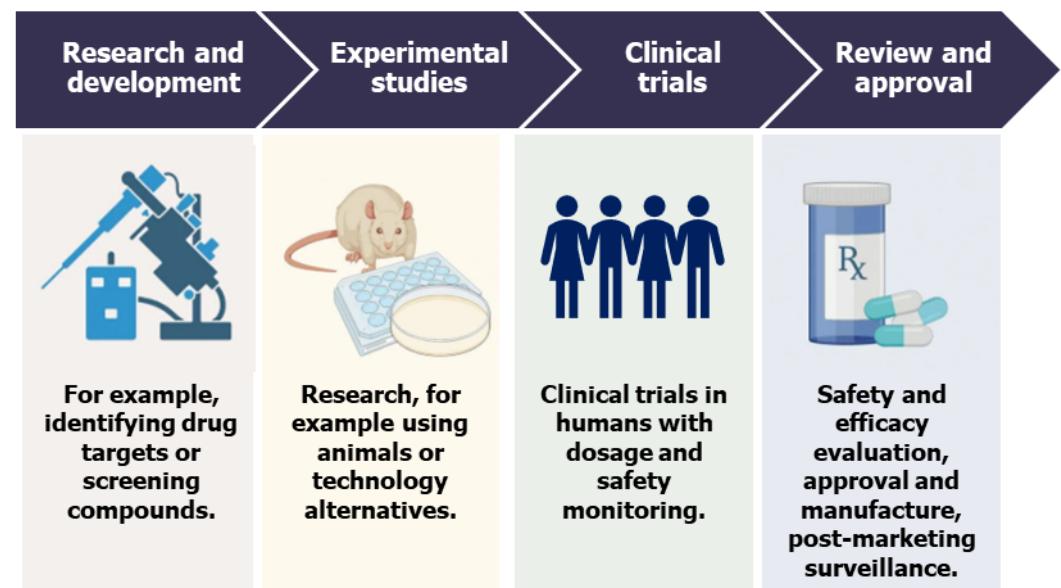
The law does not mandate animal testing, but regulators require evidence of efficacy and safety from validated tests. Regulators usually require animal tests in practice because there are few validated alternative technologies that can completely replace animals in preclinical testing.<sup>22</sup> However, if a validated alternative technology became available, it could be legally required to use that instead to satisfy UK regulatory requirements.<sup>31</sup>

The Home Office may potentially authorise the use of animals in tests despite there being an alternative accepted in the UK, if the data generated will be used to satisfy regulators in other countries who do not yet recognise the alternative for a justifiable scientific reason.<sup>22,181</sup>

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<sup>m</sup> Chemicals could include plant protection products (insecticides, herbicides), household products (cleaning products, paints), industrial chemicals, food additives, pharmaceuticals, and environmental contaminants.<sup>178-180</sup>

**Figure 3. Example of a drug discovery and development process.**



Source: Adapted from Bharatha, A. (2025).<sup>182</sup> Images from BioRender. This is a simplified illustrative example and processes may vary.

## International regulation

As life sciences research operates within a global market, international frameworks strongly influence UK regulation (table 1).<sup>183,184</sup>

**Table 1: International regulatory frameworks**

Framework	Domain	Recommendations and UK relevance
<b>The Organisation of Economic Co-operation and Development (OECD)</b>	Human and environmental safety testing of chemicals	<p>The OECD's Testing of Chemicals guidelines (TGs) set international standards for safety testing.<sup>152</sup> Data from TG methods are accepted internationally under the Mutual Acceptance of Data system.<sup>123</sup></p> <p>The UK adheres to this framework, and data on chemicals tested using this framework in another country are automatically accepted in the UK.<sup>185</sup></p>
<b>The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)</b>	Human pharmaceuticals	<p>ICH regulatory guidelines ensure the safety, efficacy and quality of pharmaceuticals. Testing new drugs on two mammal species (a rodent and non-rodent) is often required before approval in human use.<sup>186</sup></p> <p>The MHRA is a full regulatory member of the ICH.<sup>187,188</sup></p>
<b>International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)</b>	Veterinary medicines	<p>The VICH establishes safety and efficacy testing requirements for veterinary medicines. It is working towards incorporating validated technology alternatives.<sup>189</sup></p> <p>The UK is a standing member of the VICH. It does not have voting rights and is not bound by VICH guidelines, but it aligns with their principles.<sup>190</sup></p> <p>The Veterinary Medicines Directorate acts as the UK regulator.<sup>191</sup></p>
<b>The EU regulation Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)</b>	Industrial and environmental chemicals	<p>EU REACH assesses the safety of chemicals. It promotes alternative testing methods, and companies are required to share data to ensure no unnecessary animal testing. Animal research is only permitted where no alternatives are available.<sup>179</sup></p> <p>UK REACH mirrors EU REACH principles and uses OECD validated methods.<sup>192</sup> The Health and Safety Executive and Environment Agency are responsible for its administration.<sup>192</sup></p>

<b>World Health Organisation (WHO)</b>	Vaccines, biologics and public health	The WHO sets international safety standards for vaccines and drugs made from living organisms, often applied in the UK. The standards encourage reduction and replacement of animal testing in batch testing and quality control. <sup>193</sup>
<b>International Standards Organisation (ISO)</b>	Technical standards, materials, and quality systems across research and industry.	ISO develops internationally recognised voluntary standards that ensure the quality, safety and reliability of products and testing methods. Its standards support the validation, reproducibility and comparability of laboratory methods, including some non-animal and <i>in vitro</i> approaches. <sup>194</sup>  The UK participates in ISO through the British Standards Institution and adopts standards where appropriate. <sup>195</sup>

Regulatory agencies, industry representatives and model developers have stated that the UK's regulatory autonomy post-Brexit provides flexibility to align with or diverge from international recommendations.<sup>184</sup>

But industry representatives note that global marketing requirements often limit the use of alternative technologies.<sup>196</sup> Companies must meet the standards of multiple jurisdictions, including those that rely on internationally harmonised frameworks (see table 1).<sup>152</sup>

Several international bodies are updating their policies to encourage the use of alternative technologies.<sup>197</sup> For example, the 2022 US Food and Drug Administration (FDA) Modernization Act 2.0 broadened the definition of non-clinical testing to explicitly permit the use of alternative methods in place of animal testing in drug development where scientifically appropriate.<sup>198</sup>

Some technologies are recognised by regulators internationally.<sup>152</sup> For example, 2024 OECD test guidelines included approaches combining human cell-based tests, chemical reactivity tests, and computer models to test skin sensitisation.<sup>n</sup> <sup>199–202</sup>

Regulatory acceptance of methods may depend on how quickly regulatory agencies and frameworks respond to emerging evidence.<sup>121,174</sup> An example is tebentafusp, a treatment for a rare human eye cancer for which there were no relevant animal models. Its development relied on human cell-based and computer-based tests instead of traditional animal studies. Although there was no formal legal framework for approving drugs based on such data, national regulatory agencies reviewed the evidence to allow supply in the

<sup>n</sup> Skin sensitisation occurs when a substance triggers a skin reaction.

UK, the US and the EU. In the UK tebentafusp, was recommended for use by the National Institute for Health and Care Excellence (NICE) in 2025.<sup>o</sup> <sup>204</sup>

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<sup>o</sup> NICE produces guidance and standards for the NHS. It is funded by the Department of Health and Social Care.<sup>203</sup>

## 5

# Research funding and economic opportunities

## UK funding landscape

In the UK, most public funding for 3Rs research comes from the government via UK Research and Innovation (UKRI) research councils and Innovate UK.<sup>205,206</sup> This includes funding provided to the NC3Rs by the Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC).<sup>207</sup>

UK researchers can access funding through the EU's Horizon Europe programme.<sup>208</sup> Charity, third sector, and private investment is available on a smaller scale.<sup>207,209</sup>

Since 2004, the NC3Rs has invested over £100 million into research, including over £60 million in human-based in vitro models, and £30 million in contracts awarded via the CRACK IT innovation programme.<sup>p 210,211</sup> They have funded 53 PhDs in human-specific technologies since 2020.<sup>211</sup>

The 2025 government strategy commits to increasing funding for alternative technologies, with a stated financial support of £60m.<sup>31,212</sup> After its publication, the MRC, Wellcome,<sup>q</sup> and Innovate UK announced £15.9 million of funding to support in vitro disease model development.<sup>214</sup>

Funder, regulator and industry representatives said that funding councils should balance scientific innovation with safety and ethical considerations. They highlighted the need for sustained investment in skills, collaboration, infrastructure, and validation to advance reliable alternative technologies.<sup>215</sup>

Reviews of past studies could guide future funding, particularly in academic discovery research. A systematic review assessing the impact of research using non-human primates (NHPs) advised that all study results should be published, whether positive or negative, to prevent duplication and ensure lessons are learned.<sup>216,217</sup> The RSPCA suggested this could serve as a model for broader evaluation of benefit across research types.<sup>218</sup>

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<sup>p</sup> The NC3Rs CRACK IT Challenges are open innovation competitions for industry, academia, and small and medium sized enterprises to develop new technologies and approaches that replace, reduce, or refine the use of animals in research. These challenges aim to develop and commercialise human-specific technologies that address unmet research needs.<sup>210</sup>

<sup>q</sup> Wellcome is one of the largest charitable foundations in the UK, funding worldwide research aimed at solving urgent health challenges.<sup>213</sup>

## Economic opportunities

In 2019, the Centre for Economics and Business Research estimated that the alternative technology industry contributed £592 million to the British economy, forecasting this could be £2.5 billion by 2026.<sup>r</sup><sup>219</sup> Allied Market Research projected that the global non-animal alternative testing market will be worth \$29.4 billion by 2030.<sup>220</sup>

### International trade

Government stakeholders highlighted that technologies could provide economic opportunities from international trade agreements. This may depend on countries amending their animal testing requirements, as seen in cosmetics (box 2).<sup>221</sup>

#### Box 2: UK cosmetics trade with China

In 2021, the estimated worth of the Chinese cosmetics market was £50 billion. Mandatory animal testing requirements restricted UK companies from importing cosmetic products into China. However, in 2021, the UK and Chinese Governments agreed a certification system, issued by the Office for Product Safety and Standards (OPSS), enabling British companies to export 'general' cosmetics products without animal testing. However, animal testing is still required for 'special' cosmetics.<sup>s</sup><sup>196,223,224</sup>

In 2025, the OPSS signed a memorandum of understanding (MOU) with China to influence the adoption of non-animal testing methods for 'special' cosmetics for safety testing and ingredient innovation. The MOU aims to improve market access for UK–China trade of cosmetics, advance global best practice in non-animal testing methods, and drive innovation and collaboration to advance the industry. An internal estimation by the Department for Business and Trade suggested that this collaboration may contribute up to £50 million over five years in UK exports of 'special' cosmetics.<sup>225</sup>

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<sup>r</sup> This was estimated using gross value added (GVA). GVA is the measure of the value of goods and services produced in an area, industry, or sector, minus the cost of inputs and raw materials.

<sup>s</sup> In China, cosmetic products are legally classified into general cosmetics and special cosmetics. General cosmetics are products for everyday purposes like cleansing or beautifying. Special cosmetics are products with a specific modifying role, such as sun protection, hair colouring, or skin whitening. Special cosmetics make claims about their effects, so they require testing to prove they work.<sup>222</sup>

## 6

# Barriers to uptake

Researchers, government officials, and industry representatives agreed that the main barrier to the wider uptake of alternative technologies is scientific readiness to replace animal models.<sup>22,121,174,175,226–228</sup>

Alternative technologies can take a lot of time and money to develop and use, particularly if regulators require that animal models are needed alongside the alternative technology.<sup>174,229–231</sup>

## Regulatory barriers

Regulators may have limited familiarity, expertise or capacity to evaluate emerging technologies, which can delay regulatory acceptance and integration into existing frameworks.<sup>30,232,233</sup>

Some researchers said that guidance on how to submit or incorporate alternative technologies can be unclear.<sup>234</sup> Some companies are hesitant to submit data from alternative methods in case regulators reject it.<sup>235</sup> Diverging from established EU or OECD protocols could create issues for international regulatory submissions and global market access.<sup>231,234</sup>

In 2025, the government committed to upskilling regulatory assessors, and enabling regulators to provide early feedback on proposals, for example through the MHRA's scientific advice service.<sup>31</sup>

## Aligning investment

The 2025 government strategy highlighted that there is not enough funding for the development, validation and standardisation of alternative technologies. It also indicates that when funding is available, it does not continue for long enough to support their uptake in the long term.<sup>31</sup> Technology developers and industry experts have said research should focus on real-world use, as technologies can misalign with user needs when developed without early input from industry or regulators.<sup>236</sup>

The government's strategy aims to address this through increased public funding, stronger public-private partnerships and improved shared infrastructure and validation pathways to reduce investment risk.<sup>31</sup>

Funding organisations have suggested that improved classification of 3Rs research would make it easier to track work being undertaken, and to

evaluate its outcomes.<sup>30,237</sup> Suggestions include using current classification systems, such as the Medical Subject Headings (MeSH) thesaurus.<sup>t 238</sup>

## Workforce and skills

Surveys suggest many researchers are aware of, or already using, alternative technologies alongside animal models.<sup>231</sup> However, some noted that greater collaboration between teams working with animal models and those developing or applying alternative technologies could accelerate progress.<sup>30,151,239</sup>

Many professionals are experienced in animal research and may lack skills, knowledge, contacts, or confidence in alternative technologies.<sup>231</sup> Effective integration requires interdisciplinary expertise, and upskilling across sectors can take a lot of time and resources.<sup>91,171</sup>

Developing and validating new models requires staff time and effort.<sup>231</sup> Researchers may be hesitant to change where they have built a professional reputation and network centred around a specific approach.<sup>123,151,240,241</sup>

In academia, job insecurity and publishing pressures can make adopting new methods seem risky, with some funding bodies and journal reviewers favouring animal studies or asking for non-animal approaches to be validated against animal models.<sup>30,240–244</sup>

The 2025 government strategy includes a commitment to provide 3Rs training to early career researchers, research funders and other organisations using animals in research, to build expertise and awareness in alternative methods.<sup>31</sup>

Some animal researchers have reported feeling unfairly scrutinised or stigmatised due to public and political discourse against animal use, and believe there are unrealistic expectations about how soon alternative technologies could be adopted.<sup>122,119,245</sup>

## Infrastructure and costs

Universities have invested substantial time and money into developing and maintaining animal research facilities.<sup>246</sup> Some alternative technologies require specialist equipment and facilities which may not be widely

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<sup>t</sup> The Medical Subject Headings (MeSH) thesaurus is a controlled vocabulary produced by the National Library of Medicine, used to index, catalogue, and search biomedical and health related information.<sup>238</sup>

accessible.<sup>30,164</sup> Developing these technologies and their supporting infrastructure can have high upfront costs.<sup>184</sup>

Investing in shared centres for alternative methods could reduce costs and improve the accessibility of infrastructure.<sup>u 27</sup> The 2025 government strategy commits £30 million to develop a preclinical translational hub, as a public-private partnership, to accelerate development, validation and scaling of in vitro pre-clinical models.<sup>31</sup>

## Access to samples and data

### Access to samples

Human-derived clinical samples are essential for many in vitro approaches.<sup>247</sup> Specialised cells, such as cancer cells, are typically obtained from surgical biopsies.<sup>248</sup> Researchers highlighted that the process of obtaining samples from clinicians is complex and time consuming due to patient consent requirements, multiple access processes, and inconsistent information.<sup>231</sup>

Companies may enable access to cells for research, but collection, storage and processing methods are not always transparent, limiting standardisation across tests.<sup>249,250</sup> Researchers have proposed cold chain transport to enable 'on demand' access to cells, reducing reliance on central facilities or costly in-house expertise.<sup>122</sup>

The use of human samples raises ethical issues around consent and data privacy.<sup>50</sup> For example, obtaining informed consent that clearly explains how samples and associated data will be used, stored, and shared, and clarity on the right to withdraw.<sup>251-253</sup> Researchers highlighted privacy protections, such as de-identification and secure storage, as essential to prevent misuse and maintain trust.<sup>254,255</sup>

Consent frameworks can sometimes restrict the use of samples.<sup>231</sup> If a model is developed using samples which are not consented for commercial research, it is not possible for that model to be used in pharmaceutical research.<sup>256</sup>

Factors such as genetic background and ethnicity can influence responses to medicines.<sup>257-259</sup> Models using single-cell sources may not fully capture real-world variability.<sup>260</sup> For example, one study of cancer cell lines found an ancestral bias, with 62% of samples from European descent, and 29% from East Asian origin.<sup>261</sup>

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<sup>u</sup> Existing examples include the Queen Mary University of London Centre for Predictive In Vitro Models, and the Imperial College London Centre for Intestinal Systems, both of which are providing infrastructure, training and access to resources to conduct standardised in vitro research.<sup>27</sup>

## Access to data

Computer modelling can be limited by access to high-quality datasets.<sup>262,263</sup> Data varies in format, quality, diversity, and origin (including human-specific in vitro studies and animal experiments), making it more difficult to compare and integrate data.<sup>30,264</sup>

Many datasets are not publicly accessible due to commercial, intellectual property, or confidentiality reasons.<sup>265</sup> Models may be developed using incomplete or inconsistent data, making them less reliable.<sup>266,267</sup> This may lead to unnecessary repetition of tests, as researchers may be unaware that comparable studies have already been conducted.<sup>268</sup>

Researchers have said that data sharing can be limited by the lack of international guidance on data anonymisation and data sharing.<sup>269</sup> Collaborations between public and private entities could allow for protected sharing of confidential data.<sup>270</sup> The government has proposed that the Health Data Research Service could help accelerate progress in alternative technologies.<sup>v 31</sup>

The use of AI raises ethical and governance questions, such as addressing biased datasets and reproducibility of results, and challenges around data sharing and privacy.<sup>83,262,264,272</sup> For example, it can be unclear how an AI model reaches a decision, which makes it hard to trust its findings and determine who is accountable.<sup>273,274</sup> Ensuring models provide understandable reasons for their outputs is essential for validation and regulatory approval.<sup>273,275,276</sup>

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<sup>v</sup> The upcoming Health Data Research Service (HDRS) is a government initiative to provide a single, secure gateway to linked NHS health and care data. It aims to streamline research access, accelerate clinical trials, and enable faster, more impactful discoveries while maintaining high standards of data protection and public trust. It is planned to launch in 2026.<sup>31,271</sup>

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- UK Bioindustry Association (UK BIA)

- Understanding Animal Research, member of UK Biosciences Sector Coalition (UKBSC)\*
- Wellcome, member of UK Biosciences Sector Coalition (UKBSC)
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- John Kendrick, Labcorp Early Development Laboratories Ltd\*
- Dr Adjanie Patabendige, University of Derby
- Barney Reed, RSPCA\*
- Prof Paul Roach, UK Neuromorphic Computing Centre (UKMCNC), University of Loughborough
- Dr Sally Robinson, Cancer Research UK Manchester Institute\*
- Dr Dharaminder Singh, CN Bio Innovations
- Dr Sara Wells, Mary Lyon Centre Medical Research Council (MRC), Harwell\*
- Dr Carl Westmoreland, retired toxicologist

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