Summary of Facts

Department for Science, Innovation & Technology (DSIT) Response

The argument claiming over 90% of drugs fail in human trials, despite being tested on animals, disregards drugs that are tested on animals and found not to be suitable for use in human clinical trials. Drugs fail for a variety of reasons and animals are used for safety screening as well as efficacy modelling. Moreover, not all types of drugs fail at the same rate. Many do better and success rates vary widely by treatment type.

Our Reply

The Department for Science, Innovation & Technology (DSIT) are attempting to use distraction to avoid accepting that the mean 92%+ failure rate of drugs in clinical trials is abysmal. These are the facts: drugs progress into clinical trials largely on the basis of animal tests in 2 species, which suggest efficacy and safety. More than 9 out of 10 fail in human testing, and most of this failure is due to toxicity and poor efficacy. This cannot be dressed up as anything else other than the failure of animal testing.

Further: It is proved that animal tests which suggest safety add next to no statistical evidential weight to a drug also being safe in humans. This has also been accepted - albeit reluctantly - by subsequent studies involving industry. So why are the DSIT still trying to argue against this? And why are they ignoring the FDA USA making steps to move away from animal tests? We suggest it is because they cannot accept that they are wrong.

Further: of the drugs that DO make it to market - the less than 10% - many are withdrawn or have warnings added to their use, or have their use restricted.

The point about drugs tests on animals that are deemed not suitable for clinical trials: we know that some of these drugs have been rejected, yet on further testing have gone into clinical trials and made it to the market. However when animal tests falsely identify a safe chemical as “toxic,” the almost certain outcome is abandonment of further development. Undoubtedly many potentially beneficial drugs have failed animal testing and been lost to patients, even though they would have been both safe and effective. Because a drug that shows toxicity in animal models is unlikely to ever undergo human testing, the magnitude of this type of “error” is unknown. However, many highly beneficial drugs would have failed animal testing and would never have been brought to market, except that they were developed before animal testing was required. Examples include penicillin (fatal to guinea pigs), paracetamol (toxic in dogs and cats), and aspirin (embryo toxicity in rats and rhesus monkeys).

As for variability in types of drugs. This is true. But the mean is 92%, and this cannot be denied - some classes of drugs are far worse, like Alzheimer's 99.6%, cancer 94.7% and cardiovascular disease 95.2%.

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Below is the graph from Thomas DW, Chancellor D, Micklus A et al. Clinical development success rates and contributing factors 2011-2020.
Available: New Clinical Development Success Rates 2011-2020 Report

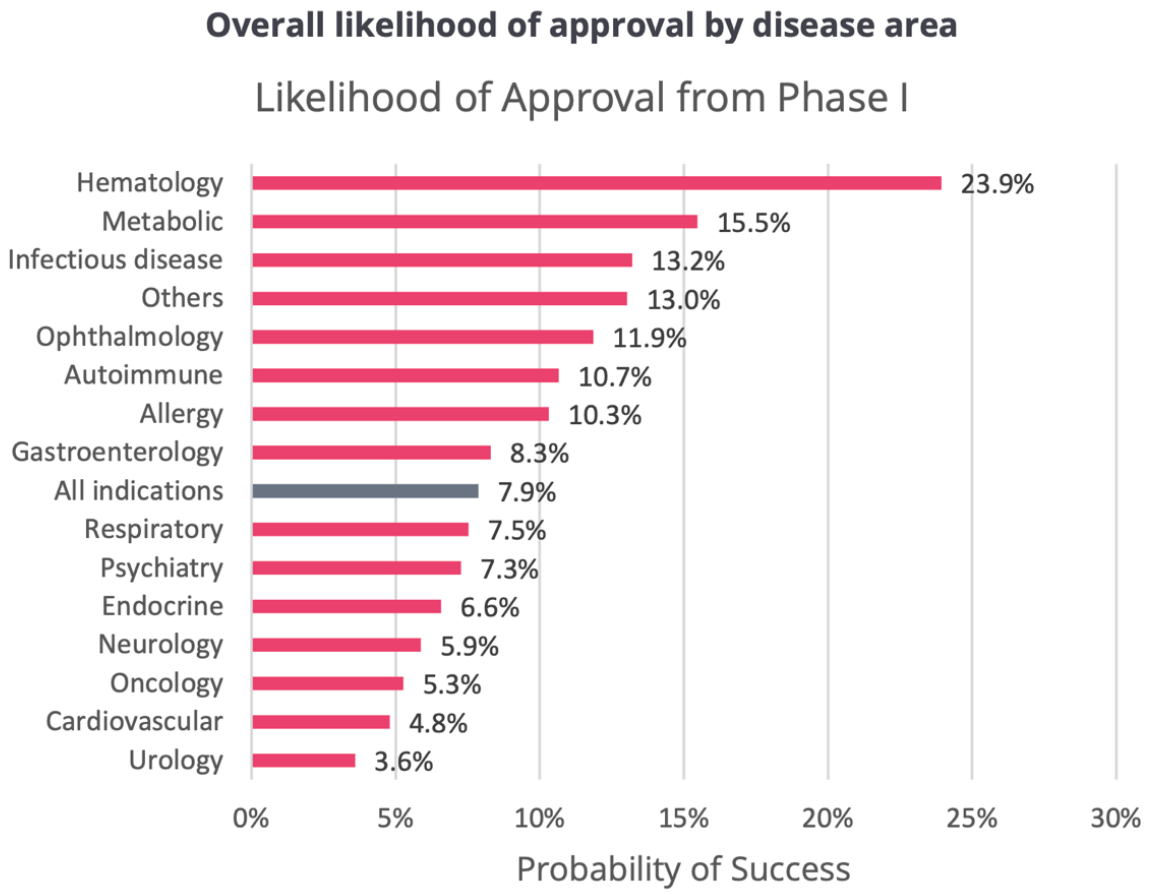

Figure 5a: Chart of LOA from Phase I, displayed highest to lowest by disease area. Source: Biomedtracker® and Pharmapremia®, 2020

The mean success rate is 7.9%, and all the areas below that are even worse. This graph is progression from human trial – if drugs fail in animals prior to reaching human trials then this is nothing to celebrate, they may have been life saving for humans. Taking all drugs in development from the start rather than human trials would be very close to 100% failure.

If something does not work you stop doing it, not phase it out over decades, so that both animals and human health are harmed. Data is quite simply not transferable with any accuracy between species, if it was we would have treatments and cures for the main human diseases.

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Around one million UK citizens have dementia, in a population of less than 70 million. This total will rise by almost half again by 2040, with one in three people born in the UK today developing dementia. More than 70,000 UK citizens have young onset dementia. Overall, Alzheimer's and other dementias are the leading cause of death in the UK, and have been for a decade. In 2019, the estimated cost to the global economy was $1.3 trillion, with around half of those costs attributed to informal care from family members and friends. This is forecast to grow to $2.8 trillion by 2030.The very poor translation of animal research into Alzheimer's disease and other dementias has been described as "a graveyard for a large number of promising drugs" given its specific failure rate: until recently of 99.6%.

On the 11th November 25 the Government published the long awaited - Replacing Animals in Science strategy Link The DSIT reference this in their petition reply.

Some comments from ourselves and other campaigns:

The strategy lacks a clear timeline, enforceable targets and legislative backing. Without clear timelines and measures of success in place with legal accountability, it risks becoming a mere PR exercise without action.

MPs Questions for legislation are:

- Will the Secretary of State commit to enshrining the targets in the strategy in law, so that industry, campaigners and the wider public have the certainty they need that this Government will move as fast as possible to end unnecessary animal testing? Legislation No answer given to the question.
- Recognising that the legal framework in the UK already requires that animals are only ever used in science where there are no validated alternatives available, the government currently has no plans to legislate further on this matter. Legislation

There is a commitment only to reduce the use of dogs and Non-human primates (NHPs) in certain tests, as opposed to ending the use of animals in research. Most testing on dogs and animals will continue well after 5 years.

Specifically the strategy refers to:

1. We will aim to use validated alternative methods to reduce the use of non-human and dogs in dedicated cardiovascular safety studies by at least 50% by 2030.
2. We will aim to use validated alternative methods to reduce the use of dogs and non-human primates in dedicated PK studies for human medicines by at least 35% by 2030

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Yet when enquiries were made via Freedom of Information Request it transpired that the numbers of dogs and NHPs used or the number of procedures on them for these studies is unknown. It is not possible to predict or aim for a % reduction without having a numerical starting point.

For the vast majority of animals used including zebra fish and rodents there is nothing meaningful at all in the strategy.

The promise is to end skin and eye irritation tests in 2026 however these made up less than 0.1% of regulatory tests in 2024. The impact for animals is minimal. animal use is in the single figures.

The number of project licences that authorise the Forced Swim Test (FST) in Great Britain has decreased from nine to a current total of only three licences. All of these licences are due to expire by 2028. Forced Swim Test The strategy admits "The test has limited scientific validity, particularly its translational relevance to human mental health disorders. Animal behaviour in the FST also lacks information on treatment latency and varies across strains and protocols. Therefore, we would expect the Home Office Regulator's default position to be that the FST does not pass the harm-benefit test required under ASPA." In the FST, it is assumed that if an animal spends more time immobile, having given up on escape, it is "depressed," and researchers presume this to be an adequate stand-in for human depression. The scientific community has widely condemned these tests as unscientific, leading agencies in the United Kingdom and Australia to prohibit their use as models of human depression or anxiety. Yet rather that stop these horrific tests right now existing projects are allowed to continue to their expiry dates in 2028.

"The last licence authorising the use of the rabbit pyrogen test was granted in 2017. The most recent reported use of the test was in 2018" Rabbit Pyrogen Test The promise to end this test this year therefore has no impact, it is not a win.

COP Non Compliance Questions as to the Code of Practice and non-compliance thereto most commonly are responded to that they will be published in the Animals in Science Regulation Unit Annual Return. Freedom of information requests for information on say extreme temperatures at MBR Acres are exempted from response as will be shown in future publications. The report for 2023 was published on 17th December 2024. The 2024 has not as of early December 2025 been published. The MP asked about non compliance in the last 12 months but details are unlikely to be published until another 12 months.

Further details are urgently needed as to £60 million funding and specifics of the new UK Centre for the Validation of Alternative Methods (UKCVAM) and a preclinical translational models' hub. It seems new funding is over a 5 year period and only £15.9 million has been put forward by the Medical Research Council (MRC), Innovate UK and the Wellcome Trust to advance new in vitro models of the liver, brain, cancer, pain and blood vessels for use as more human-relevant alternatives to animals within five UK-based teams. CN-Bio Compared to the

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financing of animal research the actual amounts being put into the development of NAMS represents significantly less than 1% even when including the £10 million to the National Centre of the 3Rs (NC3Rs). The £60 million appears to be administrative not for development of human specific methods which we would have liked to have seen year one funding to be £250 million. It is human relevant treatments that will ultimately save the NHS for future generations.

The strategy mentions funding and support to researchers to adopt alternative non animal methods, but it lacks detail on how this will be achieved. Shifting to human-specific technologies has the potential to strengthen UK science, biotech and innovation, and so there must be the prioritisation of research into these methods.

More than 2.5 million procedures are still conducted on animals each year in the UK. Mice, dogs, monkeys, rabbits, horses, fish and others may be drilled into, drugged, starved, mutilated, poisoned, cut open and abused in myriad other ways. Millions more animals are in laboratories (2017 was 1.81 million) but because they are killed without regulated use their lives are not even recorded.

We must do more than eliminate tests where replacements already exist. The strategy should right now stop the use of animals that are used in vain attempts to model human diseases.

Consider sepsis, which kills around 48,000 people in the UK each year, this is more than breast, bowel and prostate cancers combined. Despite decades of experiments, there are no targeted treatments or definitive diagnostic tools. Valuable resources are being wasted through cruel and ineffective experiments on mice and rats, even though their biology vastly differs from that of humans. Experiments are hindering progress in drug development, all treatments developed using mice have failed in humans.

We need to achieve a paradigm shift away from the UK entrenched bias toward animal use as being the ‘gold standard.’ This strategy cannot be embraced unless it plans to overcome the outdated mindset that causes researchers to cling to animal use, ignoring how severely the entrenched attachment to animal use has impeded scientific advancement at the cost of funds and lives.

Finally it is a legal requirement that project licences are only approved if potential benefits to humans outweigh actual harms to animals. On the 20th May 2025, Stephen Reed MP, then the Secretary of State for Environment, Food and Rural Affairs (DEFRA), stated the Environment, Food and Rural Affairs meeting that:

“I have spoken to a lot of the companies that are required to carry out testing on animals and, in many cases, they will tell you that they carry it out only because they are required to by regulation and legislation, not because it adds anything of value that they can use in developing better or safer products.”

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There is no doubt that Stephen Reed, when referring to 'a lot of the companies that are required to carry out testing on animals' that these will be or at least include some of Labcorp, Charles River and Sequani – these are the contract research organisations (CRO's) that do the testing for guidelines and regulations. These are also the same companies that the research beagles from MBR are sold to.

We are extremely concerned that project licences are being applied for illegally and then approved illegally by Inspectors at the Animals in Science Regulation Unit. All attempts to get more information have failed.