

The Webscout

Preclinical studies – is animal testing necessary?

The drug regulatory authorities require testing in animals, to be exact in at least two mammalian species, before the first-in-human trials can be approved. Common criticism is that the results from animal studies can merely be extrapolated to humans and are therefore an unnecessary cruelty. How valid are the results indeed, and what could be an alternative to animal testing? The following websites and documents comment on these issues.

<http://animal-testing.procon.org>

The website gives an overview on the history of animal experiments and the debate on it. Did you know that animal experiments can be dated back to ancient Greek and Roman scientists? Since then, animals have been used to experiment for the sake of mankind. Criticism of animal experiments also emerged in former centuries. Queen Victoria opposed animal testing in England. Her mindset towards animal testing strengthened the anti-vivisection campaigns, resulting in the first laws controlling animal experiments; Great Britain's Cruelty to Animals Act went into effect in 1876. The website also provides a detailed comparison of the pros and cons on this issue. The pro side argues that animal testing contributes to medical progress and that alternative testing systems are inadequate. The con side argues that animal testing is cruel and inhumane. According to the opponents, alternative methods are already in place that could replace animal testing. If you watch the debate show on the big question of "Is animal testing justified?" on YouTube (www.youtube.com/watch?v=bD51eAOPSKc), you will also get a full picture of pros and cons and an impression on the emotionality of the discussion on animal experiments.

www.piscltd.org.uk/scipubs

The PETA International Science Consortium (PISC) addresses issues related to the replacement of animal experiments by alternative techniques. They provide a list of publications

and posters on the applicability of animal study results to humans and on alternative testing procedures for pharmacological development and food and cosmetic safety.

www.piscltd.org.uk/alternatives-approved-by-regulators/

Some alternatives to animal testing have already gained approval. These include tests for eye irritation, skin irritation, and skin sensitisation, to name but a few. A detailed list and factsheets can be downloaded from the PISC website. For example, according to the European Pharmacopeia, a monocyte activation test can now be used in place of the rabbit pyrogen test for assessing pyrogenicity. The new test measures cytokine levels after exposure of human blood to the test substance.

<http://emulatebio.com/insight/functionality>

It was only recently that the US FDA announced a collaborative research agreement with Emulate, the developer of the organs-on-chips

SECTION EDITOR



Karin Eichele
info@mediwiz.de

technology. This technology uses micro-engineered living human cells to simulate human organs and can be used instead of animals in drug testing. According to Emulate, the system can predict the human response with greater precision and control than today's cell culture or animal-based testing methods.

<http://ec.europa.eu/growth/sectors/chemicals/epaa>

The European Partnership for Alternative Approaches to Animal Testing is a collaboration between the European Commission, European trade associations, and companies from seven different industries including the pharmaceutical industry. Its aim is the replacement, reduction, and refinement (the so-called "3Rs") of animal experiments in regulatory testing. Currently, the project groups focus on eight topics. One of these is the Vaccines Consistency Approach Project: Vaccine quality control includes batch testing for safety based on animal tests as per legislation. The vaccines consistency approach strives to implement the 3Rs in vaccine manufacturing by strictly applying quality systems that ensure batch consistency.

www.aerzte-gegen-tierversuche.de/agt-en/

Doctors Against Animal Experiments Germany (Ärzte gegen Tierversuche) is an association founded in 1979 that opposes animal experiments because of ethical, medical, and scientific reasons. They provide well-researched information for doctors, scientists, and the public. They also collaborate with international organizations such as the European Coalition to End Animal Experiments (ECEAE; www.eceae.org) to be heard on an EU legislator level. A film by the association (www.youtube.com/watch?v=Mo2S5wUKNySg) explains the organisation's viewpoint that animal experiments are ethically and scientifically questionable.

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