NON-ANIMAL METHODS

What is the failure rate of Animal Testing?

In 2004 the FDA estimated that 92% of drugs that pass preclinical tests, including “pivotal” animal tests, fail to proceed to the market.

More recent analysis suggests that, despite efforts to improve the predictability (through genetic modification) of animal testing, the failure rate has actually increased and is now closer to 96%.

The main causes of failure are lack of effectiveness AND safety problems that were not predicted by animal tests.

If we look ONLY at the safety data (and ignore the efficacy), we get a failure rate of around 50%.

Are they good odds to gamble your health on?

What are the main benefits to using Non-Animal Methods (NAMs)?

NAMs more accurately predict human responses to new drugs, they are cheaper than using animal “models”, you get quicker results, they cost less money and of course, they don’t involve any animal cruelty.

Vivisection has become a horrific trade, generating false claims, a false sense of safety for humans, and huge profits for the vivisectors. The most barbaric and outdated practice that is regulated across the world, and still holds back human progress.

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What's the correct name for tests that don't use animals?

It's important to understand the correct terminology as some tests still use animal parts or animal "models" at some stage and some still use animal tested ingredients or processes.

This is NOT human relevant science.

"Non-Animal Methods" of testing is the correct phrase as NO animals have been used during any stage of the testing process.

Non-animal research techniques have offered us the best contributions to modern medicine; clinical observation (monitoring patients), epidemiology (linking lifestyle factors with disease), human tissue research, organ and tissue culture, computer modelling and advanced technologies such as MRI scanners and ultrasound.

The public are increasingly turning towards wanting non-allopathic therapies, based on holistic models of health and disease with the focus on strengthening and nourishing the body's immune defences rather than waging a 'self-destructive' high tech war on pathogens, tumours and the like. All of these medical tools and techniques and many more have improved our ability to treat patients – and they owe absolutely nothing to animal experimentation.

This IS human relevant science.

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What types of Non-Animal Methods do we have available?

In Silico refers to computational models that investigate pharmacological hypotheses using methods such as databases, data analysis tools, data mining, machine learning, and network analysis tools.

In Vitro describes something "in glass" such as a test tube or petri dish. Examples of in vitro studies include the isolation, growth and identification of cells derived from multicellular organisms.

In Chemico refers to the use of abiotic (non-living) chemical reactivity methods as replacements for animal models.

Human Subject research is a systematic, scientific investigation that can be either interventional or observational and involves human beings as research (test) subjects.

What is the purpose of human subject research?

Advances in human health ultimately depend on research with human subjects. Properly controlled studies with human subjects are essential to verify any conclusions about normal physiology, mechanisms of disease, effectiveness of treatment, learning, or behaviour.

The following pages will give you a brief insight into the human relevant research tools and methods that are available right now.

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The Tox21 Program

Thousands of chemical substances exist in the world, but only a small fraction of these have been adequately assessed for their potential toxicity to humans.

Tox21 is a US federal research collaboration focused on driving the evolution of Toxicology in the 21st Century by developing methods to rapidly and efficiently evaluate the safety of commercial chemicals, pesticides, food additives/contaminants, and medical products.

The aim is to develop a new way of rapidly testing whether substances adversely affect human health.

The Tox21 program can currently test 10,000 chemicals.

The goals of Tox21 are to:

(1) identify mechanisms of chemically-induced biological activity
(2) prioritize chemicals for more extensive testing
(3) Develop models that better predict how substances will affect biological responses (predictive toxicology)
(4) Employ testing methods using human cells (in vitro approaches)
(5) Reduce time, effort, and costs associated with testing
(6) Contribute to the reduction, refinement, and replacement of animals used in toxicity testing

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Virtual Screening

Virtual screening is a computational technique used in drug discovery to search libraries of small molecules in order to identify those structures which are most likely to bind to a drug target, typically a protein receptor or enzyme.

It reduces the need of real laboratory experiments and accelerates the drug discovery process in a more efficient and economical way.

Virtual screening is a very useful application when it comes to identifying hit molecules as a beginning for medicinal chemistry. As the virtual screening approach begins to become a more vital and substantial technique within the medicinal chemistry industry the approach has had an expeditious increase.

Virtual screening has become a standard tool in drug discovery to identify novel lead compounds that target a biomolecule of interest.

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Using existing validated data via “Biobank” and “QSAR Toolbox”

UK Biobank is a large-scale biomedical database and research resource, containing in-depth genetic and health information from half a million UK participants. The database is regularly augmented with additional data and is globally accessible to approved researchers undertaking vital research into the most common and life-threatening diseases. It is a major contributor to the advancement of modern medicine and treatment and has enabled several scientific discoveries that improve human health.

Quantitative Structure Activity Relationships (QSAR) is a computational or mathematical modeling method to reveal relationships between biological activities and the structural properties of chemical compounds.

What are the goals of the QSAR Toolbox?

(1) Prevent duplication of animal tests. When existing high quality data are found, there is no need to duplicate the test.
(2) Intelligent testing strategies. By forming categories and identifying data gaps, informed testing strategies can be designed to optimize costs and number of animals required.
(3) Predict toxicity using a category approach. The results can be used for data-gap filling and as supporting evidence for read-across cases.
(4) Sustainable development and green chemistry. The toxicity of substances can be predicted even before they are produced, facilitating sustainable product development and green chemistry.

NON-ANIMAL METHODS

New Imaging Technologies

Medical imaging is the digital microscope that enables physicians to see inside the body and inside cells to screen, diagnose and stage disease; monitor treatments and disease recurrence; and facilitate medical research in areas such as drug discovery.

Here are some of the technologies used in medical imaging:

Computed tomography is an imaging procedure that uses special x-ray equipment to create detailed pictures of areas inside the body.

Magnetic resonance imaging is a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in your body.

Vascular interventional radiology is the use of imaging to guide minimally invasive vascular procedures, such as stenting or angioplasty.

Diagnostic medical sonography, is an imaging method that uses sound waves to produce images of structures within your body. The images can provide valuable information for diagnosing and directing treatment for a variety of diseases and conditions.

Imaging is an important element within the drug discovery and development process providing researchers with information that can help identify potential drug targets or see how drugs are working. Developments in this field are ongoing and technology is continuing to advance to increase efficiencies and accuracy.

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Computational Biology and Bioinformatics

Computational biology and bioinformatics is an interdisciplinary field(relates to more than one branch of knowledge) that develops and applies computational methods to analyse large collections of biological data, such as genetic sequences, cell populations or protein samples, to make new predictions or discover new biology.

In addition to this, bioinformatics is now being used for a vast array of other important tasks, these include:

Analysis of gene variation and expression, analysis and prediction of gene and protein structure and function, prediction and detection of gene regulation networks, simulation environments for whole cell modelling, complex modelling of gene regulatory dynamics and networks, and presentation and analysis of molecular pathways in order to understand gene-disease interactions.

Though the two fields are interrelated, bioinformatics and computational biology differ in the kinds of needs they address.

While both fields pursue greater utilization of our collective biological understanding, bioinformatics tends to concern itself with the gathering and collation of biodata, and computational biology with the practical application of this biodata.

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Human-Patient Simulators

Human Patient Simulators are life-size adult and infant patient simulators that replicate elements of human physiology like respiration, heart beat and pulse.

They are mechanical and computer controlled simulators that mimic human appearance and display symptoms and disease processes as they present in a real patient.

They're used to educate students and train healthcare professionals.

Simulation is particularly important for ensuring patient (and health care professional) safety in this context, where the likelihood of using the new processes is low, coupled with high risk to the patient and a high degree of angst among health care professionals.

This type of computer software allows Human Patient Simulators to replicate normal and abnormal bodily responses for educational and training purposes. Often these responses are initiated by a number of physical events taking place, such as an asthma attack. Therapeutic interventions can also be replicated under certain circumstances, including that representing a side effect of a medication.

This also extends into veterinary science.

Up to 50% of clinical hours can be replaced by simulations.

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Microfluidic chips (Lab/Organ-On-A-chip)

Microfluidics has been increasingly used in the biological sciences because precise and controlled experiments can be conducted at a lower cost and faster pace.

The organ-chips are designed to accurately recreate the natural physiology and mechanical forces that cells experience in the human body. The chips are lined with living human cells and their tiny fluidic channels reproduce blood and/or air flow just as in the human body.

A recent study using liver chips showed they correctly identified 87% of a variety of drugs that were moved into humans after animal studies, but then either failed in clinical trials because they were toxic to the liver or were approved for market but then withdrawn or scaled back because of liver damage. The chips didn't falsely flag any nontoxic drugs.

Approximately 75% of the cost in research and development is the cost of failure—that is, money spent on projects in which the candidate drug was deemed efficacious and safe by early testing but was later revealed to be ineffective, unsafe, or otherwise of limited commercial value during human clinical trials.

One of the major goals of this effort is to develop preclinical models that could enable a "fail early, fail fast" approach, which would result in candidate drugs with greater probability of clinical success, improved patient safety, lower cost, and a faster time to market.

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3D Tissue Models

Culturing cells outside of their natural environment in a laboratory under controlled conditions has become essential to scientific research. Cell culture has utility in diverse areas from stem cell and cancer research, monoclonal antibody production, drug discovery, regenerative medicine, therapeutic protein production and for modelling diseases. Cells to establish in vitro cultures can be isolated from normal or diseased tissues, be grown as adherent monolayers or in suspension, and can be established in two or three dimensions.

Tissue Model applications developed for a variety of tissues including skin, liver, stomach, kidney, and lung, organotypic models display a realistic micro-anatomy, mimic organ function, and offer insight into cell-to-cell interactions.

3D cell culture can serve as a better model system for vaccine development by providing a microenvironment that replicates the physiological setting of real cells, enabling better identification of toxicity and other unwanted issues earlier in drug development.

Using functioning human tissue to help screen medication candidates could speed up development and provide key tools for facilitating personalized medicine while saving money and help replace animals in research.

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Micro-dosing (Phase 0 Studies)

A method called "micro-dosing" can provide vital information on the safety of an experimental drug and how it is metabolized in humans prior to large-scale human trials.

Volunteers are given an extremely small one-time drug dose, and sophisticated imaging techniques are used to monitor whether the drug reaches the tumour, how the drug acts in the human body, and how cancer cells in the human body respond to the drug.

Evidence so far suggests that micro-dosing may be a better predictive tool of human pharmacokinetics than alternative methods and combination with physiologically based modelling may lead to much more reliable predictions in the future.

The concept has also been applied to drug-drug interactions, polymorphism and assessing drug concentrations over time at its site of action. Micro-dosing may yet have more to offer in unanticipated directions and provide benefits that have not been fully realised to date.

Micro-dosing can help replace tests on animals and help screen out drug compounds that won't work in humans.

We have to stop investing valuable time, money and resource into archaic animal experiments that don't work, when we now have proven human-based research methods readily available to us which provide accurate results.