ACTION PLAN FOR COMPANIES

to accelerate the transition to non-animal science in the pharmaceutical sector

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Table of contents

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Introduction

The pharmaceutical industry has a strong stated commitment to the development and uptake of non-animal approaches and has made notable recent progress. Several pharmaceutical companies have already achieved substantial reductions in their use of animals, both for research and development, and for regulatory testing purposes. However, the transition to non-animal science is a significant and complex challenge, and it may be difficult for individual companies to determine how they can best contribute, and where to begin.

This transition also demands collaborative input from a wide range of stakeholders, including for example the pharmaceutical industry, regulators, and animal welfare organisations, each bringing unique expertise, skills and perspectives. In light of extensive discussions about how to initiate and drive this transition at an individual pharmaceutical company level, an action plan has been developed to address these challenges.

The aim of this action plan is to outline specific key actions, illustrated by examples of initiatives, that pharmaceutical companies can undertake in a coordinated manner to review their own current practices and further accelerate the transition towards non-animal science for the development and testing of pharmaceuticals. While some companies may already have actions in place, these should be seen as complementary and mutually reinforcing. Greater synergy and progress towards accelerating the transition will be achieved where actions are implemented in a broad and co-ordinated way.

This action plan is not an exhaustive list of everything a pharmaceutical company can do, but serves as a guide to inspire thought, review, and action. Companies are encouraged to adopt and adapt the plan as they see fit and to endorse, promote and share their efforts with others. Endorsement of this action plan includes a commitment to review its activities internally, assess their relevance, and take meaningful steps to implement them. Furthermore, companies are encouraged to communicate their initiatives widely within the scientific community, for example through company websites, conference presentations, and meetings with regulators and authorities, and others in the sector, to amplify the impact of their efforts.

Importantly, this action plan is intended to be a living document, subject to regular review and updates. While companies are free to express additional views or pursue goals beyond those outlined here, this plan provides a shared framework to drive collective progress. By implementing and sharing these actions, pharmaceutical companies can play a pivotal role in accelerating the transition to a future of non-animal science.

Commitment to the ambition of replacing animal uses

The company should openly endorse the desirability of phasing out the use of animals in science. Consequently, the company should set this goal as one of its organisational priorities and produce a company-specific action plan tailored to the company's situation to further stimulate actions to achieve this ambition.

WHAT COULD A COMPANY DO?

- ➔ **Openly state support for the ambition.**
- ➔ **Make helping to achieve progress towards this objective an organisational priority (e.g. an explicit 'corporate goal').**
- ➔ **Demonstrate support from key individuals (e.g. CEO).**
- ➔ **Produce a company-specific action plan with clear and concrete objectives.**

Coordination among companies of the elements of the action plan

Coordination of the elements of the action plan, internally but also between companies across the sector, in line with applicable (competition) law, is crucial for effectively organising and directing the key actions. In this regard, task forces responsible for overseeing the action plan, providing guidance, and driving forward the initiatives must be established.

WHAT COULD A COMPANY DO?

- ➔ **Set up an internal taskforce to oversee the plan and proposed activities, provide guidance, and drive forward the initiative.**
- ➔ **Actively share and align actions with other companies and relevant Trade Associations.**

Clear objectives

Each action requires clearly defined and concrete objectives for how it will contribute towards reducing impacts on animals. These objectives should be accompanied by relevant and realistic Key Performance Indicators (KPIs) to measure the performance of each of the objectives over time. Having common, harmonised, easy tools for defining KPIs would be very useful. Examples of KPIs may include evidence of reducing 'severe' suffering, existence of internal structures focused on promoting non-animal science, involvement in external partnerships and collaborations related to non-animal science, evidence of working with regulators to challenge or update test requirements, investment in infrastructure and state-of-the art non-animal innovations, and support for people to increase knowledge and skills in non-animal science.

It is essential to designate responsibility for the delivery of each objective and ensure that the individuals or teams responsible have the necessary capabilities (knowledge and skills), opportunities (resources, equipment, lab space etc.) and incentives to successfully accomplish them. Associated with this, companies should clearly define internally the resource commitment they will direct towards achieving this ambition.

WHAT COULD A COMPANY DO?

- ➔ **Define clear and concrete objectives, accompanied by KPIs for each of the actions.**
- ➔ **Designate responsibility for the delivery of each objective in your company's action plan.**
- ➔ **Ensure that the individuals or teams responsible have the necessary competencies (knowledge and skills), resources (personnel, equipment, lab space etc.) and incentives to successfully accomplish them.**

EFPIA'S RESEARCH & ANIMAL WELFARE GROUP

EFPIA's Research and Animal Welfare Group carried out an internal study to attempt to define how to measure investments in 3Rs and their impacts. A wide range of quantitative and qualitative KPIs were discussed. Companies then assessed these KPIs for their relevance and feasibility within their own operations. The study revealed broad agreement on the relevance and feasibility of many of the qualitative KPIs. However, it was acknowledged that companies might measure 3Rs and animal welfare investments differently due to variations in their operating structures. Therefore, KPIs should be adapted to the way the company operates.

Analysis of opportunities, barriers and gaps

A comprehensive analysis of the current situation to identify opportunities for and barriers to the wider and faster uptake of non-animal approaches is essential for a more effective allocation of resources and efforts to ensure faster progress. Such a mapping exercise should include an analysis of whether the barriers are primarily technological and scientific, or socio-cultural (e.g. building awareness, understanding, access and confidence). It should also provide a clear overview of which animal-free innovations can already be used today and where; which animal-free innovations need further development, in particular with regard to qualification, validation, standardisation, scale-up, and implementation; and in which areas animal-free innovations are currently lacking or are less developed.

WHAT COULD A COMPANY DO?

- ➔ **Conduct a comprehensive analysis of the current situation to identify opportunities, barriers and gaps and identify scientific needs to fill information gaps and apply resources to develop the necessary methods and technologies. This includes:**
  - **reviewing exactly where your own company's work (including work undertaken in CROs) currently impacts on the use of animals in science (including the use of animal-derived materials) – stages of R&D, preclinical safety, marketing, therapeutic area, specific tests, etc.;**
  - **considering where and how your company is contributing to external initiatives assessing the current landscape and future opportunities.**
- ➔ **Reflect on how information flows into your organisation about initiatives on 'replacement' from third parties? How is this formally reviewed and engaged with?**


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EURL ECVAM REPORTS OF NON-ANIMAL MODELS

Valuable work has been done in reporting suitable non-animal models for seven disease areas by the European Commission's Joint Research Centre. These reports can be a good starting point for identifying areas and specific research contexts where advanced non-animal methods are available to replace animal-models.

3-BASKET APPROACH

The EFPIA 3-Basket approach provides a practical framework for developing plans and guiding investment decisions that will help advance the replacement of animal testing with non-animal research in the short, medium, and long term. The concept aims to develop feasible plans, milestones, and KPIs for this purpose by identifying what is possible under which conditions and where there is innovation potential for academia, startups, and established industry. This is achieved by:

1. Identifying studies that could already be scientifically replaced by available non-animal technologies if the regulatory conditions were created worldwide.
2. Identifying animal tests for which developing technologies or established scientific hypotheses for their replacement still need to be validated.
3. Recognizing areas where scientific evolution still needs time and sustainable hypotheses for non-animal methods to replace animal testing still need to be developed. In the interim, this third area requires global improvements to enhance overall animal health and the quality of experimental results.

In 2023, Merck developed the 3-basket approach and applied it in line with the current use of animals and animal-free approaches in its business areas. In 2024, the company shared the process with EFPIA, non-governmental organisations, regulatory authorities, and policymakers to achieve consensus and effective steps towards phasing out animal testing while modernising biomedical research. Merck published the method and its application in 2025.

Kleinschmidt-Doerr et al. 2025

Monitor progress

Establishing mechanisms to monitor and evaluate the progress and impact of actions is essential to demonstrate efforts aimed at replacing and reducing animal uses, and to better understand where to prioritise activities and resources. These mechanisms will also allow adjustments to be made to actions as necessary to ensure that they are in line with objectives. The number of animal uses alone would not give an accurate picture of efforts to replace animal uses. Monitoring progress requires a set of well-defined quantitative and qualitative metrics to demonstrate the impact of the company's efforts and to quantify the company's commitment to transition to non-animal science.

WHAT COULD A COMPANY DO?

➔ **Establish mechanisms for monitoring and evaluating progress and impact of actions, ensuring transparency and accountability. This includes ensuring that KPIs are being met or justifications for deviations are provided. Regularly disseminate public reports detailing findings and outcomes.**

SANOFI'S PERFORMANCE METRIC

Sanofi has adopted a performance metric to track its ambitious goal of reducing animal usage by 50% over the next decade. This indicator compares the use of animals in research, development, analytical testing and quality control between 2020 and 2030. This assessment encompasses animals used directly by Sanofi as well as those used on its behalf by Contract Research Organisations (CROs) and external partners.

MERCK'S CORPORATE REDUCTION TARGET

In 2021, Merck launched initiatives to reduce the number of animals used in tests by its Healthcare and Life Science divisions and by CROs (Contract Research Organizations) on behalf of Merck by 75% by 2040. Initiatives focusing on Basket 1, including legally required animal testing for quality assurance, are expected to reduce the total number of animals used by 50% by 2032. In parallel, additional projects aimed at replacing animal-based testing methods with New Approach Methodologies (NAMs) are expected to achieve a further 25% reduction by 2040. Progress to date shows that the company is well on track to achieve these goals.

THE BEYOND ANIMAL TESTING INDEX

The Beyond Animal Testing Index (BATI) is a benchmarking instrument designed to provide insights into an organisation's activities and contributions to the transition to non-animal science, as well as its performance in relation to others. It incentivises organisations to learn from and inspire each other in implementing research practices that do not involve animals, for the benefit of science.

II. Collaboration

Fostering collaborations and building networks, across sectors and disciplines within and among companies, and among diverse stakeholders, is pivotal for establishing a community dedicated to advancing science without the use of animals. Such collaborations help drive the development of innovative, integrative human-based solutions that can address biomedical issues more effectively. Increased cooperation with various stakeholders through participation in national and international initiatives aimed at accelerating the transition to animal-free science can also be of value to raise awareness of viewpoints, specific needs and requirements.

Collaboration between developers of animal-free technologies, end users (e.g. pharmaceutical industry scientists) and regulators is also very important. Such collaboration can ensure that the technologies developed meet the needs of end users while also complying with regulatory requirements. In addition, it can also lead to more in-depth research into the feasibility of the technologies, including how they can be integrated into the pharmaceutical industry's pipeline and how potential scale-up and manufacturing challenges can be addressed. Closer engagement with regulators can also help to promote the acceptance of non-animal test methods and reduce the need for animal use in R&D (safety and efficacy) and quality control testing by questioning the need for and value of certain tests.

The lack of a common language often poses a significant barrier in cross-disciplinary discussions and studies. Researchers from different fields frequently use specialised terms and concepts that may be confusing to others. Consequently, establishing a common language is essential to enable researchers from diverse backgrounds to collaborate more effectively. In the context of interdisciplinary collaboration, 'technology translators' can play a critical role in bridging the communication gap between developers of animal-free technologies, end users and regulators. Their assistance can facilitate the translation of complex, domain-specific terminology into clear and concise language, while promoting mutual understanding. Importantly, the context of use should be carefully considered in discussions to clarify the intended manner and purpose of a non-animal approach. This will, in turn, help to foster alignment and a shared understanding among experts from different disciplines.

WHAT COULD A COMPANY DO?

- **Overcome fragmentation of expertise by supporting collaborative working and creating moderated networks within the company and with external stakeholders (e.g. the SME sector, CROs, academia, EU agencies) to exploit the best knowledge and expertise, increase exchange of best practices, identify opportunities but also bottlenecks in the development and uptake of non-animal approaches, and build confidence in the use of new technologies.**
- **Establish collaborative platforms between developers of non-animal technologies, industry and regulators to improve and standardise methodologies.**
- **Facilitate strong collaboration with regulators to promote understanding, confidence in, and the acceptance of, non-animal test methods, and through challenging the need for and value of certain tests.**
- **Engage with technology translators to bridge the communication gap between different stakeholders.**
- **Actively participate in national and international initiatives aimed at accelerating the transition to animal-free science in order to raise awareness of viewpoints, specific needs and requirements.**
- **Carry out an internal 'audit' of skills, expertise and current practices relevant to non-animal approaches - do you have expertise within your organisation that is particularly relevant, or needed, or a particular initiative or way of working that you are proud of and can share?**
- **If developing, or thinking of utilising, new non-animal methodologies, make fuller use (especially for the preclinical domain) of available support - e.g. on issues relating to regulatory needs and acceptance, seek early engagement with the EMA via** Innovation Task Force briefing meetings, portfolio and technology meetings, qualification of novel methodologies for medicine development, or by requesting scientific advice.

The European Partnership for Alternative Approaches to Animal Testing

EPAA

The European Partnership for Alternative Approaches to Animal Testing (EPAA), a cross-sectorial and multidisciplinary partnership between the European Commission and industry, offers an important forum for collaboration and synergy across sectors, and with regulators.

ROCHE'S INSTITUTE OF HUMAN BIOLOGY

Roche's Institute of Human Biology bridges the gap between academic and pharmaceutical research by bringing together multidisciplinary teams with expertise in a wide range of disciplines (e.g. physics, chemistry, biology, engineering, computation). By working closely with Pharma Research & Early Development scientists, Roche is able to translate its models and technologies into assays for drug development.

AI-POWERED DATABASE OF NON-ANIMAL METHODS

EURL ECVAM has developed a new artificial intelligence driven database of human biology-based non-animal methods for biomedical research (BimmoH), allowing users to easily search for information on available non-animal methods within specific categories.

The database constitutes a valuable and sustainable resource for different stakeholders, including scientists, industry innovators, regulators, project evaluators or research project funding organisations.

THE VITAL TISSUE PROJECT

The Vital Tissue project aims to establish a network of hospitals and researchers to ensure that leftover tissue after surgery is not discarded but is instead made available for research.

INNO4VAC

The public-private partnership Inno4Vac addresses scientific bottlenecks in vaccine development. It brings together global leaders in the fields of clinical research, immunology, microbiology, systems biology, mathematical models, and regulatory matters to develop predictive biological and mathematical models of vaccine performance and bio-manufacturing. The industry leaders of this project ensure that the industry's needs, vision and expectations are always taken into account.

III. Exchange, accessibility and visibility of technology, knowledge and data

An increasing amount of knowledge is being generated regarding non-animal approaches; however, this knowledge is often fragmented and not always easy to find. Furthermore, certain data remain inaccessible due to confidentiality agreements, intellectual property rights, and patents. Consequently, researchers, companies, animal ethics committees, regulators, policymakers, and funders may not always have a comprehensive overview of non-animal approaches available or under development in each discipline. While raw data linked to specific compounds is unlikely to be openly shared for the reasons outlined above, the pharmaceutical industry is becoming increasingly transparent in sharing results and approaches to replace, reduce and refine the use of animals.

To further promote data sharing, a structured process should be established to enable the exchange of data wherever possible, without compromising intellectual property rights, to avoid unnecessary repetition of animal testing and facilitate the optimal implementation of the 3Rs. A 'safe harbour' approach could support this goal by allowing innovative ideas to be developed, tested and compared in a pre-regulatory environment, free from immediate legislative or regulatory consequences. Such a framework would encourage industry to share data from innovative research and testing methods, enabling their strengths and weaknesses to be explored collaboratively and confidentially. Additionally, it would enable regulatory authorities to become familiar with and confident in emerging models at an early stage, which could positively influence regulatory acceptance and use of non-animal approaches.

Facilitating efficient data sharing without compromising intellectual property rights in line with the principles of open access and FAIR (findability, accessibility, interoperability, and reusability), along with readily accessible state-of-the-art methodologies that are thoroughly described and presented, is important for accelerating innovative animal-free research. Establishing international information portals to exchange publications, data, protocols, software and other forms of scientific information quickly, easily and in a transparent manner can, on the one hand, prevent duplicate research and, on the other hand, take successful research a step further.

Furthermore, targeted case studies can effectively illustrate ongoing efforts directed towards avoiding or replacing the use of animals in research. By sharing cases where new non-animal approaches have been used successfully, the transition towards non-animal approaches can be encouraged, facilitated and accelerated. These case studies can also serve to demonstrate the feasibility and wide applicability of animal-free innovations, while seeking mutual acceptance among stakeholders.

WHAT COULD A COMPANY DO?

- **Critically review current rationale for what is 'shared' outside of the company about the work being undertaken (using animals, or NAMs).**
- **Start from a position of 'yes, unless...' - is there really a legitimate reason for holding back on sharing information? (e.g. the sharing between companies of non-clinical data from toxicology and safety assessment studies can help build databases, which can be used to generate new tools for predictive toxicological modelling).**
- **Give more visibility to existing initiatives and best practices around non-animal approaches, for example by contributing to existing or forthcoming knowledge portals that provide easy access to information on non-animal innovations, and where information can be shared in accordance with the open science and FAIR principles.**
- **Publish targeted case studies to show ongoing efforts to avoid or replace the use of animals in research, demonstrate the feasibility and applicability of non-animal innovations, and seek mutual acceptance.**
- **Share and describe what was tried and worked - and also what did not, and where problems were encountered. Include, if possible, where non-animal approaches were used for internal decision-making (e.g. exploratory and mechanistic studies), as well as in regulatory submissions.**
- **Support efforts from non-animal method developers to illustrate to the wider community specific contexts for how their technologies are of use.**
- **Establish regular exchanges with regulators for free exchange of information and ideas.**

CASE STUDIES ON NON-ANIMAL METHODS

APCRA
ACCELERATING THE PACE OF CHEMICAL RISK ASSESSMENT

APCRA, the international governmental partnership dedicated to developing innovative methods for chemical safety assessment, has published 13 case studies in recent years to explore the application areas of various non-animal methods and build confidence in their usability.

European Medicines Agency

EMA's Innovation Task Force has already introduced a safe harbour mechanism to encourage the voluntary submission of data generated using new non-animal testing models. This mechanism enables the generation, compilation and review of data, which can be used to define and/or refine a context of use for a non-animal method. It may also assist EMA in drafting qualification criteria for non-animal methods based on a context of use. Furthermore, this approach enables regulators to have greater confidence in data obtained with non-animal methods.

In its consolidated 3-year rolling work plan for the non-clinical domain (2025-2027), EMA's 3Rs Working Party has set a tactical goal to identify and ensure accessibility for all stakeholders to a database(s) of qualified/validated new approach methodologies.

SUCCESSFUL ANIMAL REPLACEMENT CASES

Examples of successful animal replacement cases from the pharmaceutical industry include the removal of the requirement for fish testing for environmental risk assessment of antibiotics, and instead adding a second microorganism species; the replacement of animal use by application of a microneedle drug delivery system in human and artificial skin; the replacement of animal use by application of human-induced pluripotent stem cells to generate functional human neurons for in vitro screening; the replacement of animal use by in vitro methods to screen for potential seizurogenic effects; and the replacement of the Rabbit Pyrogen Test and the horseshoe crab blood assay (LAL) by use of in vitro tests such as the Monocyte Activation Test (MAT) to detect pyrogens in vaccines (see for example Merck's PyroMAT® system).

IV. Infrastructure

Establishing and/or expanding dedicated infrastructure, such as skills labs and core facilities, is essential for significantly increasing the development, access, uptake, and use of existing and emerging non-animal innovations.

WHAT COULD A COMPANY DO?

- **Assess current infrastructure to identify where there is a need to build or expand key infrastructure that would allow fuller access, uptake, and use of non-animal approaches.**
- **Invest in the establishment or expansion of state-of-the-art infrastructure.**
- **Facilitate the establishment of strategic partnerships among companies to develop and share research infrastructure and platforms, where appropriate.**
- **Provide access to 'real-life' contexts – where specialists can pilot the use of non-animal methods (including to compare to or augment animal studies) to assess feasibility, help development and build confidence.**
- **Look for opportunities to be a sponsor or partner on an initiative aimed at solving a technological challenge relating to non-animal approaches, or for creating or expanding access to a new resource.**

MPS

Astrazeneca, Novo Nordisk and Merck are among the many companies who now have areas of their businesses focussed on exploiting the significant potential of microphysiological systems (MPS) for accelerating the development and implementation of effective methods of drug discovery that may avoid, replace or reduce the use of animals.

ORGANOID PLATFORM

The Belgian University KU Leuven is working on the establishment of an organoid platform to train early-stage researchers in organoid technology and to support the development of new organoid models, including the proper acquisition of appropriate human material and networking with other relevant scientific disciplines.

CENTRE FOR PREDICTIVE IN VITRO METHODS

In the United Kingdom, the Queen Mary University of London's Centre for Predictive in vitro Methods (CPM) provides researchers with access to organ-on-a-chip technology and expertise.

V. Training

To further aid in the development and broader use of non-animal approaches and increase the confidence in the results of these methods, support should be provided for comprehensive and continuous training. Different types of training will be required for the development and use of different types of non-animal innovations. Training needs to be provided for researchers, technicians, members of ethics committees and animal welfare bodies.

In parallel, collaborative mechanisms could be actively promoted. For example, co-funded doctoral or postdoctoral programmes could be established with technology developers, or internal staff could be seconded to organisations engaged in the development of non-animal methods to gain hands-on experience with model development. Beyond strengthening expertise and technical skills, such collaborative initiatives can play a pivotal role in informing the development, capabilities, and practical applicability of non-animal methods.

WHAT COULD A COMPANY DO?

- ➔ **Ensure appropriate and ongoing training programmes are available for researchers, technicians, ethics committee members and animal welfare bodies in advanced non-animal approaches.**
- ➔ **Establish collaborative capacity-building initiatives to strengthen internal expertise and inform the development and practical application of non-animal methods.**
- ➔ **Provide industry work placements for students involved in non-animal approaches.**
- ➔ **Share in-house expertise with the wider scientific community, and help establish sector-wide forums for upskilling in non-animal methods.**

TRAINING IN NON-ANIMAL METHODS

Altertox Academy provides toxicology training in innovative non-animal tools. It also provides a better understanding of EU regulatory requirements.

Similarly, ESTIV offers training in applied in vitro methods for individuals who wish to start or pursue a career in this direction or to gain an update on the state-of-the-art of applied in vitro toxicology.

Queen Mary University of London was recently awarded a £7 million grant to establish a Centre for Doctoral Training in Next Generation Organ-on-a-Chip Technologies to train the next generation of scientists and bioengineers who will drive the development and application of organ-chip technology.

VI. Internal project review

Harmonisation of the evaluation of research projects can aid the adoption of best 3Rs practices, and in particular of non-animal approaches to replace or reduce the use of animals. In particular, project proposals that lack sufficient uptake of existing alternatives to animal uses, are poorly designed, or raise significant ethical concerns should be revised, or not proceed. Enhanced and more harmonised project evaluations can be achieved, for example, by training people in charge of reviewing research projects (see section above) and establishing and publishing harmonised guidelines.

Conducting systematic reviews and meta-analyses, with the help of AI-tools, are key to provide a complete and transparent overview of the existing evidence and could help to identify bias, poor study design and reporting methods; assess the quality of findings from animal-based and non-animal approaches; and identify relevant human-based approaches that could replace animal uses.

WHAT COULD A COMPANY DO?

- ➔ **Ensure that project proposals that lack sufficient uptake of existing alternatives to animal uses, are poorly designed, or raise significant ethical concerns, are revised or do not proceed.**
- ➔ **If not already in place, establish relevant guidelines and organise regular interactions between ethics committees responsible for evaluating projects involving the use of animals, as well as animal users, to encourage sharing of best practices.**

VII. Funding

Sustainable funding mechanisms are imperative to support new non-animal technologies, and new forms of preclinical testing and keep pace with the rapid evolution of non-animal approaches. In particular, substantial investment is required to establish multidisciplinary teams, facilitate data sharing, strengthen infrastructure and provide the necessary training. Funds can also be allocated to support national and international research programs dedicated to avoiding or replacing the use of animals, or to support start-ups with expertise in non-animal approaches.

WHAT COULD A COMPANY DO?

- ➔ **Create internal and external funding mechanisms to support the key actions outlined in the action plan.**
- ➔ **Support national and international research programs aimed at avoiding or replacing the use of animals.**
- ➔ **Engage with regulators and funding bodies to ensure alignment across programmes, with a clear focus on priority areas, while avoiding gaps and unnecessary duplication.**

INNOVATIVE HEALTH INITIATIVE

The Innovative Health Initiative (IHI), jointly funded by the European Union and several life sciences industries, can make a significant contribution to the advancement of non-animal science by funding research projects aimed at developing and implementing innovative non-animal approaches to biomedical research and testing.

CREATE2SOLVE

The Dutch Create2Solve programme supports research consortia, consisting of at least one research organisation and one commercial party, in the development of impactful, animal-free innovations that should lead to marketable methods, models and/or services.

ALTERNATIVE METHODS ADVANCEMENT PROJECT

In April 2024, Charles River Laboratories launched its Alternative Methods Advancement Project (AMAP), an initiative dedicated to delivering on the 3Rs, and developing animal-free methods for drug discovery and development to reduce animal testing. This project will receive $300 million over the next five years, adding to an initial $200 million invested so far in advancing the 3Rs.

THE NC3Rs' CRACK IT CHALLENGE

The NC3Rs' CRACK IT Challenges competition funds collaborations between industry, academia and SMEs to solve business and scientific challenges to develop and commercialise emerging technologies into products and services that directly address end-user needs. Depending on the Challenge, contracts of up to £1M for up to three years are available.

Action plan for companies to accelerate the transition to non-animal science in the pharmaceutical sector

Summary of suggested actions

I. General

Commitment to the ambition of replacing animal uses

- Openly state support for the ambition.
- Make helping to achieve progress towards this objective an organisational priority (e.g. an explicit 'corporate goal').
- Demonstrate support from key individuals (e.g. CEO).
- Produce a company-specific action plan with clear and concrete objectives.

Coordination among companies of the elements of the action plan

- Set up an internal taskforce to oversee the plan and proposed activities, provide guidance, and drive forward the initiative.
- Actively share and align actions with other companies and relevant Trade Associations.

Clear objectives

- Define clear and concrete objectives, accompanied by KPIs for each of the actions.
- Designate responsibility for the delivery of each objective in your company's action plan.
- Ensure that the individuals or teams responsible have the necessary competencies (knowledge and skills), resources (personnel, equipment, lab space etc.) and incentives to successfully accomplish them.

Monitor progress

- Establish mechanisms for monitoring and evaluating progress and impact of actions, ensuring transparency and accountability. This includes ensuring that KPIs are being met or justifications for deviations are provided. Regularly disseminate public reports detailing findings and outcomes.

Analysis of opportunities, barriers and gaps

- Conduct a comprehensive analysis of the current situation to identify opportunities, barriers and gaps and identify scientific needs to fill information gaps and apply resources to develop the necessary methods and technologies. This includes:
    - ❖ reviewing exactly where your own company's work (including work undertaken in CROs) currently impacts on the use of animals in science (including the use of animal-derived materials) – stages of R&D; preclinical safety; marketing; therapeutic area; specific tests etc.;
    - ❖ considering where and how your company is contributing to external initiatives assessing the current landscape and future opportunities.
- Reflect on how information flows into your organisation about initiatives on 'replacement' from third parties? How is this formally reviewed and engaged with?

II. Collaboration

- Overcome fragmentation of expertise by supporting collaborative working and creating moderated networks within the company and with external stakeholders (e.g. the SME sector, CROs, academia, EU agencies) to exploit the best knowledge and expertise, increase exchange of best practices, identify opportunities but also bottlenecks in the development and uptake of non-animal approaches, and build confidence in the use of new technologies.
- Establish collaborative platforms between developers of non-animal technologies, industry and regulators to improve and standardise methodologies.
- Facilitate strong collaboration with regulators to promote understanding, confidence in, and the acceptance of, non-animal test methods, and through challenging the need for and value of certain tests.
- Engage with technology translators to bridge the communication gap between different stakeholders.
- Actively participate in national and international initiatives aimed at accelerating the transition to animal-free science in order to raise awareness of viewpoints, specific needs and requirements.
- Carry out an internal 'audit' of skills, expertise and current practices relevant to non-animal approaches - do you have expertise within your organisation that is particularly relevant, or needed, or a particular initiative or way of working that you are proud of and can share?
- If developing, or thinking of utilising, new non-animal methodologies, make fuller use (especially for the preclinical domain) of available support - e.g. on issues relating to regulatory needs and acceptance, seek early engagement with the EMA via Innovation Task Force briefing meetings, portfolio and technology meetings, qualification of novel methodologies for medicine development, or by requesting scientific advice.

- Critically review current rationale for what is 'shared' outside of the company about the work being undertaken (using animals or non-animal methods).
- Start from a position of 'yes, unless...' - is there really a legitimate reason for holding back on sharing information? (e.g. the sharing between companies of non-clinical data from toxicology and safety assessment studies can help build databases, which can be used to generate new tools for predictive toxicological modelling).
- Give more visibility to existing initiatives and best practices around non-animal approaches, for example by contributing to existing or forthcoming knowledge portals that provide easy access to information on non-animal innovations, and where information can be shared in accordance with the open science and FAIR principles.
- Publish targeted case studies to show ongoing efforts to avoid or replace the use of animals in research, demonstrate the feasibility and applicability of non-animal innovations, and seek mutual acceptance.
- Share and describe what was tried and worked - and also what did not, and where problems were encountered. Include, if possible, where non-animal approaches were used for internal decision-making (e.g. exploratory and mechanistic studies), as well as in regulatory submissions.
- Support efforts from non-animal method developers to illustrate to the wider community specific contexts for how their technologies are of use.
- Establish regular exchanges with regulators for free exchange of information and ideas.

IV. Infrastructure

- Assess current infrastructure to identify where there is a need to build or expand key infrastructure that would allow fuller access, uptake, and use of non-animal approaches.
- Invest in the establishment or expansion of state-of-the-art infrastructure.
- Facilitate the establishment of strategic partnerships among companies to develop and share research infrastructure and platforms, where appropriate.
- Provide access to 'real-life' contexts – where specialists can pilot the use of non-animal methods (including to compare to or augment animal studies) to assess feasibility, help development and build confidence.
- Look for opportunities to be a sponsor or partner on an initiative aimed at solving a technological challenge relating to non-animal approaches, or for creating or expanding access to a new resource.

V. Training

- Ensure appropriate and ongoing training programmes are available for researchers, technicians, ethics committee members and animal welfare bodies in advanced non-animal approaches.
- Establish collaborative capacity-building initiatives to strengthen internal expertise and inform the development and practical application of non-animal methods.
- Provide industry work placements for students involved in non-animal approaches.
- Share in-house expertise with the wider scientific community, and help establish sector-wide forums for upskilling in non-animal methods.

VI. Internal project review

- Ensure that project proposals that lack sufficient uptake of existing alternatives to animal uses, are poorly designed, or raise significant ethical concerns are revised, or do not proceed.
- If not already in place, establish relevant guidelines and organise regular interactions between ethics committees responsible for evaluating projects involving the use of animals, as well as animal users, to encourage sharing of best practices.

VII. Funding

- Create internal and external funding mechanisms to support the key actions outlined in the action plan.
- Support national and international research programs aimed at avoiding or replacing the use of animals.
- Engage with regulators and funding bodies to ensure alignment across programmes, with a clear focus on priority areas, while avoiding gaps and unnecessary duplication.

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RSPCA
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Novo Nordisk
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Merck
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