



EARA Statement: New Approach Methodologies

Various strategies, models, methods, and technologies are employed in biomedical research, tailored to the specific nature of each research need and animal models remain indispensable for many aspects of fundamental, translational and applied research. Now, the development of New Approach Methodologies (NAMs), offers researchers the possibility to integrate complementary approaches alongside animal studies when feasible, contributing to more robust and reproducible study outcomes. The choice of approach depends on the unique characteristics of the research in question and the best method, or methods, should be chosen in each case.

As the research community continuously strives to replace, reduce and refine the use of animals (3Rs), NAMs are increasingly being developed. However, animal models still remain the only valid method for many specific processes, both technical and regulatory.

Alternatives can currently address some areas of safety testing of new medicines and chemicals, but not the fundamental/basic or translational research that leads to medical treatments and drug development, such as how whole, intact organs work and respond to therapies in a living body, rather than in the laboratory. It is not (yet) possible to model systems and biological mechanisms that the scientific community does not fully understand, such as the brain and the interaction between multiple systems or organs.

In addition, some regulatory provisions require the use of animal models and this is enshrined in legislation. This is for example the case for the marketing authorisations for veterinary medicines, which require the use of animals to demonstrate safety and efficacy in the target animal population.

EARA policy approach

In its role as the voice of the biomedical community in Europe on the use of animals in research, EARA will:

- Encourage a balanced and science-based dialogue on the use of animals and NAMs in biomedical research.
- Seek active engagement with those organisations, both at EU and national level, created to evaluate and improve the knowledge of NAMs in scientific research.
- Develop and communicate robust policy positions, based on scientific evidence, that will outline where it is feasible through scientific innovation to transition towards the use of NAMs and where that transition has already been made
- Showcase, by facilitating an exchange of information from EARA members and others, where current scientific knowledge means that, in the near future, the transition to NAMs is more likely, but also highlight the risks of a premature end of animals used for scientific purposes to human and animal health research.

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- Increase the understanding that it is currently not possible to protect the health and welfare of companion, farm and wild animals without using animals from the same species.

End

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