



Alliance for Biomedical Research in Europe

The BioMed Alliance response to the European Medicines Agency's Consultation:
Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products

The Alliance for Biomedical Research in Europe (BioMed Alliance) welcomes the European Medicines Agency (EMA) guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products.

Animal experiments are still indispensable for biomedical research aiming at generating new diagnostic and therapeutic options for humans and minimizing the risks for first-in-human studies and early clinical trials.

Both aspects result from the complexity of biological interactions on the molecular, cellular tissue and organ level in a living organism.

Increasingly, experimental approaches are developed using cells and multicellular arrays *in vitro* to model biological interactions and pertinent mechanisms for health and disease.

Besides avoiding the necessity to use laboratory animals, these approaches have the advantage to provide a reduced level of relevant interactions and boundary conditions: they allow simpler testing and interpretation of results. Thus, they are optimally suited to identify targets and develop approaches for clinical treatments.

However, the reduced complexity of reductionist experimental approaches also limits the scope of functions which can be addressed and renders the results less comprehensive with respect to possible risks in the clinical application. For example, if an *in vitro* model does not have a beating heart and blood circulation, respective effects and risks will not be apparent. **Thus, to decrease the potential risk for patients, testing in a model which has all functional systems of a complete mammalian organism is mandatory.**

It is often criticized that results of animal experiments cannot fully predict reactions in human patients and thus will not be a 100% protection from risk in early clinical studies. But even between individual patients, there are very relevant differences in reactions and complications – which is evident from the large number of patients included in clinical trials.

It is thus relevant to acknowledge that no single experimental approach can predict outcome in a given patient, and therefore a wide array of approaches ranging from *in silico* and *in vitro* approaches to clinical trials is required to



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minimize the risk and maximise the potential benefit. In this context, animal experiments are still needed to optimize safety and support new modalities in diagnosis and therapy since they represent the multifaceted interactions of different complex systems and tissues.

About BioMed Alliance:

The Alliance for Biomedical Research in Europe (BioMed Alliance, <http://www.biomedeurope.org>) is the result of a unique initiative of 24 leading European medical societies that together include more than 400,000 researchers and health professionals. The BioMed Alliance was created in 2010 to gather strength across different disciplines and areas in biomedical and health research at European level.

BioMed Alliance's members:

European Association for the Study of Diabetes (EASD), European Association for the Study of the Liver (EASL), European Association of Nuclear Medicine (EANM), European Atherosclerosis Society (EAS), European CanCer Organisation (ECCO), European College of Neuropsychopharmacology (ECNP), Federation of European Biochemical Societies (FEBS), European Federation of Immunological Societies (EFIS), European Academy of Neurology (EAN), European Hematology Association (EHA), European League Against Rheumatism, (EULAR), European Respiratory Society (ERS), European Society for Paediatric Research (ESPR), European Society of Anaesthesiology (ESA), European Society of Cardiology (ESC), European Society of Human Reproduction and Embryology (ESHRE), United European Gastroenterology (UEG), European Academy for Allergy and Clinical Immunology (EAACI), European Society of Pathology (ESP), European Society of Endocrinology (ESE), European Organisation for Research and Treatment of Cancer (EORTC), European Society for Molecular Imaging (ESMI), European Association for the Study of Obesity (EASO), The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN).