

8.2 The Use of Animal in Research and Development – EFPIA Policy Statement

Introduction

EFPIA represents the research-based pharmaceutical industry of twenty-five European countries. Its members, between them, have saved and improved the quality of life for millions of people. EFPIA member companies are committed to the alleviation of suffering caused by currently untreatable or inadequately treated medical conditions, bringing new, safe and effective therapies to patients.

The process that leads to the development of a new medicine is long and complex and involves a range of different research methods. Research in animals is an essential part of that process, providing vital information that scientists and doctors need to decide if a medicine should go on to be tested in people.

EFPIA members recognise the importance of animal welfare and strive to ensure that the number of animals used in research is kept to the absolute minimum necessary to obtain the required information. They are committed to avoid or minimise the distress or pain of animals and to always treat them with compassion and respect. Non-animal methods are used wherever it is scientifically possible and where the law and regulatory authorities allow it.

Most of the effects of medicines that cannot currently be seen using non-animal methods can be predicted from well-designed animal studies. To go into human testing without the benefit of this information would expose people to unacceptable risk. It would also be illegal. With good reason, regulators around the world demand evidence from animal studies before they will permit clinical trials to be conducted.

Why animals?

When body systems work together they create new conditions that do not exist in cell culture and cannot be fully replicated on computer. The effects (both wanted and unwanted) of a medicine will ultimately depend on what happens when a medicine interacts with all the body's systems. Even after extensive testing in the 'test tube' or in cellular systems, a compound may have a dramatically different effect in the whole body – for example liver metabolism may change the structure of the molecule, the molecule may collect in the kidney or, through a very indirect route, may affect blood pressure.

As our biological knowledge increases, so too does the usefulness of non-animal methods. There is however, a long way to go. There are still enormous gaps in our biological knowledge that limit the usefulness of cell culture and computer based research. The computer that could simulate the entire workings of the brain, let alone the interaction with the heart, liver and kidney, has yet to be invented.

Well-designed animal studies will remain essential to bridge the gap between test tubes and people for the foreseeable future. The biological similarity between ourselves and other animals, together with good understanding of the differences in the biology of the various laboratory animal species, means that most of the potential effects of a medicine in the human body can be predicted from such studies.

Progress in alternatives

EFPIA fully supports the concept of the '3Rs' and its member companies constantly put them into practice. These principles include: **R**eplacement (i.e. to substitute animals with valid non-animal techniques), **R**eduction (i.e. to use methods that allow the necessary information to be obtained from fewer animals) and **R**efinement (i.e. to use methods which cause the least possible distress).

EFPIA strongly encourages scientifically sound research to reduce the need for animals. In fact, the pharmaceutical industry has been at the forefront of developments that have led to big reductions in the number of animals needed in some areas.

EFPIA has also been a major driver in the International Committee on Harmonisation (ICH) since its creation in 1990. ICH was formed to agree common testing standards and requirements, including protocols involving animals, among the medicines regulatory agencies of the US, EU and Japan. Without such agreement, pharmaceutical companies can be forced to repeat tests, using slightly varying protocols, to satisfy individual national regulatory requirements. The work of the ICH has led to worldwide reductions in the number of animals needed in certain areas.

At the same time, our increasing biological understanding is opening up new areas of research, bringing hope for the future for people living with, and often dying from, many intractable conditions. This means that animals are being used in areas of research that hardly existed before. While every effort should be

made to reduce the number of animals used in research, it would be unethical to do so at the expense of human health and well-being.

EFPIA PRINCIPLES OF ANIMAL WELFARE

Researchers and the research organisations they work for have a moral (and legal) responsibility to treat the animals with care and compassion before, during and after the research. The principles of laboratory animal welfare promoted by EFPIA are set out below:

1. Compliance with the EC Directive 86/609, the Council of Europe Convention ETS 123 and appropriate national laws governing the use of animals in research;
2. Responsibility at all times for the humane care and a compassionate approach to laboratory animals before, during and after experimental procedures;
3. The conduct of research involving animals on the basis of sound and well-defined scientific objectives and carefully controlled conditions to ensure that research does not have to be repeated.
4. Provision of properly trained and competent staff to care for the animals and to carry out experimental procedures;
5. The conduct of procedures in a way which causes the least possible distress and pain to the animals;
6. Provision of appropriate and adequate facilities for the housing and transport of all laboratory animals;
7. The choice of the most appropriate method based on sound science, in order to obtain the required information that will ensure that a potential new medicine or vaccine can proceed to further testing in man for efficacy and safety reasons.
8. The use of non-animal methods wherever they can realistically provide the required information;
9. Development of reliable and validated research methods that reduce the need for animals;
10. Promotion and encouragement for progress in developing experimental techniques which will lead to the replacement and/or reduction of tests on animals and/or the refinement of methods;
11. Support for European and international initiatives which further the above without impeding pharmaceutical research and other medical progress (e.g. International Conference on Harmonization [ICH] and the activities of the European Centre for Validation of Alternative Methods [ECVAM]);

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