ANIMAL EXPERIMENTATION FOR HEALTH RESEARCH

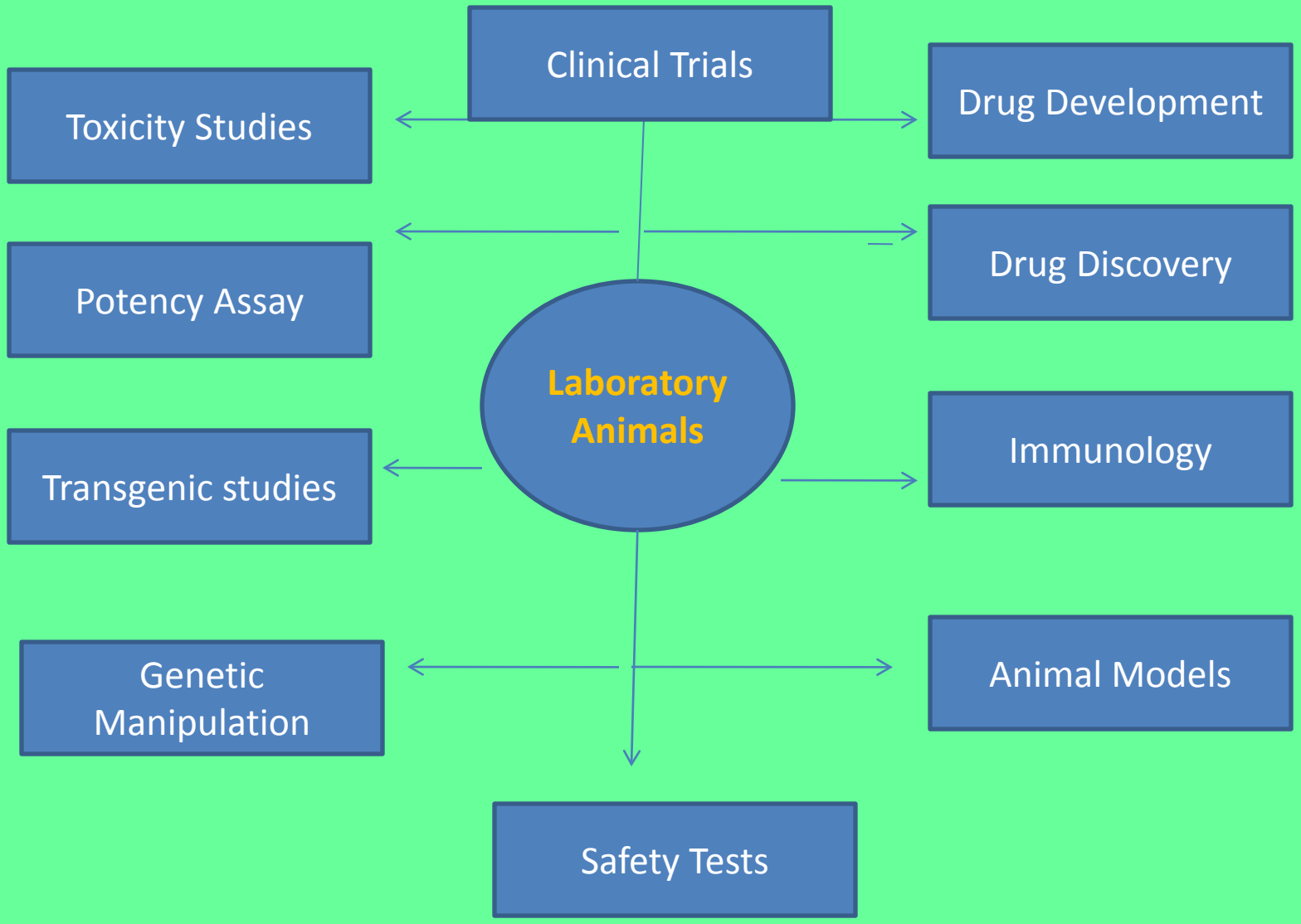
Prof. M. C. Sharma
Director
Indian Veterinary Research Institute
IZATNAGAR-243 122 (UP)

E-mail:dirivri@ivri.res.in, directorivri@gmail.com

Frontline Statement

Animal species are used in every stage of the research and development effort—from discovery, to development and safety testing, to clinical trials, and to manufacture—because their biological systems, genetic structures, and immunological responses, in various ways, closely mirror ours as a species.

Diversified Use of Animals



Magnitude of use of animals

- It has been estimated that approximately 20 million animals are being used for testing and are killed annually; about 15 million of them are used to test for medication and five million for products.

- China has become one of the biggest countries using lab animals, as is evident in the higher numbers and quality of lab animals (e.g., specific pathogen free, or SPF1; genetically modified) increasingly used in scientific research—16 million a year, compared to 12 million in the 25 European Union countries in 2005 (FELASA 2007)—and the increased publication of animal experiment results in international journals.

Japan was second only to the US, which used 17.3 million animals in 2005. The third largest use in 2005 was Great Britain, which used 1.9 million animals.

People for the ethical treatment of animals (PETA) reported that the National Centre for Laboratory Animal Sciences (NCLAS) in Hyderabad, supplies approximately 50,000 animals to laboratories every year and to 175 institutions in India, including pharmaceutical companies and educational institutions.

- In India, among rodentia group of animals e.g. mice. rat, G.pig, rabbit, mice is predominantly used in most of cases followed by other rodentia.

- The number of monkeys used in research has now drastically reduced in institutions.

- Use of some other unique animals like hamster, cotton rat, gerbil is not much common.

- There are inbred strains of mice which are used for research and genetically modified laboratory animals are also imported into India by some of institutes.

- The information with regard to available laboratory animals resource in different institutions/universities in India is not precisely known.

Infrastructure

- It seems there are about 400-500 animal facilities in the country located in various R &D institutions, universities, colleges, pharma companies, medical, veterinary and human and veterinary biological manufacturers and other private colleges.

- Sometimes the animals are not cared properly due poo infrastructure facilities to house laboratory animals in many institutions/universities/colleges that do not meet the requirements like floor area, building material, environment, bedding, caging.

Laboratory Animals as Models

The animal models specifically developed in the surgery or to understand the microbial pathogenesis continue to be important for their usage in experimentation.

There are disease specific animal species and strains for metabolic diseases, cancer and parasitic infections which offer way forward for the drug discovery. For example, Guinea pig is a best model for study of *Brucella* infection.

Focus on Alternatives

Russel and Burch, 1959 **3 R's Formula**

REDUCTION

REPLACEMENT

REFINEMENT

Other R's

Reuse

Rehabilation

- The use of sheep brain for the production of rabies vaccine has been phased out in 1992

- Classical swine fever virus vaccine is produced in PK-15 Cells instead using large number of raabits

- PPR, FMD and sheep pox vaccines are also produced using cell culture *vero*, BHK-21 and *vero* cell culture system respectively.

- The use of laboratory animals e.g., rabbit and G. pig has been now abandoned for the isolation or typing of mycobacetria with the availability of improved synthetic media.

STEM CELLS

STEM CELLS NOW EMERGING AS AN ALTERNATIVE TO LABORATORY ANIMALS

Drug company interest in stem cell drug testing was demonstrated in July 2008, when GlaxoSmithKline entered into a $25 million-plus agreement with the Harvard Stem Cell Institute.

By testing drugs on specific cells and tissues created from iPS cells, we can even predict a patients individual response to a treatment realizing the vision of personalized medicine.

In the current issue of *Stem Cells and Development (2007)*, Cezar and her colleagues revealed a novel way to test drug toxicity: by monitoring the behaviour of embryonic stem cells exposed to a drug-candidate compound.

Studying how potential drugs affect embryonic stem cells could provide a far more accurate prediction of a drug's potential toxicity than conventional animal models can.

Currently, the most successful development of stem cells as *in vitro* models for toxicology testing is in human cardiac tissue.

REGULATORY MECHANISMS IN INDIA

1. Institute Animal Ethics Committee (IAEC)
2. Committee for the Purpose of Control and Supervision of Experiments in Animals (CPCSEA)
3. Drugs & Cosmetics Act, 1940, Appendix-I
4. Department of Animal Husbandry, Dairying & Fisheries, Ministry of Agriculture, New Delhi-2001
5. Department of Biotechnology
6. The Prevention of Cruelty to Animals Act, 1960 as amended up to 30th July 1982 and Animal Welfare Board

RECOMMENDATIONS

1. A task force at country level be made to look into various aspects and available resource of laboratory animals in different institutions/universities and to harmonize the use of laboratory animals. This task force shoukd comprise of broader representation including the laboratory animal science association.

2. Data on the use of laboratory animals should be collected to know actual consumption of laboratory animals in the country.

3. Each institute/university or other organization using laboratory animals should have uniform SOP for Institute Animal Ethics Committee (IAEC)

4. Course on laboratory animal science should be included in course curriculum right from intermediate onwards and in veterinary and medical education too.

5. The training and education programme should be strengthened and institutes be identified to offer such courses

6. Breeding of laboratory animals should be planned in such a manner that there should not a need to cull unused or aged animals. This will reduce total number of animals.

7. Guidelines Reuse or recycling, rehabilitation, consumption of food animals like and disposal of used animals must be adequately proper

8. There should be an effort to outsource activities concerned to laboratory animal science e.g. like video, other visual aids for teaching and training.

9. Our Indian system of laboratory animal science should be in collaboration with international bodies like ICLAS, OIE.

10. Standard animal house design be prepared as model to be followed. With changing set up requiring Good Manufacturing Practices (GMP) and Good laboratory Practices (GLP), the attention needs to be paid towards the building designs and containment of animal houses in India.

11. Transgenic mice are widely used in genomic-based research across all therapeutic areas. New caging and housing types, such as high density ventilated racks (HDVRs), would need altered room design and are promoting the increased usage of computational fluid dynamics (CFDs) to model room environments and HVAC characteristics.

12. Animal houses be accredited by NABL

13. The delay in grant of permission to researchers by the ethical committee should also be addressed adequately so that huge financial grants under research projects do not wait for an effective utilization

14. In country at least there should be four Regional National Laboratory Animal Centres to provide genetically defined and standard laboratory animals.

15. The laboratory animal medicine, animal experimentation and vaccine production is defined under "Profession" (veterinary profession) by the Veterinary Council of India, Standard of Professional Conduct, Etiquettee and Code of Ethics for Veterinary Practioners Regulations, 1992. It should be made mandatory that the in-charge of all laboratory animal facilities should be a veterinarian.

16. Guidelines to design building may be prepared to make it easy for those institutes who lack expertise.

17. Collaboration and outsourcing some of jobs may be assigned to Laboratory Animal Science Associations e.g. LASAI and LASA

THANK YOU VERY MUCH