MOH/S/IMR/79.19(RR)-e

imr research

Highlight

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"GLP... Your safety is our priority!"

Key Messages

- Safety data produced from OECD GLP compliant studies will be mutually accepted by 36 OECD member countries as well as those adhering to the OECD system for Mutual Acceptance of Data (MAD).
- OECD GLP compliant studies ensure data quality and integrity.
- Adhering to OECD GLP principles safeguards human health and the environment.
- Safety testing is of paramount importance when conducting screening on newly developed drugs.
- The objective of conducting these studies on animals is to determine tested product's possible health risk on humans.

OECD GLP COMPLIANCE

CERTIFIED NON-CLINICAL RESEARCH FACILITY

The Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) compliance certified testing facility refers to the facilities involved in conducting pre-clinical safety studies on products intended to be registered, licensed and marketed. The GLP facility at the Institute for Medical Research (IMR) focuses on conducting in vivo safety studies aimed at determining the safety of the products proposed to be registered with the Regulatory Authorities worldwide. The studies conducted here are in accordance to the OECD Test Guideline (TG) 420, 407, 408 and 452. The IMR's adherence to the OECD GLP compliance requirements which observes the Mutual Acceptance of Data (MAD) system is in sync with that of the 36 OECD member countries namely, Australia, Canada, France, Germany, New Zealand, Argentina, Brazil, India, Singapore and South Africa. This practice enables safety data that is generated in a certified laboratory to be accepted in these other countries hence minimizing the cost, time and resources. The OECD GLP compliance is the highest standard of laboratory practice and is crucial in ensuring data quality and integrity when conducting safety evaluations on consumer product development.

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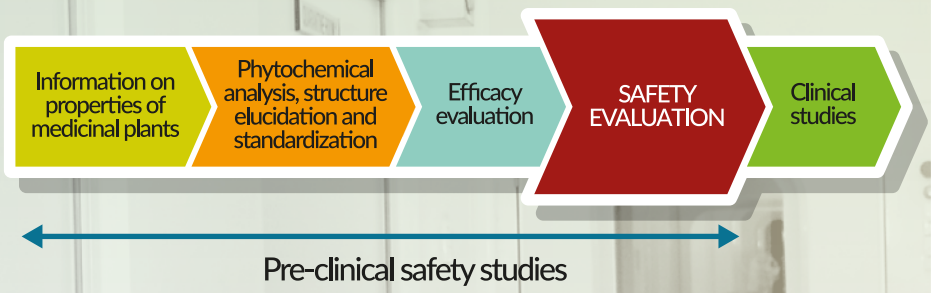
INTRODUCTION

Purpose of pre-clinical safety studies

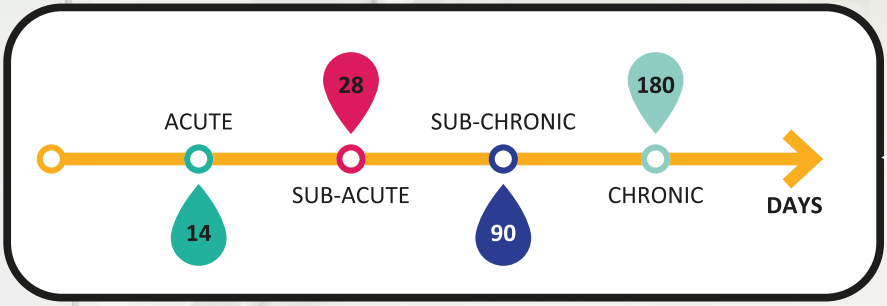
Pre-clinical safety studies are required prior to testing on human subjects. Evaluating the safety of the tested product is the main objective of pre-clinical studies conducted in accordance to the recommended guidelines. The credibility of the pre-clinical data is critical as it serves as a reference for future clinical trials on human subjects.



Categories of pre-clinical safety studies

Pre-clinical safety studies may be conducted either as a single dose or a repeated dose safety study. The single dose safety study refers to an acute toxicity study where only a single dose at different concentrations are given to the test animals. However, the repeated dose safety study involves administering repeated doses at different concentrations to the test animals. The type of toxicity study chosen is determined by the intended use and duration of the proposed product.

DURATION OF GENERAL TOXICITY STUDY



OECD GLP SERVICE IN IMR

ACUTE OECD Testing Guideline 420	SUB-ACUTE OECD Testing Guideline 407	SUB-CHRONIC OECD Testing Guideline 408	CHRONIC OECD Testing Guideline 452
• General clinical observation • Detailed clinical observation	• Body weight • Food intake	• Water intake • Organ examination • Histopathological analysis	
	• Clinical biochemistry analysis	• Haematological analysis • Functional observation	
		• Organ weight • Ophthalmological examination	
			• Urine analysis

The observation and tests that are conducted for the different types of studies.
** The above parameters are available in our facilities. Other parameters not mentioned above can be conducted per request.*

CONTINUOUS TRAINING

Comprehensive courses on OECD principles, SOP familiarisation and regular dialogue with compliance monitoring authorities and other OECD GLP compliant facilities.

OUR STRENGTH

- We are the first laboratory in Malaysia to be awarded 'OECD GLP Compliance Certificate for Toxicity Studies'.
- We professionally manage state-of-the-art facility for good laboratory practice.
- We have a dedicated team of multi-disciplinary scientific experts.
- We strive to deliver services based on strict principles of research ethics.

Functional courses are regulary conducted for study personnel.

FAQ

1) **Q: What is Good Laboratory Practice?**
   A: *Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which pre-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived.*

2) **Q: Why is GLP compliance needed?**
   A: *To ensure proper conduct of study and to promote the development of quality data.*

3) **Q: Who can benefit from GLP recognition?**
   A: *Research laboratories in the pharmaceutical, cosmetics, food additives, medical device and veterinary drugs industries.*

4) **Q: Is it necessary to follow OECD test guidelines (e.g. TG 420, TG 407, TG 408 and TG 452) when conducting pre-clinical safety studies?**
   A: *The OECD Test Guidelines are the recommended guidelines to be followed when conducting pre-clinical safety studies which is accepted by all other OECD GLP compliant facilities.*

5) **Q: What is the difference between GLP and non-GLP test data?**
   A: *Test data generated in any member country in accordance with OECD GLP principles shall be accepted in other member countries compared to non-GLP test data which may need to be tested again in the intended country to market the product. In certain countries' regulations, products intended for human use should be tested in accordance to GLP compliance.*

6) **Q: Is there any difference between 'OECD GLP' and 'good laboratory practice'?**
   A: *In pre-clinical research, the term 'OECD GLP' refers to the quality system in which all the processes involved must adhere to the principles set by OECD. A 'good laboratory practice' may refer to 'general good practices' practiced within the laboratories.*

7) **Q: On what species and strain of animal are the pre-clinical safety studies conducted in IMR?**
   A: *The pre-clinical safety studies are commonly conducted on rodent namely on species of Rattus norvegicus and the strains of either Sprague Dawley or Wistar.*

8) **Q: Who are the Compliance Monitoring Authorities in Malaysia?**
   A: *The National Pharmaceutical Regulatory Agency (NPRA) and STANDARDS MALAYSIA had been designated as the Malaysian Compliance Monitoring Authorities (CMAs) by the Malaysian Government. NPRA is the CMA for the pre-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives. Whereas STANDARDS MALAYSIA is the CMA for the pre-clinical safety testing of test items contained in industrial chemicals, pesticides, feed additives, and biotechnology (non-pharmaceuticals).*

9) **Q : Is animal welfare being taken care of?**
   A : *The conduct of pre-clinical safety studies in IMR, strictly adheres to the requirements and approval of Animal Care and Use Committee, Ministry of Health Malaysia (ACUC-KKM).*

10) **Q : When did the Non-Clinical Research Facility, IMR first receive its OECD GLP compliance ?**
   A : *07 February 2014*

IN ACCORDANCE TO:

NPRA MALAYSIA

OECD

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