**SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES**

**Osudu, Agaram Village, Koodapakkam post, Puducherry - 605502**

**Date:3.01.2022**

**From**
Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

**To**
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

**Sub: Permission to conduct value-added course: Clinical Research**

Dear Sir,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled**: Clinical Research.** We solicit your kind permission for the same.
Kind Regards

**Dr.G.Somasundaram**

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**FOR THE USE OF DEANS OFFICE**

**Names of Committee members for evaluating the course:**

Dean: Dr.Jaya Lakshmi **HOD**: Dr.G.**Somasundaram** **Expert:** Dr.S.Jai kumar

The committee has discussed about the course and is approved.

3.1.22

Dean Subject Expert HOD

Dr.G.JAYALAKSHMI, DSC., MBBS., DICD., M.D.,
DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
Osudu, Agaram, Koodapakkam Post,
Villianur Commune, Puducherry - 605502.

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY.
Sri Lakshmi Narayana Institute Of Medical Sciences,
PONDICHERRY - 605 502.

OFFICE OF THE DEAN

# Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.

[ Recognised by Medical Council of India, Ministry of Health letter No. U/12012/249/2005-ME ( P -II ) dt. 11/07/2011 ]
[ Affliated to Bharath University, Chennai - TN ]

**Circular** **Date: 10.01.2022**

**Sub**: Organizing Value-added Course: **Clinical Research** in enhancing performance skill in Second year students in **Clinical Research** reg.

With reference to the above-mentioned subject, it is to bring to your notice that a Sri Lakshmi Narayana Institute of Medical science is organizing "**Clinical Research February 2022–August 2022**". The course content is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before 31-**1-2022**.

Applications received after the mentioned date shall not be entertained under any circumstances.

**Dean**

Dr. G. JAYALAKSHMI, BSC., MBBS., DTCD., M.D.,
DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
Osudu, Agaram, Kudapakkam Post,
Villianur Commune, Puducherry - 605502.

Encl: Copy of Course content

## Course Proposal

**Course Objective:**

1.Overarching objectives of clinical trial assessment
2.Preliminary considerations
3.Process in clinical trial assessment
4.Phases of clinical trails
5.Clinical component
6.Regulatory decision
7.Data collection
8.Data management
9.Documents used in clinical Trial
10.Statistical Analysis
11.Clinical trial data Analysis

**Course Outcome:** Improving public health and safety in relation to the use of medicines; encouraging the safe.

**Course Audience: 2nd Year MBBS Students**

**Course Coordinator: Dr.G.Somasundaram,**

**Course Faculties with Qualification and Designation:**

Dr Jai kumar Assistant Professor Dept of Pharmacology,SLIMS

**Course Curriculum/Topics with schedule (Min of 30 hours)**

| SlNo | Date | Topic | Time | Hours |
|---|---|---|---|---|
| 1. | 28/2/2022 | Game with pre test | | |
| 2 | 7/3/2022 | Overarching objectives of clinical trial assessment | 4-7 PM | 3 |
| 3 | 14/3/2022 | Preliminary considerations | 4-7 PM | 3 |
| 4 | 28/3/2022 | Process in clinical trial assessment | 4-7 PM | 3 |
| 5 | 11/4/2022 | Phases of clinical trails | 4-7 PM | 3 |
| 6 | 25/3/2022 | Clinical component | 4-7 PM | 3 |
| 7 | 11/4/2022 | Regulatory decision | 4-7 PM | 3 |
| 8 | 20/6/2022 | Data management | 4-7 PM | 3 |
| 9 | 11/7/2022 | Documents used in clinical Trial | 4-6 PM | 2 |
| 10 | 25/7/2022 | Statistical Analysis | 4-6 PM | 2 |
| 11 | 8/8/2022 | Clinical trial data Analysis | 4-6 PM | 2 |
| | | | Total Hours | 30 |

**REFERENCE BOOK**

**1. Textbook of Clinical Research-Vikas Dhikav April 2016 Edition: 1stPublisher: AITBS India Editor: Dr. Vikas Dhikav ISBN: 978-93-7473-594-7.**

**2. Principles and Practice of Clinical Research 3rd Edition Editors: John Gallin Frederick Ognibene EBook ISBN: 9780123821683.**

# VALUE ADDED COURSE

1. **Name of the programme& Code**

   Clinical Research PH 04

2. **Duration& Period**

   30 hrs February - August 2022

3. **Information Brochure and Course Content of Value-Added Courses**

   *Enclosed as Annexure- I*

4. **List of students enrolled**

   *Enclosed as Annexure- II*

5. **Assessment procedures:**

   Multiple choice questions- *Enclosed as Annexure- III*

6. **Certificate model**

   *Enclosed as Annexure- IV*

7. **No. of times offered during the same year**: 1

8. **Year of discontinuation: 2022**

9. **Summary report of each program year-wise**

| Value Added Course- February 2022- August 2022 | | | | | |
|---|---|---|---|---|---|
| **Sl. No** | **Course Code** | **Course Name** | **Resource Persons** | **Target Students** | **Strength& Year** |
| 1 | PH 04 | Clinical Research PH 04 | Dr.S.jai kumar | II MBBS | **20 &February 2022- August 2022** |

10. **Course Feed Back**

*Enclosed as Annexure- V*

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute of Medical Sciences
PONDICHERRY - 605 502.

Dr.G.somasundaram

**RESOURCE PERSON**

**COORDINATOR**

**Clinical Research**

# PARTICIPANT HAND BOOK

BIHER SLIMS

## COURSE DETAILS

| Particulars | Description |
|---|---|
| Course Title | **Clinical Research** |
| Course Code | PHA04 |
| Objective | Overarching objectives of clinical trial assessment<br>Preliminary considerations<br>Process in clinical trial assessment<br>Phases of clinical trails<br>Phases -1 , Phase -11 Phase-lll, Phase -IV<br>Clinical component<br>Regulatory decision<br>Data collection<br>Data management<br>Documents used in clinical Trial |
| Key Competencies | Improving public health and safety in relation to the use of medicines; encouraging the safe. |
| Target Student | II MBBS Students |
| Duration | 30hrs Every February - August 2022 |
| Theory Session | 10hrs |
| Practical Session | 20hrs |
| Assessment Procedure | Short notes |

## INTTRODUCTION

Clinical research

**Clinical research** is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical research is different from clinical practice. In clinical practice established treatments are used, while in clinical research evidence is collected to establish a treatment.

The term "clinical research" refers to the entire bibliography of a drug/device/biologic, in fact any test article from its inception in the lab to its introduction to the consumer market and beyond. Once the promising candidate or the molecule is identified in the lab, it is subjected to pre-clinical studies or animal studies where different aspects of the test article (including its safety toxicity if applicable and efficacy, if possible at this early stage) are studied.[1][2][3]

In the United States, when a test article is unapproved or not yet cleared by the Food and Drug Administration (FDA), or when an approved or cleared test article is used in a way that may significantly increase the risks (or decreases the acceptability of the risks), the data obtained from the pre-clinical studies or other supporting evidence, case studies of off label use, etc. are submitted in support of an Investigational New Drug (IND) application[4] to the FDA for review prior to conducting studies that involve even one human and a test article if the results are intended to be submitted to or held for inspection by the FDA at any time in the future (in the case of an already approved test article, if intended to submit or hold for inspection by the FDA in support of a change in labeling or advertising). Where devices are concerned the submission to the FDA would be for an Investigational Device Exemption (IDE) application if the device is a significant risk device or is not in some way exempt from prior submission to the FDA. In addition, clinical research may require Institutional Review Board (IRB) or Research Ethics Board (REB) and possibly other institutional committee reviews, Privacy Board, Conflict of Interest Committee, Radiation Safety Committee, Radioactive Drug Research Committee, etc. approval whether or not the research requires prior submission to the FDA. Clinical research review criteria will depend on which federal regulations the research is subject to (e.g., (Department of Health and Human Services (DHHS) if federally funded, FDA as already discussed) and will depend on which regulations the institutions subscribe to, in addition to any more stringent criteria added by the institution possibly in response to state or local

laws/policies or accreditation entity recommendations. This additional layer of review (IRB/REB in particular) is critical to the protection of human subjects especially when you consider that often research subject to the FDA regulation for prior submission is allowed to proceed, by those same FDA regulations, 30 days after submission to the FDA unless specifically notified by the FDA not to initiate the study.

Clinical research is often conducted at academic medical centers and affiliated research study sites. These centers and sites provide the prestige of the academic institution as well as access to larger metropolitan areas, providing a larger pool of medical participants. These academic medical centers often have their internal Institutional Review Boards that oversee the ethical conduct of medical research.[5]

The clinical research ecosystem involves a complex network of sites, pharmaceutical companies and academic research institutions. This has led to a growing field of technologies used for managing the data and operational factors of clinical research. Clinical research management is often aided by eClinical systems to help automate the management and conducting of clinical trials.

In the European Union, the European Medicines Agency (EMA) acts in a similar fashion for studies conducted in their region. These human studies are conducted in four phases in research subjects that give consent to participate in the clinical trials.

***Main article: Phases of clinical research***

Clinical trials involving new drugs are commonly classified into four phases. Each phase of the drug approval process is treated as a separate clinical trial. The drug-development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV is 'post-approval' studies.

Phase I includes 20 to 100 healthy volunteers or individuals with the disease/condition. This study typically lasts several months and its purpose is safety and dosage. Phase II includes a larger number of individual participants ranging 100–300, and phase III includes Approximately 1000-3000 participants to collect more data about the drug.[6] 70% of drugs advance to the next phase.[7]

Before pharmaceutical companies start clinical trials on a drug, they conduct extensive pre-clinical studies.

The **phases of clinical research** are the stages in which scientists conduct experiments with a health intervention to obtain sufficient evidence for a process considered effective as a medical treatment.[1] For drug development, the clinical phases start with testing for safety in a few human subjects, then expand to many study participants (potentially tens of thousands) to determine if the treatment is effective.[1] Clinical research is conducted on drug candidates, vaccine candidates, new medical devices, and new diagnostic assays.

Clinical trials testing potential medical products are commonly classified into four phases. The drug development process will normally proceed through all four phases over many years.[1] If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population.[1] Phase IV trials are 'post-marketing' or 'surveillance' studies conducted to monitor safety over several years.[1]

**Summary of clinical trial phases**

| Phase | Primary goal | Dose | Patient | Typical number | Success | Notes |
|---|---|---|---|---|---|---|

| | | | monitor | of participants | rate[12] | |
|---|---|---|---|---|---|---|
| **Preclinical** | Testing of drug in non-human subjects to gather efficacy, toxicity and pharmacokinetic information | Unrestricted | Scientific researcher | No human subjects, *in vitro* and *in vivo* only | | Includes testing in model organisms. Human immortalized cell lines and other human tissues may also be used. |
| **Phase 0** | Pharmacokinetics; particularly oral bioavailability and half-life of the drug | Small, subtherapeutic | Clinical researcher | 10 people | | Often skipped for Phase I. |
| **Phase I** | Dose-ranging on healthy volunteers for safety | Often subtherapeutic, but with ascending doses | Clinical researcher | 20–100 normal healthy volunteers (or cancer patients for cancer drugs) | Approx. 70% | Determines whether drug is safe to check for efficacy. |
| **Phase II** | Testing of drug on participants to assess efficacy and side effects | Therapeutic dose | Clinical | 100–300 participants | Approx. 33% | Determines whether drug can have any efficacy; at |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | researcher | with a specific disease | | this point, the drug is not presumed to have any therapeutic effect |
| **Phase III** | Testing of drug on participants to assess efficacy, effectiveness and safety | Therapeutic dose | Clinical researcher and personal physician | 300–3,000 people with a specific disease | 25–30% | Determines a drug's therapeutic effect; at this point, the drug is presumed to have some effect |
| **Phase IV** | Post marketing surveillance in public | Therapeutic dose | Personal physician | Anyone seeking treatment from a physician | N/A | Monitor long-term effects |

Preclinical studies

Before clinical trials are undertaken for a candidate drug, vaccine, medical device, or diagnostic assay, the product candidate is tested extensively in preclinical studies.[1] Such studies involve *in vitro* (test tube or cell culture) and *in vivo* (animal model) experiments using wide-ranging doses of the study agent to obtain preliminary efficacy, toxicity and pharmacokinetic information. Such tests assist the developer to decide whether a drug candidate has scientific merit for further development as an investigational new drug.[1]

**Phase 0**

Phase 0 is a recent designation for optional exploratory trials conducted in accordance with the United States Food and Drug Administration's (FDA) 2006 Guidance on Exploratory Investigational New Drug (IND) Studies.[3] Phase 0 trials are also known as human microdosing studies and are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was expected from preclinical studies. Distinctive features of Phase 0 trials include the administration of single subtherapeutic doses of the study drug to a small number of subjects (10 to 15) to gather preliminary data on the agent's pharmacokinetics (what the body does to the drugs)]

A Phase 0 study gives no data on safety or efficacy, being by definition a dose too low to cause any therapeutic effect. Drug development companies carry out Phase 0 studies to rank drug candidates in order to decide which has the best pharmacokinetic parameters in humans to take forward into further development. They enable go/no-go decisions to be based on relevant human models instead of relying on sometimes inconsistent animal data.

**Phase I**

Phase I trials were formerly referred to as "first-in-man studies" but the field generally moved to the gender-neutral language phrase "first-in-humans" in the 1990s;[5] these trials are the first stage of testing in human subjects.[6] They are designed to test the safety, side effects, best dose, and formulation method for the drug.[7] Phase I trials are not randomized, and thus are vulnerable to selection bias.[8]

Normally, a small group of 20–100 healthy volunteers will be recruited.[2][6] These trials are often conducted in a clinical trial clinic, where the subject can be observed by full-time staff. These clinical trial clinics are often run by contract research organization (CROs) who conduct

these studies on behalf of pharmaceutical companies or other research investigators. The subject who receives the drug is usually observed until several half-lives of the drug have passed. This phase is designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. Phase I trials normally include dose-ranging, also called dose escalation studies, so that the best and safest dose can be found and to discover the point at which a compound is too poisonous to administer.[9] The tested range of doses will usually be a fraction[*quantify*] of the dose that caused harm in animal testing. Phase I trials most often include healthy volunteers. However, there are some circumstances when clinical patients are used, such as patients who have terminal cancer or HIV and the treatment is likely to make healthy individuals ill. These studies are usually conducted in tightly controlled clinics called CPUs (Central Pharmacological Units), where participants receive 24-hour medical attention and oversight. In addition to the previously mentioned unhealthy individuals, "patients who have typically already tried and failed to improve on the existing standard therapies"[10] may also participate in phase I trials. Volunteers are paid a variable inconvenience fee for their time spent in the volunteer center.

Before beginning a phase I trial, the sponsor must submit an Investigational New Drug application to the FDA detailing the preliminary data on the drug gathered from cellular models and animal studies.

**Phase I trials can be further divided:**

**Single ascending dose (Phase Ia)**

In single ascending dose studies, small groups of subjects are given a single dose of the drug while they are observed and tested for a period of time to confirm safety.[6][11] Typically, a small number of participants, usually three, are entered sequentially at a particular dose.[10] If they do not exhibit any adverse side effects, and the pharmacokinetic data are roughly in line with predicted safe values, the dose is escalated, and a new group of subjects is then given a higher dose. If unacceptable toxicity is observed in any of the three participants, an additional number of participants, usually three, are treated at the same dose.[10] This is continued until

pre-calculated pharmacokinetic safety levels are reached, or intolerable side effects start showing up (at which point the drug is said to have reached the maximum tolerated dose (MTD)). If an additional unacceptable toxicity is observed, then the dose escalation is terminated and that dose, or perhaps the previous dose, is declared to be the maximally tolerated dose. This particular design assumes that the maximally tolerated dose occurs when approximately one-third of the participants experience unacceptable toxicity. Variations of this design exist, but most are similar.[10]

**Multiple ascending dose (Phase Ib)**

Multiple ascending dose studies investigate the pharmacokinetics and pharmacodynamics of multiple doses of the drug, looking at safety and tolerability. In these studies, a group of patients receives multiple low doses of the drug, while samples (of blood, and other fluids) are collected at various time points and analyzed to acquire information on how the drug is processed within the body. The dose is subsequently escalated for further groups, up to a predetermined level.[6][11]

**Food effect**

A short trial designed to investigate any differences in absorption of the drug by the body, caused by eating before the drug is given. These studies are usually run as a crossover study, with volunteers being given two identical doses of the drug while fasted, and after being fed.

**Phase II**

Once a dose or range of doses is determined, the next goal is to evaluate whether the drug has any biological activity or effect.[10] Phase II trials are performed on larger groups (50–300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. Genetic testing is common, particularly when there is evidence of variation in metabolic rate.[10] When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects.

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Phase II studies are sometimes divided into Phase IIa and Phase IIb. There is no formal definition for these two sub-categories, but generally:

Phase IIa studies are usually pilot studies designed to demonstrate clinical efficacy or biological activity ('proof of concept' studies);[12]

Phase IIb studies determine the optimal dose at which the drug shows biological activity with minimal side-effects ('definite dose-finding' studies).[12]

## Trial design

Some Phase II trials are designed as case series, demonstrating a drug's safety and activity in a selected group of participants. Other Phase II trials are designed as randomized controlled trials, where some patients receive the drug/device and others receive placebo/standard treatment. Randomized Phase II trials have far fewer patients than randomized Phase III trials.

### Example: cancer design

In the first stage, the investigator attempts to rule out drugs that have no or little biologic activity. For example, the researcher may specify that a drug must have some minimal level of activity, say, in 20% of participants. If the estimated activity level is less than 20%, the researcher chooses not to consider this drug further, at least not at that maximally tolerated dose. If the estimated activity level exceeds 20%, the researcher will add more participants to get a better estimate of the response rate. A typical study for ruling out a 20% or lower response rate enters 14 participants. If no response is observed in the first 14 participants, the drug is considered not likely to have a 20% or higher activity level. The number of additional participants added depends on the degree of precision desired, but ranges from 10 to 20. Thus,

a typical cancer phase II study might include fewer than 30 people to estimate the response rate.[10]

**Efficacy vs effectiveness**

When a study assesses efficacy, it is looking at whether the drug given in the specific manner described in the study is able to influence an outcome of interest (e.g. tumor size) in the chosen population (e.g. cancer patients with no other ongoing diseases). When a study is assessing effectiveness, it is determining whether a treatment will influence the disease. In an effectiveness study, it is essential that participants are treated as they would be when the treatment is prescribed in actual practice. That would mean that there should be no aspects of the study designed to increase compliance above those that would occur in routine clinical practice. The outcomes in effectiveness studies are also more generally applicable than in most efficacy studies (for example does the patient feel better, come to the hospital less or live longer in effectiveness studies as opposed to better test scores or lower cell counts in efficacy studies). There is usually less rigid control of the type of participant to be included in effectiveness studies than in efficacy studies, as the researchers are interested in whether the drug will have a broad effect in the population of patients with the disease.

**Success rate**

Phase II clinical programs historically have experienced the lowest success rate of the four development phases. In 2010, the percentage of Phase II trials that proceeded to Phase III was 18%, and only 31% of developmental candidates advanced from Phase II to Phase III, in a large study of trials conducted over 2006–2015

## Phase III

This phase is designed to assess the effectiveness of the new intervention and, thereby, its value in clinical practice. Phase III studies are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions. Phase III trials of chronic conditions or diseases often have a short follow-up period for evaluation, relative to the period of time the intervention might be used in practice. This is sometimes called the "pre-marketing phase" because it actually measures consumer response to the drug.

It is common practice that certain Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency. This allows patients to continue to receive possibly lifesaving drugs until the drug can be obtained by purchase. Other reasons for performing trials at this stage include attempts by the sponsor at "label expansion" (to show the drug works for additional types of patients/diseases beyond the original use for which the drug

was approved for marketing), to obtain additional safety data, or to support marketing claims for the drug. Studies in this phase are by some companies categorized as "Phase IIIB studies."[15]

While not required in all cases, it is typically expected that there be at least two successful Phase III trials, demonstrating a drug's safety and efficacy, in order to obtain approval from the appropriate regulatory agencies such as FDA (US), or the EMA (European Union).

Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This collection of information makes up the "regulatory submission" that is provided for review to the appropriate regulatory authorities[16] in different countries. They will review the submission, and if it is acceptable, give the sponsor approval to market the drug.

Most drugs undergoing Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines through a New Drug Application (NDA) containing all manufacturing, preclinical, and clinical data. In case of any adverse effects being reported anywhere, the drugs need to be recalled immediately from the market. While most pharmaceutical companies refrain from this practice, it is not abnormal to see many drugs undergoing Phase III clinical trials in the market.[17]

**Adaptive design**

The design of individual trials may be altered during a trial – usually during Phase II or III – to accommodate interim results for the benefit of the treatment, adjust statistical analysis, or to reach early termination of an unsuccessful design, a process called an "adaptive design". Examples are the 2020 World Health Organization *Solidarity Trial*, European *Discovery trial*, and UK *RECOVERY Trial* of hospitalized people with severe COVID-19 infection, each of which applies adaptive designs to rapidly alter trial parameters as results from the experimental therapeutic strategies emerge.

Adaptive designs within ongoing Phase II–III clinical trials on candidate therapeutics may shorten trial durations and use fewer subjects, possibly expediting decisions for early termination or success, and coordinating design changes for a specific trial across its international locations

**Success rate**

For vaccines, the probability of success ranges from 7% for non-industry-sponsored candidates to 40% for industry-sponsored candidates.

A 2019 review of average success rates of clinical trials at different phases and diseases over the years 2005-15 found a success range of 5-14%. Separated by diseases studied, cancer drug trials were on average only 3% successful, whereas ophthalmology drugs and vaccines for infectious diseases were 33% successfulTrials using disease biomarkers, especially in cancer studies, were more successful than those not using biomarkers.[25]

A 2010 review found about 50% of drug candidates either fail during the Phase III trial or are rejected by the national regulatory agency.

**Phase II/III cost**

The amount of money spent on Phase II/III trials depends on numerous factors, with therapeutic area being studied and types of clinical procedures as key drivers; Phase II studies may cost as much as $20 million, and Phase III as much as $53 million.

Phase IV

A Phase IV trial is also known as postmarketing surveillance trial, or informally as a confirmatory trial. Phase IV trials involve the safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold (e.g. after approval under the FDA Accelerated Approval Program) Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials Harmful effects discovered by Phase IV

trials may result in a drug being no longer sold, or restricted to certain uses; examples include cerivastatin (brand names Baycol and Lipobay), troglitazone (Rezulin) and rofecoxib (Vioxx).

## Annexure- III

**VALUE ADDED COURSE** CLINICAL RESEARCH

**4. List of Students Enrolled Feb 2022 – Aug 2022**

| Sl.No | Name of the Student | Register No | Student signature |
|---|---|---|---|
| 1 | MUSALE VENUGOPAL RAO | U17MB331 | |
| 2 | NAMITA THARANI | U17MB332 | |
| 3 | NAYANA NANDANAN M | U17MB333 | |
| 4 | NEHA KUMARI | U17MB334 | |
| 5 | NEHA KUMARI.B | U17MB335 | |
| 6 | NIDHI SUNIL KRISHNAN | U17MB336 | |
| 7 | NIJITH KRISHNADHAS RAHAEL | U17MB337 | |
| 8 | NIKITA VERMA | U17MB338 | |
| 9 | NILUTPAL DAS | U17MB339 | |
| 10 | NISHANT BHUSAN | U17MB340 | |
| 11 | PANEM SAMIUNNU | U17MB341 | |
| 12 | PARTHA PRATIM BARUAH | U17MB342 | |
| 13 | PAYAL MOHITE | U17MB343 | |
| 14 | POOJALAKSHMI.P | U17MB344 | |
| 15 | PRACHI KUMARI | U17MB345 | |
| 16 | PRASANNA.B | U17MB346 | |
| 17 | PRAVEEN.V | U17MB347 | |
| 18 | PRITAM SAHOO | U17MB348 | |
| 19 | PRIYA SAXENA | U17MB349 | |
| 20 | PRIYADARSHINI MAITHY | U17MB350 | |

**RESOURCE PERSON**

**COORDINATOR**

DEPARTMENT Of Pharmacology
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502.

# SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATON AND RESEARCH

**Clinical Research**

**Annexure - IV**

**MULTIPLE CHOICE QUESTIONS**

**Course Code: PHA04**

1.What is informed consent in a clinical trial?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures.

2. Which one of the following is the last step of a clinical trial process?

a) Investigator selection

b) Patient recruitment

c) Statistical Analysis

d) Data filed and registration.

3. How many people will be selected for phase II trial?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

4.How many people will be selected for phase III trial?

a) The whole market will be under surveillance

b) 300-3000 people

c) 20-300 people

d) 20-50 people

5.What is meant by a blind subject?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

# SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATON AND RESEARCH

## MULTIPLE CHOICE QUESTIONS

6. Document mandatory to enroll subject in clinical research study?

A. Protocol

B. Case Report Form

C. Informed Consent Form

D. Investigators Brochure

7. Preclinical Studies are conducted on animals and artificial cells in labs?

A.True B.False

8. In. how many phase clinical research study is conducted?

A.5 B.4 C.8 D.5

9.To begin clinical research study it is mandatory to get approval from?

A.Sponsor

B.Regulator

C.Regulators and ethics committee both

D.Government

10. As a result of thalidomide tragedy neonatal death happened.

A.True B.False

# Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research
(Deemed to be University under section 3 of the UGC Act 1956)

## CERTIFICATE OF MERIT

This is to certify MUSALE VENUGOPAL RAO that has actively participated in the Value Added Course on "Clinical Research" held during February 2022'-August 2022Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

Dr. S. JAI KUMAR
RESOURCE PERSON

Dr.Somasundaram.G
COORDINATOR

## Student Feedback Form

Course Name: Clinical Research.

Subject Code: **PH 04**

Name of Student: Musale venu gopal rao Roll No.: U17MB331

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

| Sl. NO | Particulars | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| 1 | Objective of the course is clear | | | | | ✓ |
| 2 | Course contents met with your expectations | | | | ✓ | |
| 3 | Lecturer sequence was well planned | | | | ✓ | |
| 4 | Lectures were clear and easy to understand | | | | ✓ | |
| 5 | Teaching aids were effective | | | | | ✓ |
| 6 | Instructors encourage interaction and were helpful | | | | | ✓ |
| 7 | The level of the course | | | | ✓ | |
| 8 | Overall rating of the course | 1 | 2 | 3 | 4 | 5 |

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

**SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES**
**Osudu, Agaram Village, Koodapakkam post, Puducherry**

**Date; 28-8-2022**

**From**
Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

**To**
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry.

**Sub: Completion of value-added course:**

Dear Sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled: **CLINICAL RESEARCH on February 2022 – August 2022**. We solicit your kind action to send certificates for the participants that is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards

Dr.G.Somasundaram

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY.
Sri Lakshmi Narayana Institute Of Medical Sciences,
PONDICHERRY - 605 502.