

Course:

Methodology of Clinical Trials and Practical Implementation

Pole

- Mechanisms of Living Organisms
- Epidemiology and Public Health
- Biology of Microorganisms
- Other courses

SUMMARY

The general objective of this course is to give health professionals, students in healthcare professions and researchers working in the field, the theoretical and practical basics to enable them to design and monitor clinical trials that meet International quality standards as ICH-GCP (International Conference on Harmonization - Good Clinical Practices). These courses that address all health areas will focus on aspects related to countries with limited resources.

On line registration: <https://www.pasteur.fr/en/international/international-courses/international-courses-2018>

Contact us: email:

GwenaelleCarn@pasteur.mg / Telephone : +261 20 22 412 72

Muriel.Vray@pasteur.sn or murielvray@hotmail.com / Telephone: 221 33 839 92 47

Practical information

Location: These courses will be located at the Institut Pasteur in Antananarivo, Madagascar

Dates: From 11 to 22 of June 2018

Application deadline: 31 March 2018

Language: French

The course comprises:

The course alternately will include theoretical lectures with emphasis on the main principles in clinical trials including superiority and non-inferiority trials or new methodology (how to perform randomizations, how to handle missing data, adaptive design, etc...). and tutorials. It will be preceded by two days of introduction to epidemiology and the basics of statistics.

The content of the program is:

- 2 days for the introduction to epidemiology and the basics of statistics
- 4 days for clinical trials methodology. The following topics will be presented :
 - o The main principles of clinical trials and new methodologies used on specific populations or emergencies (adaptive methods, sequential trials...) and specific methods of interventional trials (community trials).
 - o Students will be taught how to read and interpret Clinical Trial report and its publication. These methods will be illustrated with examples. New methodologies requiring rapid responses to meet an emergency situation will be addressed (sequential trials).
- 2 days dedicated to ethics, regulatory and legal aspects
 - o description of the different actors and their responsibilities
 - o conceptual and operational definitions of ethics in research and their implications in different situations, good clinical practice and ethical rules to ensure the protection and rights of individuals and those governing the databases.
- 1 day during which partners will present their experience in completed, on-going trials or trials to be set up in Madagascar and Central African Republic: interventional trial in children with moderate malnutrition, malaria trial....
- 1 day for written exam

The committee of the course will evaluate applications.

Documents available to download:

Program
Poster
Application form

More information

Directors

Name Gwenaëlle CARN, Institut Pasteur of Madagascar
Name Muriel VRAY, Institut Pasteur of Dakar

Attendees: 20

Duration: 2 weeks

Contact:

Gwénaëlle Carn, +261 20 22 412 72, GwenaëlleCarn@pasteur.mg
Muriel Vray, 221 33 839 92 47 , Muriel.Vray@pasteur.sn or murielvray@hotmail.com

LECTURERS:

Names	Institution
Muriel Vray	Institut Pasteur de Dakar
Gwenaelle Carn	Institut Pasteur de Madagascar
Laurence Baril	Institut Pasteur de Madagascar
Rindra Randremanana	Institut Pasteur de Madagascar
Rila Ratovoson	Institut Pasteur de Madagascar
Harimanana Aina	Institut Pasteur de Madagascar
Tsinjo Fehizoro Rasoanaivo	Institut Pasteur de Madagascar
Julio Rakotonirina	Faculté de médecine et Institut National de Santé Publique et Communautaire (INSPC)
François Montestruc	eXYSTAT France
Hantamalala Vololoniaina Ravelomanantena	Centre National de Pharmacovigilance, Agence du Médicament de Madagascar
Ando Fiononana Andriamarosata	Centre National de Pharmacovigilance, Agence du Médicament de Madagascar
Herintsoa Rafatro	Institut Malgache de Recherches Appliquées (IMRA)
Mihaja Raberahona	Service des maladies infectieuses. CHU JRB

Application details:

Program of the course
Application form