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TRAINING IN CLINICAL HEALTH RESEARCH

Face-to-face AFRAVIH clinical research workshop + French-language e-learning modules

Why French-language training in clinical health research?

Major advances in the treatment of viral infections such as HIV, and also hepatitis, have been made possible by dynamic basic and clinical research. Many other themes are emerging, such as co-morbidities, associated infections, cancers and emerging infections.
Because it is important to maintain and boost research initiated, promoted and organised by the scientific community, particularly in West and Central Africa, it is more important than ever to develop research initiation training initiated by AFRAVIH in 2007, in evaluation therapeutic strategies and trials, or operational research. But also, in the future, in these regions of the African continent, to develop independent research into new drugs or new vaccines.

This is why, in partnership with ANRS-MIE, AFRAVIH is proposing in 2025 a more comprehensive "Training Clinical Health Research", in French, to strengthen the skills needed promote autonomous research, such as :

Training modules

The course comprises 7 modules

- 2 face-to-face modules, 4 days to acquire all the basic skills needed to developing a clinical research project.
- 5 distance learning modules

1. Module 1 - Building a research project (face-to-face; in Senegal)
2. Module 2 - Statistical principles applied to clinical trials (face-to-face; in Senegal)
3. Module 3 - Regulations, ethical and legal aspects, financing a company research (webinar)
4. Module 4 - Research coordination and logistics (webinar)
5. Module 5 - Pharmacovigilance (PV) (webinar)
6. Module 6 - Legislation and the investigational medicinal product circuit (webinar)
7. Module 7 - Special situations :
    1. Clinical research in crisis/epidemic situations
    2. Clinical research and vaccinology

- Modules **1 & 2 are compulsory;**
- A certificate of attendance will be issued for these 2 modules alone;
- It is not possible to follow the other modules without having attended these two sessions.
  first modules ;
- Participation **in all modules from 1 to 7** makes this clinical research training course certifiable;
- Participation in up to 4 of the 5 distance learning modules (Modules 3 to 7) is free of charge.
  but does not confer certification.

Participants

This course is aimed at doctors, biologists, pharmacists and researchers involved HIV infection, viral hepatitis, sexual health and emerging infections, and wishing to develop their clinical research skills.

Schedule and registration

- Monday 28 October: course applications open
- Monday 25 November: closing date for course applications
- Wednesday 27 November to Thursday 5 December 2024: evaluation of applications
- Monday 9 December 2024 from 2pm to 4pm: final selection of participants

Face-to-face: Presentation of the Clinical Research Workshop (Modules 1 and 2)

The aim of the Clinical Research Workshop is to train **clinical doctors/biologists, pharmacists and researchers involved in research** in the knowledge required to develop clinical research.
It takes place over 4 days and includes **theoretical training** in the essential concepts of research as well as **practical training. The theoretical training** consists plenary sessions with methodological presentations on the following topics:

- The different types clinical research study ;
- Formulate and justify a research question ;
- Defining the objectives, population and eligibility criteria for a study ;
- Designing the protocol and setting up study ;
- Define the general principles analysis and the number of patients required in the study according to the clinical research hypothesis.

Practical training involves putting into practice the concepts learned or reviewed in plenary session with the preparation a clinical research protocol:

- Each group is made up of 6 to 8 participants;
- This group work is coordinated by a clinician and methodologist duo;
- Over 3 days, each group must design, build and present all aspects of the
  a clinical research study chosen according to its field of interest;
  - At the end of workshop, each group will present its clinical research protocol.
    which will be discussed by the Education Committee.

Clinical Research Workshop programme

	Monday 7 April		Tuesday 8th April		Wednesday 9th April		Thursday 10 April
8h30	**Course presentation** C. Katlama *AFRAVIH* Y. Yazdanpanah *ANRS*	8h30-9h30	**Statistics for research** • Hypothesis testing • Confidence interval • Study size/power A. Boyd	8h30-9h30	**The errors of a study ; Study biases** S. Grabar E. Lhomme	8h30-9h00	**Writing an abstract : practical exercise** C. Katlama
9h00-10h00	**HIV and hepatitis news** • HIV: K. Lacombe • PrEP: C. Katlama • Hepatitis : G. Wandeler • Comorbidities South: R. Moh					9h00-9h30	Project presentation search group 1
10h00-11h00	**Justification for a study: de from research idea to conceptualisation** K. Lacombe	9h30-10h00	**Data validation collected** A. Diallo	9h30-11h00	**Data analysis (uni and multivariate)** E. Lhomme S. Grabar	9h30-10h00	Project presentation search group 2
11h00-11h30	*Coffee break*	10h00-10h30	*Coffee break*	11h00 11h30	*Coffee break*	10h00-10h30	*Coffee break*
11h30-13h00	**The different types study** E. Lhomme R. Moh	10h30-12h30	**Social science research and implementation** C. Boutet (SESSTIM)	11h30-12h30	**Practical exercises: diagram study** S. Grabar+ R. Moh	10h30-11h00	Project presentation search group 3
				12h30-13h30	**Drawing up a protocol + observation notebook** G. Wandeler R. Moh	11h00-11h30	Research project presentation Group 4
13h00-14h00	*Lunch*	12h30-13h30	*Lunch*	13h30-14h30	*Lunch*	11h30-12h30	QUIZ E. Lhomme
14h00-15h30	**Designing a protocol :** Objectives, evaluation criteria, defining a study population K. Lacombe / S. Grabar	14h30-16h00	**Practical exercises: statistics 1 on JAMOVI** A. Boyd E. Lhomme	14h30-16h00	**Practical exercises : Statistics 2 on JAMOVI** A. Boyd E. Lhomme	12h30-13h30	*Lunch*
15h30-18h30	**Supervised group work**	16h00-19h00	**Supervised group work**	16h00-19h00	**Supervised group work**		

Objective

Strengthen skills in clinical research by :

- training in research methodology
- acquiring skills in clinical research
- training in drawing up a research protocol
- an introduction to monitoring and analysing a clinical research project

Be immediately operational to :

- know how to formulate a research question
- define the type study best suited to the research
- organising the clinical trial
- draw up a research protocol
- plan the analysis of the study

Date and place

- The Clinical Research Workshop will take place from **7 to 10 April 2025 fi Saly, Senegal.**
- All participants and teachers will be accommodated in the same place to encourage exchanges and create potential collaborative networks.

Distance learning: Presentation of modules 3 to 7 of the Clinical Health Research Training course

The clinical research workshop has expanded to form a complete curriculum, incorporating **five additional modules** designed to cover all aspects of clinical research, from regulatory and ethical aspects to publication and data archiving.

Description of the modules:

- **Module 3 - Regulations, ethical and legal aspects, financing a company research (webinar)**
    - Provide an in-depth understanding of the regulatory and ethical framework, and the mechanisms funding clinical research.
- **Module 4 - Research coordination and logistics (webinar)**
    - Develop skills in managing coordination roles and logistical support, ensuring the quality and compliance of clinical research.
- **Module 5 - Pharmacovigilance (PV) (webinar)**
    - Training in the principles of pharmacovigilance, assessment of adverse events and the fundamentals of pharmaco-epidemiology for signal detection and risk management.
- **Module 6 - Legislation and the investigational medicinal product circuit (webinar)**

    - Acquire skills in the legislation and the experimental drug circuit, covering all stages of their management during clinical research.
- **Module 7 - Special situations :**
  1. Clinical research in crisis/epidemic situations
  2. Clinical research and vaccinology (webinar)
    - Learn more about methodologies specific to clinical vaccine research and research strategies in crisis situations.

Schedule for modules 3 to 7 of the Clinical Health Research training course

Modules	Names of module leaders	Planning
Module 1 (see research workshop clinic above)		07/04/2025 to 11/04/2024
Module 2 (see research workshop clinic above)		07/04/2025 to 11/04/2024
Platform training courses	Coordination committee	14/04/2025 a.m.
Module 3 Regulations, ethical and legal aspects, financing of a research		14/04/2025 afternoon to 18/04/2025
Case forum+ webinar last day		21/04/2025 to 25/04/2025
Module 4: Coordination and search logistics		28/04/2025 to 05/05/2025
Case forum+ webinar last day		06/05/2025 to 12/05/2025
Module 5: Pharmacovigilance		13/05/2025 to 16/05/2025
Case forum+ webinar last day		19/05/2025 to 23/05/2025
Module 6 - Legislation and the experimental drugs		26/05/2025 to 28/05/2025
Case forum+ webinar last day		28/05/2025 to 02/06/2025
Module 7: Special situations : **1. Clinical research in crisis/epidemic situations** **2. Clinical research and vaccinology**		03/06/2025 to 05/06/2025
Case forum+ webinar last day		06/06/2025 to 11/06/2025
Assessment quiz	Coordination committee	16/06/2025
Closing webinar and presentation of diploma	Coordination committee	16/06/2025

Objectives

Training in clinical health research (FRCS) aims to teach people to master all the stages involved in conducting clinical research, covering crucial topics such as :

- Regulatory and ethical framework
- Logistics coordination
- Pharmacovigilance
- Legislation and the investigational medicinal product circuit
- Vaccinology and crisis research

Training methods

Modules 3 to 7 will take place online over a period of three months, with each module lasting two weeks. Each module includes lessons given to learners by videoconference, which will be recorded and then made available on the ANRS MIE e-learning platform. Additional material (articles, resources) is also made available to deepen knowledge.

Components of each module :

1. **Theoretical training**: Lessons by videoconference, supplemented by documents and links of interest on the ANRS MIE platform.
2. **Practical training**: Interactive exercises with discussion forums, quizzes and case studies to learning by doing.
3. **Knowledge assessment**: Self-assessment quiz before and after each lesson, to assess and consolidate knowledge.
4. **Knowledge reinforcement**: An ongoing discussion forum for learners exchange views and ask questions, and a reinforcement webinar to deal with specific questions and difficulties.

Date and place

- **Online**: from 14 April to June 2025.
- **Duration of each module**: 2 weeks maximum.