Jornada informativa de las convocatorias 2025 del Partenariado en Salud Global - EDCTP3

24/02/2025

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Global Health EDCTP3

Servicio Madrileño de Salud

SaludMadrid

Comunidad de Madrid

Fundación Investigación Biomédica Hospital Universitario 12 Octubre

i+12 Instituto de Investigación Hospital 12 de Octubre

Unidad Pediátrica de Investigación y Ensayos Clínicos (UPIC). ***Servicio de Pediatría.***
Entidad: Hospital Universitario de 12 de Octubre

i+12 Instituto de Investigación Hospital 12 de Octubre

GLOBAL-PID

Innovation in Global Pediatric Infectious Diseases

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HOW IT STARTED?

JUNE 2023

Global Health EDCTP3

Work programme 2023 Global Health EDCTP3 Call topics

HORIZON-JU-GH-EDCTP3-2023-01-01: Global Health EDCTP3 Training Networks - Clinical Research Fellowships

Train skilled African researchers in the area of infectious disease research to:

- *Face clinical research challenges*
- *Efficiently carry out clinical trials*
- *Mentor young scientists*
- *Implement research results, apply knowledge into development of products and services*
- *Inform policy and practice*
- *Strengthen attractiveness of clinical research in SSA countries*

NOVEMBER 2023

SUPPORT proposal accepted!

Evaluation Summary Report

Evaluation Result
Total score: 14.00 (Threshold: 12)

JUNE 2024

Official start of the project

Supporting the next generation of African researchers on preventing HIV pediatric mortality through a training network. (SUPPORT)

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SUPPORT OFFICIAL INFORMATION

Call: HORIZON-JU-GH-EDCTP3-2023-01

Type of Action: HORIZON-JU-RIA

Acronym: SUPPORT

Number: 101145811

Duration: 54 months

GA based on the: HE MGA — Multi & Mono - 1.1

Start Date: 01 June 2024 End date: November 2028

Estimated Project Cost: €5,081,593.75

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The Global Health EDCTP3 Training Networks aim to train and develop skilled, innovative, and resilient African researchers, scientists, clinicians, and other public health professionals working in the area of infectious disease research. The main objective is that these professionals can face current and future clinical research challenges, efficiently carry out clinical trials, mentor young scientists, implement research results, apply knowledge into development of products and services and/or analyse data to inform policy and practice for better health for all in sub-Saharan Africa (SSA). Through the training being offered to the fellows, important research questions within the framework of the Strategic Research and Innovation Agenda of Global Health EDCTP3[15] will be addressed.

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EMPIRICAL

Improving Treatment for Pneumonia in HIV-infected Infants

Empirical Treatment against CMV and TB in severe pneumonia in HIV-infected infants: a randomized controlled clinical trial

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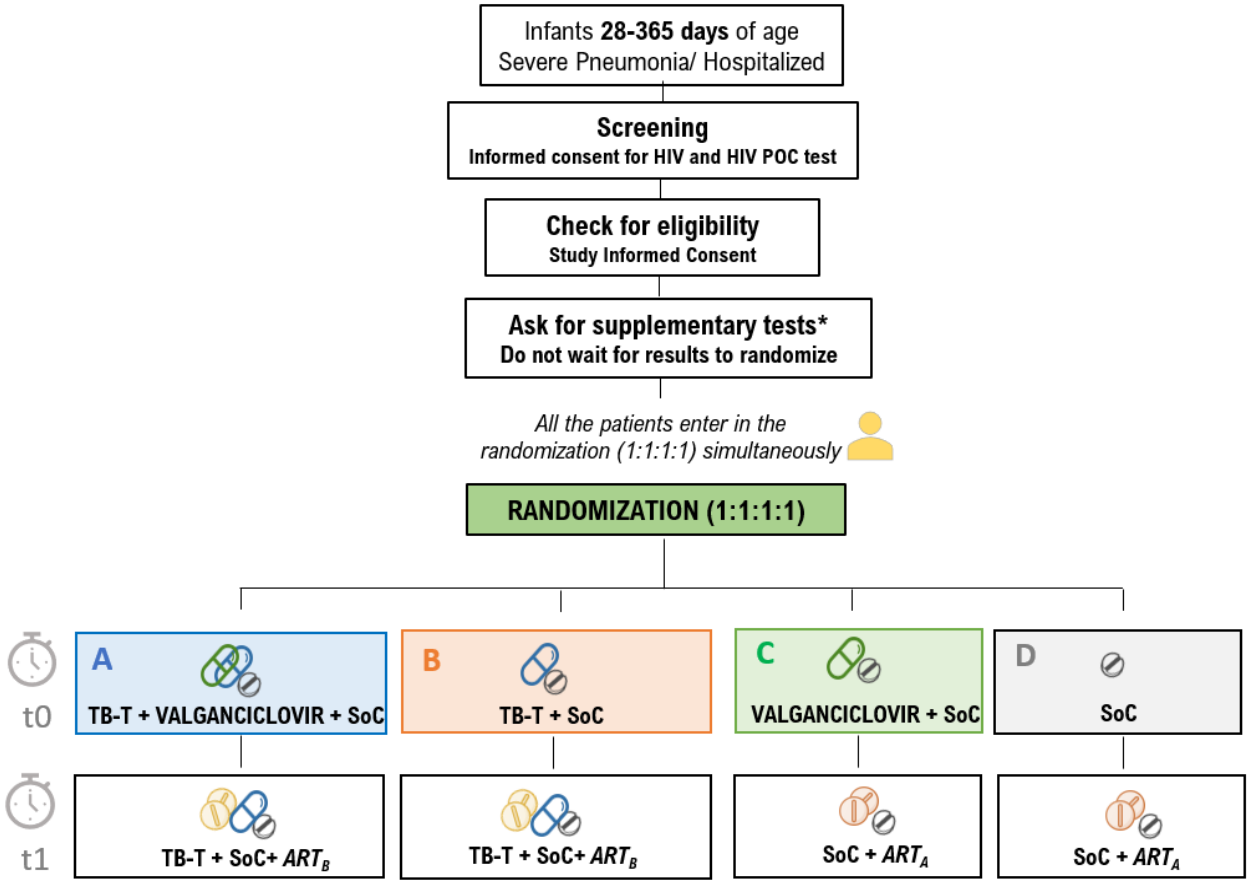
Figure 1. Flowchart of randomization scheme



CMV: Cytomegalovirus; **TB-T**: Tuberculosis treatment; **POC:** Point of care

t0: First 24h after screening
t1: +15days after randomization in naïve patients

***Supplementary tests**: Blood test (full blood cell count, blood chemistries, PCR for CMV), Chest X ray, Saliva CMV PCR test, Urine TB LAM, Nasopharyngeal aspirate and Stools (Xpert MTB/RIF Ultra).
SoC: Standard of Care (ceftriaxone + cotrimoxazole + prednisolone)
ART: Antiretroviral treatment.
- ART_A: First line ART
- ART_B: ART compatible with TB-T

Participants who are already on ART when admitted will continue on ART during admission as part of their Standard of Care. ART will be adapted to trial schedule if necessary.

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- Phase II-III, factorial trial
- Open-label
- 6 countries, 19 hospitals
- Population: 28 d-365 d, HIV+, severe pneumonia
- Sample size: 624

EDCTP

This project is part of the EDCTP2 programme supported by the European Union

i+12 Instituto de Investigación Hospital 12 de Octubre

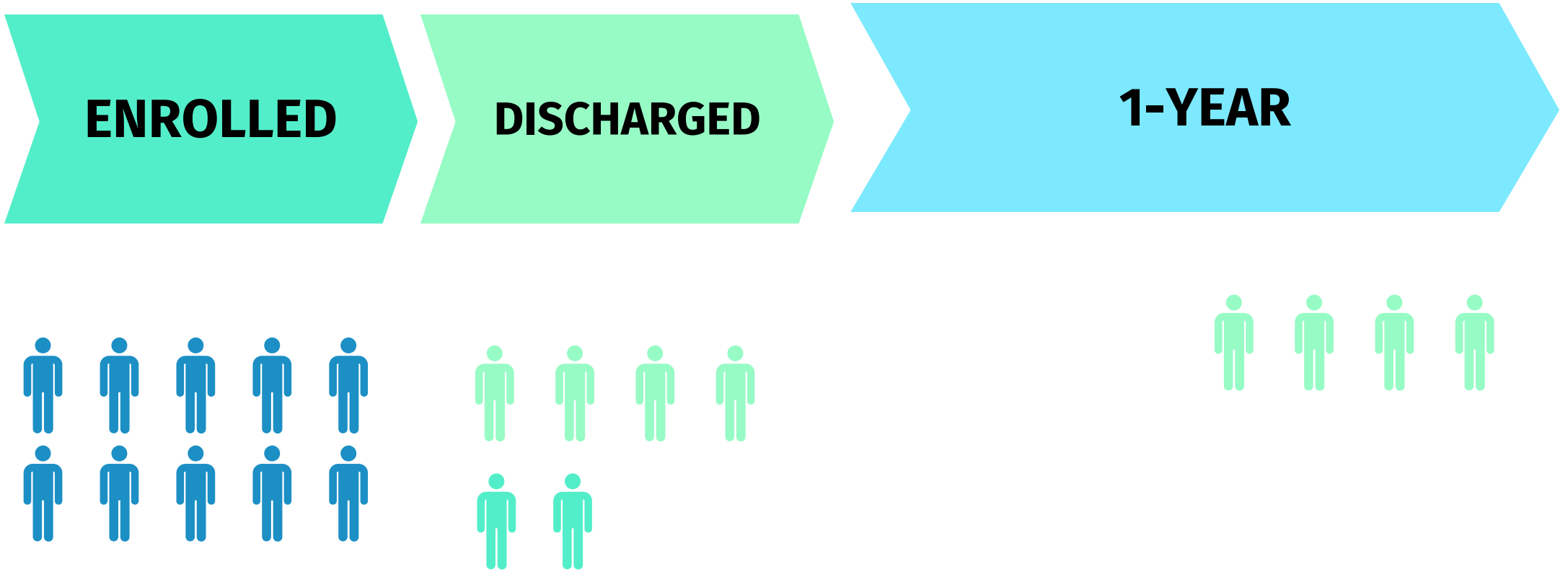
Acknowledgements

EMPIRICAL
Improving Treatment for Pneumonia in HIV-infected Infants

Endpoints and sub-studies

ENDPOINT	SECONDARY ENDPOINTS	SECONDARY ENDPOINT	SECONDARY ENDPOINT & SUBSTUDIES
			
MORTALITY	**CLINICAL**	**SAFETY**	**OTHER**
Mortality over time	Days on O2 Hospitalizations	SAES and AES	Prevalence of CMV Prevalence of TB Causes of death PK studies CMV VL Response Cost effectiveness

Outcome



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SUPPORT MAIN OUTLINE

Build a training network with SSA and European institutions from EMPIRICAL & UNIVERSAL projects

EMPIRICAL
Improving Treatment for Pneumonia in HIV-infected Infants

UNIVERSAL

- Multi-disciplinary consortium
- Well established network
- Recognised research institutions Mainly universities

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UNIVERSAL

Goals and objectives

The goals of UNIVERSAL are:

- To develop two complementary antiretroviral fixed-dose combinations for infants and children newly diagnosed with HIV initiating antiretroviral therapy, and for children failing first-line therapy who need to switch to a new treatment regimen.
- To monitor the long-term efficacy and safety of other paediatric ART formulations as they enter the market across Africa.

The objectives of UNIVERSAL are:

- To use available adult and paediatric pharmacokinetic data to **model** fixed-dose combinations and determine optimal drug ratios and unit dose to cover all paediatric weight bands, as defined by WHO
- Based on modelling results, engage and team-up with the pharmaceutical industry to **develop** two child appropriate fixed-dose combinations of HIV drugs
- Using clinical trial products, **evaluate** the pharmacokinetics and short-term safety and efficacy of the newly developed formulations
- To **monitor** these priority drugs' long-term safety and efficacy through extended follow-up of existing large-scale African paediatric HIV trials
- Incorporate strong **capacity building** through the involvement of various clinical trial sites in Africa.

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PROJECT OUTLINE

European-African Mentors

8 PhD fellows

5 post-doc fellows

5 host institutions

#	Fellow	Subject of research	Host institution	Host Mentor(s) / Secondment Mentor(s)
1	ESC1	Mortality markers	MU, Uganda	V. Musiime Q. Bassat (ISGlobal) & S. Fernández-Luis (FIBH12O)
2	ESC2	Improved follow-up to decrease PDM	UEM, Mozambique	J. Sacarlal & WC. Buck C. Moraleda & A. Tagarro (FIBH12O)
3	ESC3	CMV as PDM predictor	UNZA, Zambia	C. Chabala, V. Mulenga M. Bates (UoL)
4	ESC4	Prolonged respiratory virus infection	UNZA, Zambia	C. Chabala, V. Mulenga M. Bates (UoL)
5	ESC5	Prolonged GI & Histoplasmosis	UZFMHS, Zimbabwe	AH. Mujuru, R. Mavenyengwa A. Gilbert (UoL)
6	ESC6	Evaluate the use of AI to reduce PDM	MU, Uganda	V. Musiime JJ. Beunza & E. Puertas (UEMadrid)
7	ESC7	Improved PK knowledge	UZFMHS, Zimbabwe	AH. Mujuru, C. Nhachi T. Jacobs (RUMC)
8	ESC8	AMR in CLHIV with virological failure	UCAD, Senegal	P.M. Faye & H. Diop A. Compagnucci (Inserm)
9	MTC1	Lab Management and Colonization of MDR bacteria	UEM, Mozambique	J. Sacarlal & WC. Buck A. Gilbert (UoL)
10	MTC2	Coordination of clinical research	MU, Uganda	V. Musiime P. Rojo (UCM)
11	MTC3	Data Management of SUPPORT network	UNZA, Zambia	C. Chabala, V. Mulenga S. Domínguez (FIBH12O)
12	MTC4	Biostatistics of SUPPORT network	MU, Uganda	V. Musiime S. Domínguez (FIBH12O)
13	MTC5	Socio-behavioral Study	UEM, Mozambique	R. Capurchande M. Maixenchs (ISGlobal)

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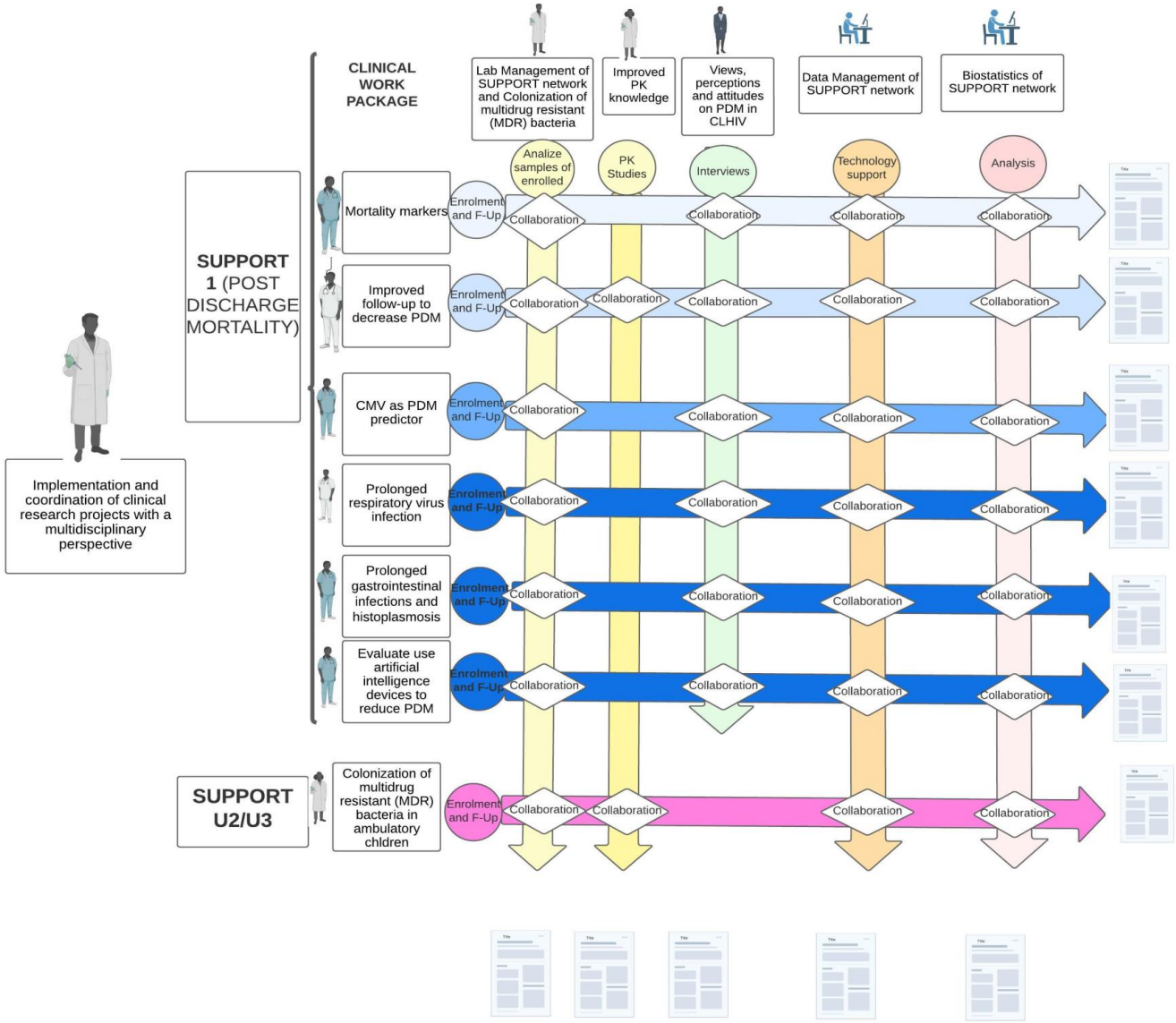
PROJECT OUTLINE

All the fellows working in collaboration with each other!



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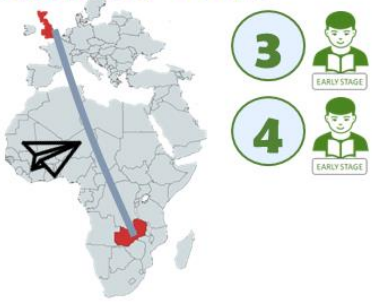
Uganda->Spain

Zimbabwe->Italy

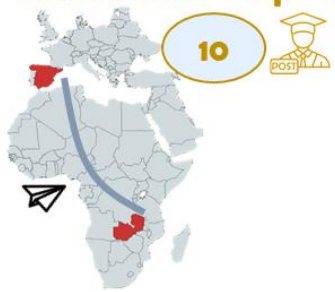
Zimbabwe->Netherlands

Mozambique->Spain

Zambia->UK



Zambia->Spain



Senegal->France

Mozambique->UK

CONSORTIUM

	Participant organization name	Country
PARTNERS	Universidad Complutense de Madrid (UCM)	Spain
	Fundación para la Investigación Biomédica del Hospital Universitario 12 de Octubre (FIBH12O)	Spain
	Barcelona Institute for Global Health (ISGlobal)	Spain
	Universidad Europea de Madrid (UEMadrid)	Spain
	Fondazione Penta ETS (Penta)	Italy
	Università degli Studi di Padova (UNIPD)	Italy
	Institut national de la santé et de la recherche médicale (Inserm)	France
	Radboud UMC (RUMC)	Netherlands
	University of Zimbabwe (UZFMHS)	Zimbabwe
	Eduardo Mondlane University (UEM)	Mozambique
	Makerere University (MU)	Uganda
	Cheikh Anta Diop University (UCAD)	Senegal
ASSOCIATED PARTNER	University of Zambia (UNZA)	Zambia
	University of Lincoln (UoL)	UK

Ongoing: addition of Herpez as a partner and removal of UNIPD

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PROJECT OUTLINE

TRAINING PROGRAM STRUCTURE

Network-wide training

Train fellows on essential concepts, methodologies, and interdisciplinary aspects to work in clinical research.

Annual seminars
Online courses
Webinars

Specialized hands-on training

Individual Research Projects to generate valuable knowledge on optimizing the clinical management of CLHIV.

Specific courses
Individual research Project
Secondment

Individual research projects focusing on research questions coming from EMPIRICAL & UNIVERSAL observations

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TRAINING COMMITTEE

MEMBERS

Internal members

Pablo Rojo	**Victor Musiime**	**Hilda Mujuru**	**Jahit Sacarlal**

Independent members

Bahati Haule	**Venus Mushininga**

Role:

1. Supervision of selection process
2. Supervision of training program implementation (yearly follow-up)

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REMINDER SELECTION PROCESS

SELECTION PROCESS

1. Dissemination of offers in national and international networks
2. Screening by central team
3. Pre-selection by supervisors
4. Interview and selection by Training Committee

179 applications received for PhD positions

27 applications received for Post-doc positions

45 interviews by the Training Committee over 12 Training Committee sessions

8 PhD fellows and **4** Post-doc fellows selected

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CHALLENGES

1. Local university requirements (extra objectives, extra supervisors….)
2. Local timelines
3. Mobility
4. Budget Unit costs
5. Pre and PostDoc Timelines 2-3 years
6. Short time proposal open and submission

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Thank you

Questions and answers

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