UNIVERSAL CAPACITY BUILDING

Training Title: CLINICAL TRIALS MANAGEMENT TRAINING

Description
The clinical trials management training focuses on improving the capacity of research staff and young investigators to design, implement, and manage regulatory clinical trials, especially paediatric clinical trials.

Target Audience
This course is designed for the benefit of young investigators and research staff of various cadres such as; investigators, clinical trial managers, doctors, nurses, pharmacists, counsellors, laboratory staff, community health staff. The focus is on research staff currently involved or who are being mentored in the management of clinical trials.

Training Delivery Method
1. Webinars
2. Online access to webinar recordings and power point presentations on the UNIVERSAL website.

Languages
The training will be delivered in both English and French to make sure that language preference for participants from Universal 1 and Universal 2 sites are addressed.

Training Evaluation
Evaluation for each session will be completed by participants as a poll or link to the evaluation form at the end of every session/module.

Access to training content after the webinars.
The recorded webinars and training slides will be uploaded to the Universal project website for free access by the UNIVERSAL project teams.

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Clinical Trials Management Training
Dates: Every 2nd and 4th Wednesday of the Month
Time: 2:00pm CEST/3:00pm EAT/ 12:00pm Bamako/ 1:00pm WAT/8:00am EST
(Time Zone converter: https://www.timeanddate.com/worldclock/converter.html)

SCHEDULE FOR ENGLISH SESSIONS

Module	Dates	Chairperson	Duration	Trainers	Zoom Webinar Details
Module 1: Introduction and overview of clinical research	14th June 2023	Sheila	1hr 45mins- **ENGLISH**	Pauline, Peter	Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_R7XAWl3qS8OKyx51yJ1C-q Meeting ID: 873 9971 4598 Passcode: 194990
Module 3: Clinical research set-up, implementation, monitoring and close-out	12th July 2023	Thera	1hour- **ENGLISH**	Pauline	
Module 2: Regulatory trial documentation, Budgets, Contracts, Quality management and Inspections	9th Aug 2023	Peter	1hr 30min- **ENGLISH**	Rachel, Loyce, Pauline	
Module 4: Managing Research Logistics (IMP, Samples, Data).	13th Sep 2023	Patricia	2hour- **ENGLISH**	Pauline, Rogers, Annet	
Module 5: Safety Reporting, Clinical trial Committee and Boards	11th Oct 2023	Pablo	1hour- **ENGLISH**	Sheila	
Module 6: Introduction to Pharmacokinetic and Pharmacodynamic studies (with practical session)	8th Nov 2023	Rogers Sekabira	1hour- **ENGLISH**	Angela/Anne	
Module 7: Introduction to regulatory processes and requirements to support regulatory filing to FDA	13th Dec 2023	Angela Colbers	1hour 30mins- **ENGLISH and FRENCH**	Melynda, Linda *(Simultaneous translation)*	

KEY:

	French only Sessions
	English only Sessions
	Simultaneous translation

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Time: 2:00pm CEST/3:00pm EAT/ 12:00pm Bamako/ 1:00pm WAT/8:00am EST
(Time Zone converter: https://www.timeanddate.com/worldclock/converter.html)

SCHEDULE FOR FRENCH SESSIONS

Module	Dates	Chairperson	Duration	Trainers	Zoom Webinar Details
Module 1: Introduction and overview of clinical research	28th June 2023	Mariam	1hr 45mins- **FRENCH**	Thera, Aba	Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_R7XAWl3gS8OKyx51yJ1C-g Meeting ID: 873 9971 4598 Passcode: 194990
Module 3: Clinical research set-up, implementation, monitoring and close-out	26th July 2023	Alex	1hour- **FRENCH**	Yoann, Yacine, Alex	
Module 2: Regulatory trial documentation, Budgets, Contracts, Quality management and Inspections	23rd Aug 2023	Mariam	1hr 30min - **FRENCH**	Thera	
Module 4: Managing Research Logistics (IMP, Samples, Data).	27th Sep 2023	Alex	2hour - **FRENCH**	Yoann, Yacine, Alex	
Module 5: Safety Reporting, Clinical trial Committee and Boards	25th Oct	Yoann	1hour **FRE**	Feriel	
Module 6: Introduction to Pharmacokinetic and Pharmacodynamic studies (with practical session)	22nd Nov 2023	Mariam	1hour **FRE**	Deborah Hirt	
Module 7: Introduction to regulatory processes and requirements to support regulatory filing to FDA	13th Dec 2023	Angela Colbers	1hour 30mins- **ENGLISH and FRENCH**	Melynda, Linda *(Simultaneous translation)*	

KEY:

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Meet our Trainers and Session Chairpersons

Here is an opportunity to meet your trainers and session moderators, as you get ready to engage with them during the training webinars.

Alex S. Compagnucci

Dr Alex S. Compagnucci, is a Clinical Research Associate with Fondazione Penta ETS.
Medical research Lead at INSERM SC10-US19
Institution: INSERM SC10-US19, France

Dr Alex is a member of the Penta Scientific Committee, and teaching staff of the PentaTr@ining programme through the Penta ID Network. She is one of the leaders of this programme in Latin America, together with the Spanish and Latin American colleagues.

Angela Colbers

Angela Colbers, is a Researcher
Institution: Department of Pharmacy at the Radboud University Medical Center in Nijmegen, The Netherlands.

Angela's focus is on pharmacology studies in pregnant women and children living with HIV. She coordinates the PANNA-network, a European network studying pharmacokinetics of antiretroviral agents in HIV.

Anne Kamphius

Anne Kamphuis, is a Pharmacist
Institution: Radboud University Medical Center
Country: Netherlands

Anne Kamphuis is a pharmacist and PhD student. She is involved in pharmacology studies with antiretroviral medicines in children living with HIV.

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Annet Nalugo

Annet Nalugo, is a Laboratory Supervisor.
Institution: Baylor College of Medicine Children's Foundation-Uganda.

Annet coordinates Laboratory research related activities at the College of American Pathologist-accredited Lab and Clinical Research Site. She has been involved in international collaborative clinical trials sponsored by US-NIH/NIAID/DAIDS, PENTA foundation, UK-MRC, DNDi and Pharmaceuticals companies. She is a voting member for the IMPAACT/ACTG Laboratory Technologist committee.

Linda Lewis

Dr Linda Lewis, is the Director, Clinical and Regulatory Affairs, Product development, Quality, Costing, and Regulatory Affairs.
Institution: Clinton Health Access Initiative, USA
Dr. Lewis provides clinical and regulatory advice to other CHAI teams and to external partners in clinical care, research, industry, and normative bodies. Given her experience working for the U.S. Food and Drug Administration, she advises stakeholders on appropriate development and regulatory pathways for high priority drugs. As a member of the PQCRA Team, she has proposed strategies and provided technical advice for developing and registering new paediatric formulations intended for use in low- and middle-income countries. As a consultant in Paediatric Infectious Diseases, she has special interest in the development of high quality, sustainably priced products for combating HIV, viral hepatitis, TB, and other infections affecting children. She also maintains an active role in pediatric drug prioritization activities with the WHO through the Pediatric Antiviral Drug Optimization (PADO) working group and the Pediatric Antiviral Working Group (PAWG).

Loyce Katusiime

Loyce Katusiime, is a Quality Assurance Coordinator
Institution: Baylor College of Medicine Children's Foundation-Uganda

Loyce is a quality assurance coordinator for DAIDS-sponsored clinical trials and CoVPN trials at Baylor-Uganda Clinical research site. She works with research teams to ensure compliance to ethical requirments, GCP guidelines, and other national and international regulatory guidelines. Her major interest is working with research teams to set-up and maintain quality assurance systems for quality data.

Mahamadou Ali Thera

Prof Mahamadou Ali Thera, is the Scientific Director at USTTB Mali.
Institution: Malaria Research and Training Center/Faculty of Medicine and Dentistry-University of Science, Techniques and Technologies of Bamako (MRTC/FMOS-USTTB)
Country: Mali
Mahamadou is an experienced malaria vaccine clinical trialist. His research focuses on the clinical development of efficacious blood-stage malaria vaccine and understanding the pathogenesis of severe malaria.

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Prof. Mariam Sylla

Prof. Mariam Sylla, is the Vice Dean FMOS.
Institution: Faculty of Medicine and Dentistry-University of Science, Techniques and Technologies of Bamako (FMOS-USTTB)
Country: Mali
Mariam is a paediatrician with extensive experience in neonatal health and in the management of HIV and opportunistic infections including tuberculosis in children. She is leading the "Centre d'"Excellence Pédiatrique pour la prise en charge du VIH/SIDA au Mali" which is the referral center for infected infants with HIV/AIDS in Mali.

Melynda Watkins

Dr Melynda Watkins, Senior Director, Product development, Quality, Costing and Regulatory Affairs, in the Global Health Sciences Department.
Institution: Clinton Health Access Initiative (CHAI), USA.
Melynda oversees a portfolio of technical initiatives to optimize pharmaceutical products for Developing Market use by developing and executing strategies for novel formulations and new doses of existing products. She also develops innovative regulatory strategies for the registration of products in multiple markets including US FDA, WHO PQ, WHO CRP, as well as through National Regulatory Authorities. She is also accountable for developing and transferring for manufacture and commercialization of better and less expensive formulations and fixed-dose combination products for adults and children suffering from chronic and acute diseases. She supports treatment optimization through the development, regulatory filing, and quality assessment of new products, diagnostics, and devices.

Pablo Rojo Conejo

Dr Pablo Rojo Conejo, is a Paediatric Infectious Diseases Specialist.
Associate Professor of Complutense University, Madrid, Spain.
Institution: Hospital 12 de Octubre, Madrid, Spain.

Pablo is a member of the Board of the Spanish Society of Paediatric Infectious Diseases (SEIP), since 2014 and now Board Member of the European Society of Paediatric Infectious Diseases (ESPID). He is a member of the Penta Network, and the PentaTr@ining program for over 10 years. He has participated in many paediatric antiretroviral clinical trials and is part of the EPIICAL project pursuing novel therapeutics approaches for early treated HIV-infected children. He is also co-Chief Investigator of ODYSSEY and Chief Investigator of the EMPIRICAL trial.

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Patricia Nahirya Ntege

Dr Patricia Nahirya Ntege, is the Director of research at Baylor-Uganda.
Institution: Baylor-College of Medicine Children's Foundation-Uganda

Patricia is a paediatrician and investigator, with more than 15year's experience in conducting paediatric and adolescent clinical trials on HIV treatment and prevention, and COVID-19. She is currently the site principal investigator on the HPTN084 clinical trial and co-investigator for several trials within the IMPAACT network, and several COVID-19 vaccine trials. Her major interest is preventive research that can reduce on the burden of infectious diseases of public health importance.

Pauline Amuge

Dr Pauline Amuge, is a Paediatrician, Research Coordinator, and Investigator.
Institution: Baylor-College of Medicine Children's Foundation-Uganda

Pauline coordinates clinical trials and operational research in paediatric HIV and TB. She has participated in several Penta-sponsored clinical trials as a trial manager and principal investigator, such as ODYSSEY, SMILE, and D3 trials. As part of the EDCTP2-funded UNIVERSAL project, she is leading the capacity building work package (WP8) together with partners from INSERM in France, SERMAS in Spain, USTTB in Mali, IAS/CIPHER in Switzerland, CHAI in USA, RUMC in The Netherlands, and Baylor-Uganda.

Peter James Elyanu

Dr Peter James Elyanu, Director of Global Health Security
Institution: Baylor-College of Medicine Children's Foundation-Uganda

Dr Peter is a Paediatrician, with over 15years' experience in designing and conducting research in paediatric infectious diseases like HIV. His PhD in Epidemiology and Biostatistics focused on long-term outcomes of children starting ART with advanced HIV disease. Previously, he coordinated the national paediatric HIV care program and update of national HIV treatment guidelines at the ministry of health. Currently, he leads multiple teams conducting surveillance and global health security activities that contributed to the control of COVID-19 pandemic and Ebola outbreak in Uganda.

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Rachel Namuddu Kikabi

Rachel Namuddu Kikabi, Regulatory Affairs Coordinator
Institution: Baylor-College of Medicine Children's Foundation-Uganda

Rachel is a public health specialist, and a bioethicist scholar, with a background in nursing. She heads the regulatory office at Baylor-Uganda where she advises investigators, and oversees ethical and regulatory compliance of research teams to research protocols, quality management systems, and national and international guidelines. She has over 15 years' experience in the conduct, management and regulation of both clinical trials, observational cohorts, and operational research.

Rogers Sekabira

Rogers Sekabira, is a Pharmacist of Record and Pharmacy Coordinator.
Institution: Baylor-College of Medicine Children's Foundation-Uganda
As a pharmacist of record for DAIDS-sponsored trials and COVID-19 vaccine trials at Baylor-Uganda clinical research site, Rogers works with the Pharmaceutical Affairs branch at DAIDS to ensure site compliance to all regulatory requirements for IND clinical trials. He develops and maintains control systems for investigational medical products.

Sheila Fernandez-Luis

Sheila Fernández-Luis, is a Postdoctoral researcher
Institution: Fundación para la Investigación Biomédica del Hospital 12 de Octubre, Instituto de Investigación Sanitaria Hospital 12 de Octubre (IMAS12), Madrid, Spain.
Dr Sheila is a Paediatrician, with a Ph.D. in Translational Medicine on the characterization of the prevention and care cascade in children living with HIV in Mozambique, from the Universitat de Barcelona and the Barcelona Institute for Global Health (ISGlobal). Her focus is epidemiological studies and clinical trials among children living with HIV in sub-Saharan Africa.

Yacine Saïdi

Yacine Saïdi, is the Head of Data Management at INSERM SC10-US19
Institution: Inserm SC10-US19, Clinical Trials and Infectious Diseases
Villejuif, France
Yacine is involved in adult and paediatric clinical trials conducted at Inserm CTU. His primary fields of interest are methodology and information systems in clinical research.

Yoann Riault

Yoann Riault, is a Clinical Project Manager at INSERM SC10-US19
Institution: Inserm SC10-US19, Clinical Trials and Infectious Diseases
Villejuif, France

Yoann manages international paediatric HIV clinical trials in collaboration with the Penta network. His main areas of interest are trial coordination and logistics in clinical research.

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