EDCTP

European & Developing Countries Clinical Trials Partnership

TDR For research on diseases of poverty

UNICEF • UNDP • World Bank • WHO

EDCTP-WHO/TDR Clinical Research and Development Fellowships

List of host organisations – 2016 Call for Proposals

The purpose of the EDCTP-WHO/TDR Clinical Research and Development Fellowship programme is to support researchers and key members of clinical trial research teams from low- and middle-income countries (LMICs) to acquire specific skills in clinical research and development through placements in pharmaceutical companies, product development partnerships (PDPs) and academic affiliated research institutions. The list of host organisations participating in the 2016 Call for Proposals, including details about the placements available, is provided below.

Host organisation	Maximum number of placements offered	Location of fellowship (city/country)	Department(s)	Topic/Disease area	Objectives of the training programme and candidate profile
Aeras	1	Cape Town , South Africa; Rockville USA	Clinical Development, Clinical Operations, Laboratory Capacity Development, Immunology, Biostatics and Data Management and Project Management	Project Management focusing on Protocol Development, Trial Initiation and Management, Quality Oversight, Laboratory selection, qualification and monitoring, sample size calculations and data management including procedures of data cleaning and data lock, project management and progress evaluation for trials, Basic immunological assays utilized in clinical trials, Overview of TB vaccine development, Community engagement, etc.	Aeras is a non-profit, biotechnology-focused product development partner focused on TB vaccine development. Aeras is a global organisation with offices in the United States, South Africa and China. Aeras has broad in-house clinical research capabilities. Clinical research is a growing expertise in LMIC and experienced clinical researchers are vital in a response to global health threats like TB. It is Aeras' objective to utilise its clinical research expertise to build clinical research capacity through hosting fellows that can be trained in areas of clinical development, clinical operations laboratory capacity development, statistics and data management, immunology and safety. Our aim is to integrate the fellows in the day to day clinical research activities allowing them to gain practical experience. Furthermore we will share knowledge exposing the fellows to general principals and concepts of clinical research. Training should allow fellows to make a positive contribution to clinical research capacity development at their home institutions. We prefer candidates that have a passion for clinical research and have had some introduction to clinical trials and a broad understanding of clinical research requirements. Candidates should have either been involved at investigator or study coordination level and be in possession of a post-graduate degree.
Barcelona Institute for Global Health (ISGlobal)	1	Barcelona, Spain	Global Health Paediatrics	Clinical development of preventive and therapeutic tools against paediatric infectious diseases	The training programme would include working hand in hand with a senior investigator on the design, development, preparation, implementation, analysis and evaluation of the findings of a clinical trial or clinical study, in close collaboration with its partner centre in Mozambique (Centro de Investigação em Saúde de Manhiça). The programme would also include the possibility to participate in field activities, to be defined by the project's Principal Investigator, in Mozambique, for a minimum of 2 months (to be extended if required). Examples of clinical trials include the evaluation of the safety and efficacy of new antimalarials or ancillary treatments, or other antimicrobial drugs; or the clinical development and

					evaluation of new vaccines against infectious diseases. Alternatively, the candidate would be able to participate in clinic-epidemiological studies in the area of paediatric infectious diseases, including malaria, pneumonia, or neonatal sepsis. Additionally, the candidate would benefit from the possibility of enrolling in one or more of the modules offered by ISGlobal in its current Masters of Global Health.
Drugs for Neglected Diseases *initiative*	2	Geneva, Switzerland	Research & Development	Clinical research projects from DNDi's portfolio, mainly neglected tropical diseases but also neglected populations suffering from diseases to which there is no access to adequate treatment, in different stages of development that will allow them to get a clear perspective about clinical trial development and management	The main objectives will be to: • Understand different steps and activities for developing a new drug (discovery, manufacturing and control, preclinical steps, clinical steps from phase I to phase IV, registration and access) • Preparation and management of a clinical trial • Supporting the existing clinical trials at the time of placement • Participation in supervision of clinical trials in the field. The ideal candidate would be a medical doctor or someone having a degree from other superior health of biological science university studies with field experience in participating in clinical trials.
European Vaccine Initiative (EVI)	2	Heidelberg, Germany	Executive Secretariat	Vaccines for diseases of poverty	The training will include 1) vaccine development principles, 2) clinical development methodology, 3) implementation and analysis, 4) project management, 5) business management, 6) principles of dissemination and communication, and 7) best practices principles and procedures. The fellows will be working on one or two projects on vaccines for diseases of poverty. They will be integrated in the project team, and will contribute to project management, process development/GMP production of vaccine, preclinical testing, filing the regulatory dossier IMPD, defining and implementing early phase clinical development for demonstrating proof-of-concept, selecting and managing sub-contractors CMOS/CROS, monitoring the quality of the partners within the consortium, writing scientific reports and publication, writing grant applications, and participating in communication and dissemination activities.

Foundation for Innovative New Diagnostics (FIND)	2	Geneva, Switzerland	Scientific Departments	Diagnostics for TB, malaria, HIV, NIDs	Diagnosis is the first step on the path to treatment and the foundation of disease control and prevention. As such, FIND has led the delivery of a number of new diagnostic tools in previously neglected areas and worked with partners to ensure their proper regulatory approval, scale-up and use. The fellowship at FIND will provide the participants the opportunity to gain hands-on knowledge and insight on the path of diagnostic test development. Participants will be able to join the preparation and conduct of multi-country trials from the sponsor's point of view, and will get a chance to interact with renowned experts in a multi-cultural environment, as well as with researchers and developers from around the world. Fellows will also be exposed to the process of global guidelines and/or policy development to support the use of new diagnostic tests. Candidates with an advanced degree in health sciences, proficient in English, who have prior experience in the areas of interest to FIND and who seek to build professional skills and experience in research are invited to submit an application.
GlaxoSmithKline UK	1	Uxbridge, United Kingdom	Diseases of the Developing World (Clinical Development)	All aspects of clinical trials performed in LMIC	
GSK Vaccines	1	Wavre, Belgium	Global Clinical Research and Development or Global clinical safety and pharmacovigilance departments (GCSP)	Malaria vaccines clinical research or pharmacovigilance	The successful candidate will work closely with the clinical research and development lead and will be part of a team within a matrix environment working to implement a clinical development plan for the RTS,S malaria vaccine. The fellow will be involved in all aspects of clinical trials that will be ongoing during the fellowship. There is also a possibility to work within the GSK vaccines global clinical safety and pharmacovigilance department. The successful candidate will be taught to actively manage and evaluate risks associated with assigned vaccine projects, and make recommendations for the management and communication of risks in accordance with global legal and regulatory frameworks. Although not mandatory, previous experience in clinical research is an asset.
Infectious Diseases Data Observatory (IDDO) and the	4	2 fellows in Oxford, United Kingdom; 1 fellow in Bangkok, Thailand and 1	Centre for Tropical Medicine and Global Health,	Infectious diseases	IDDO brings together clinical, laboratory and epidemiological data to answer specific scientific and operational questions relating to selected neglected infectious diseases and emerging infections. IDDO is building upon the success of WWARN, a scientifically

WorldWide Antimalarial Resistance Network (WWARN)		fellow in Vientiane, Laos	Nuffield Department of Medicine, University of Oxford		independent, multi-disciplinary platform that was founded in 2009 to provide the information necessary to prevent or alleviate antimalarial drug resistance and therefore reduce malaria morbidity and mortality. IDDO's vision is to provide effective control and treatment of infectious diseases affecting the most vulnerable populations. IDDO would welcome applicants interested in infectious diseases, in particular poverty related diseases or emerging infections. Successful candidates would have experience in clinical trials or surveillance activities and would like to gain knowledge in data management, statistics of individual patient data meta-analyses and pharmacology, or the ethics of data sharing and community engagement. Successful fellows will be hosted at the Centre for Tropical Medicine and Global Health, University of Oxford and will be placed in either Oxford or overseas research units in Thailand (focus on pharmacology and pharmacometrics) or in Laos (focus on medicine quality).
Infectious Disease Research Institute (IDRI)	1	Seattle, USA	Formulations department	Vaccine adjuvant formulation, manufacture, and quality control (applications include Influenza, Tuberculosis, Amebiasis, and Leishmaniasis)	The objectives of the IDRI training programme include development of pharmaceutically acceptable vaccine adjuvant formulations for clinical use to prevent and/or treat infectious diseases such as influenza, tuberculosis, amebiasis, and leishmaniasis. The fellow will be exposed to various aspects of vaccine adjuvant development, including process development and scale-up, physicochemical characterisation and quality control using methods such as HPLC and dynamic light scattering, and compatibility testing with relevant vaccine antigens. The preferred candidate profile includes experience with the manufacture or characterisation of nanoformulations such as oil-in-water emulsions, liposomes, or aluminum salts, as well as biomolecules such as nucleic acids, protein antigens, and Toll-like receptor ligands. The ability to develop and apply effective quality control physicochemical analytical assays is also preferred. Fellows will have the opportunity to be involved in the development of adjuvant formulations at various development stages, including from discovery through clinical testing.
International Vaccine Institute (IVI)	2	Seoul, Republic of Korea	Clinical Development & Regulatory	Clinical Development & Regulatory department: clinical research design,	Mentorship will be provided to the fellow bya direct supervisor who has more than 25 years of experience in vaccine clinical development internationally. In addition, ad hoc support will also be

			department; Epidemiology Department or Policy and Economic Research Department	essential guidelines and international regulation in clinical research, clinical trial monitoring, analysis of data, clinical administration skills, scientific presentation & Communication, clinical study reporting writing and publication and grant writing. <u>Epidemiology department</u>: vaccine delivery projects, disease surveillance and burden of disease studies <u>Policy and Economic Research Department:</u> research projects to support policy and vaccine introduction	provided by colleagues of the Development and Delivery Unit from the Data Management and Biostatistics Department, Epidemiology Department, in the Policy and Economic Research Department, and other units to provide guidance of activities on daily basis. At the end of the fellowship, it is expected that the fellow will have consolidated the following knowledge and skills: • Clinical trial design, essential guidelines, international regulations in clinical research, clinical trial documentation, professional and ethical conduct in clinical research, clinical trial operations, analysis of clinical trial data, publication and grant writing • Understanding of disease surveillance programmes, burden of disease studies, vaccine delivery projects • Design of research projects to support policy and vaccine introduction, cost of vaccination campaigns, cost of illness and cost-effectiveness studies • Vaccine manufacturing process and technology transfer. It is expected that the fellow will be assigned specific tasks and is invited to participate in various project meetings, internal scientific meetings, and as budget permits, attend national or international meetings. Since programmes involve several departments, IVI will also encourage the fellow(s) to interact with other departments listed above. The fellow(s) will benefit of this cross-learning experience and acquire a broader view of clinical development and delivery. Preferred profile: Medical Doctor, or Doctor in Pharmacy (additional expertise such as Epidemiology is welcome) with experience and strong interest in public health, vaccine development and / or vaccine delivery (EPI) and some experience in management.
Janssen Pharmaceutica	1	Beerse, Belgium	Research & Development Departments	Product/clinical development	The researcher will be placed in one or more R&D departments focusing on product/clinical development. The researcher will become a member of a team with the objective to gain knowledge and expertise in many aspects of product and/or clinical development.
Julius Clinical	2	Zeist, Netherlands	Clinical Operations, Data Management,	Setup and conduct of various Phase II-IV clinical	Julius Clinical is a combination of an academic and clinical research organisation dedicated to the preparation and conduct of

			Regulatory, Clinical Support, Safety and Pharmacovigilance, and Science & Business Development	trials	outcomes trials that have high scientific and societal impact, bringing innovative treatments to market, and potentially changing the way medicine is practiced. Working at the forefront of clinical research, Julius Clinical incorporate lean and novel practices to ensure clinical trials are performed efficiently and cost effectively. The successful fellow will engage and interact with Julius Clinical personnel to learn these best practices and help implement them in real time. From the very beginning of a trial (thinking along with Scientific Officers), during the start-up phase (Ethics Committee/Competent Authority Submissions and site selection), execution phase (Data management and Monitoring), and close out phase (Data Bases Lock, Reporting, Clinical Study Report), the fellow will have access to all stages across (potentially) different ongoing trials to learn and gain exposure to the full trajectory of a clinical trial. The successful fellow possess a strong academic interest, flexibility, an eye for detail and acumen to ask critical questions, desire to learn from others and share experiences, and an entrepreneurial spirit.
Luxembourg Institute of Health (LIH)	2	Luxembourg-city, Grand Duchy of Luxembourg	Competence Center in Methodology and Statistics	Data Management of clinical data, statistical methodology and analysis of clinical trials and epidemiologic studies	This training focuses on principles and concepts related to the conduct of clinical data management and the different types of epidemiological study design and clinical trial designs. The training covers Overview of Clinical Data Management in the Regulatory and Quality Context, CDM Personnel Component, Computerized Systems, Developing Case Report Form, Development of CDM Plan and Database Design, CRF Receipt, Data Entry and QC of Data Entry, Data Verification, Data Validation, Database Lock, Transfer and Exporting, Aspects Related to MedDRA Coding and CDM, CDM Report, Listings, Tables, Figures and Statistical Analysis.Planning of studies with different designs will also be part of the training. Methodology of the statistical analysis will be learned from descriptive statistics of population/sample characteristics and study parameters to so-called but important univariate analysis. Statistical methods will also be addressed and depending on the project some methods will be applied. A personal project will be discussed with the home and host institutions supervisor. This personal project will include methodology, statistics and publication writing that will lead

					to the submission of an article before the end of the fellowship.
Medicines for Malaria Venture (MMV)	1-2	Geneva, Switzerland	Medical, Translational or Product Development department	Anti-malarial drug development	The main goal for the placement is to acquire knowledge, experience and to develop skills for conducting clinical research, clinical trials from phases IIa to phases IV, related to tropical diseases, especially malaria. The work will be focused on the preparation, initiation then safety follow-up of the on-going studies in collaboration with the studies' partners. The candidate should ideally be an MD with knowledge in infectious diseases, tropical diseases or malaria, with special interest in safety and pharmacovigilance. As malaria is a disease affecting mostly children and pregnant women, pediatricians and/or gynecologists/obstetricians are especially encouraged to apply. The candidate could also be a scientist or public health specialist with knowledge in the processes of disease endemic countries Ethical Committee review and Regulatory Authority review.
Members of the Institut Pasteur International Network Association	8	1 fellow in Paris, France and in Dakar, Senegal; 1 in Yaoundé, Cameroon; 1 in Antananarivo, Madagascar; 2 in Ho Chi Minh City, Vietnam and 2 in Phnom Penh, Cambodia, 1 in Rio de Janeiro. Possible other locations to be defined	Institut Pasteur, Paris-France; Institut Pasteur Dakar-Senegal; Centre Pasteur Cameroon ; Institut Pasteur Madagascar ; Institut Pasteur Ho Chi Minh City-Vietnam ; Fiocruz Rio de Janeiro-Brazil	Infectious diseases, in particular on : - Hepatitis B vaccination - Measles immunization in HIV patients - TB diagnostics - Malaria treatment - Pneumococcal vaccination - Hepatitis B and TB prevention and treatment - HIV treatments	The training programme proposed by members of the Pasteur International Network Association include: • Elaboration of the Clinical Development Plan • Study preparation: study design, concept and main protocols; case report forms, informed consent and logistics • Study implementation: pre-study contacts, study initiation, monitoring • Study reporting: data validation, study reports, scientific communication • Administration and documentation: filing, tracking, financial agreement • Project planning and monitoring, including human and financial resources management • Review of the scientific literature, knowledge of operating standard procedures, ICH and GCP guidelines.
Merck	1	Switzerland, Germany or USA	Research & Development of the biopharma sector in	Drugs, devices and diagnostics with a focus on schistosomiasis and	The fellow's work would be focused on R&D programmes for health solutions in infectious diseases, from a clinical standpoint. Placed in the R&D/Global Health organisation to work on programmes under

			the healthcare business	malaria	the Global Health team's responsibility, the fellow will become a team member of selected R&D projects targeting schistosomiasis and malaria. In particular, to contribute to the scientific and clinical discussions for strategy and plan, and to prepare clinical study-related documents (e.g. protocols and reports). By working closely with global project teams, the fellow will learn aspects around governance, leadership and project management as well as clinical best practices, clinical trial set up and execution across all phases (I-IV) of clinical development. Through his/her clinical-related expert profile, he/she will also gain scientific and technical know-how and experience through exchanges at all levels at Merck and with external partners. In addition, the fellow will participate at Internal Learning & Development trainings, including modules on biostatistics and data management, design and conduct of clinical trials, registration process, integrated product development, portfolio management and marketing, that should be beneficial to the fellow's career while enhancing, more broadly, local capabilities.
Novartis Institutes for BioMedical Research (NIBR) & Novartis Pharma	2	Basel, Switzerland	Clinical Sciences and Innovation department of the Novartis Institutes for BioMedical Research (NIBR) and Novartis Global Drug Development (GDD)	Clinical Sciences and Innovation department of NIBR: focus on the operational aspects of early phase clinical trials in various therapeutic areas including anti-infectives Global Drug Development (Established Medicines and Infectious Disease Development) of Novartis Pharma: supporting the development of novel antimalarial compounds as part of therapeutic and/or prophylactic regimens	In NIBR, the fellow will be involved in the planning, management and evaluation of early phase clinical trials (Phase 1 and 2a). Specifically for early phase clinical trials: the fellow will gain knowledge on the scientific concepts and clinical trial designs, acquire expertise and understanding in clinical pharmacology clinical trials operations, study and site management, learn PK/PD and safety data analysis relevant to early phase clinical trials, develop skills in clinical study reporting (clinical study reports, briefing books, and Investigator's Brochure [IB]). At Novartis Pharma AG, Established Medicines & Infectious Diseases Development the candidate will receive a specialised training programme on Clinical Trials in Infectious Diseases with a focus on Tropical Medicines. Working with the Malaria Development Teams he/she will be involved in a variety of activities tailored to their career development needs and the stage of our assets during their time with the team. Potential activities include the design and implementation of Phase 2 or 3 multinational Clinical Trial programme(s), writing or updating of the clinical trial protocol, IB and Microbiology Manual, finalisation or interpretation of the

					results from the study's Statistical Analysis Plan, clinical input into Country & Site Selection, implementation of activities with a Clinical Research Organization, ongoing study clinical data review, preparation for Investigators' meetings, and ongoing integration into the Core Clinical Study team.
Sanofi Pasteur	1	Mexico City, Mexico	Clinical Science	Planning and development of clinical trials	The selected fellow should play an active role in all aspects of planning and development of clinical trials related to the platform in Latin America, including analysis of epidemiological scenarios of main public health diseases that could be possible targets in the vaccinology area. During this period, the fellow will be part of the activities of the platform, including the scientific basis of the projects, the development of the protocol, collaboration in the selection of possible sites for studies with respective interaction with principal investigators responsible, ethical committees and health authorities. All activities will take place under the menthorship of a senior regional director of clinical science and the collaborative work of other members of the clinical development department in Latin America and other global regions.
Swiss Tropical and Public Health Institute (Swiss TPH)	1	Basel, Switzerland	Medicines Research	Conduct and monitoring of clinical trials with emphasis on poverty-related diseases in low resource settings	The training programme will include all aspects of GCP in theory and practice, and managerial and monitoring of clinical trials including safety reporting. A successful candidate will have a background in medicine or a relevant life science field (MSc, PhD) and is interested to spend his future career in the area of medicines development and/or clinical trial development and speaks English. French is an asset.