EDCTP

TDR For research on diseases of poverty
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2017 Call for Proposals

EDCTP-TDR Clinical Research and Development Fellowships

Call Identifier: TMA2017IF

The purpose of this Call for Proposals is to provide funding towards actions that aim to support researchers and key members of clinical trial research teams from sub-Saharan Africa (SSA) to acquire specific skills in clinical trials research through placements in pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs. The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are currently working on activities in the scope of the EDCTP2 programme.

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2017 Call for Proposals – EDCTP-TDR Clinical Research and Development Fellowships
List of host organisations

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
European Vaccine Initiative (EVI)	2	Heidelberg, Germany	EVI Headquarters: Project Management Unit	Project management in vaccine development	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/Good Manufacturing Practice (GMP) production of vaccine, preclinical testing, filing the investigational medicinal product dossier (IMPD), defining and implementing early phase clinical development for demonstrating proof-of-concept, selecting and managing sub-contractors (Contract Manufacturing Organisations(CMO)/Clinical Research Organisations (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	Clinical research: diagnostics development and clinical trialling leading up to an expert review by the World Health Organization (WHO)	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 Clinical Research and Development 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	Global Health R&D	Late stage clinical development	The clinical development section of the GSK Global Health R&D Unit is mainly based in Stockley Park, UK. Having hosted four previous fellows, we understand the training we offer in medicine discovery to development and post-licencing needs to be tailored to the needs of the successful candidate to prepare them for a higher career in clinical research. Thus, access to learn from our dedicated discovery groups (e.g. TB & malaria), regulatory and manufacturing colleagues is as important as the exposure to time spent with our clinical trials teams. In addition, recent fellows have honed their management and leadership skills – key areas of focus for reintegration. We look forward to hosting our next fellow.
GlaxoSmithKline Global Health Catalyst Team (Africa NCD Open Lab)	2	Stevenage, United Kingdom	Global Health Catalyst Team (Africa NCD Open Lab)	The mechanistic underpinnings of dual disease burden, with a focus on the link between infectious diseases and non-communicable diseases in LMICs; Enteric Infectious Diseases; Respiratory Infections; Determinants of TB	The successful fellow will be physician (MD) or scientist (Masters or PhD) with at least four years of clinical or research experience. Physicians who obtained an MD degree as their primary medical qualification should show evidence of post-graduate research activity such as research publications and or formal research training (e.g. MRes, MPH, MSc, PhD). The final curriculum/programme will focus on a specific project within any of the broad Global Health catalyst themes of interest. The projects will be adapted and tailored to the individual fellow and GSK's expertise. Depending on the fellow's needs and/or interest, the programme will seek to provide the following additional

				treatment response, and association with chronic lung diseases; Asthma in children and Adolescents	competencies including, but not limited to: • Understanding epidemiological approaches to assessing disease burden • Understanding mechanistic approaches of interrogating infectious disease aetiology, manifestation, complication and treatment response in sub-Saharan Africa • Understanding drug discovery and development approaches with an emphasis on methods used in tackling neglected tropical diseases • Learning and/or consolidating skills in good clinical practice, good laboratory practice training and medical ethics • Formulating research questions and scientifically robust study design • Enhancing biostatistics capabilities for early and mid-career researchers • Data management and data integrity • Skills in research publication with impact.
GSK Biologicals	3	Wavre, Belgium	Clinical Research and Development department or Vaccine Clinical Safety and Pharmacovigilance department	RTS,S malaria vaccine/ vaccine projects in accordance with global legal and regulatory frameworks	The successful candidate in clinical research and development will work on the candidate RTS,S vaccine development under the supervision of the clinical research and development lead. The candidate will work in a team to implement a clinical development plan in accordance within a legal and regulatory framework. The candidate will also develop skills in pharmacovigilance, project management, regulatory compliance and good practices that will be useful in the oversight of human research. The successful candidate in Clinical Safety and Pharmacovigilance will work in a team under the supervision of the lead Safety Evaluation and Risk Management Physician. The candidate will contribute to the safety monitoring of assigned GSK vaccine(s) and will be taught skills and processes for effective pharmacovigilance during clinical trials and after vaccine approval, as well as reporting vaccine safety information to the appropriate legal and regulatory

					entities.
International AIDS Vaccine Initiative (IAVI)	1	London, United Kingdom	Human Immunology	Advanced laboratory skills, GCLP compliance, laboratory quality systems and safety procedures	The fellow training programme at IAVI is aimed at providing a learning environment at the forefront of vaccine development with access to cutting-edge innovative clinical technologies. Activities include learning advanced laboratory skills, GCLP and laboratory Quality Systems, immunology training, quality assurance/best practice principles and procedures; with opportunity to gain knowledge on multi-country Clinical Research in Africa with a short on-site learning experience. The Fellow will work closely with clinical, laboratory and program staff across the organisation. The Fellow will have exposure to the full trajectory of a clinical trial, interacting with vaccine development and biomedical experts in a multi-cultural environment. The applicant will have an advanced degree in health sciences such as immunology, virology, biology or a related academic background. Successful applicants would have prior experience in clinical trials with good clinical skills and who seek to expand their professional research skills and knowledge in laboratory work, clinical/lab data management, quality systems and working in a global scientific network of clinical vaccine research with researchers and industry partners from around the world motivated to end the AIDS epidemic.
Infectious Diseases Data Observatory (IDDO) and the WorldWide Antimalarial Resistance Network (WWARN) at the University of Oxford	4	Oxford, United Kingdom	Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine, University of Oxford	Infectious diseases affecting LMICs	The Infectious Diseases Data Observatory (IDDO) brings together clinical, laboratory and epidemiological data to answer specific scientific and operational questions relating to selected poverty related diseases and emerging infections. IDDO is building upon the success of the WorldWide Antimalarial Resistance Network (WWARN), a scientifically 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 and governance 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 Oxford, UK with the possibility of short periods spent at our overseas research units in: Thailand (focus on pharmacology and pharmacometrics); Laos (focus on medicine quality); South Africa (focus on pharmacology) and; Darwin, Australia (focus on *P.vivax* malaria).
Janssen Pharmaceutica N.V.	1	Beerse, Belgium	Global Clinical Development Operations (GCDO), Infectious Diseases and Vaccines (ID&V)	Development and execution of clinical trials for HIV/AIDS, Tuberculosis, vaccines development (Ebola, HIV) or other neglected tropical diseases of relevance to the Janssen portfolio	Janssen has a growing interest in clinical trial execution in sub-Saharan Africa due to its evolving portfolio and has interest to help build, through this fellowship programme, strong foundations for clinical trial excellence in the region. The objective is to provide the fellow opportunities to gain knowledge and practical expertise in many aspects of a clinical trial. The fellow will become member of a global clinical operational team to conduct clinical trials in the sub-Saharan African region related to HIV/AIDS, Tuberculosis, Vaccines development (Ebola, HIV) or other neglected tropical diseases Janssen supports in collaboration with partners. The Fellow will be in charge of pre-feasibility of protocols to be conducted in the region, identify investments to be made/gaps in terms of regulatory framework, capacity building (infrastructure/resources) and make proposals for operational readiness of investigational sites and countries. The fellow will be involved in region specific quality oversight issues, is expected to actively build relationships/network with local stakeholders (academia, NGOs, local CROs or other development

					partners) and regulatory bodies in various countries of SSA and build a framework for operational excellence. He will be involved in internal decision making related to portfolio decisions for placement of trials in certain countries and provide input related to CRO selection to support the trial.
Julius Clinical	2	Zeist, Netherlands	Clinical Operations, Data Management, Regulatory, Clinical Support, Safety and Pharmacovigilance, and Science & Business Development	Phase II-IV clinical trials	Julius Clinical is a scientific contract research organization dedicated to the preparation and conduct of 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 effective. 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.
Novartis Institutes for BioMedical Research (NIBR)	1	Basel, Switzerland	Clinical Sciences & Innovation	Translational medicine: operational planning, management and evaluation of early phase (Phase I/Phase IIa) clinical studies	The Fellow will be involved in the operational planning, management and evaluation of early phase (Phase I/Phase IIa) clinical studies, under the assigned mentors at the Clinical Sciences and Innovation department in Translational Medicine, Novartis Institutes for BioMedical Research. These clinical studies are designed to profile safety, tolerability, pharmacokinetics, and pharmacodynamics of novel compounds to provide their early

					proof of efficacy in humans. Objectives of the training will include: • To understand the clinical trial process and its milestones, focusing on operational aspects, from set-up to reporting; • To understand the Sponsor's organization and expectations from an Investigator, to foster future collaborations; • To understand the scientific background of clinical trials and how results from a clinical trial directly impact the labelling/scientific development of a compound.
Novartis Pharma AG	2	Basel, Switzerland	Global Drug Development/Anti-infectives	Clinical research and development processes related to the global development of new anti-infective/tropical disease molecules	The training programme will help the fellow to acquire specific skills in global clinical research and development processes. The programme will include experience building and training on study designs including protocol development, operational aspects of clinical trials in different phases (I-IV), statistical skills, personal efficacy in a team-based/networked environment, patient safety monitoring, Good clinical practice and ethical principles, data management, monitoring and analysis, Quality Assurance and Quality Control, general communication and other skills. The fellow should have an academic background in one of the life-sciences (preferably medicine, but related sciences considered as well) with practical experience in a clinical development setting in the region of origin. In addition the fellow should possess adequate English language skills, both in speaking and writing.