Clinical Research and Product Development Fellowships (CRDF)

List of host organisations for 2019 Call for Proposals*

**EDCTP eligible organisations only*

TDR For research on diseases of poverty

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2019 Call for Proposals – Clinical Research and Product 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, candidate profile, training competencies and practical information*
Drugs for Neglected Diseases initiative (DNDi)	1	Geneva, Switzerland	R&D department (NTDs initiative)	Clinical research projects of the filariasis program, in different stages of development	The main training objectives will be: • 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 • Support 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. Language and estimation of living costs*: The working language will be English. The living costs in Geneva is around 5400 CHF per month (e.g., rent 2000 CHF, insurances 400 CHF).
European Vaccine Initiative (EVI)	2	Heidelberg, Germany	EVI Headquarters: Project Management Unit	Project management in vaccine development	The overall objective of the training offered by EVI is to facilitate critical decision-making in vaccinology by providing fellows with an overview of the field, from antigen discovery to vaccine development and clinical trials including the regulatory and ethical requirements for the clinical development of vaccines. Specific objectives are 1) to learn the practical aspects of managing vaccine development, in both pre-clinical and clinical stages, 2) to address the financial, legal and intellectual property management of vaccine projects, and 3) to participate in the fundraising for product development. Training will be provided through workshops,

					seminars, conferences, as well as hands-on activities (learning by doing). The fellows will be working on one or several projects on vaccines for diseases of poverty or emerging infectious diseases. Fellows will be integrated in the project team, and will contribute to the management of the projects, including aspects on e.g. process development/GMP production of vaccines, preclinical testing, filing the regulatory dossier IMPD, defining and implementing early phase clinical trials for demonstrating proof-of-concept, selecting and managing sub-contractors CMOs/CROs, monitoring the quality of the partners and subcontractors, writing scientific reports and publications, writing grant applications, and participating in communication and dissemination activities. The fellows should have an academic background with an interest in infectious diseases, in particular diseases of poverty and emerging infectious diseases. Successful applicants would have prior experience in clinical trials and seek to expand their professional skills in project management and vaccine development. In addition, the fellow should possess adequate English language skills, both in speaking and writing. Language and estimation of living costs*: the working language will be English. The living costs in Heidelberg may vary depending on expectations, but estimated costs per months are: rent for a furnished studio (€600), health insurance (€300), internet/mobile phone (€50), public transport ticket (€50), food, warm clothes, etc. (€500-1000).
Foundation for Innovative New Diagnostics (FIND)	1	Geneva, Switzerland	Scientific Departments	Clinical research	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 with 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.
GSK Global Health Unit	1	London, UK	Global Health Pharmaceutical Unit	Drug development programmes, including early and late phase clinical trials for potential new medicines for tuberculosis, leishmania and malaria	<u>Competencies:</u> Technical and scientific proficiency in English language. <u>Candidate profile:</u> • Some clinical trial experience would enable the candidate to maximise their learning potential • Familiarity with malaria or tuberculosis preferable • Some prior involvement with academic research or publication would be useful • Able to work alone and in teams • Adaptable and organised • Leadership skills or leadership potential • Must be able to demonstrate how this placement will fit into their overarching career path and how the experience will benefit their local health ecosystem. <u>Training objectives:</u> These can, to some extent, be tailored to the wishes of the candidate within the framework of clinical drug development for tuberculosis, malaria and leishmania. The unit has expertise in the design, operation, management and reporting of clinical trials in both high (early phase) and low (late phase) resource settings and project management, including in public-private partnerships.

					There may be the ability to spend limited time gaining experience in clinical trial regulatory, pharmacology and modelling, drug discovery and manufacturing areas, but these should not be the focus of the candidate's objectives. There would not be a significant laboratory component, though limited placements in toxicology or in-vitro/in-vivo efficacy may be possible. HIV is not within scope of the Global Health Unit within GSK pharmaceuticals, nor is vaccine development. Language and estimation of living costs*: The working language will be English. The UK is a high-income country and living cost in London are higher than the rest of the UK.
GSK Biologicals	3	Wavre, Belgium	Clinical Research and Development department or Vaccine Clinical Safety and Pharmacovigilance department	Management and evaluation of risks associated with assigned vaccines in accordance with legal and regulatory framework	The successful candidate(s) in Clinical Research and Development will work in a team and be involved in all aspects of clinical development of an assigned vaccine. The candidate will develop skills in clinical trials oversight, project management, GCP, regulatory compliance and pharmacovigilance which will be useful in the oversight of human research. The successful candidate(s) in the Vaccine Safety and Pharmacovigilance department will work in a team and actively contribute to the safety monitoring of assigned GSK vaccine(s). The candidate(s) 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. The working language will be English.
Infectious Diseases Data Observatory (IDDO)	4	Oxford, United Kingdom	Centre for Tropical Medicine and Global Health, Nuffield Department of	Poverty related infectious diseases and emerging infections affecting low and middle-income countries, in particular the disease portfolio of	IDDO brings together clinical, laboratory, health and epidemiological data to answer specific scientific and operational questions relating to selected poverty related infectious 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

			Medicine, University of Oxford	malaria, visceral leishmaniasis, schistosomiasis, soil transmitted helminths, melioidosis or Chagas.	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 infectious 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.
International AIDS Vaccine Initiative (IAVI)	1	London, UK	IAVI Human Immunology Laboratory (HIL)	Advanced laboratory skills; activities include learning on GCLP compliance and laboratory Quality Systems as well as laboratory safety procedures	The IAVI-HIL will support the training of scientists or clinicians who wish to extend their knowledge of laboratory techniques for research and processes to support clinical trial operations, assessments and quality requirements. The candidate will receive training in advanced laboratory research techniques including high dimensional flow cytometry, viral inhibition assays, epitope mapping and next generation sequencing technologies. The placement will also include development of skills to assess immune responses in clinical trials, potentially including assay development and validation, assay transfer, and conduct of assays for clinical trials to GcLP standard. The project will support on-going immunology activities within the department and may include assay development and validation for clinical trials, technology transfer of clinical assays, conduct of immune assays to GcLP standard for clinical trials, research-based projects using advanced techniques such as multi-dimensional flow cytometry, Viral Inhibition Assays and Next Generation Sequencing and participation in project team meetings, as appropriate. The preferred candidate will have a keen interest in laboratory processes and techniques, with a particular interest in IAVI's

					mission. Previous laboratory experience would be advantageous, but not essential. Clinicians with an interest in conducting clinical trials and developing an understanding of laboratory processes will also be considered.
Novartis Institutes for BioMedical Research (NIBR)	1	Basel, Switzerland	Clinical Sciences and Innovation Department	Operational aspects of early phase clinical trials in various therapeutic areas	At Novartis Institutes for BioMedical Research (NIBR), the fellow will be involved in the operational planning, management and evaluation of early phase clinical trials (Phase 1/2a). These clinical studies are designed to profile safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of novel compounds and to provide their early proof of efficacy in humans. The fellow will gain knowledge on the scientific concepts and clinical trial designs, the clinical trial process and its milestones, study and site management, PK/PD and safety data analysis relevant to early phase clinical trials, and clinical study reporting. The working language will be English.
Novartis Pharma AG	1	Basel, Switzerland	Novartis Global Drug Development (GDD) – Global Health Development Unit	Development of novel antimalarial compounds or lifecycle adaptive development as part of therapeutic and/or prophylactic regimens	At Novartis Global Drug Development (GDD), the fellow will receive a specialized training programme on clinical trials in Tropical Diseases with a focus on Malaria where we have a number of active studies ongoing or due to start in the next year. Working with the Malaria Development Team, 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 program(s), writing or updating of the clinical trial protocol, Investigator Brochure (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. The working language will be English.

*Practical information such as estimation of living costs in a certain country is provided to guide applicants when preparing the budget as part of their application to EDCTP.