2018 Call for Proposals

Clinical Research and Product Development Fellowship scheme – list of potential host organisations (for placements funded by EDCTP)

2018 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 and candidate profile
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. 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 or emerging infectious diseases. 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 publications, grant applications, and participating in communication and dissemination activities. The training will be provided through workshops, seminars, conferences, as well as hands-on activities (learning by doing). 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.
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.
GSK Biologicals	3	Wavre, Belgium	Clinical Research and Development department or Vaccine Clinical Safety and Pharmacovigilance department	Clinical development of the RTS,S malaria vaccine / management and evaluation of risks associated with vaccine projects in accordance with global legal and regulatory frameworks.	The successful candidate(s) will have an opportunity to work at GSK Biologicals Clinical Research and Development department where they will be involved in all aspects of clinical development of the RTS,S malaria vaccine or in the Vaccine Safety and Pharmacovigilance department where they will be actively involved in the management and evaluation of risks associated with assigned vaccine projects in accordance with global legal and regulatory frameworks. The candidates will develop skills in clinical trials oversight, project management, GCP, regulatory compliance and pharmacovigilance which will be useful in the oversight of human research.

Infectious Diseases Data Observatory (IDDO) and the WorldWide Antimalarial Resistance Network (WWARN) at the University of Oxford	4	Oxford, United Kingdom and Bangkok, Thailand	Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine, University of Oxford	Infectious diseases affecting LMICs.	IDDO brings together clinical, laboratory and epidemiological data to answer specific scientific and operational questions relating to selected neglected poverty related diseases and emerging infections. IDDO is building upon the success of 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 neglected 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 our overseas research unit in Thailand (focus on pharmacology and pharmacometrics).
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.
Novartis Institutes for BioMedical Research (NIBR)	1	Basel, Switzerland	Clinical Sciences & Innovation	Operational aspects of early phase clinical trials in various therapeutic areas (including anti-infectives).	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 scientific concepts and clinical trial designs, the clinical process and its milestones, study and site management, PK/PD and safety data analysis relevant to early phase clinical trials, and clinical study reporting.
Novartis Pharma AG – Global Drug Development (GDD)	1	Basel, Switzerland	Global Drug Development (GDD)	Supporting the development of novel anti-malarial compounds or lifecycle adaptive development as part of therapeutic and/or prophylactic regimens.	The fellow will receive a specialised 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 within the team. Potential activities include the design and implementation of phase 2 or 3 multinational clinical trial programmes, writing or updating of the clinical trial protocol, Investigator Brochure (IB) and Microbiology Manual, finalization of interpretation of the results from the study's Statistical Analysis Plan, clinical input into country and site selection, implementation of activities with a Clinical Research Organisation, ongoing study clinical data review, preparation for investigators' meetings, and ongoing integration into the Core Clinical Study team.

Takeda Pharmaceuticals AG	1	Zurich, Switzerland	Vaccines Business Unit	All aspect of Vaccines Clinical Development, particularly clinical development on viral vector transmitted diseases (Dengue, Zika), Norovirus vaccine development, including trials of different phases I, II and III.	The applicant will have the opportunity to participate in all activities of the clinical team for a clinical programme – including, but not limited to, development of all clinical documents (e.g. clinical study protocols, clinical study reports, clinical development plans, submission documents (if applicable)) and will be included in medical oversight of clinical trials. In addition, the applicant will be able to gather knowledge with the support of the biostatistics team, the epidemiology team, the clinical serology team and other parts of the clinical development team at Takeda VBU. Cross functional interaction and participation in cross functional teams (e.g. clinical program or study teams) will be part of the fellowship. The candidate will be assigned relevant tasks to apply the knowledge acquired. Preferred profile: MD, interest/experience in Vaccinology, public health interest, paediatric and/or infectious disease specialisation.