DETAILS ABOUT THE PLACEMENTS

**European vaccine Institute (EVI), Heidelberg, Germany**

The overall objective of the training offered at 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 fellow will be working on one or two projects on vaccines for infectious diseases of poverty or emerging infectious diseases. The fellow 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 publications, writing grant applications, and participating in communication and dissemination activities. Training will be provided through workshops, seminars, conferences as well as hands-on activities (learning by doing). Fellows will be placed at the EVI Headquarters in Heidelberg, Germany, focusing their work on project management in vaccine development.

**Foundation for Innovative New Diagnostics (FIND), Geneva, Switzerland**

Diagnosis is the first step on the path of treatment and the foundation of disease control and prevention. As such, FIND has led the delivery of a number 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 training knowledge and insights 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 diagnostics tests.

**FIOCRUZ, Rio de Janeiro, Brazil**

The fellows will be placed in the Clinical Research Platform of the Vice-Presidency of Research and Biological Collections (VPPCB)/Fiocruz focusing their work on clinical trials, controlled and randomized, phases 2 or 3, involving neglected diseases, such as, malaria, chikungunya, Chagas disease, mucosal leishmaniosis, cutaneous leishmaniosis. Currently, the Clinical Research Platform core team is composed of 13 coworkers fitting the following roles: 01 Coordinator, 05 Clinical Project Managers, 01 Quality Assurance Manager, 06 Clinical Research Associates (CRA), 01 Clinical Data Manager, 01 Clinical Data Assistant, 01 Communication Manager and Educational Manager, 01 Pharmacovigilance Manager, 01 Pharmacovigilance Assistant. The team may get larger as other collaborators, such as additional CRAs and statisticians, are hired on-demand for specific clinical projects. Our Clinical Research Platform-VPPCV/Fiocruz team coordinates relevant initiatives in
Fiocruz, like Fiocruz Clinical Research Network and Fiocruz Biobank Network, and is supporting 27 clinical trials. Moreover, since 2011, we have been coordinating a post-graduation course for training Clinical Research Associate at Fiocruz. TDR fellows might join some modules. Fiocruz is a renowned research excellence in Latin America and can provide a good experience for the fellows’ professional careers.

**GSK Biologicals, Wavre, Belgium**

The successful candidate will have the opportunity to work at GSK Biologicals Clinical Research and Development department where they will be involved in all aspects of 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.

**Infectious Diseases Data Observatory (IDDO), Oxford, UK**

The Infectious Diseases Data Observatory (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 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, 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).

**Infectious Diseases Research Institute (IDRI), Seattle, USA**

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 characterization 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 characterization 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.

**Institut Pasteur de Madagascar, Antananarivo, Madagascar**

1- The research fellow will work on plague and integrate a team conducting a non-inferiority randomized efficacy trial for bubonic plague performed with the collaboration of the University of Oxford, the Central Laboratory for Plague at IPM, and the University Hospital in Antananarivo. This will give him/her the opportunity to learn about the methodology of such trial, the operational aspects and the analyses and reporting of such trials. The research fellow will be mostly based at the IPM, but might have the opportunity to travel abroad (UK). In addition, he/she will participate in the different trainings and conferences organized by IPM and the International Network of the Pasteur Institutes. He/She might contribute to other studies as the trial will take 50 to 70% of his/her time, according to the study stage. Native English speakers are welcome, French lessons will be organized to facilitate integration such as accommodation based at the IPM campus. E-learning training for Good Clinical Practices will be available using the Global Health Network.

2- The Mycobacteria Unit and the Unit of Epidemiology and Clinical Research at IPM are involved in several operational research projects on pediatric tuberculosis. While young children are the most vulnerable to tuberculosis (TB), existing TB diagnostic tests are unreliable and not suitable for children. Different blood tests are recommended or meet WHO quality standards to measure either TB infection (Quantiferon) or to diagnose the disease (3GqPCR). The objective of this project is to determine which biological tests to detect TB disease or infection in children are the best. Given the difficulty of collecting venous blood in children, the alternative of using capillary blood by "Dried blood spot" seems relevant. The TDR-EDCTP fellow will participate in the establishment and evaluation of the use of DBS for Quantiferon and 3G-PCR testing from the capillary blood that will be collected in children.

**ISGlobal, Barcelona, Spain**

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 one or more clinical trials, or clinical studies conducted by the institution, in close collaboration with its partners in Mozambique (Centro de Investigacao em Saude de Mahinca). The programme would also include the possibility to participate in field activities to be defined by the project PI, in Mozambique, for a period of 2 months (extensible if required). Examples of clinical trials could include the evaluation of the safety and efficacy of new anti-malarial or ancillary treatments, or other antimicrobial drugs; or, if possible, the clinical development and evaluation of new vaccines against infectious diseases. Fellows will also get involved in the safety monitoring unit, in the process of being developed at ISGlobal and tasked with the monitoring of the safety of clinical trials conducted in the field. Alternatively, the candidate would be able to participate in clinic-epidemiological studies in pediatric infectious diseases, including malaria, pneumonia, meningitis 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 master of Global Health or Clinical
Research, as well as other short courses offered by ISGlobal in collaboration with the University of Barcelona.

**International Vaccine Institute (IVI), Seoul, South Korea**

IVI is committed to supporting and mentoring a young scientist from a low- or middle-income country to oversee clinical trial conduct at different steps of development including SOPs and ICH-GCP principles trainings.

**Janssen Pharmaceutica NV, Beerse, Belgium**

Janssen has a growing interest in clinical trial execution in sub-Saharan Africa (SSA) 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 trials. The fellow will become member of a global clinical operational team to conduct clinical trials in the SSA 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.

**LIH-Competence Center for Methodology and Statistics, Luxembourg**

The goal of the training is to learn about clinical data management processes and their implementation, the concept of statistical analysis data and the use of “R” to carry it out.

The specifics objectives are:

1. Clinical data management in the regulatory and quality context:
   - Case Report Form (CRF) creation with Ennov Clinical
   - Code book creation with Ennov Clinical
   - Data base creation with Ennov Clinical
   - Entry data with Ennov Clinical
2. Methodology and statistical univariate and multivariate analysis:
   - Statistic initiation with R
   - univariate analysis with R
   - multivariate analysis with R
**Novartis Institutes for BioMedical Research, Basel, Switzerland**

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.

**Novartis Pharma AG, Global eDevelopment Drug (GDD), Basel, Switzerland**

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.

**Swiss TPH, Basel, Switzerland**

One of the aims of the Swiss TPH Department of Medicines is to contribute to bridging the “translational gaps” in the R&D-process of medicines targeted at populations in resource limited economies. Its role is mainly the provision of resource efficient services in clinical trials, training related to clinical research and participation in academic research collaborations. The Clinical Operations Unit (formerly PMU) is the academic contract research organization in the last 15 years at the Swiss TPH. It contributed to clinical trials in malaria (vaccines and drugs), tuberculosis (vaccines, drugs and diagnostics), human African trypanosomiasis (drugs), helminthic diseases (drugs), Ebola (vaccines) and other infectious diseases (vaccines and drugs). Services range from clinical trial management to selected contributions for site selection, design, organization, conduct, and/or monitoring of clinical trials. The focus is on poverty related and tropical diseases in low resource or industrialized countries. The new Medicines Implementation Research Unit strives to overcome bottlenecks in bringing interventions to the patients, and the Clinical Research Unit is the academic clinical research center of the Swiss TPH as it contributes to the advancement of medicinal products through innovative investigator initiated trials.

The training programme will include all aspects of GCP in theory and practice, projects and quality managerial aspects of clinical trials, including safety reporting and ethical considerations. A successful candidate will have a background in medicine or a relevant life science field (MSc / PhD), is interested to spend his future career in the area of medicines development, clinical trial operations or clinical research and speaks English, French is an asset.
TAKEDA Pharmaceuticals International, Zurich, Switzerland

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 programme or study teams) will be part of the fellowship. The candidate will be assigned relevant tasks to apply the knowledge acquired.

Triclinium Clinical Development, Tygerberg, South Africa

As a full-service Contract Research Organization, TCD can offer aspiring clinical investigators a mentored hands-on rotation in activities, including study protocol development, clinical site set-up and evaluation, compilation of regulatory and IRB applications, project management, data management, medical monitoring, pharmacovigilance, quality assurance and medical report writing to international standards. He/She would also spend time with monitors at well-established research sites and observe the practices of experienced principal investigators and site staff.