Médecins Sans Frontières (MSF), an international medical humanitarian organization created in 1971, provides medical assistance to populations facing life-threatening crises. Mainly focused on areas of armed conflict, MSF also works in epidemic outbreaks, natural disasters or situations of exclusion from healthcare. The French section of MSF works in some thirty countries.

EndTB trial, part of endTB project (Expand New Drug markets for TB), is an international multicentre randomized therapeutic trial to evaluate short, oral drug regimens for treatment of multidrug resistant tuberculosis. The trial is a collaborative project among Partners In Health (PIH, Boston USA), Harvard Medical School (HMS, Boston USA), Médecins Sans Frontières (MSF, Paris, France [OCP] and Geneva, Switzerland [OCG]), the Institute of Tropical Medicine (ITM, Antwerp, Belgium), Epicentre (Paris, France), and is funded by UNITAID. The trial will be implemented in Georgia, Kazakhstan, Kyrgyzstan, Lesotho, and Peru.

Mission and Responsibilities

The Clinical Trial pharmacist will bring an expertise in Investigational Medicinal Product (IMP) management, knowledge of the clinical trial regulations and drug safety and other relevant skills and experience to the implementation of an international multicentre randomized therapeutic trial. S/he will ensure that the trial complies with all applicable regulatory requirements pertaining to IMP manufacturing, handling and storage, including ICH-Good Clinical Practice (ICH-GCP), Good Manufacturing Practice (GMP), Good Pharmacy Practice (GPP) and relevant national guidance.

Position

This position is part of the Clinical Trial Team, which includes Central Principal Investigators, Co-Investigators, Clinical Trial Manager, Study Coordinator, Pharmacovigilance, and endTB Coordinating Pharmacist, at the Central level, hereafter called “Central Team”. At the Central Team, the Clinical Trial Pharmacist will work closely with the Clinical Trial Manager, MSF study coordinator, Central Principal Investigators, and PV officer. At site level the Clinical Trial Pharmacist will work closely with the trial site PIs, site study coordinators and site pharmacists. S/he will liaise with MSF Logistique in Bordeaux, France, and keep the Central Team apprised of
study drug inventory, projection, and ordering timelines. This position will be directly supervised by the endTB Trial Manager.

**Main Activities:**

**Prior to the start of the trial, the Clinical Trial Pharmacist will:**

**Study documents:**
- Develop all pharmacy-related study documents and forms (e.g. Pharmacy Plan, drug accountability logs, etc.)
- Develop SOPs relating to IMP management (e.g., reception, dispensing, accountability, return, destruction, etc.)
- Coordinate with MSF Logistique and endTB coordinating pharmacist to gather and make available to sites all essential documents pertaining to and necessary to permit importation of the IMPs (e.g. certificates of analysis, lot numbers, monetary values, GMP compliance certificates, etc.)
- When required, support the Central Team in finalising investigator brochures.

**Admin activities:**
- Ensure all structures, project plan and Gantt chart, guidance and documentation relating to the pharmacy activities for the trial are in place before initiation of the trial.
- Assist the endTB trial site in obtaining regulatory approval for importation of IMPs and other trial drugs
- Facilitate custom clearance when required

**Trial sites preparation:**
- Conduct pre-trial assessment of pharmacy facilities and resources available in trial sites and support site study coordinators and their team in upgrading them in compliance with ICH standards for clinical trials
- Support selection of site pharmacists in trial sites.
- In liaison with site study coordinators and site pharmacist, and MSF-Logistique, define which order/freight documents are required for drugs and medical items of the trial
- Support site study coordinators and site pharmacist to develop forecasts and define a schedule for orders/deliveries on site; inform the endTB Trial Manager, the endTB Coordinating Pharmacist and MSF Logistique accordingly
- Follow-up all drug and medical item orders for the trial
- In collaboration with MSF-Logistique, the sponsor, Central Team and site study coordinators and site pharmacist ensure the appropriate labelling, transportation, custom clearance and field delivery of all trial drugs (IMPs and non-IMPs).
- Provide training on IMP management to trial site teams

**During the conduct of the trial, s/he will be responsible for:**
- Assist site study coordinator and site pharmacist in ensuring optimal stock management of trial drugs (IMPs and non-IMPs) and other medical supplies, including follow-up of disposal of IMPs
- Assist site teams in troubleshooting problems that arise with storage, packaging, dispensation, return, destruction of IMPs and non IMPs
- Monitor trial drugs consumption and expiry (IMPs and non IMPs) in all trial sites and ensure trial teams place orders in a timely manner
- Organise regular trial site visits (at least 1 visit per site/year) to ensure compliance to endTB SOPs in terms of pharmaceutical management and to train new MSF staff joining the site trial teams

Qualifications

Required
- Registered Pharmacist with a pharmacy degree or higher
- Experience in (GCP-compliant) clinical trials
- Strong organisation and planning skills and experience in networking
- Deadline-adherent and adaptable
- Excellent interpersonal skills and a proven ability to gain buy-in and commitment from a range of people
- Proven experience of working independently under minimal supervision
- Fluency in written and spoken English
- Ability and willingness to travel and work overseas (up to 20% time)
- Ability to work with teams in different locations

Preferred
- Experience working as a pharmacist with MSF
- Experience working in or with resource-limited health systems
- Postgraduate training in clinical trials
- GCP certification
- Knowledge and understanding of the treatment options and challenges for TB and MDR-TB
- Understanding of the WHO pre-qualification program.

Conditions
- 3 years full time position
- Based in Europe with frequent travels to Bordeaux (MSF Logistique) and to the sites
  Occasional travels to Geneva, Boston and Paris
- Consultant position preferred

How to apply

Interested candidates should forward their cover letter and curriculum vitae to scollin@paris.msf.org, stating "Clinical Trial pharmacist" in the subject line.

The deadline for applications is August 9th included.