



## **Clinical Trials Operations Manager**

<b>Accountable to:</b>	Chair of EBMT PCTC (Prospective Clinical Trials Committee)
<b>Duration of Role:</b>	Initially 2 years, with the prospect of an indefinite contract subject to performance
<b>Location:</b>	London-based for at least the first 2 years
<b>Key Relationships:</b>	Prospective Clinical Trials Officer, PCTC, EBMT Board, Industry Advisory Group, Protocol Review Committee

### **Summary of the post:**

To provide expertise and direction to the EBMT Board; develop and implement management structure for administrative sponsorship requirements; support the execution of high quality international clinical trials, and to ensure the implementation of:

- ICH GCP
- Clinical Trials Directive (2001/20/EC)

The post holder will report to the PCTC and work to annual objectives as defined by the PCTC, in agreement with the Board and in consultation with the Industry Advisory Committee

### **Summary of responsibilities**

1. To develop and lead a broad management strategy for the conduct and sponsorship of international clinical trials (Phase II - IV) across multiple indications through the Working Parties, Clinical Trial Offices and through the use of internal resources or CROs.
2. To secure funding to support the Clinical Trials infrastructure and to develop collaborative initiatives with Industry and other organisations working in the field of haematopoietic stem cell transplantation.

3. To manage negotiations and contract agreements with Industry partners interested in running trials in collaboration with the EBMT.
4. To provide up-to-date expert advice to the Board on national and international legislative requirements for sponsorship and good conduct of academically-led clinical trials.
5. To assist the Board in its legislative responsibilities, by leading a small Clinical Trials Management team to oversee and audit all clinical trials sponsored by the EBMT under EU Directive requirements, to ensure (a) compliance with national laws and (b) effective execution of all assigned trials to meet project milestones, timelines and budget limits.
6. To lead the development of internal SOPs, regulatory and safety documents.
7. To work with the Prospective Clinical Trials Officer to identify, review, and propagate best practice among EBMT Clinical Trial Offices (London, Leiden, Paris), and implement efficient standardization among the offices.
8. Responsible for management of Clinical Trials budget in agreement with Executive Committee and in consultation with PCTC.
9. To act as a focal point for interaction with Industry Advisory Group, ensuring good practice is widely shared.
10. Travel nationally and internationally as required
11. Representing the EBMT at conferences and meetings as required

### **Person Specification**

1. Hands-on experience in top level management of clinical research in the academic and/or industrial setting

2. Thorough knowledge and understanding of national and international regulatory requirements and impact on development of academic phase II-IV clinical trials.
3. Excellent communication and negotiation skills.
4. Skilled in project and people management, with ability to successfully lead small multifunctional and multinational teams.
5. Excellent decision-making and organisational skills with the ability to work to, or re-negotiate, deadlines.
6. Must think critically and creatively and be able to work independently and determine appropriate resources for resolution of problems.
7. Is recognized as an expert in legislative requirements for clinical trial sponsorship both internal and external of the EBMT.

**Education and Experience Requirements** (E = essential, D = Desirable)

1. Requires MD, PhD or similar degree in a relevant scientific discipline (E)
2. Clinical background or equivalent, plus minimum 10 years relevant experience in clinical research (E)
3. Up-to-date knowledge of relevant regulatory guidelines for the sponsorship of academically led clinical trials (E)
4. Experience of International clinical trials (E)
5. Functional knowledge to initiate, author or contribute to SOP development, implementation, and training (E)

6. Experience with presentations at international meetings and before executive staff (E)
7. High level of English (E)
8. Computer literate (E)
9. Demonstrable ability to manage budgets (E)
10. Knowledge of the haematology and/or oncology field (D)
11. Experience of trials in a multi-professional environment (D)
12. Experience of submitting EU funding applications (D)
13. Foreign languages (D)
14. Flexible approach to hours worked (D)