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[CureHHT.org](http://CureHHT.org)

## HHT Therapeutic Background

Cure HHT is an advocacy Foundation created in 1991 to provide insight, disease management, directed research dollars and infrastructure to perform clinical trials for Hereditary Hemorrhagic Telangiectasia. The disease was originally named Osler Weber Rendu Syndrome in the early 1900's, a disorder now explained by known gene mutations. Our patients have an abnormal vascular development biology, which leads to bleeds from the nose and the gut, as well as blood flow changes in the liver, resulting in heart failure. While there is some reduction in survival in these patients, the most relevant symptoms are nose bleeds, striking anemia in addition to heart failure. These elements lead to a poor quality of life, among the nearly 1.5million people with this disorder globally. At this time there are no FDA approved, registered treatments, and the off-label pharmaceuticals are partially helpful and poorly studied.

Over the last several years, a biologic pathway has been discovered which when partially blocked leads to substantial benefits to the patient. One of those agents is a repurposed drug, now re-formulated, which is taken orally, and produced by our foundation. This molecule has demonstrated profound success in nearly all of the few patients given the product. We presented these data to the FDA, and achieved Breakthrough Designation. Further, our proposed clinical trial has also been recently funded.

Our program will have approximately 12 sites, and the expected study duration will be approximately 3 years, and incorporate multiple vendors such as a Clinical Research Organization, central laboratory, drug manufacturing, drug distributors, as well as virtual platforms. While a project manager will be assigned from the CRO, the sponsor actively seeks a senior Project Manager to oversee the operations of this program. Key to this effort, will be the seamless integration of all of these clinical partners, including the Cure HHT Foundation Board of Directors. A successful candidate will need to have both the background, and the soft skills to enable successful achievement of the project goals of completion, timeliness as well as budgetary constraints. The Cure HHT Project Manager will be a critical member of our team.

## **Project Manager Pharmaceutical Development Bleeding in Hereditary Hemorrhagic Telangiectasia**

Cure HHT (also known as HHT Foundation International) is a 501c not-for-profit organization, whose mission is to find a cure for the severe bleeding associated with a genetic vascular disorder Hereditary Hemorrhagic Telangiectasia (HHT). We are constructing the team to operate an intensive and exciting Phase II/ III study that will test a product that could limit the substantial anemia, use of transfusions and frequent, often daily nose bleeds that make the quality of life for the patients difficult and isolating. The FDA has provided our program with a Breakthrough Designation. We seek a project manager to join our group.

**Your responsibilities:** Your primary responsibility is for the operational delivery of this HHT study with respect to time, budget and quality. This includes:

- Oversight/management of the CRO
- Engagement and management of all vendors
- Responsibility for Trial Master File and all study level documentation
- Oversight and management of study drug distribution to sites/patients
- Ensuring compliance with ICH/GCP guidelines and all applicable regulatory requirements
- Integrating and communicating with study PIs, key contacts at the Foundation, study medical monitor and Study Executive Committee
- Contribution to planning of the NDA or additional studies that might be required in the future.

### **Knowledge, experience and required abilities:**

- Past experience in running a Phase III FDA regulated trial
- Experience in managing and coordinating projects and people
- Study management experience from planning/study start-up through final reporting
- Presentation capability, e.g. to a Foundation Board and Investigator Executive Board
- Ability to work independently and take accountability for ensuring delivery
- Experience in outsourcing and management of external vendors including quality control
- Experience as the single point of accountability for study budget
- Ability to handle stringent documentation requirements
- Understanding of ICH/GCP guidelines and regulatory requirements

### **Required Experience:**

- Bachelor's degree in life sciences or related discipline
- At least 5 years of experience in pharmaceutical industry or CRO, specifically in area of clinical operations

- Flexible, structured and goal-oriented team player
- Oral and written communication skills in English are necessary for the position.
- Salary commensurate with experience

**Contact Person:** Marianne Clancy

Please email your CV and cover letter to: [employment@curehht.org](mailto:employment@curehht.org) If you have any questions, feel free to contact us at 410-357-9932. Read more about Cure HHT and HHT at [www.curehht.org](http://www.curehht.org)

Cure HHT does not and shall not discriminate on the basis of race, color, religion (creed), gender, gender expression, age, national origin (ancestry), disability, marital status, sexual orientation, or military status, in any of its activities or operations.