POSITION: Clinical Research Associate II **DATE:** September 2021

REPORTS TO: Associate Director, Clinical Development **STATUS:** Full-time, Exempt

DEPARTMENT: Clinical Development and Operations (CDO)

ACCOUNTABILITY OBJECTIVE:
As a Clinical Research Associate II ("CRA"), this position will primarily be an "in-house CRA role" responsible for assisting with clinical operations activities for clinical trials. This position offers a unique opportunity to work on outsourced clinical trials and participate in clinical operations oversight and clinical development activities as Impel continues to grow and bring more functional responsibility internally.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

- Support the Clinical Project and Program Managers in planning, setting up and executing assigned clinical trial(s)
- Manage defined aspects of clinical trials to ensure trials follow SOPs, FDA regulations and ICH/GCP guidelines
- Provide Sponsor oversight compliant with GCP and local RA regulations for various tasks as delegated by the Impel clinical lead(s)
- Assist and oversee contracted CROs with start-up activities including IRB submissions
- Oversee contracted CROs in preparation of study documents (e.g., study plans, site training materials, lab manuals, methodologies, site tools, worksheets, study trackers) by providing input or review as assigned
- Assist Data Management and CROs in the development of eCRFs and eCRF completion guidelines (eCCGs)
- Review completed eCRFs or data listings for accuracy, assist with data discrepancy management by the CROs and perform associated trainings/re-trainings as needed
- Perform ongoing review of (electronic) Trial Master File (eTMF) held by CROs to ensure files are maintained in compliance with GCP, FDA, and ICH guidelines and prepare for transfer to Impel
- Assist TMF specialist (internal or external) with TMF review and reconciliation activities
- Facilitate information flow between clinical study vendors, clinical project team members, other members of the Clinical team (including CRO) and other staff as appropriate
- Assist in vendor selection activities and oversight (including CRO selection)
- Assist the Impel clinical trial lead(s) in writing and updating sponsor oversight plans for clinical trials, and conducting tasks on the sponsor oversight plan(s)
- Represent Impel Clinical trial team in project team meetings with CRO and internally
- Coordinate review of informed consent forms (ICFs) and other study documents

- Review and provide constructive feedback on study monitoring reports and follow up letters if applicable
- May assist in conducting site qualification, co-monitoring pre-study, site initiation, interim monitoring and close out visits as needed/requested
- Participate in internal, investigator, and vendor meetings and/or training
- May be assigned duty of vendor management
- Create, maintain, and/or review trackers which monitor project compliance and performance and provide reports to Clinical trial lead and CDO management
- May be tasked to maintain or review databases for appropriate study administration and/or oversight
- Participate in team meetings and generate meeting agendas and minutes and monitor action item completion

EDUCATION, EXPERIENCE AND/OR SKILLS REQUIRED

- Bachelor's Degree (or equivalent) in a science, health, or related field, or relevant industry experience for the equivalent period
- 5+ years relevant experience in pharmaceutical industry or CRO
- Prior remote and on-site monitoring experience required
- Experience supporting clinical trials
- Solid working understanding of clinical protocols, CRFs, and all other associated study documents
- Experience generating clinical documents
- Experience in CRO and vendor oversight and management strongly preferred
- Knowledge of drug development, FDA, and GCP regulatory guidelines is a plus
- Proven ability to learn and adapt in an evolving work environment
- Proficiency in computerized information systems and standard application software (e.g., MS Word, Excel, PowerPoint, Adobe Acrobat)

CULTURAL COMPETENCIES

- **Collaborative**: Works together in an intersection of common goals by sharing knowledge, learning, and building consensus with others.
- **Flexibility**: Develops new or diverse strategies to achieve organizational goals. Able to lead in a changing and challenging work environment. Manages competing demands and unexpected events.
- **Ownership:** Demonstrates full ownership and takes accountability for the actions and execution of both self and the department.
- **Leadership**: Ability to be dynamic and visionary, and able to define clear and specific objectives, tasks, and responsibilities.
- **Initiative**: Measures self against a standard of excellence. Demonstrates persistence and

overcomes obstacles, takes calculated risks to accomplish goals. Ability to work a demanding, primarily self-directed work schedule.

- **Professionalism**: Works well in a fast-paced environment; treats others with respect and consideration; accepts responsibility for own actions. Understands business implications of decisions, aligns work with strategic goals. Meets deadlines and commitments.
- **Communication Skills**: Clearly and persuasively communicates verbally and in writing. Listens and seeks clarification; manages difficult situations; maintains confidentiality. Demonstrated ability to present complex scientific and medical information to a range of audiences.
- **Problem Solving**: Conducts appropriate analysis and makes clear, consistent, and timely decisions.
- **Detail minded**: Demonstrates accuracy and thoroughness; monitors own work to ensures quality and organization. Strong attention to detail while multitasking.

PHYSICAL DEMANDS

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. Must have demonstrated ability to multitask in high pressure, changing conditions. Sitting, standing, stooping, and lifting of packages up to 30 pounds may be required.

WORKING CONDITIONS

When based in the office, expect a noise level typically moderate for offices and labs.

PRIMARY LOCATION & TRAVEL

Office location will be determined by incumbent current primary residence. Note that travel up to 20% to meet the ongoing needs of the business, some of which may be international, so a current passport is required. In-person training will be conducted in Seattle, Washington soon following hire.