CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. CareDx offers AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection. CareDx is developing additional products for transplant monitoring using a variety of technologies, including AlloSure®, a proprietary next-generation sequencing–based test to detect donor-derived cell-free DNA after transplantation.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP® is a set of HLA typing used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE® is the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: www.CareDx.com.

Clinical Research Associate I, II, or III

In this position the CRA will play a key role in supporting the design, implementation and conduct of the next stage of state-of-the-art clinical utility prospective multicenter trial(s) that may help change the standard of care and improve patient outcomes in renal transplantation. The candidate will also help manage other ongoing studies.

Specific responsibilities include, but are not limited to:

Interaction with Clinical Sites

- Conduct site selection visits
- Conduct site training and study site initiation visits.
- Clinical monitoring ensuring compliance with Good Clinical Practices (GCP) and applicable SOPs and regulations.
- Perform Study Close out visits
- Support sites in study conduct (e.g. provide guidance on case report form [CRF] completion.

Communication

- Act as a liaison between our company and clinical sites including clinical investigators and other health care professional involved in clinical study
- Generate clear and concise trip reports and site contact documentation
- Creation and distribution of monthly status reports/study newsletters

- Collaborates with internal cross functional teams (Biostatistics, R&D) for project milestones

Study Documents

- Assist in generation of study related documents such as protocols, case report forms, informed consent documents, instructions for use manuals and site training materials

Data Management

- Ensure quality of data for data lock.
- Report hotspots or trends in clinical events from data listings in the study and coordinate with medical monitor(s).

Study Administration

- Manage and Maintain Trial Master File
- Track enrollment and compliance to all necessary activities related to study follow-up visits and take corrective actions as necessary to meet study performance and quality objectives.
- Maintain study trackers
- Manage product inventories for clinical studies
- Contributes to the development and management of the study timelines, resources, budget, risk and quality plans; ensures accurate tracking and reporting of study metrics.

Financial

- Prepare and negotiate site budgets.
- Process documents related to payments (e.g. investigator payments for rendered services).

Qualifications

- Degree/certification in life sciences, health sciences or equivalent degree/experience (e.g., BS, RN, RT)
- 2-10 years experience with clinical studies and data collection
- Ability to travel 5-10% in support of the primary clinical activities
- Knowledge of ICH GCP.
- Experience in working as part of a study team.
- Effective written and verbal communication skills.

Additional Information:

Benefits & Perks: We provide Medical, Dental, Vision and Life Insurance, Flexible Spending and Dependent Care, Commuter Accounts, 401(k) match, 3 weeks of vacation, 5 days sick leave, 1 personal floating holiday, 9 paid holidays, gym reimbursement, yoga onsite, ping pong, foosball, BBQ's, social hours, and more!

CareDx, Inc. is an Equal Opportunity Employer.

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Please send cover letter and resume to: HR@CareDx.com

CareDx, Inc. is an Equal Opportunity Employer.

Staffing Agencies and Recruiters:
We appreciate your interest in CareDx, Inc. To develop a working relationship with us, we ask that you please contact our Human Resources Dept. at HR@CareDx.com. All employment openings are managed through our Human Resources Dept. The CareDx, Inc. hiring managers and employees will not accept unsolicited resumes from any source. Submission of unsolicited resumes in advance of an agreement between the Human Resources Dept. and the recruiter does not create any implied obligation on the part of CareDx, Inc. **Therefore, we request that recruiters do not contact employees directly in an attempt to present candidates.** We thank you in advance for your cooperation and look forward to possible job search collaboration in the future!