Biomapas is a functional and full outsourcing solution provider to the global life science industry, with key expertise in Clinical Trials, Regulatory Affairs and Pharmacovigilance. With headquarter in Lithuania and offices in Switzerland, Russia, Georgia, Ukraine and Sweden. Biomapas operations are spread over 5 continents, concentrated in Europe, Russia and former CIS region.

Biomapas is looking for **Senior Clinical Research Associate with deep experience in Regulatory field** to join our ambitious and growing team in Russia.

Key role responsibilities include but not limited to:

- Performing country feasibilities, recruiting potential investigators, preparing EC submissions, translating study-related documentation, organizing of meetings and other tasks as instructed by supervisor;
- Negotiating study budgets with potential investigators/sites and assisting in agreements negotiation;
- Performing regulatory document review/local adaptation and submission to regulatory authorities;
- Conducting pre-study, initiation, monitoring, and closeout visits for research sites;
- Performing source document verification and case report form review;
- Checking drug storage conditions and accountability through clinical trial;
- Performing adverse event and serious adverse event reporting and follow-up;
- Assessing patient recruitment and retention;
- Site administrating and site monitoring responsibility for clinical studies according to Standard Operating Procedures, ICH Guidelines and GCP;
- Completing Serious Adverse Event (SAE) reporting, processing production of reports;
- Managing investigator/site paymentsManage and oversight Local Regulatory Officers and Regulatory Affairs Specialist to ensure appropriate communication channels are maintained and reporting schedules adhered to.

Key experience, required skills and competencies

- Preferable education of Science in health-related field;
- At least 3 years CRA experience;
- Experience in RA submissions preparation;
- Excellent knowledge of English language, both oral and written;
- Thorough knowledge of ICH Guidelines and GCP.

Additional information

- This is a full time home based position;
- We expect candidate to be based in Moscow region;
- Travelling capacities are required;
- This position requires good communication skills and fit to a person who is confident enough to manage a lot of on- going projects;
- The ability to work independently and as a part of a team.

Please apply to **HR@biomapas.eu**

Thank you for attention!
Kindly inform that only selected candidates will be contacted.