IBD REGISTRY PHARMACOVIGILANCE & STUDIES MANAGER

The IBD Registry Ltd is the first and largest repository of inflammatory bowel disease data (IBD) in the UK. Approximately 500,000 people in the UK suffer from this debilitating, not well understood and difficult to manage disease. Our mission is to improve the health of people living with inflammatory bowel disease in the UK by the collection and analysis of data in order to improve understanding of the care of people with IBD and their treatments and to facilitate research. With almost 200 NHS hospitals participating with us and over 67,000 patient records, we are one of the largest registries in Europe.

Our not for profit organisation is young, small and growing rapidly, with considerable successes already in the field of health informatics. We work with hospitals, doctors and nurses across the UK and with drug studies, the NHS and key universities. Further information can be found on our website www.ibdregistry.org.uk

We developed two years ago our pharmacovigilance programme, including software and already have underway three drugs under multi-year study. We have supported one major clinically-led study, have another about to start, with a business goal to support more studies in IBD as part of our purpose. As well as our clinical relationships, we have an active and successful Industry Working Group and hold a well-attended annual Industry Forum.

ABOUT THE ROLE

We're looking for a motivated and organised Pharmacovigilance (PV) & Studies Manager to manage the successful delivery of our pharmacovigilance programme together with the design, delivery and development of our IBD studies support programme. This role includes:

- responsibility for our pharmacovigilance / post-marketing surveillance study programme, including contracting, study design, analysis and reporting
- leading the development and delivery of our studies programme, supporting studies to be able use the Registry's infrastructure for data collection
- acting as an ambassador and promoting the use of the UK IBD Registry, for studies, for post-marketing surveillance and research, plus other related activities that may arise.

As per the introduction, IBD Registry is currently a small organisation with a very flat management structure. It is therefore essential that applicants recognise that this a

very hands-on role, with the postholder playing an active role in delivering the projects. All the projects are fundamentally related to health data in some way, particularly in respect of data flows across the organisation and beyond, and so confidence and capability with technical solutions and data is essential.

ABOUT YOU

To be successful in this role you will be an experienced and delivery-focused project manager in the field of pharmacovigilance projects, clinical studies or trials, or similar health studies, with a strong understanding of the way the biopharmaceutical industry works, especially in its interactions with academic and non-commercial organisations like ourselves.

You will be both organised and adaptable and with a strong eye for detail and quality. You will have a track record of delivering projects to time and budget .Your most important attributes will be your rigour in thinking, readiness to learn and your 'can do' mindset. Above all, you need to believe in our mission and want to join us to make a difference: our small team makes a big difference in IBD across the UK and this needs to be more than 'just a job' for you.

You will have a strong academic qualification record, and for this role, you will have come from the healthcare or pharmaceutical industries, or as a possible alternative from a highly-regulated sector where both data protection and delivery are critical.

JOB TITLE

PV & Studies Manager

REPORTING AND KEY RELATIONSHIPS

The role reports to the CEO, with key relationships with the Client Services Manager, the Data & Analytics Manager and the Data & Analytics Manager. There is also a key relationship with the Clinical Lead for Industry & Collaboration as part of the Clinical Leads group.

ROLES AND RESPONSIBILITIES

PV and Studies Programme Management

1. Lead and manage the Registry's pharmacovigilance (PV) programme and the Studies programme, delivering projects and client satisfaction within both programmes

2. Lead and manage the pre-sales element of the PV and Studies programmes, working with clients as required to develop protocols, delivery agreements, IG agreements and budgets that will form the basis of each project, working at all times within the relevant internal and regulatory requirements (i.e. post-market authorisation surveillance, HRA research, etc)

3. Be the primary point of contact for each PV or studies customer, engaging with them with a highly professional approach to develop and enhance our relationship with them specifically, and our reputation more widely

4. Lead and manage the on-boarding of new PV or studies, ensuring sites engaged in the key activities take actions within the required schedules, and reports status at the required timetable within procedures

5. Ensure a well-documented documentation trail exists of all our activities in tis area, to support our audit and compliance requirements

6. Working in all activities within our standard procedures and guidelines, involving our external specialists and the CEO as required and appropriate, and at all times within the limits of your delegated authority.

7. Working with the Data & Analytics team, ensure the correct functioning of the PV and study software and tools, and oversee the development, test and rollout to any changes that may be required

8. Working with the Data & Analytics team, ensure that the required PV and study data is extracted on time and to schedule, and undertake any statistical analysis required for project reporting

9. As part of solution-finding with the client, undertake key data activities such as: mapping datasets, matching data capture tools to the desired outcomes, etc and produce client-facing reports that summarise the solutions

10. Design and document reports and presentations clearly summarising key activities, presenting for appropriate approvals

Industry Relationships

11. Maintain an active radar for relevant new developments in the PV and studies field, sharing knowledge in our CRM system and in line with our standard procedures

12. Maintain an active network of industry relationships, widening and building on our existing relationships within our Industry Working Group, sharing knowledge as above

13. Play an active role in the ongoing development of positive relationships within our Industry Working Group and Forum, contributing to design and content of meetings, communications, publications etc.

14. Ensure that our industry supporters are appropriately recognised in acknowledgements, including on our website, and that updates and reports on our activities are provided as appropriate and within our internal guidelines

15. Review and propose further development to our internal guidelines and processes in this area, to ensure that they are fully aligned with our growth and development in this field

16. Act as an ambassador for the IBD Registry

Information Governance (IG) and Compliance

17. Understand our IBD Registry Information Governance (IG) policies and procedures and ensure the effective incorporation of these across all projects

18. Ensure that all proposals are compliant with external regulations and guidelines, including GDPR and other key IG, plus the HRA, ABPI and our s251 provision awarded by the CAG.

19. Ensure that all proposals are compliant with our internal guidelines, including especially our full IG Framework and the data security provisions in the DSP Toolkit from NHS Digital

20. Raise and liase with the SIRO on any elements of the project that relate to Information Governance or Data Security, and undertake any related work in strict adherence to the guidelines and instructions.

21. Model to staff at all times the rules set out in the guiding IG documents

22. Lead on the ongoing development of our Data Access Protocols, which will ensure transparency and clear

Other

23. Maintain an up to date awareness of Health and Safety legislation, demonstrated in safeguarding the actions of both yourself and others at all times

24. Be a role model and champion of professional working and change in a fast moving environment

25. Work within company policies and procedures at all times, proactively raising suggestions for improvement where-ever seen, and writing procedures or supplying content for them where required and requested.

26. Maintain appropriate records and logs as may be required (proactively suggesting if none) so that there is an identifiable and clear trail of information.

27. Deputise for the CEO as may be required

28. Undertake any other duties as may be reasonably expected and are commensurate with the level of the post.

PERSON SPECIFICATION:

About your education

- Strong academic record with a degree in a relevant subject (e.g. maths/science, information, technology), ideally with a further qualification in project or business management

About you as a person

- Organised, able to plan work and deliver to plan on time
- Methodical, organised and accurate, with attention to detail
- Excellent written and verbal communications skills
- Innovative and pro-active problem-solver
- Confident with using technology throughout our work
- Effective team player, responsive to feedback, keen to learn and grow
- Experience or understanding of inflammatory bowel disease
- Excellent interpersonal skills, and ability to act as an ambassador for the IBD Registry

PERSON SPECIFICATION:

About your skills and experience

- Practical and significant experience of running projects in research and/or clinical studies run by the biopharmaceutical industry, including a strong understanding of pharmacovigilance
- Strong understanding of the governance involved in research and studies, including ethics and consent, protocol development and approval
- Experience of the design, set up and regulatory requirements of clinical trials and/or post-marketing surveillance
- Demonstrable experience and strong understanding in statistical analysis in a health data setting, such as real world longitudinal population studies and drug monitoring/adverse events studies
- Demonstrable solutions skills in designing customer-facing data projects, including dataflow mapping, data modelling, client documentation
- Demonstrable understanding of information governance and compliance, especially in the field of confidential health data

- Track record of positive relationship building leading to collaborative projects

SALARY AND OTHER DETAILS

This is a permanent term role initially for 1 year for 24 hours per week (can be worked over 4 or 5 days/week) and offering a salary between £37,000 - £48,000 FTE (40 hours) depending on relevant skills and experience.

We make appointments at an initial salary level (90 or 95% of the proficient salary) or at the depending upon skills and abilities as assessed during the recruitment process. On successful completion of probationary period, proficient salary will be re-assessed).

We offer 25 days holiday each year plus 8 Bank Holidays (all FTE, pro-rata for part time); plus a 5% employer's contribution to your pension.

Our fulltime (FTE) working week is 40 hours/week, and there may be a requirement to periodically work outside of standard office hours (usually remotely), for example, to fit in with clinical schedules.

Our office is in Epsom, only minutes from the station in brand new offices in a bright modern complex including library, cafes and restaurants. Epsom itself is only 30 minutes train journey from Waterloo, Victoria and Blackfriars, 15 minutes from Wimbledon. For meetings with stakeholders travelling into London we are fortunate to have a base at the BSG or RCP, both overlooking Regent's Park and an easy 20 minute journey from Victoria.

OUR RECRUITMENT PROCESS

During the COVID-19 restrictions, our interviews will be by Teams video call. We hold a multi-stage interview process (timetabled close together) including an initial interview, practical tests to be done offline, and a post test interview

Additionally, the successful applicant will be fully supported to work from home for the initial period where restrictions on non-essential travel are in place.

There is no fixed closing date for this role. We want to appoint quickly, and we will be shortlisting and inviting to interview on a rolling weekly basis by the end of each week (Fridays). We will close the process when we have appointed a candidate. Our interview process will involve a combination of two Teams video calls and 2-3 practical relevant tasks done offline, to allow you to demonstrate your ability in relevant key areas. This also aligns with how we work, which is very focused on end results.

HOW TO APPLY

To apply, all candidates are required to complete and submit our Application Form. This is an online application form that is asks questions in four sections: about you; about your education; about your experience; and about your fit for the role. The application form is available on our website and also here: https://tinyurl.com/y2cs7ly9

Please note that we will not accept applications that are just a generic CV and that we can only accept applications from candidates who have the right to work in the UK.

If you have any questions, or would like to talk with us beforehand, please email Katie Gray on finance@ibdregistry.org.uk (also for a talk - so that we can arrange a time for a conversation).

Your referees may be contacted prior to a final decision being made, and only after you have attended the interview and with your permission.

An employment decision and offer of employment will be made promptly. We will be looking for the successful candidate to start as soon as possible.

This document describes the main elements of the job. This a new role in a young organisation and this description is a guide to the expectations and main duties as we understand them currently, but it is not intended as a wholly comprehensive or permanent schedule and is not part of the contract of employment. This document is subject to review