(Clinical) Biomarker expert (d/m/w)

Freelance-ID: OCR-FL-1161

Tasks:

- Supports the pharmacodynamics, prognostic and predictive clinical biomarker strategy implementation
- Provides general technical consultancy in her/his field of expertise (in particular ligand binding based platforms etc. in single-plex and multi-plexing)
- Responsible for the execution / operationalization of work packages in her / his field of expertise such as assay development, validation, transfer, and assay implementation, as well as monitoring biomarker analyses in clinical trials (at external service providers)
- Review of specific analytical biomarker method(s); technical assessment of Service Agreement between external vendors, Quality Assurance and Procurement/Legal (Business Development)
- Developing Biomarker analysis and assessment strategies including evaluation and decision making on selected technology and definition of performance criteria
- Contribution to and review of documents from her/his area of expertise for each specific trial (including but not limited to LSD, LES, CTP, amendments, …);
- Preparation of a dedicated biomarker analytical study plan (review / editing) linked to a specific trial in close collaboration with CBD colleagues and other relevant functions
- QA-GCP interaction including technical support for CRO audit; interaction/supportive activities for regulatory authorities interaction;
- Support pharmacodynamic data analysis & interpretation
- Support early exploratory biomarker hypothesis testing according to biomarker development plan
- identification, qualification and selection process of external vendors (service providers and suppliers), and the surveillance of selected vendors with appropriate QC data check

Requirements:

- PhD or MD degree or equivalent in the field of (Bio-)Chemistry, Biology, Pharmacy, Life Sciences or similar
- Strong understanding of quality related requirements in drug development and in GXP-related areas and beyond (e.g. CLIA)
- A minimum of 5 years experience in clinical biomarkers and translational research in a pharmaceutical company or equivalent
- Demonstrated hands-on experience in biomarker analysis (cellular, protein and/or small molecule) – biomarker assay development and validation and clinical samples testing
- Proven experience in reviewing clinical trial related documents from his/her area of expertise (e.g. LSD, LES, CTP, CTP amendments)
- English: fluent (verbal and writing)

Additional Information

Location: Darmstadt

Project start: February 2021

Duration: 12 months

Availability: 4-5 days/week

On-site: 10%

Remote: 90%

Your OCR contact

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