GlaxoSmithKline is one of the world's leading pharmaceutical and healthcare companies, with statisticians and programmers working in Research and Development at UK, US and India sites. The Quantitative Sciences division includes a Clinical Programming department, sitting within the broader SPDS group, covering all phases of clinical drug development and commercialisation in a wide range of therapeutic areas. In recognition of the developing sophistication and technical requirements of the role, Clinical Programming was formed as a standalone department distinct to Clinical Statistics about 3 years. In addition to the group's activities supporting GSK's pipeline of drugs, key accountabilities include developing and implementing strategies for programming resourcing using both internal, external, onshore and offshore resource; driving CDISC implementation for the reporting of clinical trials; and identifying and implementing IT solutions to offer further benefit and efficiency for the group's activities. The complexity of the role of the Clinical Programming department as a whole has led to the need for a high-level lead programmer that is responsible for programming activities across an asset/indication within a therapeutic area.

The Key Responsibilities of the role are General/ Project Management, Communication, Representation, Documentation, & Project Data Strategy and Asset Submission Strategy.

General/ Project Management:

Overall Programming Accountability for Project & Project Oversight

- Know the status of each study, be aware of any study and project delays and study priorities, and new studies etc. Read, understand, retain knowledge of the Protocol.
- Provide this oversight in alignment with the company Oversight Guidance and in collaboration with the Clinical Programming Therapeutic Area (TA) Head.
- Regular interactions with Lead Programmers to ensure high level awareness of individual studies

Study Scheduling

- Understanding upcoming studies and timelines.
- Prioritise study reporting within project.

Programming Budget Estimations

- Provide finance with various contract estimates on a quarterly (or as required) basis. For fully outsourced studies (DM, S&P, Clinical, Operations etc), provide review of the RFP (Request For Proposal) and subsequent budget grids.

Resource Planning

- Influences and contributes to the overall outsourcing strategy (i.e. Fully outsourced, functionally outsourced, contingent workers, in-house programming resources)
- Identify intra-project resource conflicts and resolve where appropriate

- Review Global Study Planner (GSP, tracking document of all planned and active studies) with Lead Programmers on a regular basis and ensure Lead Programmer(s) keeps GSP up to date.

Programming Staff Recruitment

- Participate in the recruitment process for assigned projects

Audit Preparation

- Act as the point of contact and represent Clinical Programming for any internal or external audits.
- Co-ordinate any audit preparation work.

Communication:

Updates

- Provide programming status updates for project to Clinical Programming TA Head.

General Issue Escalation

- Ensure appropriate escalation to Clinical Programming TA Head of project level and previously escalated study level issues (to include CRO quality issues).
- Raise programming best practices/documentation (i.e. CDISC, Study Data Standardization Plan [SDSP], etc) to the wider project team and escalate any issues directly to the project team.

Lines of Communication

- Act as the primary Clinical Programming project contact for project team and other internal and external parties including other GSK functional lines, functional outsourcing or fully outsourced.
- Liaise closely with Lead Programmers, Project Statistician, Project DM, if one exists.
- Facilitate communications between Lead Programmers and other study internal and external groups for the project (e.g., Outsourcing Communication Plans, confirm communications are strong between functional lines within the studies of the project).

Cross-Project Clinical Programming Support

- Drive and act as project contact for cross-project Clinical Programming collaboration and information-sharing.
- Where the project uses an asset which is used by another project, ensure appropriate communication.

Representation:

Represent Clinical Programming at Internal Meetings

E.g.:

- Project (and study, where appropriate) meetings.
- Product Investment Board
- Foundation / submission related meetings
- Study results review meeting

- Medical Development Team (attendance and contribution)

Represent Clinical Programming at External Meetings

E.g.:

- Key regulatory engagements (Pre-IND, IND, EOP1, EOP2, Pre-NDA, NDA, etc.).

After Action Review Meetings

- Contribute to (or lead) any post-delivery after action reviews for studies within the project.
- Ensure that actions from the reviews are applied across the project.
- Refer for action at the level of the Clinical Programming Line as required.

Documentation:

May Contribute to Content of Document Properties

E.g.:

- Summary documents
- Regulatory responses
- Reviewing any Analysis Plan(s) involving meta-analyses or integration across studies

TA Head Delegate

- May act as delegate to TA Head, where requested

Oversight Documentation

- Ensure consistency of oversight documentation between studies, which should increase reporting quality and allow a further risk-based approach.

Project Data Strategy and Asset Submission Strategy:

Overall Accountability for Clinical Programming Aspects Of A Submission

- Work closely with submissions experts to ensure submission is successfully planned and executed

Plan and Manage Study Data Standards Versioning Strategy Across Asset. Plan and Manage Pre-Submission Activities

- Ensure CDISC standards are used consistently across studies for a project and adhere to GSK's CDISC conventions.
- For studies not using CDISC, plan and coordinate any conversion efforts required.
- Drive creation, maintenance and management of content for the Clinical component of the Study Data Standardization Plan (SDSP).
- Ensure aligned implementation of core, TA and asset-level data standards, methodologies, graphics, etc across studies within the project.

Data Integration

- Plan data integration strategy and implementation, in collaboration with Project Statistician.

Plan and Manage Submission Activities

- Oversee identification, preparation and delivery of components for the submission which are the responsibility of clinical programming, including but not limited to, study data packages and outputs, site listings, analysis programs for review by agency, strategic planning and documentation.

Cross Project

- CDISC subject matter expert for project or point of contact for CDISC matters/questions

In summary, the role of the Project Programmer is to align studies' planning, resourcing & execution from a Clinical Programming standpoint; to engage cross-functionally to leverage expertise and add value wherever possible; and to facilitate a complete, consistent and well-documented submission with transparency of data flow, processing, and derivations.