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Advancing Clinical Programming Through Centres of Excellence

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ABSTRACT

Centres of Excellence (CoEs) are emerging as a transformative approach in clinical programming within GSK, designed to enhance quality, efficiency, and innovation. CoEs bring together specialized expertise and resources to address niche areas, fostering collaboration and driving best practices across global portfolios. CoEs operate as centralized hubs of expertise, supporting critical activities such as data analysis, reporting, and compliance with regulatory standards. By leveraging agile methodologies and advanced technologies, CoEs streamline workflows, improve cross-functional collaboration, and ensure consistent, high-quality deliverables. Their collaborative and standardized approach position them as a critical enabler for advancing clinical research and meeting the demands of accelerated timelines in global studies.

INTRODUCTION:

Traditional project aligned resource model for analysis and reporting of clinical trials data have long been standard practice in clinical programming. However, increasing study complexity, accelerated timelines, higher data volumes, and growing demand for specialized analyses have highlighted the limitations of these models. There is a clear need for more cost-efficient, flexible, and responsive resourcing approaches. The Centre of Excellence (CoE) model addresses this need by bringing together specialized expertise to support niche areas such as Pharmacokinetics, biomarker analysis, and complex therapeutic endpoints, while embedding best practices, innovation, and consistent quality across the clinical development portfolio.

Why Centres of Excellence in Clinical Programming?

CoEs drive excellence through shared standards and expertise. Key benefits include:

Standardization: Delivering consistent, reproducible analysis workflows.
Quality & Compliance: Improving compliance with regulatory submission standards.
Efficiency: Supporting clinical trial analysis and reporting with high efficiency and quality aiding in accelerating submission process.
Capability Building: Developing deep expertise, upskilling personnel, and supporting development.
Innovation: Driving new ways of working, piloting, and adopting technologies.
Cross-functional Alignment: Enhancing collaboration with teams beyond clinical programming.

Traditional Resourcing Model vs CoE Model

The Centre of Excellence (CoE) model offers significant advantages over traditional clinical programming resourcing practices. It emphasizes centralized hubs of deep, niche specialization, ensuring that domain and programming expertise is concentrated and readily accessible by augmenting study programming teams. Resourcing is driven by portfolio priorities and fluctuations, allowing for optimized resource allocation flexibly. The model promotes standardization and reusable technology, which enhances consistency and reduces variability. Efficiency is achieved by leveraging experience reuse for faster execution, while quality is maintained through embedded best practices. Innovation is a key focus, with dedicated efforts towards the development and adoption of advanced tools, methods, and novel technologies. They act as career development opportunity for programmers in developing deep expertise in diverse areas. Furthermore, knowledge management facilitates effective sharing of insights and expertise across teams. Lastly, the CoE model ensures predictable and expert engagement, fostering increased confidence among stakeholders.

Specialized Focus Areas Driving Clinical Programming Excellence

While study programming teams play a pivotal role, Centres of Excellence add distinct value in areas that require deep domain expertise, complex analytical processes, and advanced programming skills to deliver specialized analysis packages. Examples include:

- **Complex Study Designs**: Adaptive, platform, seamless trials, etc.
- **Therapeutic Area Expertise**: Microbiology, HIV, RECIST, biomarkers, etc.
- **Standards & Automation**: CDISC, R packages, macros.
- **Innovation & Analytics**: R/Python, automation, AI/ML.

Case Study: Establishing a Pharmacokinetics (PK) Programming CoE

Why PK programming considered for establishing CoE in GSK

- PK analysis programming involves highly complex data flows, derivations, and study-specific workflows
- Heterogeneous study designs make it difficult to build and maintain robust, reusable standard programs
- Late data availability to preserve blinding significantly compresses programming and delivery timelines

The CoE Intervention: Strategic Solution

- Conducted a pilot with a focused three-member PK programming team to assess feasibility and strategic value. Results are compellingly positive improving efficiency and quality
- Adopted Agile Ways of Working, tailored to PK analysis and reporting needs with dedicated SCRUM master
- Established a PK Centre of Excellence (CoE) as strategic hub to support PK analysis programming across portfolio to centralize expertise and standardize execution
- Scope encompasses PK-related CDISC domain programming, TFL development, and process improvement initiatives

Agile CoE Operating Model and Key Roles:

Component	Description
Self-Organizing Squads	Autonomous squads managing workflows and execution independently.
Accountability for Delivery	Each study has a designated SPOC responsible for PK deliverables and stakeholder engagement.
Squad Manager	Provides resource strategy and prioritization, engages senior stakeholders, champions standards and novel technologies, and embeds continuous improvement through retrospectives.
Scrum Master	Facilitates agile ceremonies and coaches squads to promote transparency, collaboration, and continuous learning.
Agile Ceremonies	PI planning, sprint planning, regular stand-ups, and retrospectives supporting predictable delivery and continuous improvement.

Outcome:

The implementation of the agile CoE operating model enabled optimized capacity utilization through the dynamic allocation of PK expertise across studies, allowing resources to be flexibly deployed in line with evolving priorities. Improved visibility into workload and work-in-progress enhanced transparency and facilitated proactive planning and decision-making. Collectively, these improvements strengthened responsiveness and quality of delivery, ensuring timely and focused support for high-priority and complex PK analyses across the portfolio.

Conclusion:

Adoption of an agile Centre of Excellence operating model provides a scalable and sustainable approach to delivering complex clinical trial analysis in an increasingly demanding clinical development environment. They supplement study programs effectively in accelerating programming deliverables. By combining deep domain expertise with structured agile practices, the model enhances flexibility, transparency, and accountability while maintaining high quality standards. This approach enables organizations to respond effectively to evolving study needs, dynamic resource needs, optimize the use of specialized talent, and embed continuous improvement across the portfolio, thereby establishing the CoE as a key driver of efficient and high-quality clinical programming delivery.

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