



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.

This presentation aims to:

- Define the concept and strategic importance of CoEs in clinical programming.
- Highlight the benefits of CoEs in standardization, capability building, and innovation.
- Share insights from successful implementation and benefits through a case study.

Agenda

Presentation Duration: 30 mins

- ❑ **Introduction to Centre of Excellence Concept**
- ❑ **Traditional Resourcing Model vs CoE Model: Benefits**
- ❑ **Case Study**
- ❑ **Challenges and Challenges and Mitigation Strategies**
- ❑ **Q&A**

What is a Centre of Excellence?

A strategic approach to quality, capability and collaboration

Centre of Excellence (CoE) is a dedicated team that brings together experts and resources to support niche areas, to drive best practices, innovation and high performance across the portfolio

Hub of deep expertise

Driver of innovation

Central source of
governance and support

Why are we using Centres of Excellence in Clinical Programming?

Driving excellence through shared standards and expertise



Standardization: Deliver consistent, reproducible analysis workflows



Efficiency: Support clinical trial analysis and reporting with high efficiency and quality



Innovation: Drive new ways of working, pilot and adopt technologies



Quality & Compliance: Improve compliance with regulatory submission standards



Capability Building: Develop deep expertise, upskill people, and support development



Cross-functional alignment: Enhance collaboration with teams beyond CP

Traditional Resourcing Model vs CoE Model – Key Differences

	TRADITIONAL CLINICAL PROGRAMMING	COE MODEL	BENEFIT OF COE
STRUCTURE	Study-centric, siloed teams	Centralized expertise hub	Consistency and scalability
EXPERTISE	Broad generalist skillsets	Deep, niche specialization	Higher quality for complex designs
RESOURCING	Reactive and study-based	Planned and portfolio-driven	Optimized capacity and predictability
STANDARDIZATION	Variable practices across studies	Common standards and reusable assets	Reduced rework and variability
EFFICIENCY	Learning curve repeated per study	Faster execution through experience reuse	Shorter timelines
QUALITY	Dependent on individual experience	Embedded best practices and peer review	Sustained quality at scale
INNOVATION	Limited bandwidth to innovate	Dedicated focus on tools and methods	Faster adoption of innovation
KNOWLEDGE SHARING	Informal and inconsistent	Structured knowledge management	Organizational learning
STAKEHOLDER EXPERIENCE	Inconsistent support	Predictable, expert engagement	Increased stakeholder confidence

Specialized Focus Areas Driving Clinical Programming Excellence



Complex Study Designs

Adaptive, platform, seamless trials



Therapeutic Area Expertise

RECIST, Microbiology, HIV– Snapshot



PK/PD & Advanced Domains

PK, immunogenicity, biomarkers



Standards & Automation

CDISC, R packages, macros



Innovation & Analytics

R/Python, automation, AI/ML

Case Study

Pharmacokinetics Programming CoE

PK Programming CoE: From Complexity to Measurable Impact

Problem

Why traditional PK programming struggled



Highly complex derivations and data workflows



Multiple study designs limiting standardization



Late data availability to preserve blinding, compressing timelines

Solution

PK Centre of Excellence (CoE)



Impact

What changed — **measurable outcomes**



Optimized capacity utilization



Improved responsiveness for high-priority and complex PK analyses



On-time delivery of support despite late data cuts

Specialized CoEs + Agile execution = **predictable, high-quality** delivery in complex clinical programming domains

Glimpse into Agile Squad World – Key entity for successful CoE model

Self-Organizing Squads

- Squads manage their own processes and workflows independently

Accountability for Delivery

- Each study will be assigned a SPOC
- SPOC is accountable for PK deliverables of the study and study stake-holder engagement

Scrum Master

- **Enables effective Agile ceremonies** (PI, sprint planning, stand-ups, retrospectives) to ensure smooth, predictable delivery
- Coaches squad on agile fostering transparency, collaboration, and continuous learning

Ceremonies

- Program Increment Planning
- Sprint Planning
- Regular stand-ups
- Retros

Squad Manager play key role in

- Resource strategy, prioritization, and stakeholder engagement
- Champions adoption of standards, Novel Technologies, and best practices
- Embeds continuous improvement through sprint retrospectives and learnings



CoE Challenges and Mitigation Strategies

- Limited availability of niche expertise (e.g., PK, Biomarker analysis)
 - Leverage SMEs as **capability multipliers** through mentoring and embedded coaching
 - Invest in **continuous skill development** and structured upskilling within the CoE
- Competing priorities due to changes in analysis requirements, timelines etc.
 - Squad Managers actively **engage senior stakeholders** to align work with pipeline priorities
 - Collaborate with study squad enabling shared responsibilities, provide consulting
- Managing competing stakeholder expectations across multiple functions
 - Clearly define **scope, roles, and expectations** upfront

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Additional GSK Presentations on Agile for Clinical Data Reporting



- Agile Development Methodology for Delivery of the Clinical Data Pipeline, Ben Arancibia and Michael Rimler, 2021 PHUSE US Connect



- An Agile Approach to Onboarding, Ben White (GSK), 2023 PHUSE EU Connect



- The Implementation of Scrum Framework in Clinical Programming Teams, Polina Kornilova, GSK, 2024 PHUSE Single Day Event, Hertfordshire, United Kingdom



- Agile? WoW! How Agile Ways of Working can Drive Value for Conventional Clinical Trial Reporting, Sheetal Patel and Michael Rimler, 2024 PHUSE EU Connect ET08: Why Be Different? Shouldn't



- Everyone Be Using Agile to Deliver Their Clinical Trials? by Michael Rimler

Thanks

Q&A



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