Outsourcing: CRO Oversight – GSK's journey over the last few years

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Agenda

- Introduction
- Resourcing Models
- Oversight Tools/Processes
  - Oversight Plan
  - KO Meeting, Minutes Templates
- After Action Review
  - Feedback
- Experience using outsourcing at GSK

Introduction

Setting the Scene (Definitions)

- What is Outsourcing?
  - An agreement in which a company contracts out a part of their existing internal activity to another. Outsourcing can provide the following benefits for a company:
    - Reduce costs | Reduce overheads | Flexibility

- How is outsourcing utilised in the Clinical Trials industry?
  - A Pharmaceutical/Biotechnology company (Sponsor) will use a third-party vendor (CRO) to provide the services required to support the development of their drugs/devices.

- What is Oversight? Why is it required?
  - Oversight is providing a risk based approach to combine and leverage QA and QC practices in order to ensure that the third-party (CRO) has delivered to the Sponsors' expectations
  - GCP guidelines state that the Sponsor is accountable, which is where oversight comes into play to provide documented evidence that the clinical trial has been conducted according to GCP ICH guidelines.

Introduction

Framework

Resourcing Models

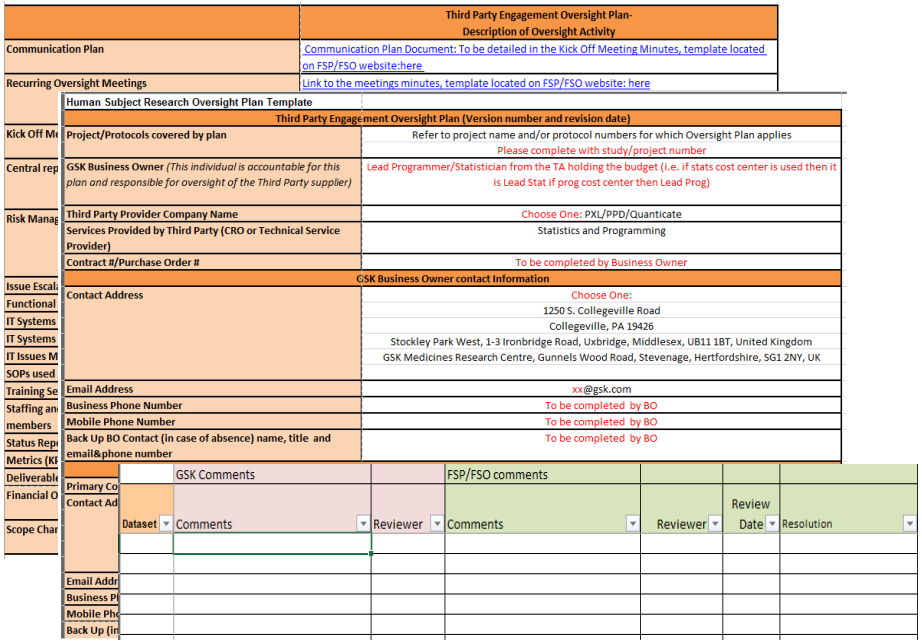
- Resource in-house
  - Use of GSK internal resource (including contractors)
- FSO (Full Study Outsourced)
  - All Clinical Trial functions are outsourced (inc. Study Management, Data Management, Statistics & Programming, Medical Writing)
  - CRO use their own processes/tools to deliver the work package
- FSP (Functional Service Providers)
  - Statistics & Programming activities
  - CRO use GSK processes/tools to deliver the work package

GSK Oversight applied
Risk-based approach, using:
QA (Quality Assurance)
QC (Quality Control)

Oversight Tools

1) Oversight Plan

- Key Information related to the Work Package
  - Compound, Protocol, Personnel Contact Details, etc.
- Issue Logs
  - Datasets | Tables | Listings | Figures
- Study-specific Checks
  - Dataset Specifications
  - Display templates/mock-up shells
  - Versions of Data Standards



	Third Party Engagement Oversight Plan- Description of Oversight Activity
Communication Plan	Communication Plan Document: To be detailed in the Kick Off Meeting Minutes, template located on FSP/FSO website:here
Recurring Oversight Meetings	Link to the meetings minutes, template located on FSP/FSO website: here

Human Subject Research Oversight Plan Template	
Third Party Engagement Oversight Plan (Version number and revision date)	
Project/Protocols covered by plan	Refer to project name and/or protocol numbers for which Oversight Plan applies Please complete with study/project number
GSK Business Owner *(This individual is accountable for this plan and responsible for oversight of the Third Party supplier)*	Lead Programmer/Statistician from the TA holding the budget (i.e. if stats cost center is used then it is Lead Stat if prog cost center then Lead Prog)
Third Party Provider Company Name	Choose One: PXL/PPD/Quanticate
Services Provided by Third Party (CRO or Technical Service Provider)	Statistics and Programming
Contract #/Purchase Order #	To be completed by Business Owner
GSK Business Owner contact Information	
Contact Address	Choose One: 1250 S. Collegeville Road Collegeville, PA 19426 Stockley Park West, 1-3 Ironbridge Road, Uxbridge, Middlesex, UB11 1BT, United Kingdom GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK
Email Address	xx@gsk.com
Business Phone Number	To be completed by BO
Mobile Phone Number	To be completed by BO
Back Up BO Contact (in case of absence) name, title and email&phone number	To be completed by BO

	GSK Comments		FSP/FSO comments			
Dataset	Comments	Reviewer	Comments	Reviewer	Review Date	Resolution

Oversight Tools

2) Kick-Off Meeting

- Suggested topics for discussion
  - Welcome, Intros
  - Key Milestones/Timelines
  - Overview of Key Documents (e.g. Protocol, RAP)
  - Scope of work / deliverables
  - Roles & Responsibilities
  - Additional Info (e.g. systems, tools, processes)
  - Communication (Issue Logs, Meetings, Minutes, Escalation Procedure / Back-ups)
  - Documentation
  - AOB

Agenda Item	Responsibility
Welcome – Introductions Name, Role, Location, Relevant Experience	ALL
Key Milestones/Timelines Including, but not limited to: For RAP execution studies (for each reporting effort): RAP availability, Data availability, Pre-programming start, LSLV, SDTM availability, DBR, DRF, Delivery for stage 3 review, SAC , Archiving date, Anon date) For End to End as above plus FPA RAP CSR	GSK
Overview of Protocol and RAP For RAP execution – high level summary of key information from the Protocol and RAP in the context of the compound and where the study fits into the development plan. For End to End studies – high level summary of compound and where study fits into development plan	GSK
Project Scope / Deliverables (review of WRF / assumptions) • Protocol • Randomisation • RAP • SAC • Dry Runs	GSK/FSP

Oversight Tools

3) Meeting Minutes

- Template
  - Date of Meeting, Location (TC / VC / F2F)
  - Attendees (Present | Absent)
  - Agenda Items
    - with decisions documented
    - with action items for those things to be followed-up on
    - future (deferred) discussion points
  - AOB
- Approval
  - get them agreed by both CRO and Sponsor to ensure all on the same page

Meeting Title	GSK/FSP Meeting
Date	19th November 2014
Location	Objectives
Live Meeting	

Attendees	
GSK FSP	
Apologies	
	NONE

AGENDA ITEMS	
	AOB

Actions from Previous Meeting	
Item 1	Description
Item 2	Description
.....	

After Action Review

Feedback

- Close-out
  - Recognition of completion of study/reporting effort (thanks!), ensuring all deliverables have been fulfilled according to scope of work
  - Archival, Return of all artefacts (as per TMF)

- Lessons Learned
  - What went well?
  - What didn't go well (and why)?
  - Improvements for future working together
  - Feedback to GSK Governance (and CRO) on Key Performance Indicators (KPI)

Meeting Title	GSK/FSP After Action Review Meeting
Date	
Location	
Live Meeting	

Attendees	
GSK	Lead programmer, Lead Statistician
FSP	Lead programmer, Lead Statistician
Apologies	
	NONE

AGENDA ITEMS	
	1. **Initial expectations (Project Scope)** 2. **What actually happened** 3. **Differences** 4. **What went well?** 5. **What didn't work so well (and why)?** 6. **Lessons Learned:** • What should we start doing? • What should we stop doing? • What should we continue doing? Please ensure that the process flow for review of KPIs with service credits attached is performed at the After Action Review Meeting. The process flow can be found here: Link

Detailed Minutes	
1.	
2.	
3.	

Support

Training, SME team, Governance

- Training
  - GSK Third-party Resourcing SOP + e-learning module for tool-kit
  - Available to FSP vendors, train the trainer approach
- Subject Matter Experts
  - Programmers & Statisticians for each TA
- Governance Board / Escalation
  - Next layer of support with issues

Implementation on GSK studies

1) Resourcing Model selected

- Decision for resourcing model
  - Project/Study team to determine which functions are going to be outsourced (strategy, availability), S&P only or Study Management, DM functions too?
  - Complexity of the study, where is the expertise (i.e. internal or external)
  - Typical sequence for selection of resourcing:
    - In-house
    - Our strategic partners (prior experience/working relationship, on our systems/tools/processes allows us to minimise transfers, easier/faster review)
    - Non-preferred vendors (other CROs that are experts in a particular area, cost-effective alternatives)

- Have we selected the right resource model?
  - At GSK we have many TA, and each team works a little different (same company tools/processes, but different resourcing strategies based on complexity of studies, resource availability), on some occasions a resource option works well for one package but isn't necessarily appropriate for another

Implementation on GSK studies

2) Oversight Tools

- What works well with the Oversight Tools?
  - On the whole, the framework is good and helps us with efficiency (i.e. pre-filled sections to save time filling them, prevent human errors with typos)
  - They have evolved based on feedback from S&P teams using them

- What doesn't work well with the Oversight Tools?
  - Not every work package is the same. Team need to use common-sense approach sometimes to ensure it makes sense and is clear
  - Tools tend to work well, but the mechanism for sharing them between GSK and the CRO can be an issue (i.e. multiple copies edited at the same time when file is not in a shared area). Good communication required or better mechanism for sharing tools required.
  - Under/Over QC of work – too little that you can't provide sufficient evidence of oversight or too much and you risk wasting too much time repeating what the CRO have already performed (i.e. defeats the object of outsourcing in the first place)

Implementation on GSK studies

3) Study Specific Checks

- It is important that we perform a QA and not a fully QC of deliverables.

- It can be difficult to figure out where to focus the QA
  - A risk based approached needs to be taken where high risk items or deliverables are checked with an expected tolerance/threshold for level of quality we would expect.
  - If the expected tolerance/threshold of QA is not exceeded then we can be comfortable that the quality is satisfactory.
  - However, if the expected tolerance/threshold of QA is exceeded, then we need to increased our level of checking.

- Everything regarding what QA checks we are performing, what issues we identified from our checking and verification that the vendor had resolved all issues identified, needs to be documented as part of our Oversight documentation.

Conclusions

- Does Outsourcing work?
  - Yes and No.
    - Some work packages are handled well and delivery is on-time and few issues.
    - The following factors assist effective outsourcing work:
      - Good communication skills
      - Clear and transparent specifications
      - Good quality of CRF data
      - System/Tool stability
      - Sufficient time/resource (to help prevent human error issues)
      - Stable team (less turnover of personnel) and good documentation (to assist handovers if absolutely necessary)
      - Stable scope of work (or clear updates when mandatory)
- Does this framework work for all work packages?
  - No. It's a risk-based approach and not every work package is identical. This is a good framework that has evolved for us and is better than nothing, but still requires GSK (and CRO) personnel to think and be prepared to challenge items that will not work/need to be adapted

Questions

- Thank you for your time and attention to this presentation.

- **Questions?**

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