

# Digital Technology & Patients Tools in Clinical Trials

## Management of service providers

- PART 2 -

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2017/november



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Dedicated to eCOA & Patient Engagement

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# Introduction

Getting the business  
is one thing, keeping  
it is another:

*“Coming together is  
a beginning; keeping  
together is progress;  
working together  
is success.”*

Henry Ford <sup>(1)</sup>

## Moving on from the “Selection & Evaluation of Technology Service Providers White Paper Part 1”, this white paper focuses on management of Technology Service Providers.



It aims to tackle some of the following questions concerning industry practices when conducting the management/oversight of its drug development programmes with its technology vendors:

- How to share with technology providers, the pharma company strategy/business objectives, to make them clear and transparent to enable the provider to support the companies’ direction & growth? How to align the strategies/culture/processes to ensure long-term value creation together with short/mid-term service delivery?
- What portfolio information is shared with service providers to show mutual business intent towards a strategic/long-term business venture?
- If multiple providers are selected how to deal with the complexity of different relationships across different functions/projects/programmes to achieve harmonisation, efficiencies, value, transparency as well as compliance to regulatory requirements.
- And if there are several providers how to best support the integration of new technology sourced using the internal IT platform/architecture. How can the company leverage the same technology across the company in different functions or business units?
- What should be the duration of the deal for programme needs mitigating the risk of potential obsolescence of the technology? Does the ROI calculation justify the expenditure to make the technology 21CFR Pt 11/GCP compliant and what are the regulatory hurdles to be overcome?

In a recent interview <sup>(2)</sup>, Jean-Yves Rotté-Geoffroy - CPO, GlaxoSmith-Kline said:

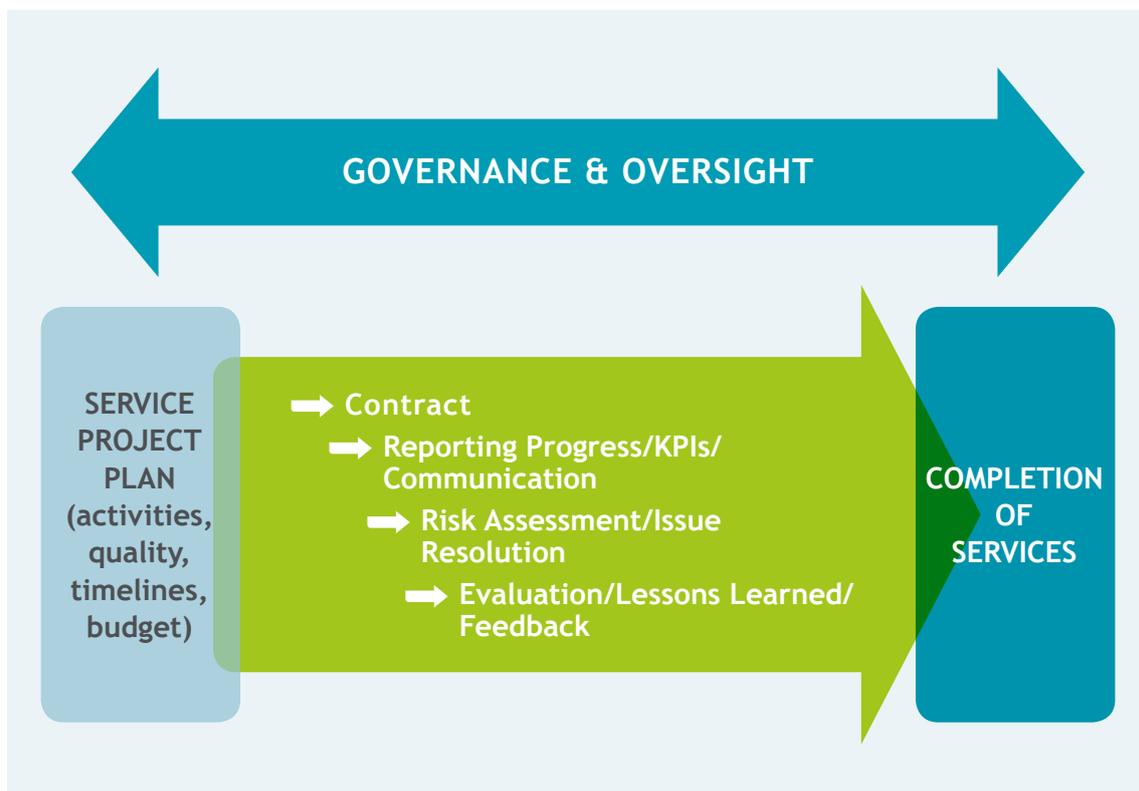
- “ Know your business... Know your suppliers. When I was a young buyer, I complained about a supplier I found difficult and my boss told me off. He was right. If procurement does not love suppliers, who will? They are your company’s external resource. Most people in procurement

are curious, externally focused, they find externally an infinite pool of outstanding capabilities, talent, solutions and they want to bring them in. Through an intimate knowledge of suppliers and external markets, procurement helps identify, select, develop and manage the best ones with a view to maximizing their contribution to the strategy. Not a procurement strategy, but the business strategy, the only one that matters.”

“ ...It is harder to visit your suppliers than to ask them to visit you, but how well do you know them then?”

Selecting and managing your technology providers in the pharma/ healthcare industry, be it e-PRO, e-COA or other technologies, is becoming just as if not more important than selecting your full-service or FSP Service Provider (SP) <sup>(3)</sup>. Thus, the objective of this second white paper is to provide guidance on how to develop, build and optimise the business relationship between sponsor and the technology provider (Figure 1) to enable short term project delivery as well as to promote a culture of “trust/confidence” for mutual, long-term business growth.

**Figure 1: Governance & Oversight of an Outsourced Project/Service**



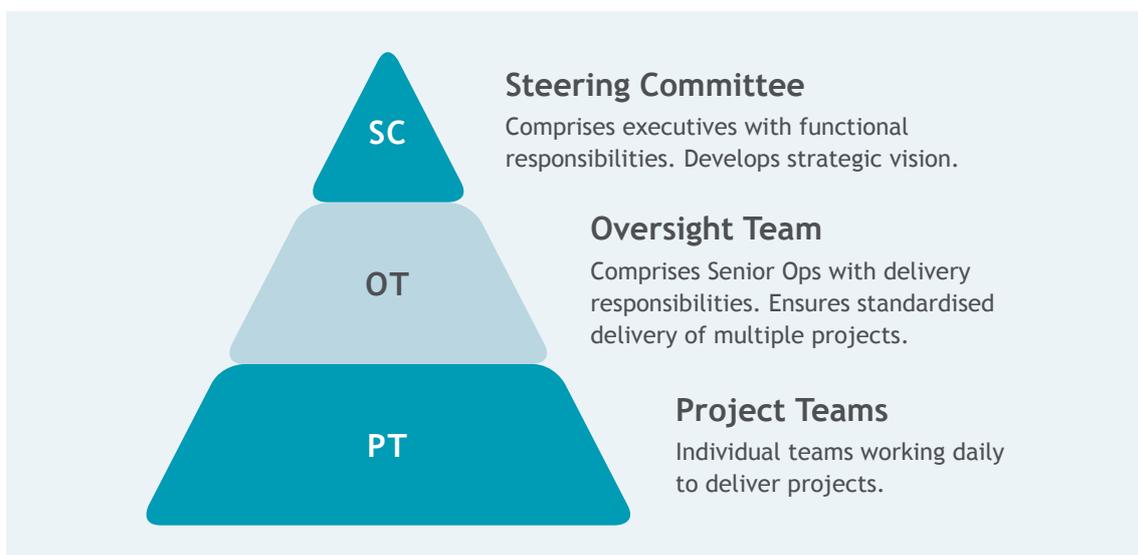
# Overview



Whether in the project plan/master agreement and according to business relationship type, joint discussions followed by a written agreement on the degree of governance and oversight management should describe/outline the nature of the desired business relationship. The list of elements to be considered in this process are:

- An adapted governance model - relationship type: strategic, preferred provider, risk-sharing, tactical, other (Figure 2)
- Governance charter to oversee the business relationship
- Role & responsibilities of the Steering Committee (if applicable)\* (degree of senior management involvement & sharing of portfolio information)
- Role & responsibilities of the Oversight Team (in relation to the D2D operations team)\*
- KPIs - Business & Operational, use of a balanced scorecard and/or a business health-check tool
- Communication type & frequency (Operational, Oversight & Steering committee levels)
- Risk management - risk identification, stratification and management
- Issue escalation/resolution
- Product lifecycle management (if applicable)
- Lessons Learned meetings/workshops

Figure 2: Example governance model



\*In a hybrid model, the Steering Committee and Oversight Team may be one and the same meeting at different time points with different objectives

# Contract - Legal Agreement



**Master Agreement:** Once the decision has been taken, the master technology/service agreement can be finalised. Comments from the technology SP legal department will have been provided during the due diligence process. Thus, it's time to get on the phone to agree on the minor changes and to negotiate the important clauses around technology ownership/IP, liabilities/indemnities, data/cyber security, dispute resolution & termination. When doing so it's worth bearing in mind the relationship type entered into and whether this may evolve over time.

**Work Order/Statement of Work:** The work orders will need to be adapted based on the deal i.e. a one-off study/pilot study, a programme or licensing of technology. Whatever the deal the costing should remain as transparent as possible, keeping costs simple and allowing for risk management & contingency planning for unanticipated changes in the clinical programme which is essential. Agree on the functions/competencies working on the project, the seniority level needed and the time allocation to the project.

**At a minimum, the work order should outline:**

- Description of technology/service scope
- Product lifecycle management (if applicable)
- Key contacts, back-up and replacement strategy
- Roles and responsibilities Sponsor-SP (Consider a RACI grid, if there are more than two parties e.g. Device Provider, Data Provider & Sponsor)

- Audits and frequency
- Compliance to regulations/directives
- No sub-contracting unless prior written approval
- KPIs on quality & delivery - with periodic sanity checks
- Competency evaluation/sign-off of key team players
- Reference to a governance structure and an oversight plan
- Regular reviews on progress by operations & business relationship & lessons learned



## TIPS

Is the contract sufficiently detailed to cover the roles responsibilities and the risks of each partner without being too detailed (no-one will look at it)? Does it outline the back-up plan for when things go wrong and does it enable the parties to choose the best resource when turnover inevitably occurs?

Short-term contracts may be appropriate as fast changing technologies translates to the importance of keeping business opportunities open and avoiding commitment to one sole partner.

# Reporting, KPIs, Communication



When planning the outsourcing of a project, aim to have the kick-off/team launch meeting as early as possible. One of the common issues raised by SPs is that they are often involved at “too late” a stage in the development programme. Some SPs suggest that they are approached by pharma when 80% of IT-related thinking has already occurred making it difficult for SPs to contribute/input with their expert knowledge. Bringing in or using new technology can be expensive/high-risk so finding a way (once CDAs are in place) to share as much as is feasible on the business technology strategy, can benefit long-term business objectives.

It’s important to involve all partners/service providers, i.e. integrated team approach, in the kick-off/launch meeting. Japanese companies like Toyota have been conducting operational meetings with multiple providers since the 1950s<sup>(4)</sup>. Their “multiple provider” meetings/sharing initiatives benefited their business through performance improvement for all involved, “the whole” rather than one company only.

**Operational implementation:** The kick-off/launch meeting may include the review of:

- Project/service objectives
- Team organogram & organisational org charts - joint/sharing
- Team members & back-ups
- Process, roles & responsibilities (back-up)/RACI chart
- Project/programme management plan
- Timelines (critical *versus* non-critical milestones)
- Reporting/dashboard, KPI & tracking process - both for an executive summary and for a detailed day to day progress report (with a shared point/web portal accessible by key team members/stakeholders involved)
- Systems/tools to be used on the programme (e.g. CTMs, patient devices)

- Communication plan
- Risk management plan (clinical & technology risks)
- Issue management plan



It is quite probable that the contract will change/require modification at the implementation state. This is not unusual as the level of discussion at the kick off/launch meeting is far more detailed than that of previous discussions.

## ✓ Reporting/KPIs

**Address the questions: to whom are we reporting, what, how and when?**

The reporting dashboard will be used and reviewed by senior management, the oversight team and operations thus it is important to keep this as simple as possible in terms of collection of progress data. Whether it is the sponsor or the providers tool, there needs to be agreement on the content and who/how it is updated as well as when it is updated.



Avoid the use of a sponsor and a provider reporting tool as inevitably there will be differences that arise along the progress of the project which will cause potential frustration/confusion and unnecessary loss of time/resource. Provide a shared point (be it web-portal or other location) accessible to all team players where all project information can be stored/updated/reviewed.

## KPIs - Business & Operational

The objective of the project/service key performance indicators (KPIs) is to identify service delivery & to provide a sanity check/confidence (at 25, 50,75 % of service completion) that the project is on target to succeed in delivery of the agreed milestones/activities, budget tracking and quality.

### Business KPIs

Address the questions: are we developing a business relationship/culture based on trust/confidence that can/will be long-lasting? Is there an ongoing business interest to collaborate for both parties? Are we synergistic and efficient in our operations?

Some KPIs for consideration are:

- Relationship questionnaire - Sponsor/SP team satisfaction
- Audits - # of critical findings
- Employee retention - Sponsor/SP
- Skill base/competency levels (scientific & IT)
- % invoices paid on time
- Trending of issues - major/minor

### Operational KPIs

There are several initiatives/groups focussing efforts on the harmonisation of KPIs/metrics to be used in the clinical development arena e.g. AVOCA & MCC (Metrics Champion Consortium). A new area for KPI development is in the review of new technologies in clinical trials. The question to be addressed is how to measure the performance of technology/systems as a specialised service offering? As a new area for consideration, it is essential that pharma and SP jointly develop the KPIs that are meaningful to both organisations: indicators of delivery and a sanity check that we will attain quality (data integrity), timelines & cost objectives.

Thus, here are for consideration some KPIs that may be used for technology services:

- Device reliability
- Delay for device provision/replacement
- Infrastructure - speed of network connectivity (downtime/failure)
- Functional capacity & reliability

- Cybersecurity/information security/leak
- Cycle time from request to delivery
- Percentage of issues solved by the first call/contact



## TIPS

**Keep the KPIs “S.F.M.” - Simple, Few & Meaningful...**

Too often in the industry a tracking tool is developed with too many KPIs which becomes too resource intensive to update and to maintain! Then to add insult to injury, the tool gets dropped and is no longer updated/used by the team as members become focussed on the priorities of day-to-day project delivery.

## ✓ Communication

All projects between different functions and different organisations need to have a communication plan adapted to the simplicity/complexity of the project and its stakeholders/team players involved.

A communication plan may include:

- Frequency, objectives, participants, methods/systems for project/information exchanges
- Agreed rules e.g. who is/are the main contact(s), who to put on copy of communications
- Communication flow: Identify those functions that will have direct contact with equivalent function in the provider company
- Meetings: lead-times (1) for provision of draft agenda to allow feedback & preparation, and (2) review & distribution of meeting minutes
- Communication alerts: messages may be labelled “Important” and/or “Urgent” to get priority action/attention from the team
- Expected response turnaround time to written communication/requests
- Need to update the project plan and/or contract according to progress



## TIPS

- Reminder for meetings: minutes or a brief summary in writing is a confirmation of the verbal exchange and of what you have understood (or not) - we don't always go away with the same information/understanding so written follow-up/confirmation in a timely manner is key to understanding and progress.
- Avoid "nice to have" participants in the planned meetings.
- It's important not to underestimate the complexity/potential barriers of communication across languages, culture, generations, seniority, time zones and technology!
- When fighting fires, it's important to keep one's cool, to focus on the facts and to identify actions (let your steam off later!). "In the heat of the moment it is very easy to judge others by their behaviour and ourselves by our intentions" so to collaborate in a team the ability to "actively listen" to understand is critical.

# Risk Assessment & Issue Resolution



The problems/risks associated with a clinical programme are well-known, e.g. delayed ethics committee approval, problems with import license for IMP (Investigational Medical Product) shipment to sites, internet connectivity for sites/patients accessing databases, web portals, hand-held devices (lifecycle if long-term study). Thus, an essential part of the project plan is to list those potential risks, identify the probability and impact of their occurrence and propose a mitigation plan accordingly (3). This is a joint effort between sponsor and service provider and is part of the review meetings (be it every month, quarter, other) to identify the need for action, its timing and the nature of the action.

This may also be reflected within the contract under the heading of contingency activities/tasks to be triggered for specific situations.



## TIPS

The mitigation plan may require supplementary expenditure or extension of timelines, thus keeping senior management informed of these eventualities, in a timely fashion, will promote an expeditious approval of the business case for extra funding (if this has not already been anticipated upfront in your project/contract contingency plan).

### ✓ Issue management plan

The issue management plan is part of the risk management plan so it is worth managing these in the same tool/system. An issue log is an important tool to track the day to day operational issues that arise, to identify their nature (technical, quality, timelines, cost, interface), to define whether the issue is minor/major/recurrence, the priority for resolution and the levels of the escalation process if resolution does not occur within the agreed timelines and/or actions. For this reason, an escalation plan/escalation organogram is a helpful tool for the project team to develop.



## TIPS

- Do's: Do get confirmation that the issue is one and the same for you and your partner that you are not talking at odds. Do consider whether SP senior management can support resolution efforts by contacting your management.
- Don'ts: Don't let it drag on - especially when it becomes major or critical. Don't let it create a negative team atmosphere (blame culture) or create an "Us versus Them" feeling. Don't let it become personal - you are both trying to do a good job with the resources you have.



# Evaluation Lessons Learned

Performance is not isolated to KPI/metric monitoring it is about continuous learning for continuous improvement - “how can we do better the next time?”. It’s also about creating a positive team environment where employees are motivated/autonomous/challenged and want (and are committed) to do a good job.

Instigating an evaluation/lessons learned “culture” throughout the project/relationship and at key points (at least in the middle and at the end) agreed by both parties is an investment that will pay off. It will enable:

- Best practices to be identified and implemented to develop operational efficiencies (processes/systems)
- Improvement of performance on future programmes
- Identification of competency gaps and related solutions
- Identification of new ideas/approaches as well as
- Creating a “feel good” team atmosphere

It will give time to discuss/share ongoing actions to clarify misunderstandings/ expectations of both parties (using objective examples to demonstrate the point) and to improve communication/ understanding. This is especially important when either partner is entering into a new service field e.g. new technology not previously used.

It will also serve to better understand contractual obligations/matters that can be better described/improved in later service work orders.

In some instances, using an independent person (facilitator/mediator) outside of the project/service delivery team (with no conflicting interests or biases) may be useful to get agreement on outcomes.

Evaluation/lessons learned exercises will determine, if appropriate, the need to modify procedures/processes, the contract or (as a last resort) personnel if the project/service lacks the competencies required for successful delivery.



## TIPS

Include in the contract the need, frequency, participation of lessons learned workshops. Encourage that these be a F2F exercise to promote relationship building for effective communication and understanding of needs.

Whether or not there is a change in business strategy/interest which curtails a long-term business relationship, the conduct of such reviews will promote learning & continuous improvement for both parties.



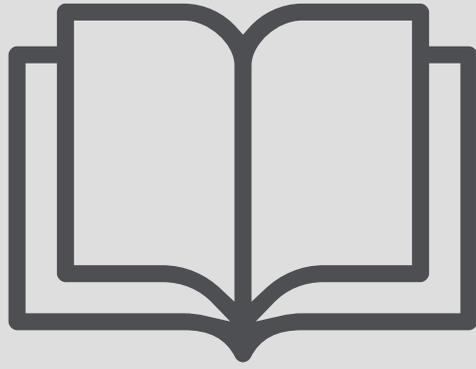
# In Summary

## It's important to implement and manage:

- Adapted governance/oversight levels/checks for the relationship type
- A contract that describes the intent of the business relationship
- Short product lifecycle management in long-term clinical studies
- Simple, few, meaningful KPIs to support reporting/delivery
- Pro-active risk assessment and a robust issue escalation process
- Ongoing evaluation of the project/service
- Competency/resource level reviews (scientific & IT)
- Ongoing review of the mutual business interest to collaborate

Building the relationship, knowing what makes the other company tick, what motivates people to come to work every day and “how we do it here” is an important part of the business collaboration and business “culture”. We know well that what often kills a deal isn't finances, legal or organisational infrastructure but rather the chemistry/interest between senior members of partnering organisations. And the chemistry between the operational staff that need to make it work!

Building the relationship is important. How far we take it will depend on the value the partnership generates <sup>(5)</sup>.



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