

Building a new outsourcing strategy - a large pharma case study

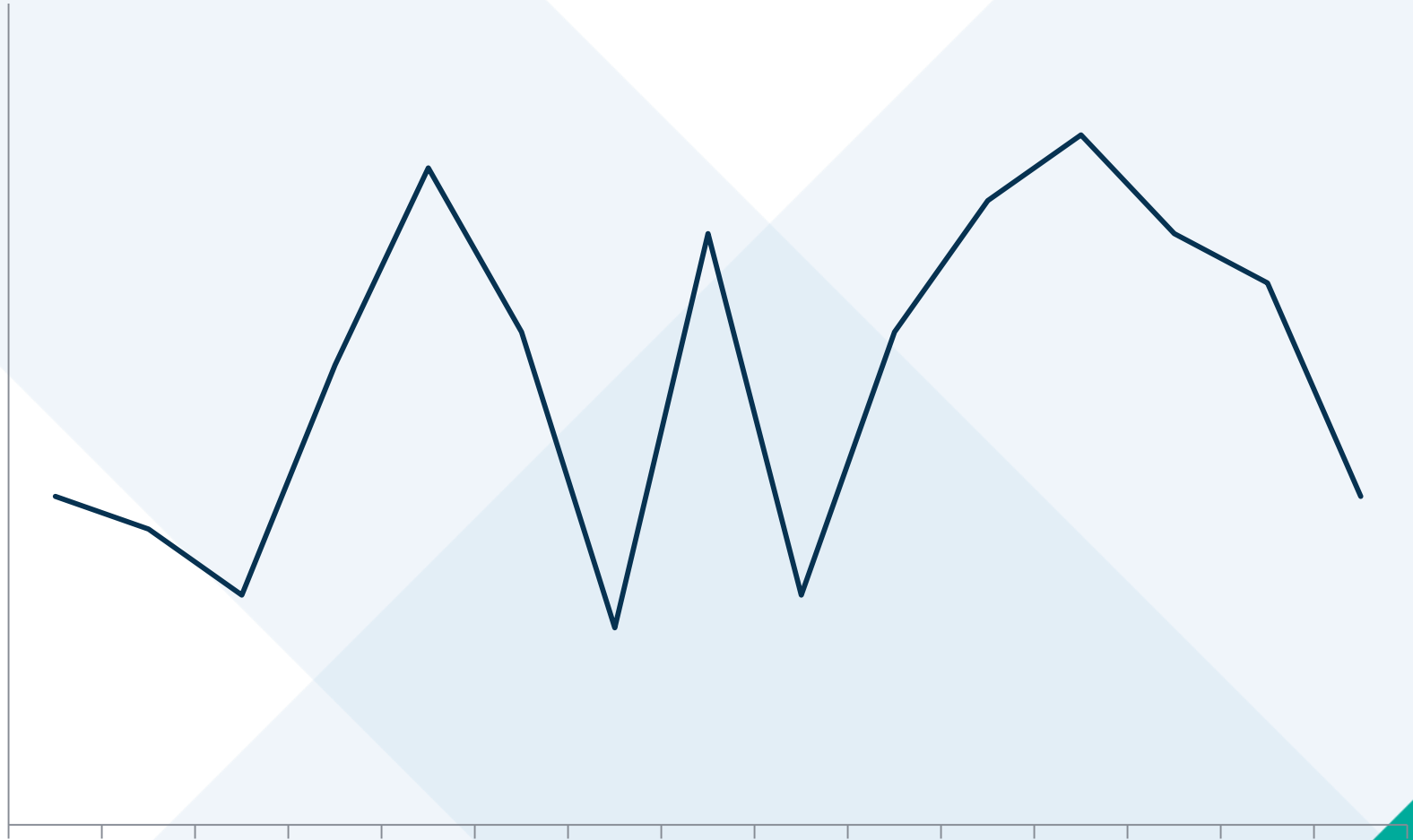
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Case Study

- Outsourcing of Study Start-up, Monitoring and Project Management for Phase II-IV studies
- Transitioned all European activities to ICON in 2009/10

What should we outsource?



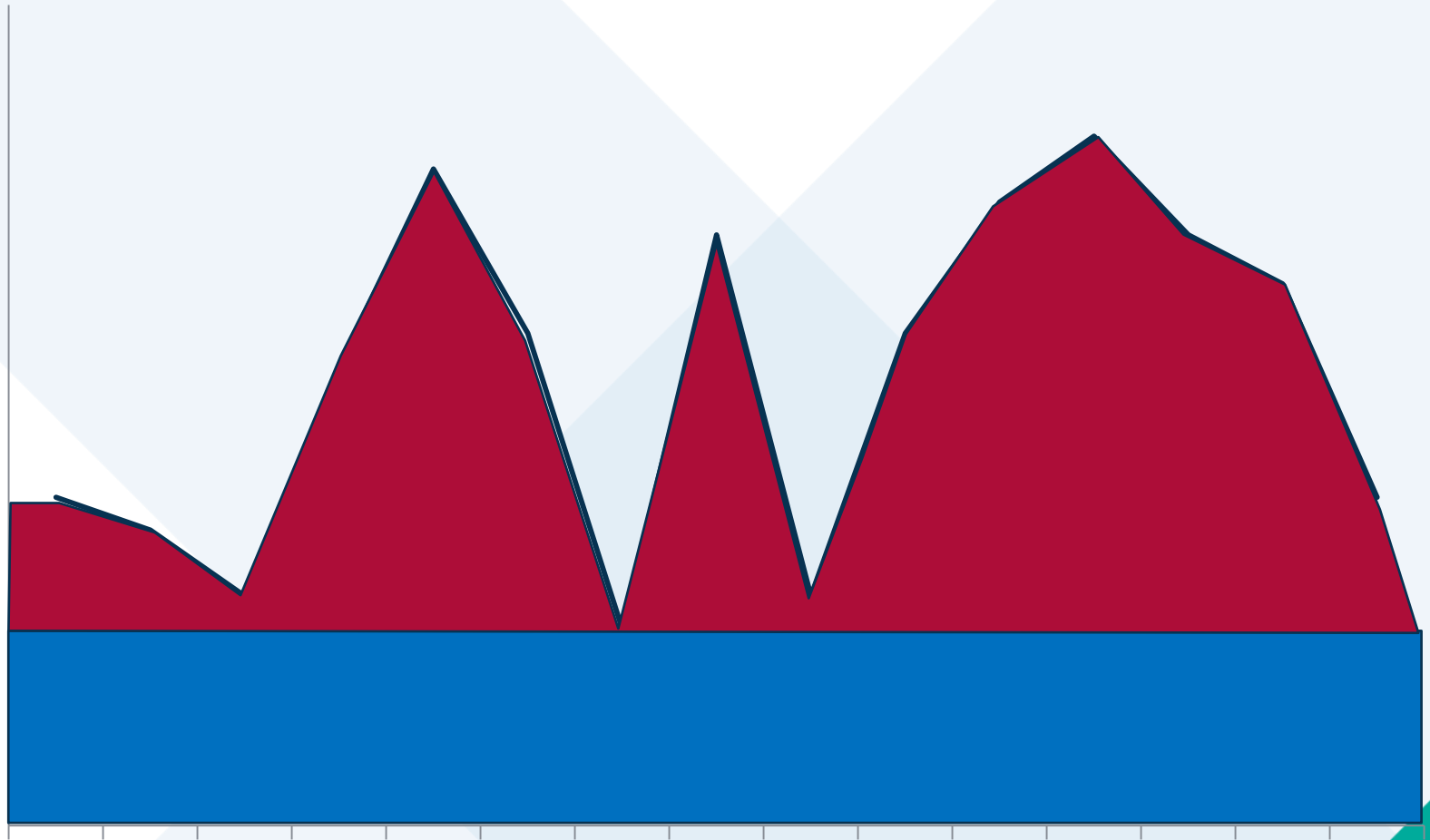
All work done in house?



All work done in house

- ✓ High control.
- ✓ Single model, better standardisation.
- x Needs high levels of spare capacity to resource the peaks.
- x Redundancies followed by rapid hiring and training.
- x Temptation to delay studies due to lack of internal resources.
- x High levels of fixed costs especially if using permanent staff.

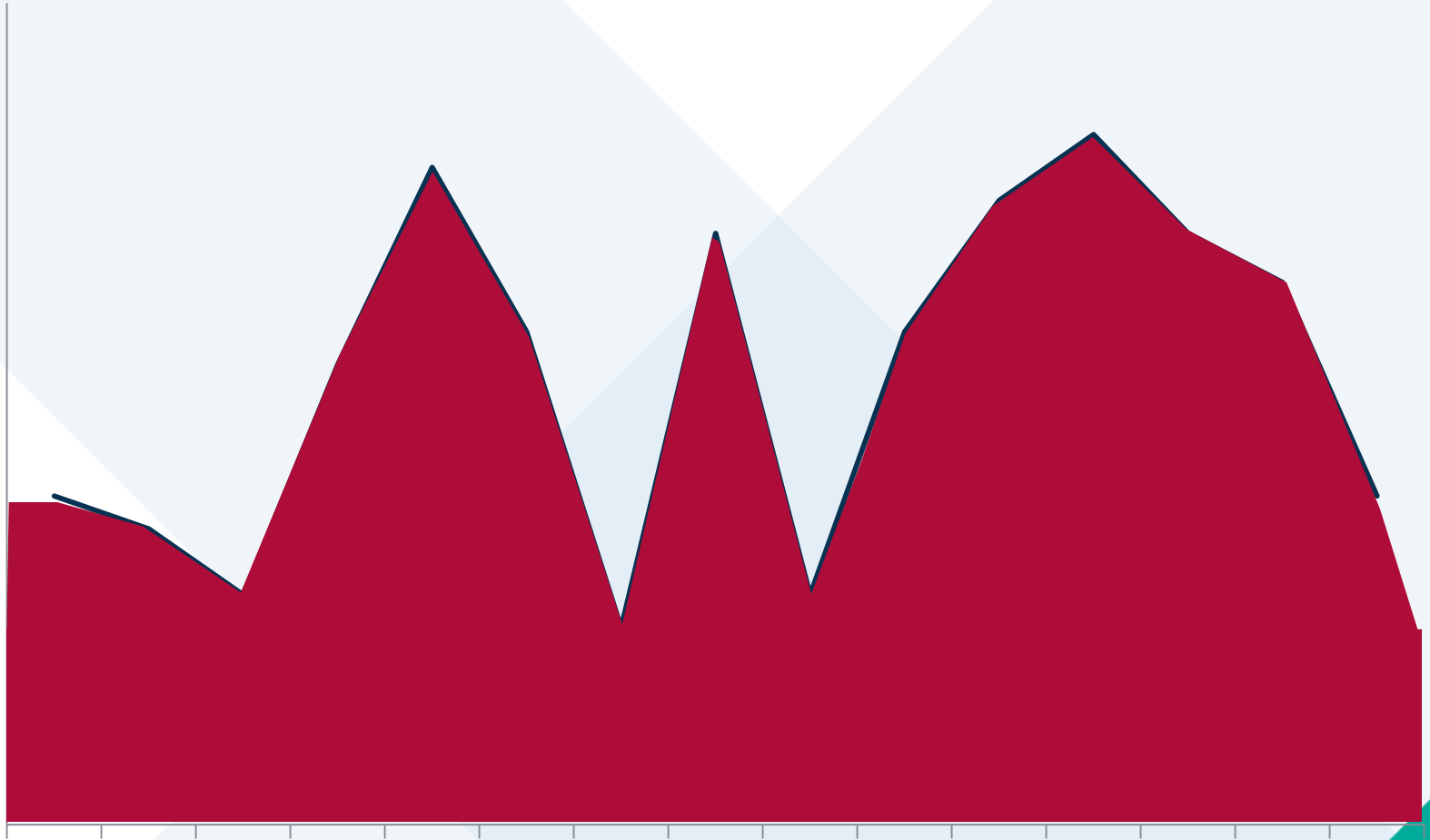
Resource to the troughs?



“Resource to the troughs”

- ✓ Theoretically most cost effective
- x Mixed model – reduced standardisation.
- x Large variation in outsourcing make less attractive to CROs.
- x Can we accurately predict how deep the troughs will be?
- x Resources may not be the “right resources” for a study.
 - x Geography
 - x Language
 - x Skill set
- x Outsourced studies difficult to bring back in-house when resources become available.

What do we outsource?



Fully Outsourced strategy

- ✓ Do not need to worry about resourcing peaks and troughs.
- ✓ Able to set up partnership agreements.
- ✓ More attractive to CRO
 - ✓ Agreed procedures
 - ✓ Reduced Costs
 - ✓ Standardised Processes
- x Less control
- x Loose in-house expertise. Difficult to bring in-house at a later date.

How should studies be outsourced?

Contingent labour



Contingent labour

- Mixture of outsource and in-house where an internal study team is heavily augmented by contractors.
- ✓ Flexible – only hire what you need
- ✓ Sponsor has high level of control over project.
- x Must recruit, train, coordinate and manage newly formed teams.
- x Little retained knowledge.
- x Difficult to hold team to account.

Full Service Outsource



Full Service Outsource

- Many functions from a study are outsourced to a single CRO
- ✓ CRO coordinates between functions themselves.
- ✓ Less finger pointing when things go wrong.
- x Difficult to find a CRO which is strong and can provide a competitive advantage in all functions.
- x Many CROs subcontract work in order to provide additional functions

Functional Outsource



Functional Outsource

- One function (or small number of related functions) from multiple studies are outsourced to a single CRO
- ✓ Can select specialist providers providing competitive advantage.
- ✓ Selected functions can be off-shored to low cost geographies if desired.
- ✓ Can standardize between projects.
- ✓ Regarded as most cost effective.
- x Sponsor must coordinate between providers.
- x Can result in finger pointing when things go wrong.

How many vendors?

Many



Tactical Outsourcing

- Every study is outsourced as an individual piece of work.
- Use a wide variety of CROs
- ✓ Can select best CRO for each study.
- ✓ Moderate accountability – “if you don’t do this study well you won’t get another”
- ✓ Good for niche studies
- x Inefficient
- x Less opportunity for standardisation across studies, dedicated teams etc.
- x Poor negotiating position

Small number (2-4)



Strategic Outsourcing (Preferred Partner)

- List of up to 4 CROs with agreed pricing and terms & conditions.
- Niche studies can be placed elsewhere
- ✓ Some choice to select best CRO for each study.
- ✓ High accountability – “if you don’t do this study well you will loose a lot of future business”
- ✓ Some opportunity for standardisation, dedicated teams etc. across studies.
- x Less choice
- x Need to decide how to divide studies between CRO. Outsource each study?
- x Failing to maximise economies of scale.

One



Strategic Outsourcing (Strategic Partner)

- One CROs who runs all studies.
- CRO responsible for finding, contracting and managing CROs for any work they can't do.
- Model used by Lilly and many other human pharma companies.
- ✓ Very High accountability – Issues can be escalated up to very senior levels. Full governance structure.
- ✓ Significant cost savings.
- ✓ Able to work with CRO to design processes, access to teams that work extensively on Lilly studies.
- ✓ Efficient (company oversight, contracting, quality, senior management).
- x Heavily dependent on one company.
- x No ability to match CRO skills to individual studies.