



BUILDING THE INDUSTRY'S FIRST DYNAMIC MAPPING SOLUTION

A White Paper by Strategikon Pharma



Untangling the Knot of Clinical Trial Bid Grid Mapping

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Building the Industry's First Dynamic Mapping Solution: **Untangling the Knot of Clinical Trial Bid Grid Mapping**

Mapping: A Dual Industry Perspective from Sponsors and CROs

Bid grid mapping is a well-known and yet an unaddressed outsourcing challenge, facing both biopharmaceutical Sponsors and their service providers, especially the Clinical Research Organizations (CROs). For outsourcing and proposal managers alike, it has become one of the most time consuming and error prone activities in the due diligence and bidding processes.

A few scenarios will be reviewed to gain deeper understanding of the landscape starting with the CRO and Sponsor points of view of the outsourcing process. Like many core processes in the clinical development arena, bid grids, or budget grids, are incredibly complex and have never been standardized. Most CROs have developed internal costing tools, predominantly Excel-based, incorporating a high level of sophistication centered around clinical trial assumptions (study specifications), resources and activities, e.g., minor and major tasks. Several factors directly impact the CRO budget structure: company size, array of services provided, acquisition history and legacy, resource naming conventions, activities, and cost drivers. Most CROs budgets are built on activity-based costing models, allocating resources to minor tasks based on several dimensions, such as geography, role mix, protocol complexity, therapeutic area, outsourcing strategy, or specific costing model. The resulting budget structure often contains thousands of lines, organized in different buckets, e.g., “major tasks,” “services,” “service categories”, each representing the unique organizational structure, preferences, and budgeting legacy of each CRO.

From the Sponsor side, the biopharmaceutical companies generally outsource >75% of their clinical pipeline, >\$50b per year, using different outsourcing models such as full-service, hybrid, functional service provider, and fixed cost to name just a few. They are seeking the CRO expertise in clinical development and soliciting bids either at tactical (competitive) or strategic level (preferred partners). Since each CRO has developed its own unique budgeting model, it is virtually impossible to conduct an “apples-to-apples” comparison of the budgets or cost drivers without normalizing the differences in the budget structure. To ease the effort, every prominent Sponsor has developed its own unique budget structure, usually a fraction of the size of a CRO's, highly aggregated and simplified to ease the due diligence work of the outsourcing managers. A 2019 Sponsor survey by Strategikon revealed that >90% of the Sponsors have some kind of standardized template for CRO services (figure 1).

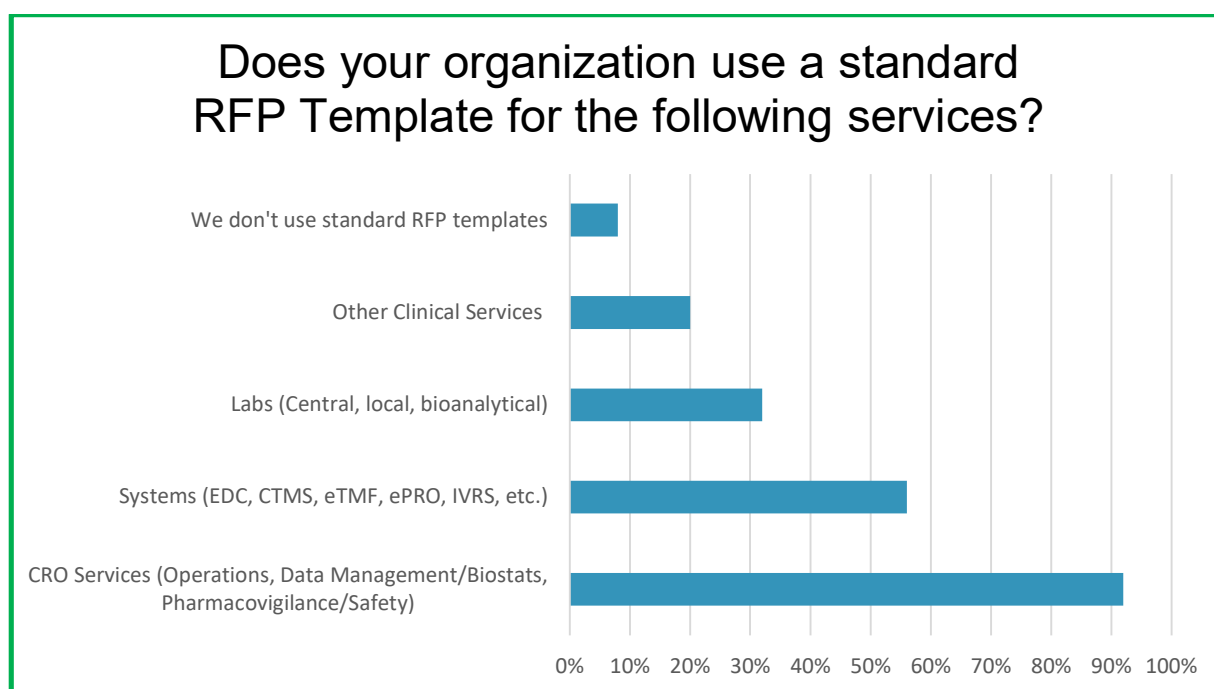


Figure 1: Strategikon Pharma Sponsor Survey – 2021

A Process with No Common Language Leads to Frustration

To find a common language between the Sponsors' and CROs' specific budget language, bid grid mapping was born. It is a tedious, imprecise, subjective and error prone technique, employed by either Sponsor or CRO, to attempt to demystify the structural and nomenclature preferences of each party involved.

The Sponsor Process

A typical bid management due diligence process at a Sponsor goes like this: the Sponsor starts with an RFP structure containing assumptions and budget activities grouped by services or major tasks, e.g., Medical Affairs, Project Management, Study Start-up. This structure has either been created internally or inherited, typically from an acquisition. Countless hours are spent by multiple departments, including procurement, clinical operations, and finance, in finalizing the budget grid. The resulting bid grid is then shared with the tactical or preferred service providers during the bidding process with the expectation that the proposal is returned in the Sponsor template. For preferred partners, the process typically involves multiple sessions between the biopharma company and the CRO, aligning definitions, breaking down each line item into the required resources, designing different bidding combinations, such as fixed cost blended with variable units and developing complex mapping instructions with roll-up units and artificial unit names. This process takes months for the Sponsor and CRO to redefine, rename, and reconfigure the bid template. Our survey reveals in Figure 2 that "demystifying the budget", along with variance analysis and remapping are the greatest pain points in Sponsor due diligence.

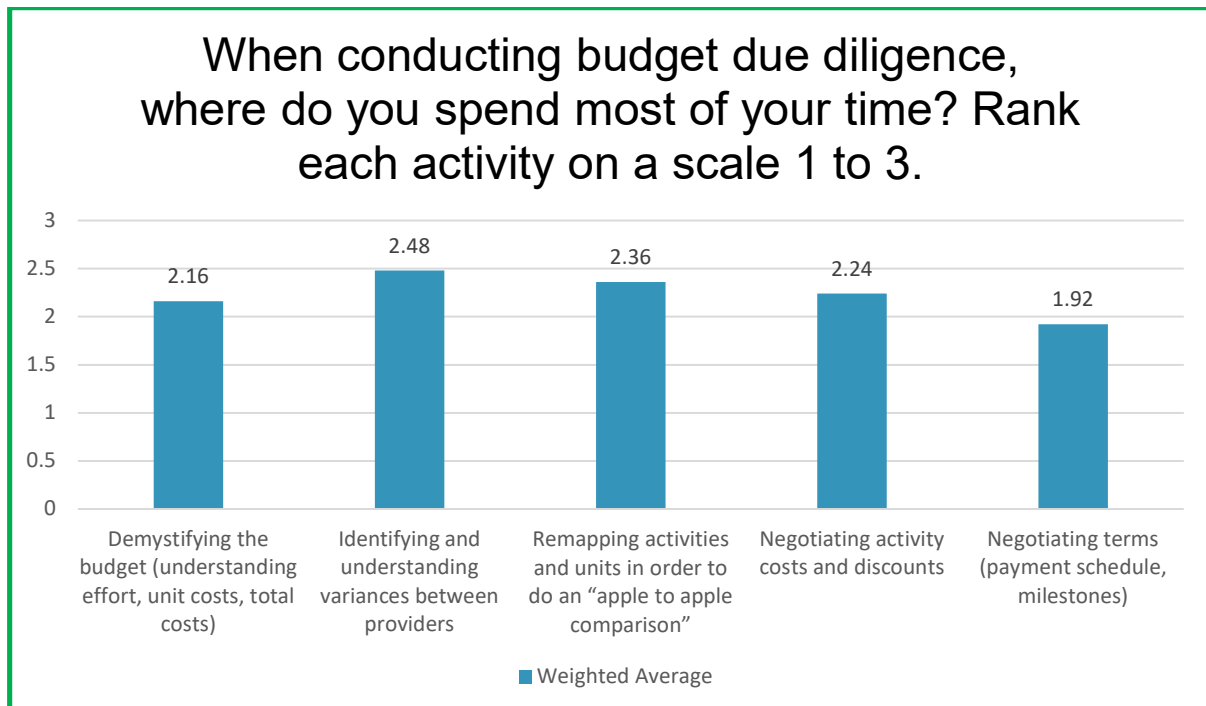


Figure 2: Strategikon Pharma Sponsor Survey – 2021

The CRO Process

Once completed, the CRO's proposal team is equally busy. Regardless of the level of mapping engagement with the Sponsor, the CROs need to program the Sponsor template mapping (usually via Excel macros), carefully grouping their own minor tasks into the Sponsor's roll-up unit, changing calculations for unit cost, documenting meticulously the resulting resourcing aggregations, the changes in cost driver relationships and definitions of the artificial units. A daunting task, this is often squeezed down to less than a week to fit the typical Sponsor bid submission timeline of two weeks per RFP. "Mappers" are usually lower-level proposal team members, often located in lower cost locations and less skilled in the clinical budgeting art. Their lack of experience results in mapping errors, definition misinterpretation and of course, regardless of the skill set, subjectivity is omnipresent. Figure 3 illustrates just how long these tasks take.

Even if the Sponsor chose to accept what is normally termed as "CRO native bid grid," essentially allowing the CRO to use their own bid template, the mapping exercise does not go away, only shifts from the CROs' team to the Sponsor's team. This is the typical scenario for biotechs who are too small to exercise leverage on the CRO to induce them to map to their standard template, or more commonly, because the "standard" is lacking altogether due to the limited outsourcing experience of the biotech. In these cases, sometimes the clinical operations team of the biotech, or a consultant, takes the native bid grids of the various participating CROs and aligns them side by side for comparison, using their own subjective interpretation of the various budget buckets and activities and minimally engaging the CROs in the mapping exercise. The resulting due diligence rarely identifies the true causes of the cost differences, costs the Sponsor team sometimes hundreds of hours in a large competitive bid involving multiple CROs. Finally, the effort does not lead to substantial savings, or any savings at all. Quite the contrary, the biotech ends up overpaying compared to other pharma employing more sophisticated outsourcing processes.

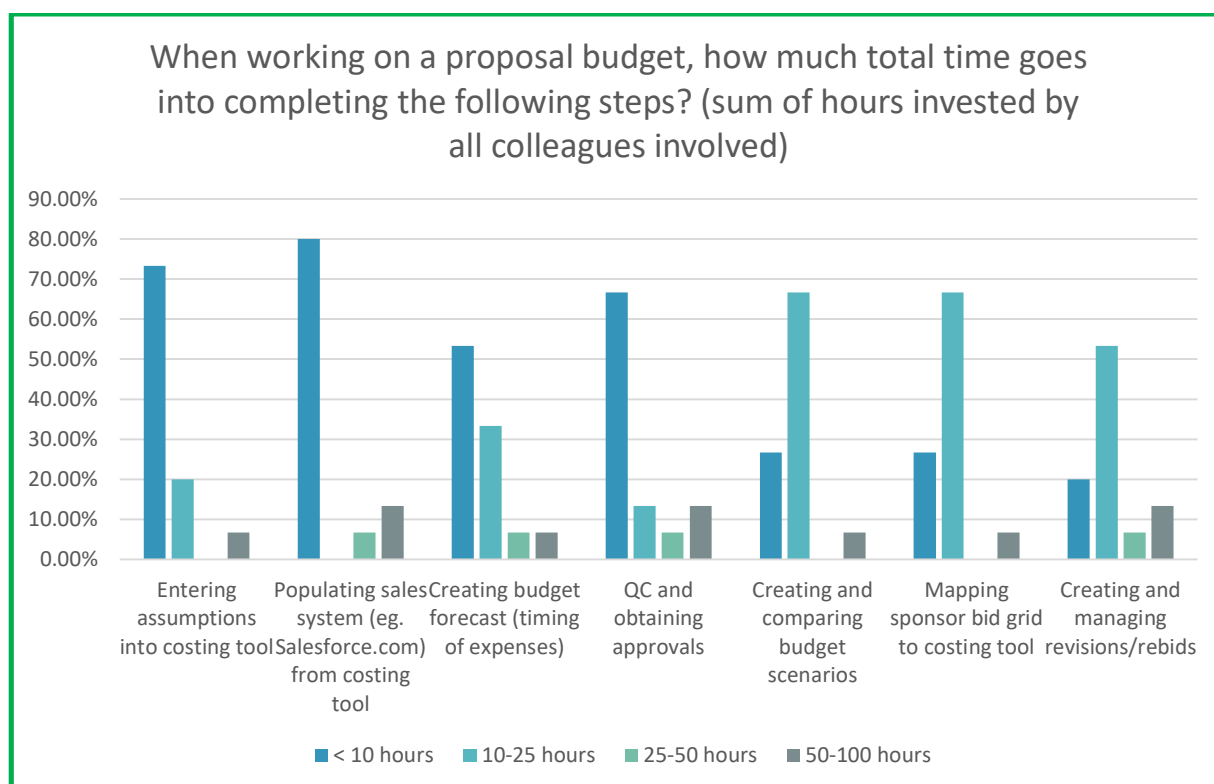


Figure 3: Strategikon Pharma Sponsor Survey – 2021

The Change Order Process

Of course, the initial mapping is only the first step of this frustrating and highly tedious process. Budget templates are never static as the CROs change costing tools, the Sponsors change costing models, and the clinical studies are growing in complexity, driven by adaptive designs, decentralized trials or regulatory changes. Change order management is yet another effort involving customized remapping or completely changing the respective documentation, reprogramming and legacy grid maintenance. The impact of changes can be severe. In a recent relationship between a mid-pharma and a top CRO, the CRO could not agree to maintaining the legacy mapping key the Sponsor was used to as it would change the CRO's cost structure. This resulted in the termination of the entire relationship. Even in absence of structural template changes, the mapping needs to be update for every change order, change in scope, reforecasting exercise. No wonder the "mappers" are some of the busiest staff members of a CRO proposal team. The Strategikon survey, figure 4, clearly depicts how painful the mapping is in the change order process.

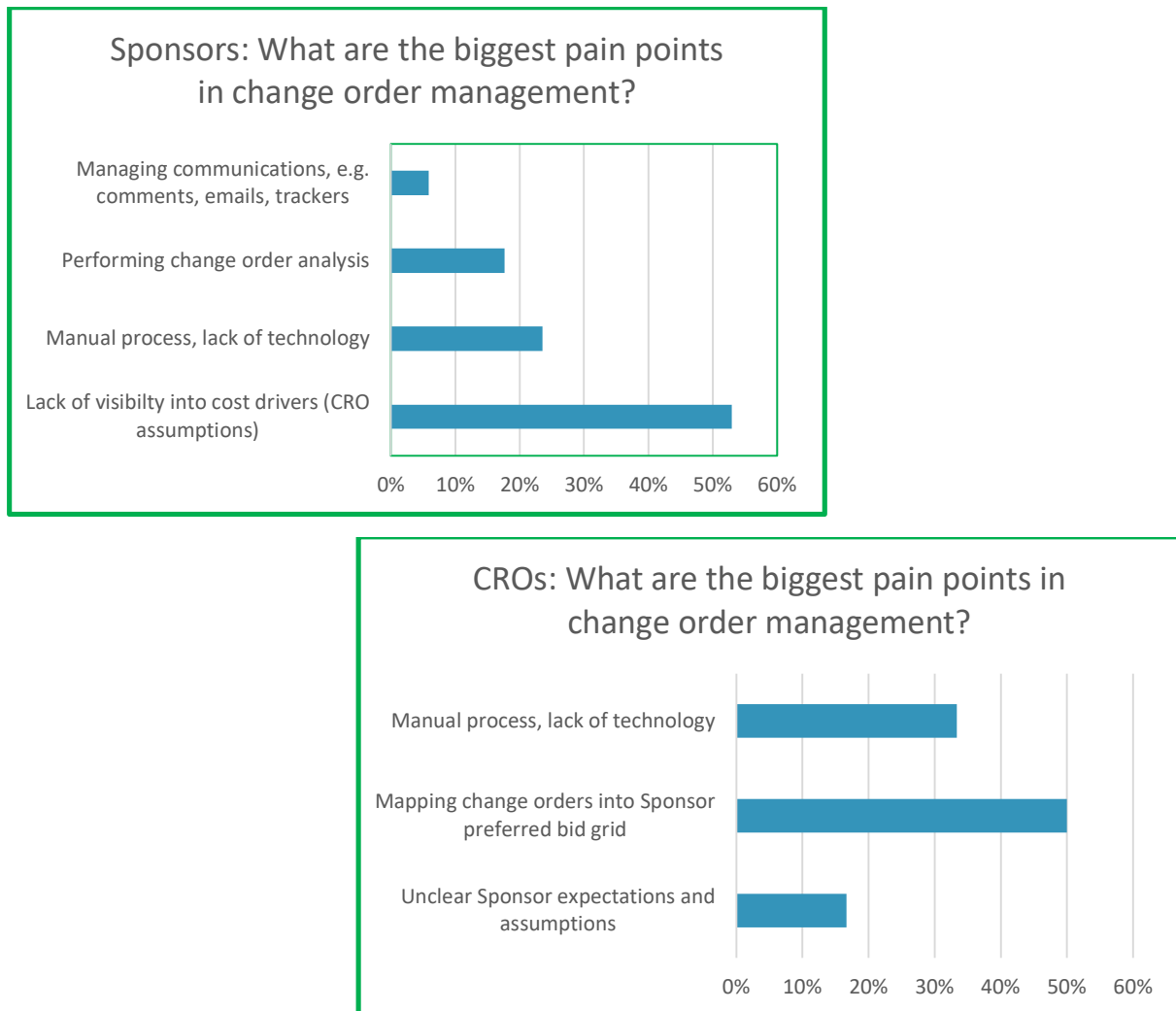


Figure 4: Strategikon Pharma Sponsor Survey – 2021

However worrisome, the Survey results are not surprising for either outsourcing or proposal professionals. More than 50% of the sourcing experts struggle with the lack of visibility in the CRO cost drivers, although they are often direct contributors to the pain point by forcing the CROs to reduce the number of drivers and activities reported to match their condensed bid grid and RFP template. Equally frustrated are the CROs who face challenges both from time-consuming manual processes and lack of technology as well as the re-mapping effort during change order negotiation and out-of-scope reporting.

Industry Demands: There's Got to be a Better Way!

So how is the industry benefitting, if at all, from mapping? What have we achieved after collectively spending thousands of hours in template development, due diligence, programming and change management? Have we achieved better visibility into each other's costing model? Have we built a stable foundation of true collaborating partnering and joint resource management? Unfortunately, the results of this massive effort have not paid off and continue to cost the industry: upwards of 10% of the total

pipeline outsourced budget, lost data and analytics on budgeting and costs, not to mention the very high user frustration due the pain and inaccuracy of the existing process.

Strategikon's Clinical Maestro team embarked in a journey of detangling the mapping problem to ultimately provided solutions that support both Sponsors and CROs. Through multiple thought leadership events and polls, user forums and requirements gathering sessions, Clinical Maestro experts not only revealed the pain points of the industry that needed to be addressed but also compiled the industry's wish list. In a 2021 poll on outsourcing practices, we asked the industry (both Sponsors and CROs) to list their expectations on technology impact. No surprise, communication and process improvements are at the top of the list.

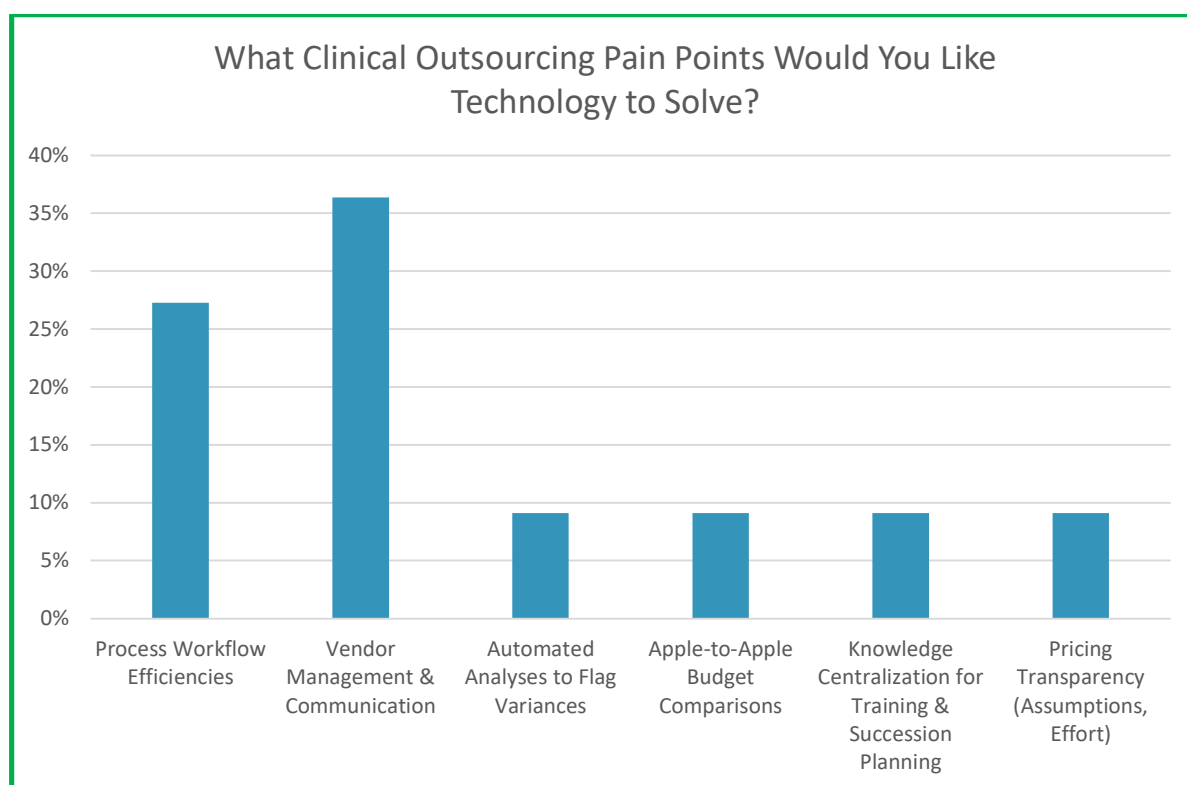


Figure 5: Proventa poll sponsored by Strategikon, 2021

In reference to the pain points related to change order management, poll responders identified "less mapping" as the single largest impact solution, along with availability of benchmark data for costing.

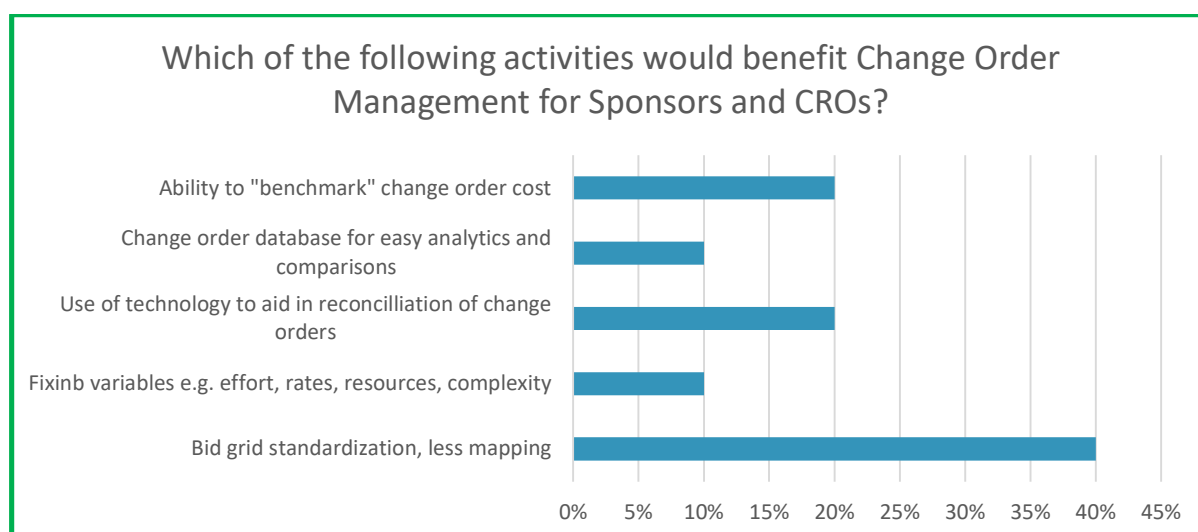


Figure 6: Strategikon Pharma Sponsor Survey – 2021

Of course, the overwhelming opinion of the industry is that the path to less mapping will come from a higher degree of bid grid standardization:

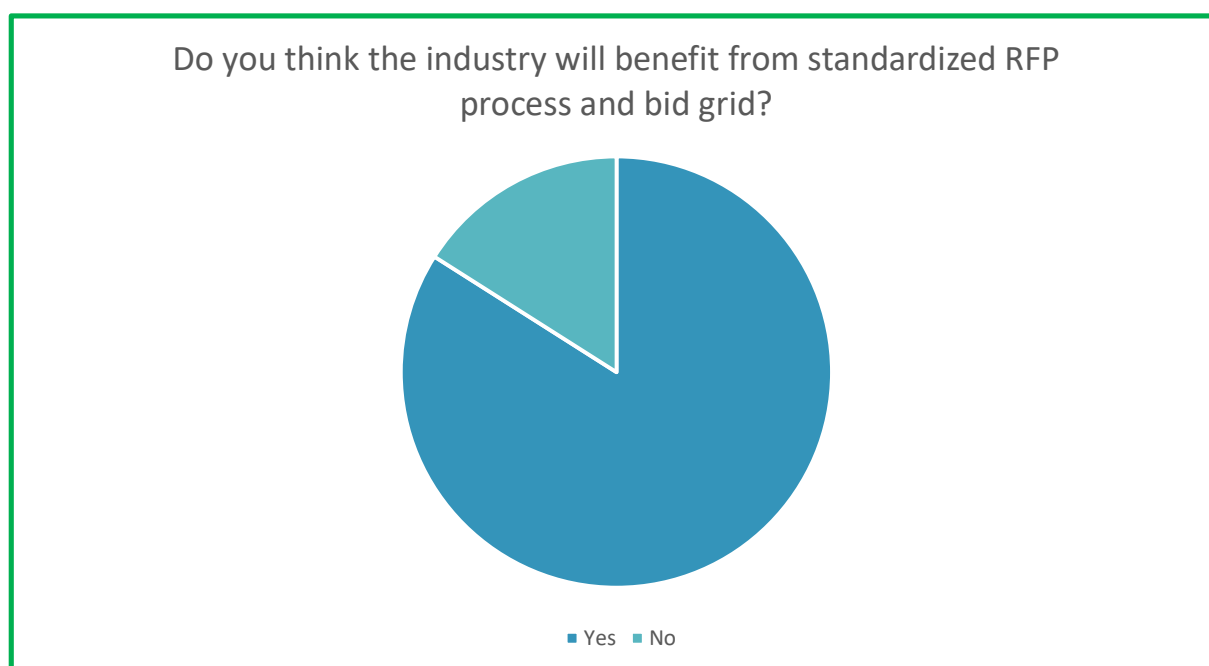


Figure 7: Strategikon Pharma Sponsor Survey – 2021

A Bright Future - Finally, Mapping High Tech!

The problems and struggles discussed, combined with the extensive research by Strategikon's Clinical Maestro team, has established the industry need to eliminate error-prone Excel-based bidding and mapping activities and the requirement for long term technology solutions. These new solutions will significantly reduce the cost and effort of bid grid mapping, increase the speed, efficiency and effectiveness of proposal and due diligence teams. Above all, it will increase the quality of the overall due diligence, pricing, and negotiation processes. Strategikon developed successful SaaS solutions for all three principal improvements cited in the comprehensive 2021 industry survey (figure 8):

- 2019: Strategikon launched Clinical Maestro **SOURCE™**, the industry's first dedicated RFP management solution for Sponsors
- 2019: Strategikon launched Clinical Maestro **PORTFOLIO™** equipped with standardized CRO bid grid templates, assumptions and loaded with industry's most advanced study budgeting technology. Additionally this was fueled by Clinical Maestro **Data Trove™**, our extensive cost benchmark database for budget development.
- 2021 Strategikon launched Clinical Maestro **CORE™**, the industry's first pricing solution for CROs and other clinical service providers.

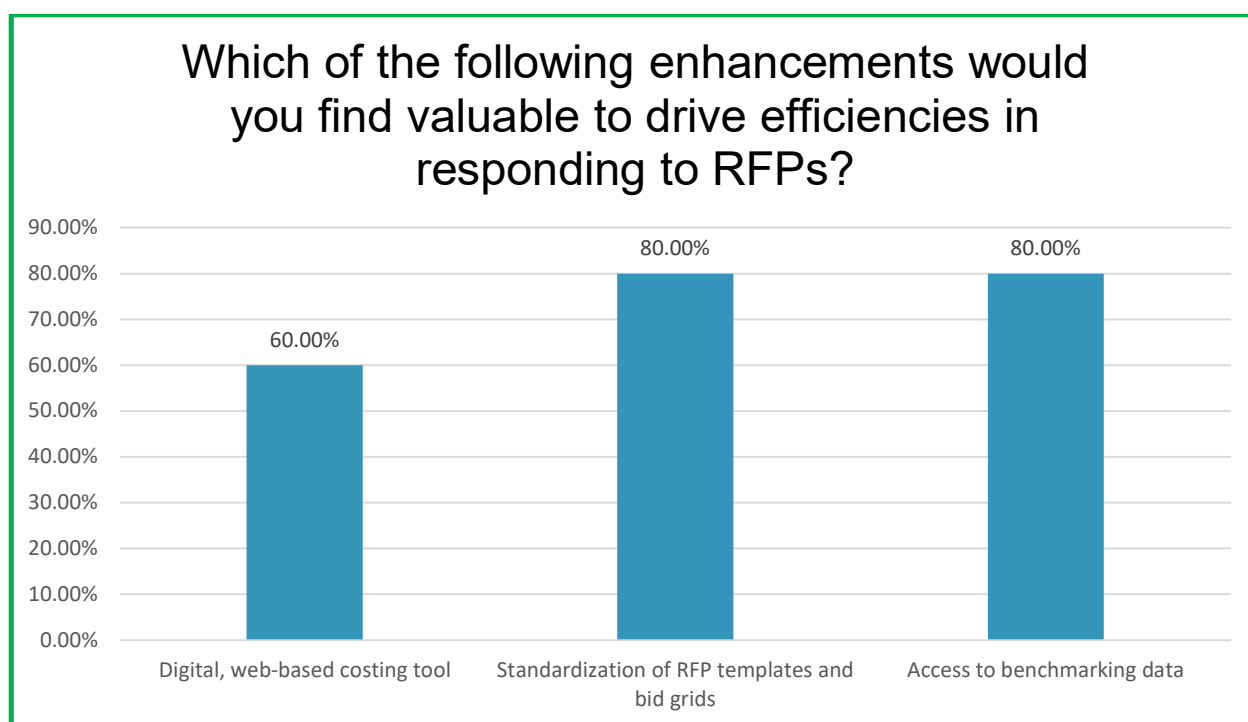


Figure 8: Strategikon Pharma Sponsor Survey – 2021

The combination of these three Clinical Maestro solutions opened the doors to significant efficiencies and savings for both Sponsors and CROs:

- Sponsors adopting Clinical Maestro standard templates shortened the time allocated to RFP development and bid due diligence by 75% and created a more robust process toolset with **SOURCE™**;
- CROs bidding in Clinical Maestro **SOURCE™**, saved time in bid mapping by having to only develop mapping key to Clinical Maestro, thus reducing mapping effort and number of mapping keys that would otherwise be required by Sponsors;
- Both Sponsors and CROs leveraging the benchmark intelligence from **PORTFOLIO** were able to price more accurately while increasing the transparency of due diligence process through standardized nomenclature, activity and cost driver definitions, and a greater level of granularity at the assumptions level.

Despite the bidding and pricing efficiencies, one core activity remained Excel-based: the infamous mapping exercise. For CROs bidding in Clinical Maestro template, mapping to their native bid grid was still conducted outside of the system and had to be maintained according to internal processes. For Sponsors not adopting the Clinical Maestro template, the benchmarking intelligence was lost in the RFP process, as it requires mapping between the Sponsor and Clinical Maestro grids.

In 2021, Strategikon embarked on a discovery process to identify best in class solutions for the ardent mapping problem. In partnership with a leading biopharma company, Strategikon sought to resolve the pain points this Sponsor was experiencing and that clearly remained unresolved in the industry. After numerous reiterations and incorporating additional feedback from leading industry and pricing experts from both biopharma and CROs, the Clinical Maestro team designed the ultimate mapping technology to radically transform this costly, inaccurate and highly frustrating routine process.

The first focus was on developing 2-way mapping technology to allow both Sponsors and CROs to map each other's preferred template to Clinical Maestro.

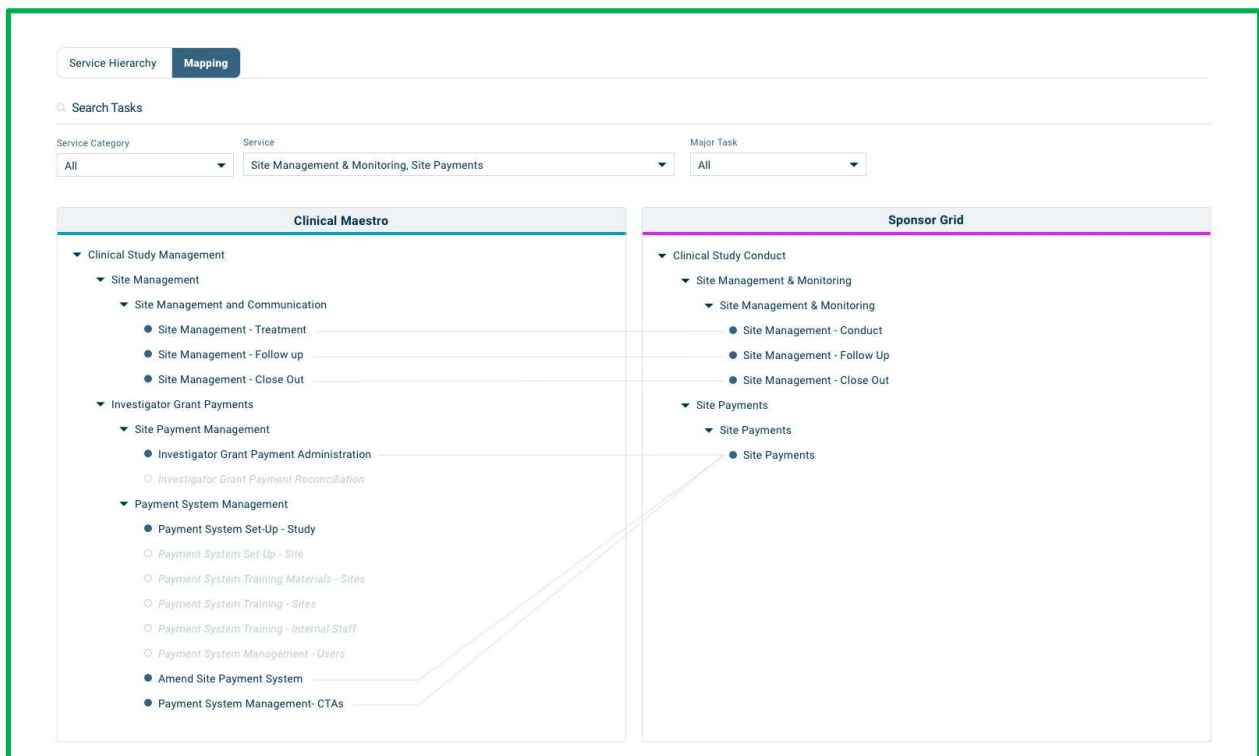


Figure 9: Clinical Maestro 2-Way Mapping Technology for Sponsors and CROs

2-way mapping technology allows Sponsors to dynamically design any bid grid template in Clinical Maestro and map it to Clinical Maestro to maintain benchmark data availability, subscribing to same set of cost drivers and study specifications. CROs can deploy the same technology to map any two bid templates, between legacy costing tools, between costing tool template and Sponsor's or between their native template and Clinical Maestro. The mapping key is self-configurable, can be set-up in minutes and is free of the macros or other basic mapping technique resulting into high degree of accuracy, confidence, and repeatability.

The next evolution step in the 3-way mapping, which allows three bid grids to be mapped at the same time, between each other, and to Clinical Maestro. This unique mapping technology is a game changer. It allows CROs to develop the mapping key directly on the Sponsor instance and then bidding in the native template, with Clinical Maestro automatically converting the native bid grid to the standard based on the mapping key. The results are >90% efficiencies in bidding, essentially nearly eliminating the manual mapping, while giving the Sponsors full transparency into the native bid grid structure.

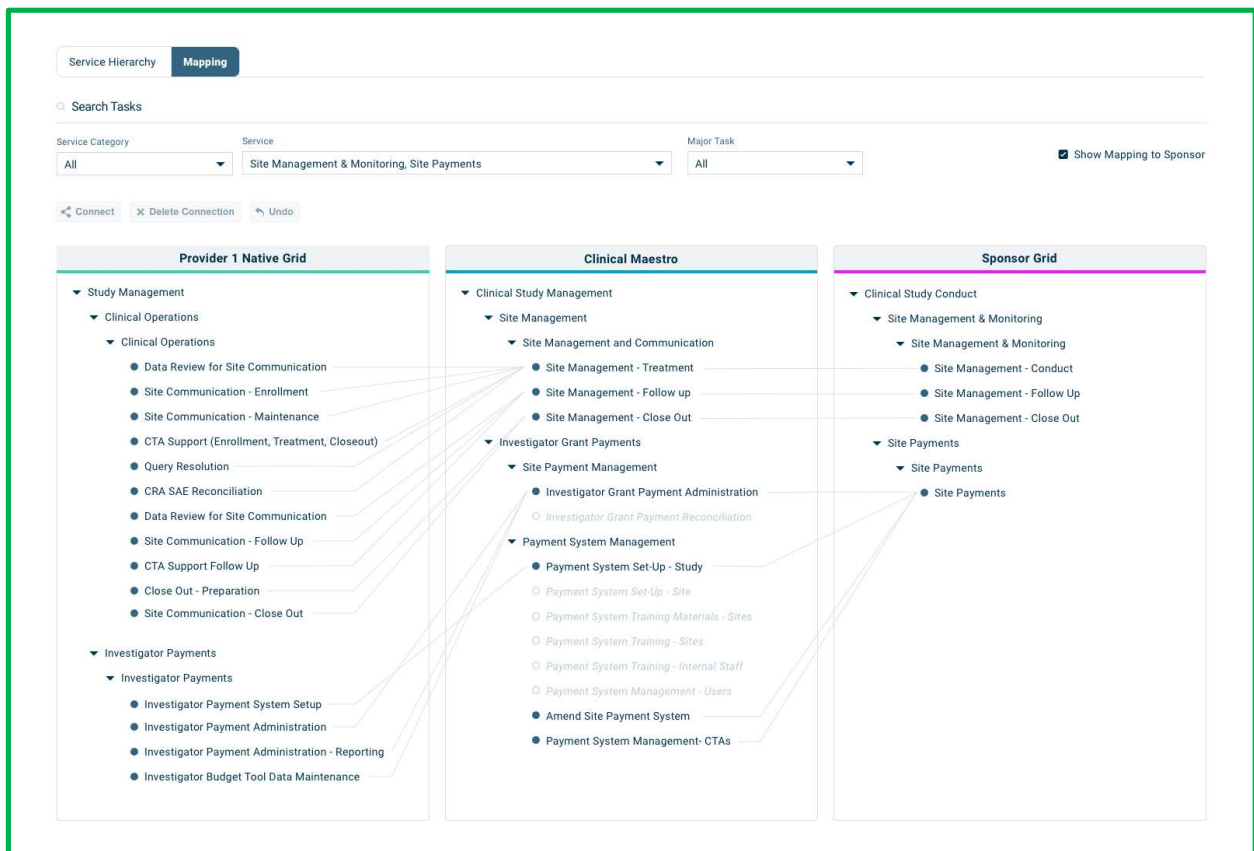


Figure 10: Clinical Maestro 3-Way Mapping Technology for Sponsors and CROs

With 3-way mapping, the Sponsors have now access to the most advanced template development and mapping technology, while preserving the integrity of the preferred bid grid, easing the CRO partner work and change management process and dramatically increasing both visibility and accuracy of the due diligence process. The communication between Sponsors and CROs is considerably improved with full change traceability and app-based threaded communication.

Both 2-way and 3-way mapping can be set-up directly by Sponsors and CROs in the Clinical Maestro configuration panel. The dynamic mapping key includes ID, unit, task and definition tracking for full visibility by all parties involved, a full approval workflow and ability to self-manage configuration changes as the relationship progresses or mutual needs change. At the individual bid level, the CROs can submit the proposal budget in their “native” structure with Clinical Maestro automatically converting the submission to the Sponsor unique structure while maintaining ability to edit and/or modify the mapping key and have full view into the mapped activities and corresponding unit structure.

With so many benefits for both Sponsors and CROs, Clinical Maestro mapping technology is clearly breaking new ground in outsourcing and proposal management, eliminating one of industry’s most costly and time-consuming efforts. Both Sponsors and CROs will now enjoy >90% effort reduction coupled with >99% mapping error elimination, greater transparency and improved collaboration between all the key stakeholders of the outsourcing process. Estimated cost savings range average one hundred hours per

bid, excluding change orders: with over 20,000 proposals prepared per year, Clinical Maestro is positioned to **save the industry over two million hours a year!**

About Clinical Maestro by Strategikon Pharma

Clinical Maestro by Strategikon Pharma is the industry's flagship tool for managing clinical business operations for both biopharmaceutical companies and their clinical service providers. The Sponsor platform is composed of 4 individual modules that can be deployed individually and integrate seamlessly, each addressing a major pain point in clinical outsourcing: clinical study planning and budgeting ([PORTFOLIO™](#)), RFP management and proposal due diligence ([SOURCE™](#)), study reforecasting and accrual management ([LEAD™](#)) and vendor performance management and governance ([VISION™](#)). The combined usage of the Clinical results in >x10 ROI on software investment stemming from greater planning accuracy, leveraging of benchmark data in bid negotiations, speed in delivery and more efficient utilization of resources.



New Ways to Solve Old Problems.

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