

Projects with Impact

Our client needed a solution that could provide repeatable benefits for Clinical Outsourcing.

Selecting the best Clinical Trial Partners based on the Data

A HighPoint Solutions Case Study

Traditional Wisdom Fallacy: Vendor Selection Edition

Our client, like all Life Sciences companies conducting clinical trials, lived the typical procurement lifecycle of proposal-bid-evaluate-select to obtain the partner resources for their clinical trials.

Sourcing aggregated data from disparate sources, transposed data to Excel templates (new each time), tediously working through the process with vendors, only to close it down after selection and start over again for the next need. The process was inherently inefficient, incredibly redundant, completely opaque, and only in place for one reason: this is how we've always done it. Aside from the headaches of each individual project, tons of information that could be reused to make decisions or save time for future projects was lost.

We had a better idea. **What if vendor selection data could be standardized, captured, and repurposed?** Why are we living with a broken process just because it's always been that way?

Our client needed to step outside the allegorical cave, and wanted a technological solution that could span all study use cases and provide repeatable benefits for Clinical Outsourcing. Understandably this would be a solution to enable innovation and decision making across the clinical study outsourcing lifecycle.

We envisioned a solution that would:



Improve bid comparisons



Create extensive reporting and analytics



Standardize assumptions



Provide historical reference

Here's the problem: after extensive research, our client found an out-of-the-box solution doesn't exist to fit these needs. And that's why they turned to the Salesforce Force.com platform and HighPoint Solutions' experts.

Putting Theory to Practice

Our Big Idea

We wanted to consolidate detailed study assumptions and budget requirements in a cloud-based solution. We wanted a technological solution that allowed us to control both data integrity and consistency. We wanted to compare bids and budgets, accurately answer budget questions, and shorten the review and approval cycle.

Perhaps the gutsiest part of our idea, though, was a platform that could compute cost metrics for benchmarking and analytics, provide **uniform and reliable** portfolio level reporting, and actually populate contractual documents from the system.

Our Big Plan

Despite the overwhelming checklist you'd imagine, we started where you start all projects of this magnitude: collaborating with the stakeholders. In this special case, we needed to work closely with our client's partner CROs to develop one common budget language. Once all parties were on the same page we developed the prototype reports we wanted the platform to auto-generate, so we could eventually reverse engineer the delivery of those views.

With the skeleton of the solution mapped out, we moved on to planning the system migration of ongoing study budgets and assumptions. We leveraged **authoritative data from sponsor systems** and warehoused all data in a cloud-based system. The cloud-based warehouse automated access to all information by the sponsor.

Our Big Deployment

To bring our idea and planning to fruition, we held a thorough review of the business requirements with the technical team, which ensured the technical team was well aware of our business needs and expectations. Our technical team built validation rules and controls, ultimately following an iterative build process across the entire project to ensure that each sprint built upon the next. The iteration process proved most valuable, in that it allowed our team to demo and test each component before building upon it with the next iteration, saving time and headaches. If anything "broke", we only needed to go back one iteration and not break apart the entire system.

If an iterative process was most valuable to the project, not rushing UAT and training was the philosophical cornerstone for our success. End user adoption is crucial to any new technology roll-out, regardless of size or impact, and UAT and training are crucial to that adoption.

After UAT and testing was complete, all we had left was to grant direct access to CROs to enable data import and begin using the robust reporting capabilities we built to enable **nimble business decisions**.

Our Solution in Action

Resource Name	Region	Proposal_Service__c	Proposal__c.Unique_Name__c
SUMMARY		\$33,280.00	\$96,536.67
Program Director	North America	\$0.00	\$1,299.73
Project Manager	EMEA Tier 1	\$0.00	\$1,855.65
	North America	\$1,840.00	\$0.00
Senior Biostatistician	North America	\$0.00	\$2,079.93
Senior Project Manager	North America	\$1,800.00	\$0.00
Statistical Programmer	North America	\$0.00	\$3,346.80
Study Start-up Project Manager	Argentina	\$0.00	\$549.45
	Asia Tier 1	\$0.00	\$6.95
	Australia	\$0.00	\$412.80
	EMEA Tier 1	\$0.00	\$286.21
	North America	\$0.00	\$352.93
Study Trial Master File Owner	EMEA Tier 2	\$1,080.00	\$0.00

Compare CRO Bids Directly (Optional)

- Compare estimates from multiple vendors
- Align on items from same resource / same region

Check Errors and Variances

- Normalize data coming in from CROs
- Notify when variances occur
- Track progress across all projects

Proposal Assumption Name	Requested	Received
Project Number (CRO ID)	-	9002-TBD
Budget Version	-	Proposalv1
Pfizer Study Designation	-	Start With Part
Project Title (Description)	-	A PHASE 2B, D SUBJECTS WI
Pfizer Investigational Compound	-	PF-04065842
Business Unit	-	0
Therapeutic Area	-	0
Assumption for Standard Single Units (e.g. study, protocol, database)	-	1
Number of Regions	5	9
Australia Sites	Preferred	0
Number of Screened Subjects	-	500
Number of Completed Subjects	-	224
Number of Follow-up Subjects	-	0
% of Enrolled Subjects with an SAE	-	2.88%
Total Number of Reportable SAEs	-	0
Maximum Number of Subject Visits	-	19



Visual Data Analysis

- Comparison and data analysis on every stage of data aggregation
- Visual analysis of variances
- Operational to historical data comparison
- Portfolio level reporting

Moral of the Story...So Far

Taking a rapid development approach gave the client and CRO team the opportunity to start working through a conference room pilot (CRP) phase within weeks. This enabled them to provide valuable feedback to the development team to meet user and process capabilities that are beyond what any other tool has previously attained. **Our client can now:**

01

Quickly and easily compose the requests for proposals, reusing information for work orders across multiple requests

02

Obtain the status and progress of responses to help provide information on progress and any potential issues in responses

03

Compare costs and related assumptions across the partner CROs

04

Manage subsequent Change Orders, include a history as well as the total project costs

05

Transparency into resources assigned, locations or regions as well as rate differences

What the Future Holds

Despite our vendor management solution being awarded FullForce status in 2016, HighPoint and our client aren't done yet. The application we developed is just the beginning of the vendor selection evolution we're spearheading in the industry, and here's a look at some of the additional capabilities we're working to build:

- **Further analysis of cost drivers**
- **Integration with other clinical and financial applications**
- **Forecasting and what-if scenarios for planning**
- **Portfolio budgetary views from past and current study views**
- **Incorporation of actuals and accruals for variance reporting**

For more information on any of the material you've read, please feel free to reach out to Lior Keet directly.

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