

CLINICAL TRIAL DATA MANAGEMENT TECHNOLOGY: BUILD OR BUY?

April 17, 2019

ABSTRACT:

In today's fast paced world, every company is a digital company.

Rapidly evolving technology, new business models, regulatory uncertainty and changing payment models, ever more stringent demands from regulators and customers make build versus buy decisions critical for any clinical trial operation considering how to improve the technology that drives their organization. Hence, how a clinical study organization comes to their build or buy decision is of strategic importance, far beyond a simple cost comparison. Buy versus build tests leadership as never before-and it is only becoming more challenging. How should you approach these decisions? What are some of the factors to consider? When is it advantageous to build your own solution, rather than trust a supplier partner that makes it their business to stay on the cutting edge of technology?

In this white paper, we'll discuss some of the pitfalls clinical trial organizations need to consider in their build versus buy decisions and discuss when it is most appropriate to develop your own technology and when it's more advantageous to seek external solutions.

You don't have to search long and hard to realize that new tools and solutions become available daily. In this new and evolving technological age, it's easy to have a "let's build something similar" mentality when it comes to creating your own technology solutions to meet the challenges you face in business. After all, who knows your business better than you? And who else is best suited to solve your problems?

Yet, many companies tread lightly at the idea of building their own solutions, understanding that the effort may detract from other core business functions, goals, or similarly-timed objectives. Some leaders

take objection to moving the slightest bit off center when it comes to their work force’s capabilities – despite whether the task was for their own benefit at the heart of it all.

But before giving up on in-house operations, leadership must objectively assess their company’s capabilities and ask themselves,

“Can our core competencies in technology development measure up against world-class standards?” Chief Procurement Officers, with their

proficiency in overseeing and managing third-party suppliers to generate the highest possible level of quality and productivity, know the right questions to ask to make these determinations. Among them: If our

manufacturing or HR capabilities are below global benchmarks, can they be improved to reach maximum performance and efficiency, and would the benefits of those capabilities surpass the benefits that we would obtain from outsourcing? If so, what resources are required, and how long would it take to reach noticeably improved performance? Are technology innovation and alignment necessary for us to have a competitive edge? Do our customers expect a high level of service and response, much greater than we could offer if we outsourced call centers?

To compensate, many companies choose to leverage external resources (not necessarily offshore) to bring their ideas to life. Using an outside vendor to develop applications for clinical trial use is common and can reap significant gains from these benefits:



There is No Long-term Commitment

One of the most overlooked benefits of leveraging external resources is the ability to bring in an expert on a project basis without committing long term (and paying the associated costs). You may really need someone with one skillset now but need someone with a totally different skillset in a few months.



No Office Distractions

Many office environments are huge distractions for developers. With lunch, office chit chat, and commuting, there is little time left for developers to get actual work done at the office.

Additionally, this usually means developers must work way more hours than necessary, which hurts morale and possibly company culture. Using an external yet focused resource solves this.

“Can our core competencies in technology development measure up against world-class standards?”



Low Cost

Some vendors are able to bring economies of scale due to more efficient processes, and in some cases leverage offshore and hybrid-shore teams thus managing the cost of labor. This includes the management overhead and support infrastructure which would be beyond means of your average company with a focus in clinical studies. It's often true that offshore labor is cheaper but one needs to temper expectations in that some of the cost savings will be lost to time zone, language and cultural differences – but still savings will be significant if the project is managed right.

It's important to consider the extra time associated with managing and preparing an external project. Often, comparing explicit costs leads to the fallacy of not considering opportunity costs and to assuming that one hour of labor is equal everywhere and for everyone. Whereas, in fact 62% of offshore IT contracts cost much more than businesses expected mainly due to project mismanagement and not taking the time and distance into account during planning. These are issues that professional outsourcing organizations can and have been managing.

Clinical trial organizations should lead business units in conducting detailed analyses that thoroughly evaluate how their build or buy strategy impacts their business strategy

What metrics do most businesses currently use to determine if they should build it or buy it?

Most clinical trial operations come to the conclusion of whether to build or buy based on a simple question: “Does it solve an immediate need, and can a solution be developed internally to solve it more quickly and cost effectively?” This is truly a practical way of approaching the problem – and one of the most, if not *the* most common decision-making focus around the Build or Buy question . But, in reality, clinical trial operation have several corresponding IT needs to be addressed simultaneously. So which takes priority? How long will development take to resolve that single issue, when potentially multiple needs could be met with a reasonable margin of additional expense and time? Would the final solution make your clinical trial operation merely on par with other providers in the marketplace, or would it give you a competitive edge that would add to the businesses bottom line and strategic advantage over time?

What approach better addresses the build versus buy question holistically?

At the end of the day, clinical trial organizations should lead business units in conducting detailed analyses that thoroughly evaluate how their build or buy strategy impacts their business strategy – taking into account costs, benefits, risks, and rewards of a home-grown development solution or buying one that can meet their needs while maintaining the organization’s growth velocity.

There are four factors that product/ operations teams often labor over (or if they don’t they should!) They are: Risk, Economics, Strategy, and Time. Let’s explore each of these as a core area of focus.

Risk

At the heart of every business decision is risk. Taking risks empowers companies to establish new limits and reach higher goals. Every organizational structure embodies boundaries or comfort zones where people often like to stay within. Yet when they take risks, they can eradicate old ways of thinking, enhance their business outlook, and improve their ability to achieve at higher levels.

An organization that is mature at taking risk has a methodical approach to risk assessment and mitigation. In this context, for example, is able to evaluate the potential quality, reliability of the overall development effort, and predictability of solution – and compares outsourced solutions with in-house services. They also consider risks inherent in the process of identifying and selecting the right supplier and structuring a workable ongoing relationship.

Economics

It’s self-evident that the economics around building or buying a technology solution for your clinical trial matter significantly. Yet the exercise of determining the true cost or the real economic benefit of building or buying is frequently overlooked or underrated in the process. When analyzing the economics around the viability of developing a technologic solution for clinical trials, one must consider:

- Outsourcing on all or partial capital expenditures
- Return on invested capital and return on assets
- Potential short or long-term savings achieved
- The impact of diverted investment funds, including opportunity cost and interest
- The time cost of resources and support, especially in outsourced solutions vs the time and cost of resources to manage and maintain an internally developed solution

Strategy

Choosing to develop a problem-solving solution with in-house capabilities is a sound strategy when a product or a function is critical to a company's performance or is considered a core operation. On the other hand, the strategy of buying a solution through outsourced resources can be advantageous when:

- The process of creating the solution is outstandingly complex or potentially frustrating for internal business units
- The operation is not a crucial cog in the final service or solution
- The market capabilities to develop are well-documented and relatively straight-forward
- The supplier, as a past partner or with noteworthy past performance, is known for their innovation

Time

While the economics of development is less overlooked or underrated, it's the measurement of time for development that is most flawed or inaccurate. This has significant impact on whether the development should occur in the first place, let alone, whether you should build or buy the solution.

Time can make or break your project, and demands respect in the build versus buy conversation. As noted under Economics the "opportunity cost" of not bidding on a study in the case of a CRO or not launching it because the lead time to internally developing a systems is prohibitive can in and by itself be sufficient justification to outsource or buy.

To help us make sense of it all, here is the R.E.S.T. spectrum of whether to Build or Buy:

Build



Buy

Build if ...

Risk

- There are few alternative solutions
- The issues or the solution involves sensitive matters/material
- There is high supply risk

Buy if ...

Risk

- There are proven external options that address the great majority of your predetermined requirements
- The deliverable is experimental in nature

Economics

- Low internal cost for development
- High internal skills for development
- Higher quality if built in-house
- Investment cost equals ROI

Economics

- High implicit/explicit cost or opportunity cost for development
- Political/cultural pressures could impede the quality of the output

Strategy

- Building it in-house directly determines the service or product differentiator
- The market's ability for development is limited or hampered
- There are significant synergies across internal business units
- High control of market by the competition
- New innovation

Strategy

- External solutions provide tactical advantages in features, scalability, and/or integration
- Low control of market by competition
- Low barriers to customization and reconfiguration
- Low or no strategic competitive advantage

Time

- There are short lead times between supply and usage
- Development timeline does not conflict with or complicate other development
- Time sensitivity AND complexity is high

Time

- Time pressures could impede the quality of the output
- Development timeline is fixed and immovable
- Complexity limits the ability to specify measurable milestone dates or timelines
- Historic issues around ability to meet internal deadlines

Conclusion

In summary, while the solutions available to clinical trial organizations have increased in number and complexity, the flexible options to resolve technology needs that could make a huge impact have also increased. With these increased options, leadership must be ever more “in tune” to what their organizations strategy is, and how their build verses by decision making process is aligned with their future trajectory.

It’s no longer necessary, nor always prudent, for an organization to succumb to the “we must build it ourselves” mentality, as there are a myriad of providers offering full or partial solutions for just about every clinical trial software challenge. Neither is it a given that an outside solution can provide the strategic edge that your organization needs when developing technology externally. The key is to effectively consider, analyze and evaluate the factors that come into play and weigh it against the company’s short and long-term goals. When there is alignment here, you can move forward with confidence that you will have benefited your organization in the process.

REFERENCES:

1. <https://blog.kissmetrics.com/in-house-or-outsource/>. Data drawn from the Kissmetrics Blog Post: “Should You Hire an In-House Developer or Outsource Overseas?” Stella Fayman, October 2013
2. http://www.strategyand.pwc.com/media/file/Strategyand_Make-or-buy-sound-decision-making.pdf. “*Make or Buy: Three pillars of sound decision making*” Strategy& (Formerly Booz & Company. Detlef Schwarting and Robert Weissbarth. 2011
3. http://www.huffingtonpost.com/stacia-pierce/why-taking-risks-comes-wi_b_4235351.html “*Why taking risks comes with Great rewards*” The Huffington Post. Stacia Pierce. Jan 23, 2014

For more information:



Adaptive Clinical Systems
1175 Marlkress Road #2632
Cherry Hill, NJ 08034 United States
Tel: 856-452-0864
Email: info@adaptive-clinical.com