TriTiCon Articles

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Introduction & Recap

The number of systems under the 'eClinical' umbrella is long and can be quite overwhelming. The question then arises: Should you have your own system at all? How do you approach system selection ?

In the first article in this series, we looked at the value of letting go of the "traditional" way of approaching systems in clinical development. Why? Several factors come into play. Firstly, technical development is simply going too fast. Secondly, your company´s situation is your own. Each company's combination of history, stage, organization and strategies are different. Therapeutic area, types of compounds, pipeline and trial designs are different.

That's not to say that everyone is unique and need a radically different approach: it revolves around the same considerations and steps, but to optimize the result, you need to base your systems strategy exclusively around your own situation.

In the second article we discussed which strategies are required and how to start building the foundation: standards, storage and oversight.

In the first chapter of this third article, we will look at selecting systems by considering the key drivers for a) deciding whether to have your own system or not, and b) selecting the right system (and provider). Subsequently, we will evaluate the most common systems, one by one. So first up, how do you decide on and select systems?

#1 #2 #3a #3b #3c #4

About these articles

This is the first of article 3 in TriTiCon's series on eClinical solutions and implementations.

In our first article we looked at the value of letting go of the "traditional" way of approaching systems in clinical development. In the second article, we followed this up with a discussion about the strategies required to build the foundations such as standards, storage and oversight. Next up in this series is the debate of selecting systems, whether to own or source, and recommendations for how to approach the selection itself. This will be followed-up in article 3b, where we apply these principles to an EDC system selection. Following this, article 3c will discuss ePRO and so on for the most common systems. Lastly, in article 4, the important topics of compliance and oversight will be addressed.

Own or source? – ***Why and why not***

The system or the service – What do you need and what are you buying ?

Macro criteria – ***More than what the system can do***

Highest score, but - Is the "winner" good enough ?

You can source it all – ***Except the ultimate responsibility***

Selecting systems – If, how and what

Own or Source

Should you have your own systems at all? And if so, when? As we learned in articles 1 and 2, it depends on a multitude of factors. So, what are the pros and cons when using CRO systems on a trial-by-trial basis, compared to company-owned systems?

First, let´s differentiate "owned" (where you own the license and control the configuration of the system installation) from "hosted" (where someone else manages the physical servers on which the system runs, including installing and managing the system). Not too long ago this was one "package" – with ownership came hosting responsibility. However, this is no longer the case, and today, more or less all systems are going hosted or to the "cloud". So for the purpose of this article, let´s firstly define ownership and what comes with it:

Ownership – in this article:

- You control the system contract
- You can configure the system your way, i.e. to support your processes in an optimal way
- You own system libraries (standards) and any developed components or code
- You can establish components (forms, reports, exports, integrations) on system levels and across trials
- You have all your trials in one place
- You can have different vendors or CROs working in the system any way you want

In other words, ownership gives control that can be used to drive benefits such as cross-trial consistency, efficiencies, timelines and quality. As a result, it also increases internal resource flexibility since it is the same system process and set-up on all trials. In comparison, sourcing trial-by-trial will only give you a certain degree of this.

So, how do you assess if you should own a system or not? The first consideration is determining what benefits ownership will create for your company. When you assess these benefits, key factors are your sourcing model and the actual users (you, the CRO or site) of the system in play and the positive impact you can get from configuration, standard libraries etc. These benefits will obviously scale with the number of trials, and therefore, your second consideration is the number of trials.

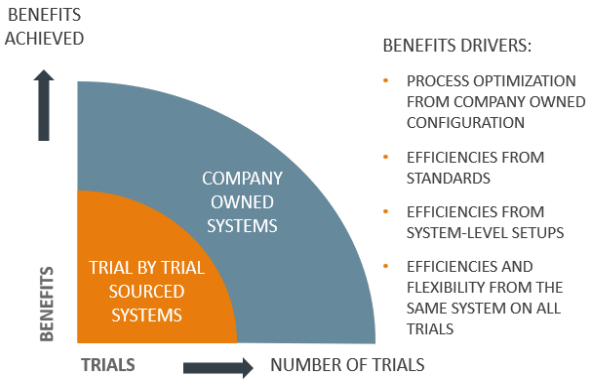

Figure 1:
Benefit drivers for system ownership

What are the disadvantages? Well, even if you can easily buy your way out of hosting, but ownership still comes with some additional responsibilities which require resources and knowledge.

Note: if you work with different vendors for different trials, thereby utilizing a spread of systems, most of this responsibility remains (and to some extent gets multiplied) as an oversight responsibility. Based on this, system ownership burden is your third consideration. As a sponsor you are always ultimately responsible for the systems used. We will look more at this in *Article 4 – Implementation*.

Your fourth consideration is cost and conditions. For the direct system cost (license, hosting) as well as contractual conditions, you can generally get a better deal if you contract directly with a provider than trial-by-trial with a CRO. It typically requires a few trials in order to get some proper leverage in the negotiations, but if you have a handful of trials (in the pipeline), the savings and contractual benefits can be significant. And of course, owning equals mandate, and you might be able to select a totally different – and much cheaper – system.

System or Service

The second key question is whether you select a service or a system – or as in most cases, both? The answer requires and evaluation of the need and importance for each of these parts.

If you have simple trials, simple processes, and plan to build EDC in-house, you can go for a simpler (and cheaper) system since service availability is of limited importance.

If you have complex trials with a lot of different players involved and you plan to find a service

provider for building EDC, integrations etc., then you are probably looking for a more complex system, and the availability of qualified service providers is essential.

Some systems are more tightly tied with services and special expertise than others, and in these cases, the service availability naturally has a higher importance in your selection; the type of services you need depends on your organizational and sourcing strategy. Some systems are more complex, and if you are more dependent on specific features of the system, system functionalities get a higher priority when selecting.

Example 1 ePRO

- ePRO has a narrow set of functionalities (maybe not without challenges, but the system doesn´t have that many functions or features and they all do more or less the same).
- It is, in most cases, bought together with a comprehensive and specialized trial delivery service-package (instrument licensing, set-up, feasibility and validity testing, translations, logistics, help-desk). The service-portion is comparatively high compared to the low technical differentiation between the providers.
- In this case you are selecting service more than system. The system must of course have the required functionalities, but if you can't get the required services to go with it, no functional bells and whistles can ever help you. With this said we do see that the landscape around ePRO systems and services is about to change and we will provide our insight about this in our upcoming article about ePRO/eCOA.

Example 2 Safety Systems

- Safety systems have a comparatively wide and advanced set of functionalities, some of them with very specific requirements from authorities.
- For example, advanced technical requirements which are required to interact with specific gateways for submitting data electronically to authorities. As a result, it is an extensive exercise to implement the system, but then it is comparatively static. You are therefore less dependent on services for your daily trial execution.
- In this case the specific functional requirements carry a higher weight than the services. If the system cannot do what you need it to do on a functional level, you simply cannot use it.

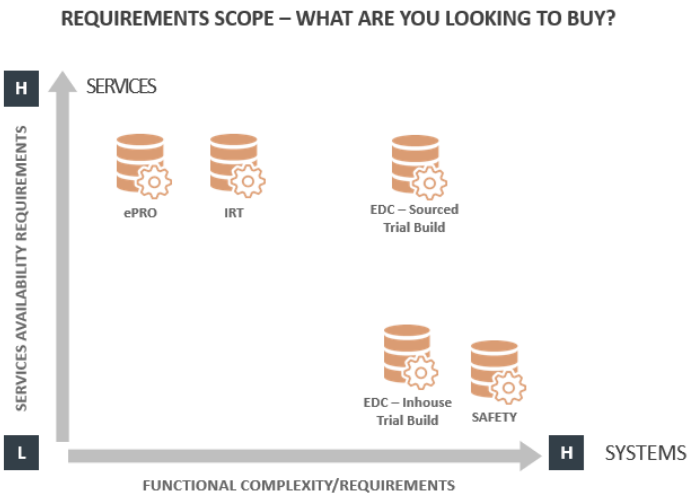

Figure 2:
Generalized typical SYSTEM-SERVICE balance for common clinical trial systems

How to Select

Gone are the days of listing 400 technical requirements and rating 5 systems against these, before selecting the one with the highest mathematical score (with more or less advanced weighting and scoring algorithms).

It has become clear that system (and service) selection is complex, and that there are several other aspects to consider than just technical requirements. The good news is that this also makes it easier, since it not only can be used to efficiently narrow down on systems and providers that are relevant, but also helps in identifying key criteria for selection. In Figure 3 below you can view the recommended steps to take during this process.

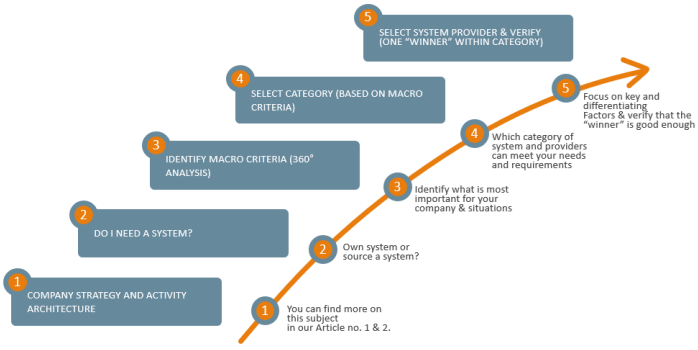

Figure 3:
Steps to select system and provider

As we learned in Article 1 and 2, it is firstly important that you define your company strategy for how best to collect, manage and store your clinical data and further decide on a activity architecture that will support your strategy. Once this is established and you in the 2nd step has concluded that you do need your own system, your 3rd step is to identify your macro criteria.

The macro-criteria are key criteria across all aspects of the system and services, and they will help you to efficiently identify the system category and type of provider as possible solutions for your needs. You can categorise the macro-criteria in several ways. Figure 3 illustrates one example, but the key thing is to consider all aspects from must have functionality, to system maturity and financial stability of the provider.

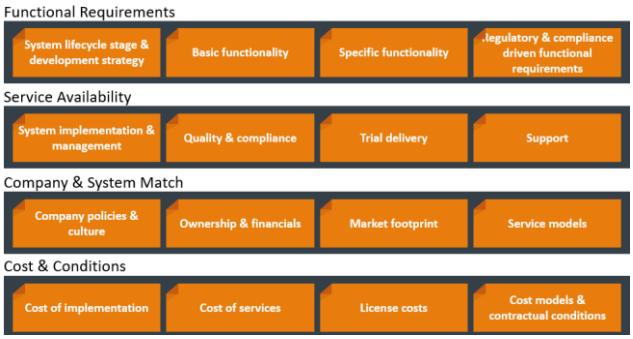

Figure 4:
Macro criteria categories

It is about understanding what is important for you in the bigger picture, to compare options focusing on your macro-criteria. It is why we recommend you to perform a 360º requirements analysis based upon your findings. A simplified example of 360° requirement analysis is shown in figure 5.

It illustrates that, depending on company strategy and stage, the balance between macro-criteria is significantly different and these two companies should be looking for different categories of systems and type of providers – not comparing systems in different categories based on functionality score. If you end up with more than one option, you can now compare based on what you have identified as most important and differentiating.

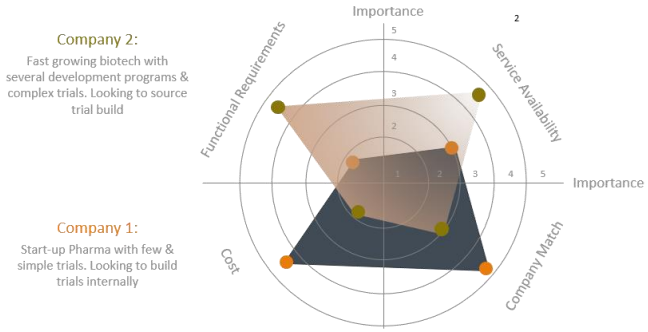

Figure 5:
EDC system macro criteria examples

The 4th step is to find options within your chosen category based upon your macro criteria, and subsequently verify that these are feasible options. This is of course not done in one day. But you will learn that 2-4 criteria in each macro criteria category will not only help you narrow down your options to very few candidates, it also helps to ensure an organizational alignment and form a solid, yet simple documented basis for the decision. Furthermore, establishing this foundation also helps in focusing and driving your implementation in everything from contract negotiations to training objectives.

You should now have a solid basis to move into the 5th step, which is your selection of a system/provider(s). It is key to verify that the" best option" fulfils your minimum requirements, in all aspects. It might be tempting to select that one remaining option, even if, for example, the provider is not financially stable. You might even pick the" best of the worst" option, despite knowing that it will be a struggle to work with, just so you can get on with it. This will most likely come back to hurt you!

Therefore it is important to seriously consider any "red lights", ensuring that you are willing to accept the risks and consequences, and that you have mitigation plans in place. If you end up with no options, since even the best option is not good enough, it is time to re-evaluate steps 3, 2 and maybe even no. 1.

5 essentials for selecting systems

- Own or source? – When do the benefits of ownership outweigh the burden?.
- System or service? – What is it you need? And can you get it?
- Macro criteria – Looking beyond system functionalities for key factors for system and vendor selection.
- Verify the "winner" – Is the best option good enough? Don't run the red lights.
- Sponsor responsibility – You still have the responsibility for system compliance, also when you source. It is just how you ensure it, that matters.

Summary

The benefits of owning a system can be significant. Especially if it is a system where standards bring quality and efficiency, the system supports more complex processes and/or your therapeutic area and trial designs drives complex trial execution.

But always remember who the actual users are, and the benefits or disadvantages for all users. The benefits typically scale with the number of trials, so don't wait too long to assessing what is best for you and making informed decisions on your systems strategy.

It is not only the users that vary with different systems, it also depends on your company's own situation and what you need (and what you bring yourself) in terms of services and knowledge. In most cases you need a combination of system and services, and the weight between them varies from one end of the spectrum to the other.

With this increasing complexity and multi-factor assessments, the next step in the process – macro criteria – is critical to make sure you select something that actually works. But it is also making selection a lot simpler - more factors, makes it easier to differentiate on a higher level – on system category and vendor type, without having to dig all the way down to functional (or service) details. The macro-criteria are also a great guidance for your implementation; what are the key objectives, what am I expecting to achieve with this implementation? We will look more at how this all plays out for each type of system in subsequent articles.

Next Article

In this article we discussed the essential steps and process that you should consider when you are deciding whether to own a system or not, and subsequently, how to select a system. In our next article(s) we will elaborate further on this topic by applying these considerations to the most common systems, starting with EDC.

About TriTiCon

TriTiCon provides expert consultancy for Clinical Data Processes and Systems. When establishing solutions for the handling of clinical data, TriTiCon will help you all the way from initiating the process to end-user training.

TriTiCon combines the 3 Tiers of Subject Matter Expertise, Strategic Understanding and Project Management to fit the needs of each specific situation or stage of a project.

TriTiCon is not a CRO but can help you manage your clinical trial set-up and execution, and can support you with everything from vendor selection and contracting, through set-up, operations and oversight.

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