TriTiCon Articles

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This is the first article in TriTiCons series on eClinical solutions and implementations – breaking up with history and challenging the illusion of the low-risk approach.

In this series we will take a closer look at the background, strategy and also at practical aspects for process and systems for clinical development, primarily for dealing with clinical data. Commonly known as "eClinical", the electronic (rather than paper-based) solutions available for supporting processes and managing clinical data are not new anymore, yet are still an ongoing transformation in many companies – or are part of a company scale-up in others. Furthermore, it's common for companies that made the transition several years ago to re-visit their processes and systems, which may have become outdated due to a changed technical, business or regulatory landscape.

In the beginning of the series, we will look at some of the common eClinical implementation pitfalls and how to get started in the right direction. From there we will look at the typical system landscape, discuss various options for implementation and finish up with practical recommendations.

In addition to the "eClinical" term defined above, we will use the term "solution" for the people (including organisational and/or sourcing models, competencies and resources), processes and systems required to execute the required task, or to "do the job".

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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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Breaking up with history

– The illusion of the low-risk approach

When faced with new needs or notorious problems with processes or systems – whilst already being overloaded by trial execution work, dealing with company change or growth, establishing partnerships or ensuring funding – it is very easy to look at the process and system challenges and say, "let's do as the others (read big pharma or CROs) – we know that works".

Using the "let's use what we already know works" thinking makes a lot of sense. Why invest time and money or introduce risk in processes or systems by re-inventing the wheel? However, this thinking actually has a fundamental flaw, and in fact often increases the risk of issues, as well as time and costs.

You can't just copy what others do and use their approach as your low-risk approach. You need to create your own strategy, approach and solution. The positive aspect of doing this is that it is easier, quicker and cheaper than ever.

This is the first article in TriTiCons series on eClinical solutions and implementations, where we break-up with history and challenge the illusion of the low-risk approach.

Make your own decisions – break-up with the low-risk illusion!

Do the commonly used solutions actually work (well)?
The way you want them to?

Can you truly implement the very same solution, and do you actually ***want*** to?

Doing ***the same*** is doing something ***different!***
Same components + different situation = different result.

The ***right decisions*** have a high risk ***of failure*** – if you make them based on incorrect assumptions.

The illusion of the low-risk approach

Working with process and system implementations, primarily in small and mid-size pharma/biotech, I have often found myself involved in discussions about low-risk decisions and approaches. Many companies – often those who are growing rapidly and have a strong focus on one or two 'make or break' products – are fully occupied with making the right decisions about their products (funding, partners and organization), and don't want to spend a lot of time discussing system selections or sourcing models. This is entirely understandable! There are millions of other things they want to and should spend their time on, and rightfully so. Why should a company take risks on processes and systems when drug development is risky and costly enough in itself? In this situation it is justifiable and wise to play it safe and make it easy.

The problem arises when one bases a low-risk approach around arguments and rationale such as:

– "We'll do the same as the others, they must know", or

– "If it works for the big pharma's and CROs, it must work for us".

Alternatively, employees may share experience from previous work in other companies e.g. ***"I am used to…".*** The primary issue is that these arguments are based on the following two key though false assumptions:

– What the others do actually works ("well") – and will work for you.

– The situation is the same and you can implement it (all) in the same way.

In my opinion:

– Many solutions today do not work very well: they are rigid, cause quality issues, are not efficient and they are expensive.

– Your situation is different (though not unique) and solutions cannot be implemented and used in the same way.

5 statements to watch out for:

1. "It works for them, so it must work for us".
2. "That is what everyone else is using, so it must be good".
3. "This is the way I have always done it".
4. "The CRO/vendor are the experts, we'll let them decide".
5. "Let's just get these trials started and deal with the technical things later".

Why the statement "it works for them" is not a valid argument

Whilst established solutions might do the job, they have typically been implemented step-by-step over a 10–20-year period using the technology and activity architecture that was available and optimal at that time. Changing fundamental system components and processes in a large company at the same time as changing roles, competences and the organisation, is not an easy task. Firstly, organizational and trial legacy can make it challenging to truly optimize an existing solution. Secondly, older systems and technologies often have their base set-up built on older processes and technology (paper, phone and fax), and replacing these can be extremely demanding.

Additionally, and in my personal opinion, many companies have and still tend to oversize and over-complicate solutions. This tendency exists because of the search for the 'Holy Grail of eClinical' – the need to have everything automated and integrated in one massive solution. The problem is that previous technology was not mature enough for this level of integration, and processes and standards were (and are most often still not) not fixed or stable enough to enable this to be effective or realistic. As far as I have seen, present day implementations rarely work as intended, and more often than not, increase the risk of delay and disconnection from the business. This in turn enforces sub-optimal processes.

In summary, existing solutions are doing the job purely by 'being established', though in my opinion, are not showing evidence for a low-risk, proven solution that works well. At least not if the essential attributes such as 'resource efficient', 'cost effective', 'flexible' and 'having the required capabilities' are put together with the words 'proven' and 'well'. The key point is that the process should be adjusted to the system and not the other way around.

**Do the commonly used solutions actually work (well)?
The way you want them to?**

Why "therefore it must work for us" is not a valid argument

A solution, such as a process and system, will only give the same result when used across multiple companies if the setting is the same, i.e. if it is used in the same way, and if the solution is the same.

Most likely, your company's situation will be different when compared to most other companies (and even more different from a CRO). You may, for example, work in a different indication, using new and different trial designs and have a focus on early stage trials rather than late stage and post-marketing. Often, you may have a different partnering model and typically a different sourcing model. Whereas another company might be large and benefit from scale, you might be small and only have a few trials. These central aspects which highlight how companies can differ from one another, forms the basis underlying the whole setting for the eClinical Solution – a solution that works in one setting is not necessarily (and most likely not) optimal, or even functional in another.

Furthermore, it is important to recognize that a solution that has been implemented in larger companies will have been established over time using significant man-hours and requires a significant number of people to maintain it. The larger the system, the larger the implementation required, and few companies have either the calendar time or internal resources to manage this. So the important question to address is: 'Even if you want to, can you actually achieve the same implementation?'

Doing the same is doing something different!

When the right decision gets you into serious problems

Choosing big market leader systems or CROs may indeed be the right decision for you. However, being aware of the false low-risk decision rationale is essential. When starting the process with false assumptions, even the right solution decision has a high-risk potential of failing, since the approach, risk-identification, method of implementation etc., are likely go wrong. The result can easily be result in overbuilt and unnecessarily expensive systems, implementation problems and cumbersome processes that can have a significantly negative impact on your trial execution and submission work.

The right decisions have a high risk of failure – if you make them based on incorrect assumptions.

The true low risk approach – informed and less is more

Now we have talked about how NOT to approach your eClinical implementation, what should you actually do? That's what we'll spend the next couple of articles looking at. But for a start, the hard truth is that you must make active, informed decisions from the beginning. Even if you copy what others do or outsource it all, there are still decisions to be made.

The positive side to approaching this implementation is that it is easier and cheaper than ever due to an increasing abundance of providers alongside better technology. Hosted and cloud solutions allow step-wise and flexible approaches, lower implementation efforts and quicker start-up times. You can afford to make only a few, key decisions/requirements to your providers, and by controlling these from the beginning, you will quickly be off to a positive and future-proof start.

5 essentials to get started:

1. Make your own informed decisions. You are not unique, but you are also different from most others. What you need and how you get there is based on your specific situation.
2. Make a plan. You don't have to do it all at once! The importance lies in doing it in the right order and in due time.
3. Less is more! Keep it simple, identify the key requirements and be pragmatic about how to address them. Content will always win over the wrapping.
4. Relax, it is not rocket-science! There are just a lot of things that are not (and should not) necessarily be your company's core competence or main focus.
5. Read the next article in the series!

Summary

Standards, systems and processes are key, both for effective trial execution and to ensure data quality and regulatory acceptance of your data. The processes and systems you have chosen to collect, manage and store your clinical data (the "eClinical Platform") are the very foundation for this work. If you are about to establish these solutions (as a new company or as a strategic change) you cannot copy "established" solutions – what others do – and expect them to work in your company. These solutions might not actually work very well in other companies, so the problems will simply be transferred to your company. The reality is you need to create your own "solution" and this is made feasible by the fact that it is easier, quicker and cheaper than ever.

If you are a big company with already established solutions, it might be time to re-visit the fundamentals of your set-up. Over time, there is always a risk that technology becomes oversized, expensive and ineffective and subsequently gets disconnected from your business. Activating new possibilities is essential by starting fresh with today's technology and providers.