

# Choosing the Right EDC/DM Partner: Critical Considerations for Small- to Medium-Sized Life Sciences Organizations

**W**hether you are a start-up pharmaceutical or biotech company, a medical devices innovator, or an established organization you want to be equipped with the best possible solution for your study.

For small- to medium-sized organizations finding an eClinical partner that is not only competitive but the correct fit is crucial to both program and organizational success. Successful organizations all have one thing in common: they consider all elements of a trial, including vendor selection, from a strategic perspective. Asking the right questions will help you make the most informed decision.

## Are You Starting With the End Game in Mind?

Your choice of an EDC/DM partner is critical. It is important to establish at the outset that your provider will support you both technically and operationally through to the end — through to submission. This requires asking the right questions and obtaining the right information about expectations and deliverables throughout the entire course of a project.

One of the keys to study success is the focus of the partners on the study details, specifically the planning and strategic thinking that goes into the initiation of the study. Will your provider engage with objectives of your study

protocol and apply technical and operational solutions that help achieve them? Are they able to provide the technical solutions that optimize your study design and management? They need to understand your goals as well as your challenges, and advise you from a technical perspective with the operational considerations factored in.

Starting with the end in mind is even more essential in smaller organizations. Proper diligence in planning is vital in maximizing efficiency and maximizing limited resources.

## Do You Own Your Data?

It is important to understand and clearly define the parameters around access to your data ahead of time to ensure there aren't any surprises. Direct access to your data can also give you more independence. Are you able to run reports yourself with a few clicks in real time for multiple sources of data such as EDC, central lab, inventory for a combined patient profile report? Or, do you need to make a request of an external party? How does the provider balance your independent access along with data integrity?

For a small organization, timely access to relevant data can mean the difference between success and failure. Data accessibility should not be a road block to meeting your study milestones.

## Are the Tools and Services Unified?

There are many interpretations of the term unified. It is important to understand how your prospective provider's offering is assembled and if the tools and services are 100% engineered and managed in-house. Is the product an integrated solution? Does the partner provide a part of the platform or services through another partner? Does it subcontract for services? Is all technology delivered by a single source?

There are major costs on

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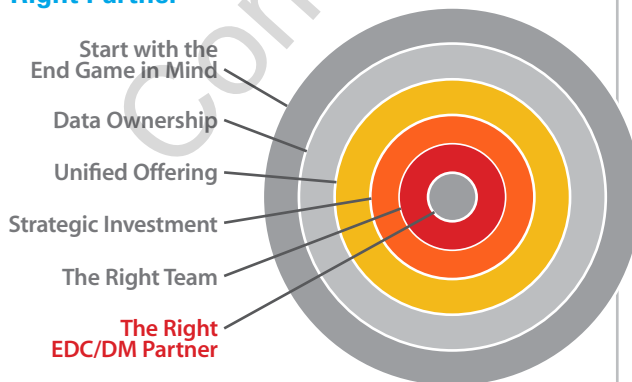
poorly interfaced technology. Working with different systems leads to a loss of information available, as well as additional resources or costs associated with system validation for each module that you need to connect. Can you access a patient profile report with all aggregated data? Do you have access to all integrated status reporting? How does your chosen solution affect study start-up? How many systems do you have to do UAT on? How many separate and distinct systems do you have to maintain data connections for? Ensuring that you do due diligence around these questions is essential because every integration or point of access is a potential point of failure and issues in this area will have an even more significant impact on a small organization.

## How Do You Maximize Impact for Your Investment?

Expanding the technology footprint may cost more in the short term but can greatly enhance the overall study, your actionable data, real-time knowledge, and key business decisions — therefore lowering costs in the long term. It is important to establish that the vendor meets all your current needs and has the potential to meet your future needs; can they scale with your organization?

The impact of decisions you make at the

## A Targeted Approach to Selecting the Right Partner



time of investment may only become apparent as you progress through your study. One common issue involves the pricing model used by the provider; does it open the potential for uncertainty and risk?

It is critical to examine closely pricing models that are based on data points or usage — for example number of queries, rounds of revision or the number of edit checks. What steps do these vendors take to limit change orders?

There are also considerations around offerings containing bundled services, as they can ultimately come in at a higher relative cost for smaller programs because you are paying for services you may not use. A modular option can offer a more competitive solution — one where you can choose precisely the functionality you need.

### The Right Team — Will This be a Relationship That Works?

Continuity and fit are crucial factors in keeping projects on schedule and within budget. The right team will take a comprehensive approach in overall study design and management.

A further success factor is selecting part-

ners familiar with the particular challenges and nuances of your program.

Will the team remain the same for the duration of the project? Does the team have the right experience? Are the organizations' cultures a fit? Does the provider have experience supporting sites in the geographies that you are working in? Does the provider have experience in your therapeutic areas and in working on similar types of studies, and if so how much? Do they offer specific solutions for your therapeutic area?

For a small organization, these relationships are central to success. A EDC/DM partner's team becomes a true extension of your own study team.

### What About Working with a CRO?

There can be many benefits to working with a CRO, especially when your needs are complex and you are not able to provide the right internal resources. However, as a small-to medium-sized organization, you will want to be confident that they are providing the right fit for you and that you are presented with a range of options in terms of tools and solutions to get the results that matter most to you.

You want to ensure when working with the CRO's partners that you are not sacrificing on a unified offering. How is the CRO bringing together the different pieces they are providing?

### Powerful Tools are Especially Important for Small- and Medium-Sized Organizations

Even small organizations should be working with best in class and enterprise-level technology and services. Indeed, it is even more important for smaller organizations to have powerful, comprehensive tools.

Reducing risk, saving time and being well informed so that you can make critical decisions as soon as possible will give you the edge that you need. <sup>PV</sup>

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For more information, visit [axiommetrics.com](http://axiommetrics.com)

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