

# EDC Evaluation Question Guide

**How to use this question guide:** These questions are used to spark conversation and uncover any blind spots you may be missing in your vendor vetting process as well as things the vendor hasn't considered when evaluating your specific needs.

Pay attention to not only the answers the vendor provides, but how the vendor answers the question. Is the sales rep quick to give a stock answer? Is s/he actively looking to better understand the intent of your question? These are all clues that will give you a sense of the level of service and support you will receive after go-live.

## Cost

- How are you pricing your solution? Based on studies?
- If it's a license structure, how is the license cost structured? Is it a complete license cost or broken down into modules?
  - Examples: Do you charge extra for a targeted SDV approach? Do you charge extra to use a local lab's functionality?
- Is there cost to have EDC data fed into other systems like CTMS?
  - What is the effort/cost involved to make other system integrations happen?
  - If we're running more than one study, is there a setup cost for every integration from EDC to CTMS?
- Is there an additional cost associated with customized data extractions?
- How many upgrades are done a year and how much do they cost?

## Efficacy

- What are standard build times?
- Is a library of CRF standards available?
- What's the process for creating a form?
- Can forms be reused / repurposed across studies?
- What is the standardization and structure of forms?
- Are there hints/tips available throughout the study design/build process?

- How easily can we make custom forms (i.e., a form with a dropdown menu?) Does this require programming or is this a drag-drop feature?
- What are the system's reporting capabilities?
- If we work with a CRO, do we have autonomy to pull reports or will we be dependent on the CRO for reporting?
- Does your system have dashboards or does that data need to be exported into spreadsheets?

## Support

- What does your onboarding process look like? Who is involved? What's the level of self-service training/materials vs. 1:1 support?
- How much support is recommended to develop in the system and then how much support/training is recommended to use the system?
- How much support do you provide during the lifetime of the study (i.e., after go-live)?
- If you use a ticket support system, what's your guaranteed turnaround time for response?
- Is there an option to have direct access to support once the study is live?
- What's your training and support model as you release new functionality and upgrades?
- How did you support and train CROs before go-live?

## Adaptability

- How does your EDC handle amendments?
- How much effort does an amendment require?
- How long does an amendment typically take from your end?
- How flexible is the system once the study is live? (i.e., ad hoc changes or custom reports)
- From a technical standpoint, what's the impact on my team as well as end users when making an amendment? Is there downtime?
- How does the information in other systems (such as IRT or eCOA) integrate and merge with EDC data?
- How easily does EDC integrate with other data systems such as IRT data or IRWS? CTMS?
- How flexible are data extractions?