

CHECKLIST FOR EVALUATING EDC SYSTEMS FOR YOUR STUDY

THE BASICS

- Is the EDC system interface user-friendly and modern? Are studies easy to build with both drag and drop and XML capabilities?
- How does training and support work? If you have an urgent support question, will your question get answered swiftly by a team member or will you be stuck in a never-ending phone tree?
- Is the EDC system HIPAA, CFR 21 PART 11, and GDPR-compliant?
- Are the costs straightforward? Is the price tag free of hidden fees, such as excessive training or start-up costs?
- Does your EDC system provide the features you need for your specific trial/phase? If you are running a phase I study, are you evaluating simplicity, speed, and monthly cost? If you are running a phase II or III study, are you evaluating scalability and more advanced features? If you are running a late phase study, are you evaluating features/add-ons, such as outcomes, eCOA/ePRO, language localization, while considering long-term cost?

THE FEATURES

- Does the vendor offer popular features/add-ons, such as medical coding, randomization, and eCOA/ePRO?
- Does the vendor offer more advanced features/add-ons, such as programmable edit checks, risk-based monitoring, language localization, and form versioning?
- Is the EDC system hosted on a private cloud for increased privacy, performance, and power?

