SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

10 Expert Recommendations for Smoother EDC Implementations

A Quick-Reference Guide for Biotechs

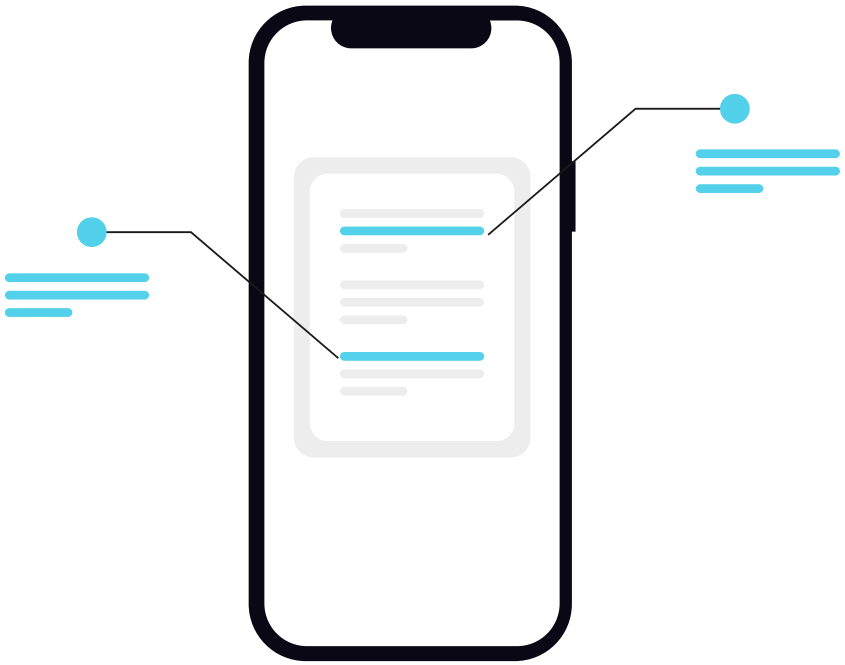
Small biotechs face unique EDC implementation challenges that larger pharma companies never encounter. Limited budgets, lean teams, and frequent protocol changes create a perfect storm of complications. After two decades of guiding biotech EDC implementations, I've seen the same costly mistakes repeated again and again.

Here are ten critical insights every biotech should know - gained from decades of experience.

Jan Breemans serves as Senior Director of Data Management Consulting at Signant Health, bringing over two decades of clinical data management expertise.

His experience spans implementations of EDC and other systems in biotech across all phases of the development lifecycle, from Phase I to late-stage, making him uniquely qualified to understand the challenges small biotechs face.

1 Protocol amendments are inevitable - plan for them



On average, every clinical study undergoes two or more substantial protocol amendments. For biotechs, updating systems due to protocol amendments is a painful and tedious process. Look for EDC solutions that allow seamless mid-study eCRF updates to reduce this burden.

2 External data integration is more complex than you think

Most studies collect substantial volumes of non-CRF data from central labs, ECG, imaging, etc. While larger organizations rely on clinical data management systems, smaller biotechs need an EDC that easily integrates with multiple data sources - supporting both automated integration and manual uploads for maximum flexibility.

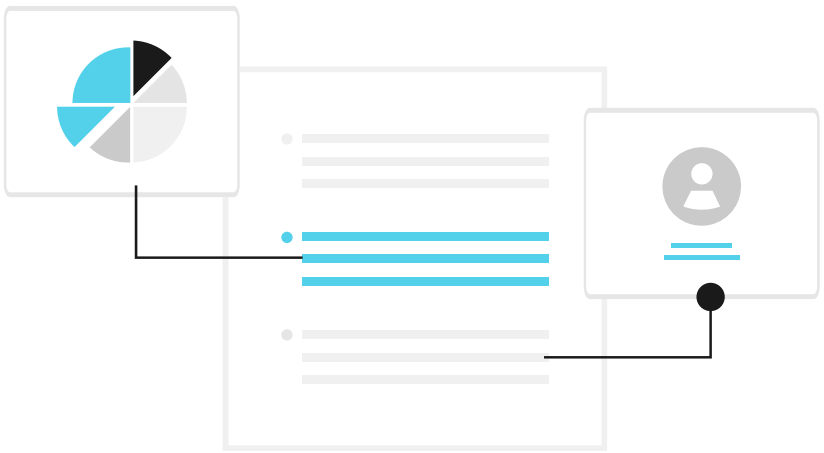
3 Maintain control of your risk-based monitoring strategy

Targeted monitoring offers clear benefits for monitoring costs and data quality. However, small biotechs often need more direct oversight and flexibility than traditional monitoring approaches provide. Choose an EDC that gives you ownership over monitoring rules plus complete transparency.

4 Data access delays can kill study momentum

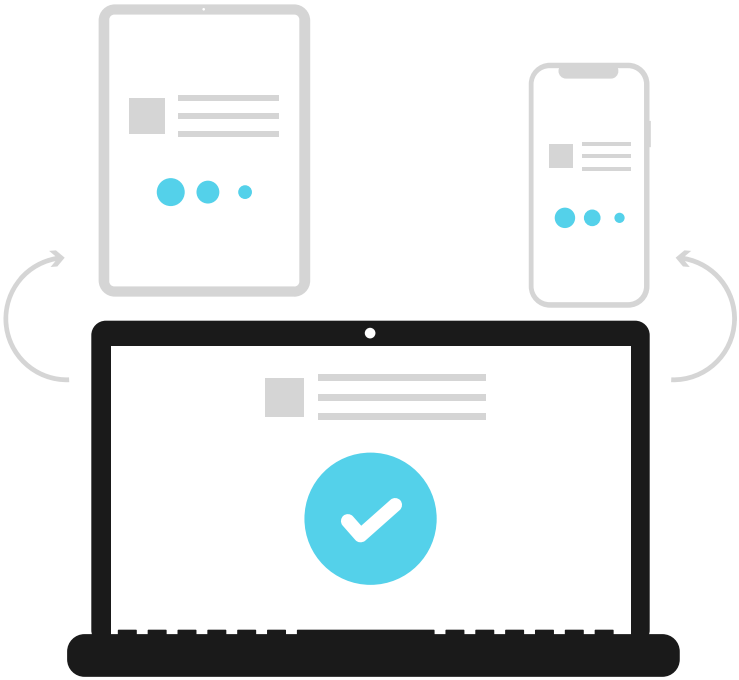
Biotechs often struggle to get study data when needed. You need the ability to extract data in CDISC ODM format either on-demand or on a predefined schedule. This enables quick reactions to issues and provides analysis-ready data when you need it most.

5 You don’t need enterprise pricing for enterprise features



A full-functioning EDC with market-leading features shouldn’t break your budget. Many biotechs avoid leading EDC solutions due to cost, but there are options that deliver comprehensive capabilities at biotech-friendly pricing.

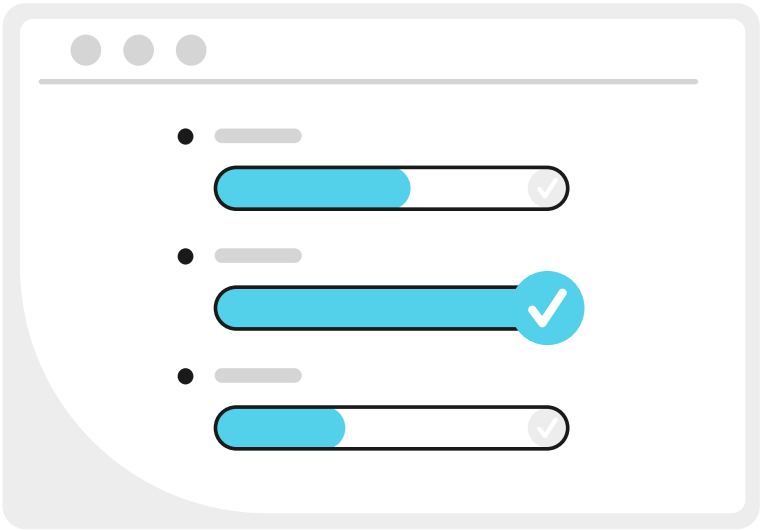
6 One system should handle all your trial types



Your EDC should offer all capabilities needed - from medical coding to local labs - suitable for any trial type. Whether it's Phase I, proof-of-concept, safety follow-up, or compassionate use programs, you shouldn't need different systems for different programs like larger organizations.

7 Site usability directly impacts data quality

Great usability for sites isn't a nice-to-have — it's essential. Complex systems create site burden, decrease compliance, and ultimately compromise your data quality. Prioritize intuitive, user-friendly interfaces that minimize training needs.



8 Integrated patient engagement eliminates data silos

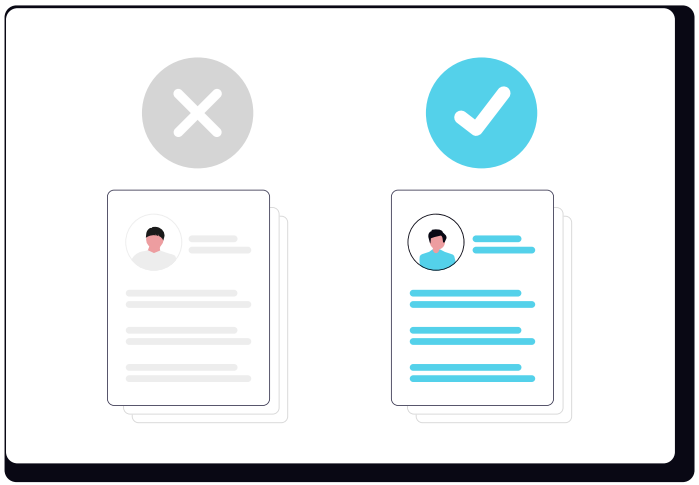
The ability to collect patient surveys and perform remote touchpoints (televisits, eCOA) should be fully integrated with your EDC system. Separate platforms create disconnected data and operational headaches.

9 Implementation flexibility protects your CRO relationships

Your EDC choice shouldn't dictate your CRO selection. Look for solutions that can be implemented by either the vendor's team or your CRO of choice. This flexibility ensures you can maintain valuable CRO relationships.

10

Expertise gaps are real - choose partners who fill them



Small biotechs often lack dedicated data science expertise, forcing reliance on multiple vendors, CROs, or consultants. Partner with EDC providers who offer the necessary guidance and support throughout implementation and beyond.

Ready to implement an EDC system designed for biotech?

Contact our team to discuss how Unified Platform EDC addresses these exact challenges.

Learn more about Signant's EDC solutions

ABOUT SIGNANT HEALTH

SIGNANT HEALTH

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