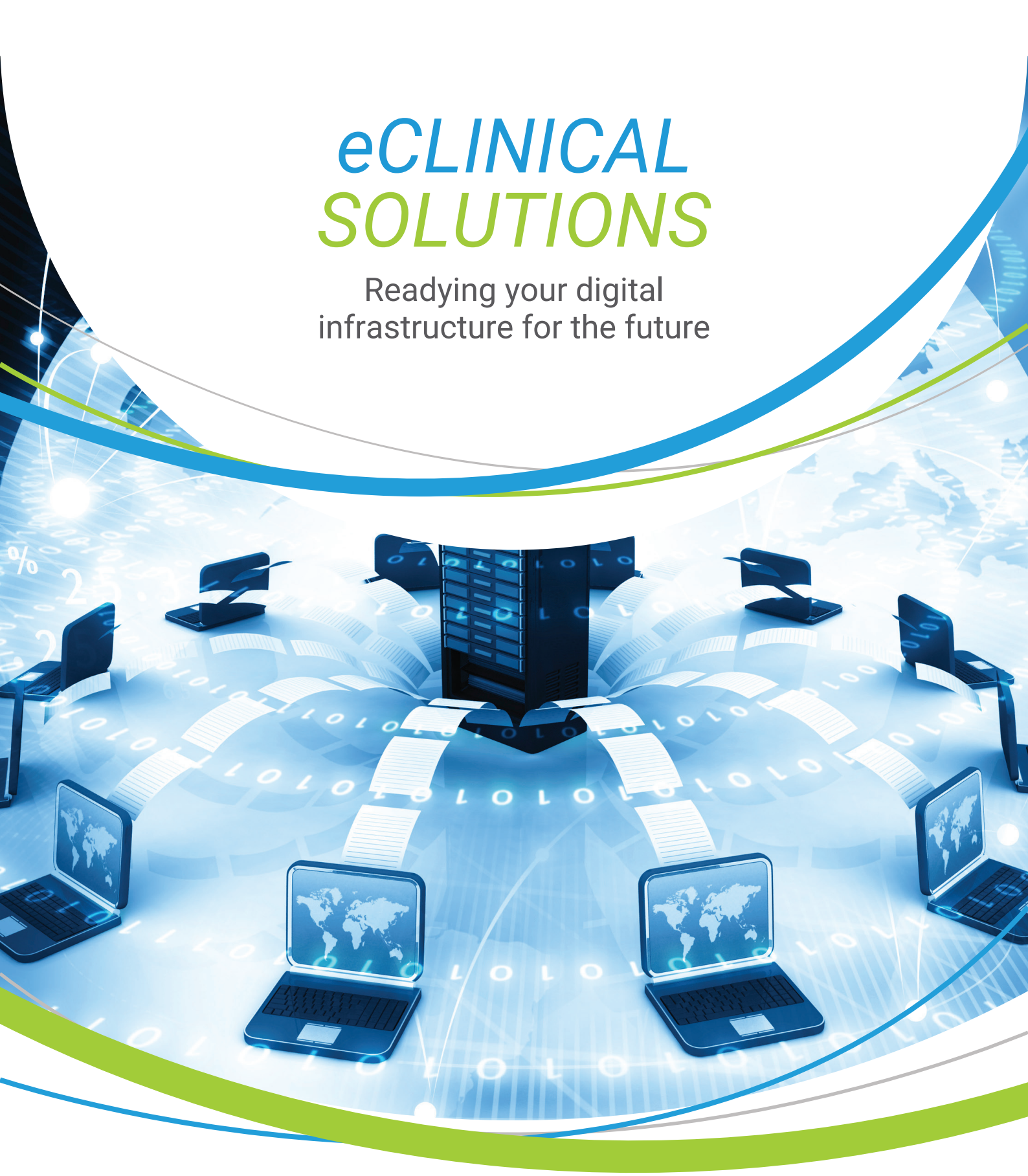
eCLINICAL SOLUTIONS

Readying your digital infrastructure for the future



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A very well know yet unaddressed challenge in life sciences research is identification, implementation and scaling of technology and systems. As an evolving biopharma or biotech, the focus on progressing the development cycle can dilute the need to invest in technology. Although, the lack of control on your infrastructure can impact the core of your development- your clinical data.

Business problem

When an emerging biotech moves across Phase I to Phase III development, the CRO partners continue to change as does the technology platforms leveraged, leaving the study data scattered and vulnerable. At the time of submission, this emerges as a key problem area-consolidating, cleaning, and readying your data to support meaningful outcomes. This process is time, cost and resource intensive, and challenges meeting the submission deadline.

Our solution

Our goal is to give you complete control of your clinical data right from when you define your clinical program until when you are ready to submit. We do this is by helping you assess your technology needs, create an infrastructure strategy, blueprint the scaling up across phases and most importantly centralize your clinical data.

In other words, it shouldn't matter how many vendor partners you engage through clinical development, your data is on your own systems and you have complete autonomy over it.

End-to-end portfolio of solutions

Clinical infrastructure	Quality and compliance	Computer system validation (CSV)	Consulting
• EDC • CTMS • IVRS/IWRS • ePRO • eCOA • eTMF • RIMS • Data security- Azure and Microsoft	• Identifying and implementing QMS • Building work instructions and SOPs • Quality trainings	• System qualification • Operational qualification • Performance qualification • User acceptance testing	• Vendor qualification • Landscape analysis • Clinical system evaluation and gap analysis

Case study

Client: US-based emerging oncology biotech

- An early-stage oncology biotech with a promising SIK inhibitor therapy for ovarian cancer needed a partner to support all their data and statistics needs
- Being a virtual team, the resources were lean, and budgets limited
- Their phase I study had already enrolled 9 patients using the site-based data system. They needed a scalable partner to get them submission ready and in limited time

Algorics solution

Team was involved in assessing the need of this biotech and conducting a gap analysis of where they need to be in terms of the technology to support their development journey.

The following activities were delivered successfully-

- Setup the entire quality management system including the SOPs and work instructions
- Helped them identify and successfully implement an EDC system as per their needs
- Managed end-to-end data migration
- Algorics also supported the implementation of eTMF and safety platforms

Customer testimonial

"We are delighted to have found a strategic partner in Algorics who are sensitive to the needs of smaller organizations and able to scale up and down with us as our requirements change. Partnering with Algorics has allowed us to focus on the clinical development of our portfolio of indications, safe in the knowledge that the infrastructure that we rely on to ensure quality systems and regulatory standard data are in place, independent of which CRO we work with to deliver the clinical operations."

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If you are in early development and are looking to identify what technology solutions will support your clinical phases ahead, we would be happy to have a conversation. Reach us at **hello@algorics.com**

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