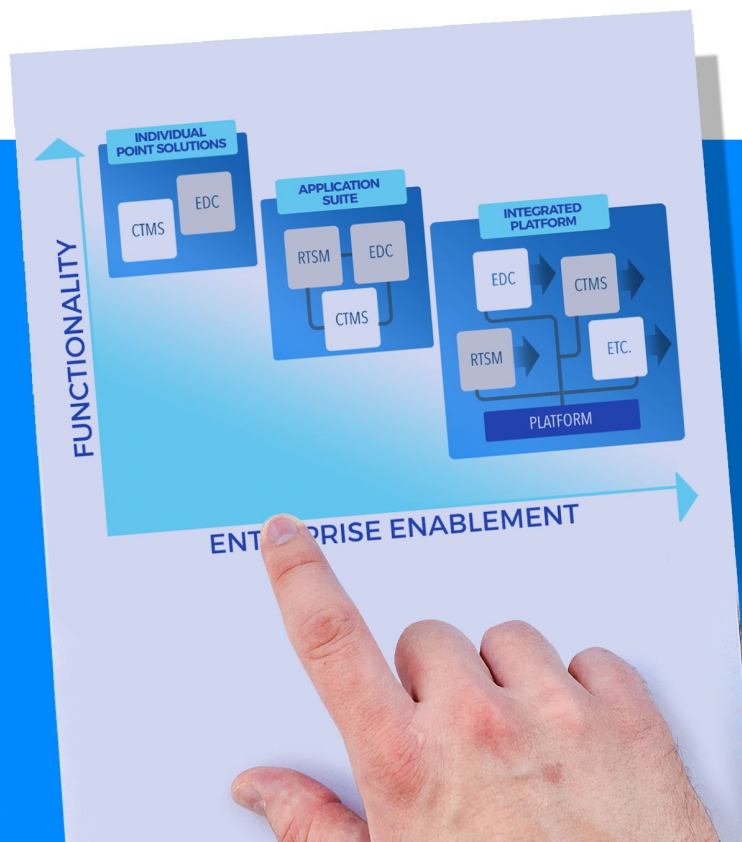adaptive **Clinical** SYSTEMS

6 THINGS TO KNOW WHEN CONSIDERING DATA VENDORS

and the key questions you should ask.

6 Things to know when considering data vendors, & the key questions you should ask.

The increasing variety and velocity of clinical data combined with heavy regulatory emphasis on holistic oversight with a 360-degree view of all study data is of the highest strategic importance to sponsors. Data volume and the increased demand for near real-time reporting and visualization requires integration of data across the spectrum of study vendors (eClinical like EDC and CTMS, IRT, mHealth, CROs, core labs and EHR/EMR). Adaptive Clinical System's eClinical Solution is designed to deliver a unified data solution for sponsors and CROs that seamlessly and intelligently brings together disparate data for faster, better trial execution and compliance. Our Adaptive eClinical Bus® has been described as "The Dream Tool" for clinical trial execution. Gartner named us as a valued contributor* among eClinical platforms.

If the intelligence and reporting that leadership, clinical operations, outsourcing, and data science teams need seems out of reach, this handy explainer will make clear we have the solution not just for integration but **total clinical data interoperability** – that is, **the Adaptive eClinical BUS**®.

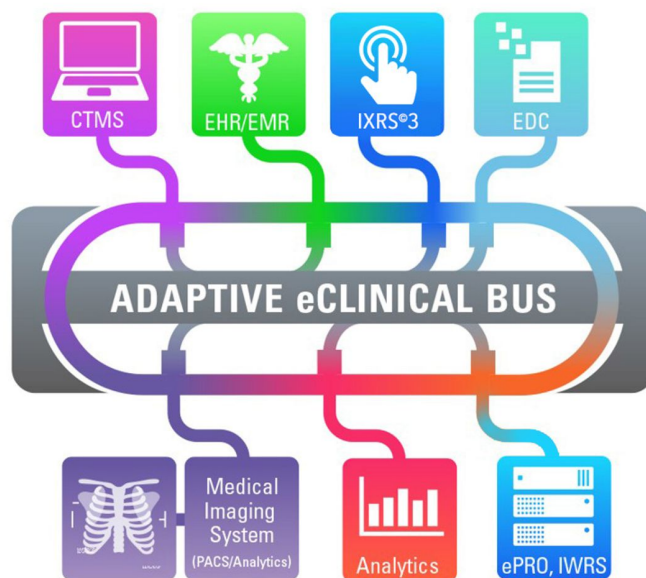## The Challenge: Substantially improve trial execution
The Solution: The revolutionary Adaptive eClinical Bus®

1 From Siloed Data to *Strategic* Data – The Single Source of Truth

Clinical trial complexity means choosing between best in breed solution vendors (genomics, biomarkers, eClinical Tools, wearables, EMR's) and integrating solutions and services from cloud-based eClinical platforms to support trial conduct and capture of critical primary and secondary endpoints. The Adaptive eClinical Bus® leverages refined and improved open-source components and global delivery models. The solution is scalable and flexible to meet your specific data integration needs no matter the protocol design or variety of partners:

- Electronic Data Capture (EDC)
- Electronic Medical and Health Records (EMR/EHR)
- Clinical Trial Management System (CTMS)
- Medical Imaging
- ePRO/eCOA

- mHealth
- Finance/ERP
- Interactive Web Response System (IWRS)
- Analytical/Data Visualization Systems
- Electronic Trial Master File (eTMF)

adaptive clinical SYSTEMS

You get the freedom to choose ANY of the best clinical trial tools, and we help you bridge and glue them together to suit your clinical strategy. Leverage your proprietary systems, identify the best partners, and apply our clinical data know-how to build clinical intelligence into your trials, and manage the risks of human error that come with incomplete and delayed data from multiple sources. You can further customize rules by building clinical derivations and data thresholds, making efficient use of subject matter experts on your staff. Others have achieved 70% reuse of design content regardless of clinical technology.

If you're talking with another vendor, you may want to ask:

- Is your software proprietary and how do you manage validation and releases?
- Are your modules/products truly integrated into a platform?
- What additional resources will I need to manage batch uploads and APIs?
- What happens if I have a study amendment?

2 Experience True Interoperability

Enable real-time interoperability with ANY third-party tool anytime through our robust connector suite. Our configurable clinical rules engine eliminates duplication of data by capturing and transmitting eSource data. It can auto-populate EDC forms directly from EMR. Reduce transcription errors and cost resulting in improved quality of data. The data warehouse tackles data repository and migration needs with ease. Sync databases and apps into a central data warehouse with the Adaptive eClinical bus. Others have experienced 55% reduction in data management, data reformatting and aggregation and **43% reduction in time spent verifying source data.**

If you're talking with another vendor, you may want to ask:

- Is your solution scalable to support early phase through post-approval?
- Is your data ingestion engine bi-directional?
- Does your implementation staff have deep expertise?

3 Control your Budget, and Your Resources

The Adaptive eClinical Bus leverages refined and improved open-source components and global delivery models. The service is scalable and flexible to meet your specific data integration needs and budget restrictions and requires no capital investment with minimal IT involvement.

A pay-as-you-go subscription model allows you to lease capabilities and modules based on the needs of a specific study protocol only when and for how long (weeks, months, years) you need them. You pay for access only while your study is in progress, enabling you to maintain little or no IT overhead between studies.

The Adaptive scalable EDC is available for hosting smaller studies for use as a data monitoring and trial management dashboard,or for data consolidation of larger multi-EDC studies. It is available out of the box with the eClinical Bus, or you can replace it with your preferred EDC solution.

If you're talking with another vendor, you may want to ask:

- Can I re-use my connectors across my program or organization?
- What are your cost drivers (e.g. number of sites, patients, users)?
- What level of IT resources will I need to sustain and support your solution?

4 Maintain Regulatory Compliance & Close Oversight for Data Confidence

All data are housed in the strictest compliance with all privacy and security provisions of HIPAA, the process quality guidelines of GxP, GDPR, and requirements of 21 CFR Part1 1. Detailed audit logs and reports enable review and oversight of all data at any time. Adaptive Clinical Systems will even host your proprietary system—using a platform as a service (PaaS) model—for rapid deployment to as many sites as needed without any IT involvement and with the lowest total cost of ownership (TCO). All servers are housed at a Tier-1 data center maintaining SSAE 16 SOC1 (supersedes SAS 70 Type II audit) certification and meeting ISO20000-1, and ISO/IEC 27001:2013 standards for service and information security. Data Center Statement and associated documentation are available as part of vendor audit.

The Adaptive eClinical Bus ensures continual software and technology upgrades and service updates in a fully validated environment. This pre-validated service enables the fastest study setup including custom electronic CRFs, and most robust protocol integration for studies of varying complexity. Some have experienced a 68% reduction in study setup time and 27% reduction in resources.

The Adaptive Help Desk is available 24/7, and a dedicated IT Project Manager will coordinate all setup.

If you're talking with another vendor, you may want to ask:

- Is your cloud GDPR compliant and do you have support documentation?
- Can your system de-identify PHI (patient health information)
- What security SOPs and processes do you have in place?

5 Get Real-time, Relevant Insights and Reporting.

Big data is great, but then what? With the Adaptive eClinical Bus®, users gain access to any data source to view up-to-the-minute, real-time data from any integrated software system. This eliminates the need for costly source data verification steps as the data are directly captured from the source systems. CDISC, HL7, SAS export modules simplify downloading data to all major post-study analysis tools. Data are maintained in native CDISC format at all times, allowing you to see interim "snapshots" of data in a standardized form. An open-source BI/Analytics tool is also available. Build in clinical intelligence to avoid human error associated with transferring data among disparate systems. In addition, you can personalize the rules by building clinical derivations and embedding your own clinical "know-how," making efficient use of subject matter experts on staff.

If you're talking with another vendor, you may want to ask:

- Can you ingest non-ODM data and transform?
- Do you have SDTM transformation as a standard deliverable?
- What level of clinical data management experience does your team have?

You may be thinking data – but we're a step ahead of the pack. We're thinking the **entire clinical trial operation.** This includes the eClinical platform and supporting applications including customers, ecosystems, intelligence, IT systems. It includes trial participants, vendor partners, IoMT Devices, and cloud infrastructure. Adaptive Clinical Systems has set the bar in elevating eClinical platforms to where they need to be – not just for today, but for tomorrow. To sum up our offering, we are described by our customers as:

- "Interoperability on steroids"
- Scalability to support early phase through post-approval
- More than just data ingestion - Adaptive Clinical Systems' eBus is bi-directional
- Adaptive Clinical Systems supports multiple data sources beyond EMR
- Senior leadership with deep tech and clinical trial data domain expertise
- Truly real-time intelligence for risk management, CRO oversight, financial management, and meaningful reporting
- A platform to help sponsors and CROs operationalize, not just visualize.

Plug into "The Dream Tool" – our Adaptive eClinical Bus® for ultimate control with empowering insights.

About us

Adaptive-Clinical Systems® created the only proven technology platform that lets you quickly go from integration to interoperability across all eClinical tools, leveraging a re-usable connector library and intelligent middleware. Our clinical rules engine not only moves, but can also transform data, all on a fully validated platform compliant with CFR 21 Part 11. The proven cloud-based Adaptive eClinical Bus R solution unifies disparate data. It helps increase efficiency, enhance collaboration, and improve trial performance – and is modernizing data flow from any data source, now and in the future.

To unify your data, go to adaptive-clinical.com, email info@adaptive-clinical.com or call 856-452-0864.

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