Enterprise Prancer Integrations (EPI)

Knowledge Sharing Series

Enterprise Prancer Integrations (EPI)

Introduction

Over the past decade, clinical research operations have increasingly relied on a highly integrated ecosystem of clinical software. The demand for Randomization and Trial Supply Management (RTSM) data as a source for supply actuals, logistics, and subject information has surged. Integration of this data across clinical trial systems is essential for enhancing planning, improving analysis, and reducing administrative overhead, all of which contribute to the success and efficiency of clinical trials.

To meet this demand, 4G Clinical is not only scaling the volume and variety of integrations, but also the infrastructure that supports them.

The Problem: Scaling Enterprise Integrations

In the traditional approach to data integrations, requirements are often evaluated on a study-by-study basis. While this method may work for individual trials, it falls short when applied to sponsors with extensive pipelines and multiple RTSM implementations. Large sponsors managing multiple trials achieve maximum impact from their logistics and analytics integrations by applying them to their entire portfolio, requiring consistency and scalability. The more systems connected in support of a trial, the greater the need for uniformity across these connections. It is more efficient for partners to establish sponsor-level standards than it is to design study-specific data capture across multiple clinical systems.

Even more critical than implementing integrations consistently for all new studies is the ability to be flexible and amend those integrations during the live study. When a sponsor requires a change—such as adding a new data field to a dashboard or altering site activation criteria—that change needs to be rolled out across the entire client portfolio. Why only include the Site Activation Date for one study's data warehouse transfer when it can be included for all studies? It is inefficient to implement and amend sponsor-level integrations on a study-by-study basis. Redundant configuration increases complexity of small changes, resulting in less flexibility when updates are needed.

Enterprise Prancer Integrations (EPI)

Integrations infrastructure should match its function. Sponsor-level integrations require centralized configuration management so that integrations can be easily applied and updated across the entire portfolio of clinical work.

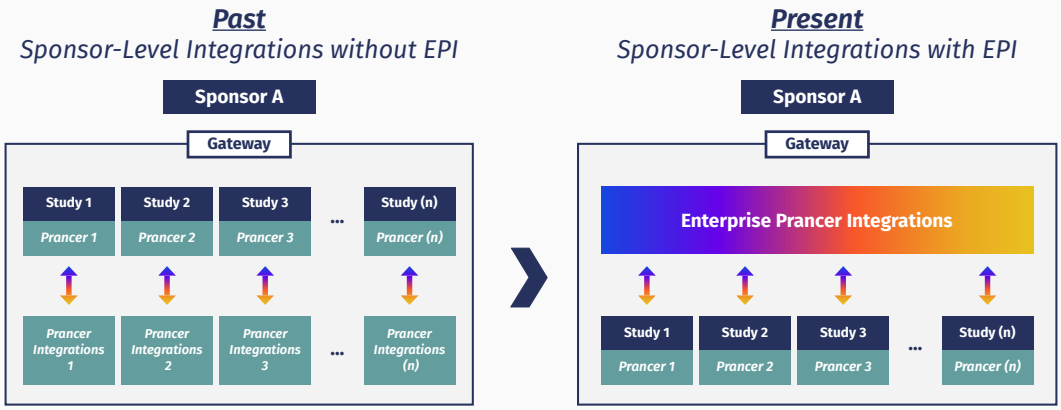
Simply put, enterprise clients require enterprise integrations.

The Solution: Enterprise Prancer Integrations (EPI)

To address these challenges, 4G Clinical developed the EPI platform. EPI is a sponsor-level integrations platform designed to centralize integration configurations into a single codebase, enabling the streamlined application of integrations across all studies within a sponsor's portfolio. EPI lives above the study-specific applications of Prancer RTSM® but can run parallel with the existing study-level instances of Prancer Integrations (PI). This means that existing, study-specific integrations such as EDC integrations can continue to run in PI, while sponsor-level integrations are converted or implemented in EPI.

EPI: Enterprise Prancer Integrations

- Amending Enterprise integrations at a sponsor level
- Rapid new study setup and rapid amendment / fix rollout
- Override at study level possible



Enterprise Prancer Integrations (EPI)

- Prancer 1 identifies the Prancer substack that hosts Study 1 config. Prancer 2 identifies the Prancer substack that hosts Study 2 config, etc.
- Prancer Integrations 1 identifies the Prancer Integrations substack that corresponds to the Prancer 1 substack. Prancer Integrations 2 identifies the Prancer Integrations substack that corresponds to the Prancer 2 substack, etc.
- Basically, in the "Past State," every sponsor has a URL that denotes their stack, for example: sponsor.4gclinical.com. Within that stack there is a single Gateway instance, which can be thought of as the user access layer.

Within one stack there is a single Prancer substack per study.
Example: Study 1 (Prancer 1) Study 2 (Prancer 2)

Then there was also a single Integrations substack per study. Example: Prancer Integrations 1, Prancer Integrations 2, etc. These are in gray because that was the "old" way of doing it (having an integrations substack per study, that is)

PAST (No EPI)

Gateway (login layer that manages user access for all studies among other things)		
Prancer (study-level RTSM config)	*Prancer Study 1*	*Prancer Study 2*
Prancer Integrations (study-level integrations config)	*Prancer Integrations Study 1*	*Prancer Integrations Study 2*

Gateway (login layer that manages user access for all studies among other things)		
Prancer (RTSM config.)	*Prancer Study 1*	*Prancer Study 2*
Enterprise Prancer Integrations aka EPI (sponsor-level integrations config)		

Enterprise Prancer Integrations (EPI)

Centralized Configuration for Enterprise Clients

EPI makes established integrations immediately available for all existing and future studies. Additional studies can be added to the existing integration framework with a single click, significantly reducing the time and resources required for setup.

The centralized integrations configuration also ensures that any changes or updates are applied uniformly across all studies. This is particularly advantageous for enterprise clients advancing their partner systems and needing to retrofit existing studies with their newest standards. One of the key benefits of EPI is its ability to pivot quickly in response to changing sponsor requirements. In a dynamic clinical trial environment, the ability to implement changes across all studies simultaneously is essential. EPI ensures that sponsors can adapt to new requirements without the burden of adjusting on a study-by-study basis.

Scalability and Flexibility

EPIs center sponsor-level requirements while maintaining the flexibility needed for minimal study-specific adjustments. This approach ensures that as sponsors introduce new systems—such as data warehouses, dashboards, or Clinical Trial Management Systems (CTMS)—the EPI platform can uniformly extract and manage data across all trials. This scalability is critical in supporting sponsor-level data management and operational efficiency. EPI addresses the need to apply integration requirements across a sponsor portfolio but still respects the unique elements of each protocol.

Enterprise Prancer Integrations (EPI)

- Faster implementation for new studies
- Faster change management
  - Updates do not require study-level deployment
- Centralized error logs
  - Beneficial for testing and support
- One-time configuration reduces errors
- Product Auto Upgrades
  - Bug fixes + new features are always available

4G recognizes that each sponsor has unique requirements for integrating their suite of clinical solutions. EPI includes a new way of managing Extract, Transform and Load (ETL) data processing that allows for greater flexibility in the development process. ETL tasks that were previously hardcoded into the product code are now elevated to a configurable workflow in the database that can be easily updated during the integration build. Rather than updating the product with specific ETL tasks to meet new user requirements, EPI is designed so that we do not need to anticipate each partner's unique requirements but can adapt and deliver a flexible solution upon request.

Auto Upgrades

A core feature of EPI is the "Auto Upgrade" functionality, which applies the most recent product version to each sponsor's EPI implementation. Following the Software-as-a-Service (SaaS) upgrade model used for the Gateway Product, EPI product releases are built so that each product version is backwards compatible and can be released to live systems as they are available. This approach is also paired with a short release cycle to contain the impact of each release and quickly address any gaps. Auto upgrades are a key feature of 4G Clinical's enterprise, offering to deliver the most advanced product solutions to live studies and ensure that a client's entire portfolio is supported by a consistent operational model.

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Impact and Benefits

The implementation of EPI offers several key benefits:

Consistency Across Studies: By centralizing integration configurations, EPI ensures consistent application of data integration standards across all trials, reducing variability and potential errors.

Faster Implementation: The platform minimizes the need for repetitive, study-specific customizations, freeing up resources and reducing administrative burden. This results in faster integration implementation and changes for our partners.

Improved Data Management: EPI supports consistent data extraction and integration across multiple systems, enhancing the sponsor's ability to manage and analyze trial data across their portfolio. This is a particular benefit for data warehousing.

Scalability for Enterprise Clients: As sponsors expand their clinical research portfolios, EPI provides a scalable solution that can accommodate new studies and systems.

Conclusion

The EPI platform represents a significant advancement in clinical trial data integration by addressing the access and flexibility required by sponsors with multiple studies and highly integrated digital ecosystems. By addressing the limitations of study-level integration implementation and providing a centralized, scalable solution, 4G Clinical's product development has enabled sponsors to achieve greater efficiency, consistency, and flexibility in managing their clinical and operational data. As the demand for integrated data continues to grow, EPI is a critical tool for sponsors looking to achieve maximum impact from their integrated systems.

Meet the **Author**

About the Author

Meaghan Griffith, is Integrations Manager at 4G Clinical. With over a decade of experience in the clinical trials industry, she has held progressive leadership roles across business systems analysis, project management, and systems integration.

Throughout her career, she has played a key role in the design, implementation, and support of randomization and trial supply management (RTSM) systems, with deep expertise in integrating these platforms with external vendors and technologies. Her work is grounded in a commitment to operational excellence, innovation, and client satisfaction, helping to streamline study builds and optimize supply chain operations in support of faster, more effective clinical trials.

For more details on how 4G Clinical can assist you visit **4gclinical.com**

Contact us **info@4gclinical.com**

About us

4G Clinical's suite of innovative RTSM and clinical supply optimization software provides the right-sized support for any phase or trial complexity. At 4G Clinical, all studies are supported by a team of RTSM experts to advise trial teams on the best path forward. Our operations team distinguishes itself through their extensive industry expertise and deep understanding of trial designs and mid-study adjustments. As a critical partner throughout clinical development, we can help you seamlessly transition and scale your trials through both protocol and supply complexities to help **bring crucial medicines to those who need them, *faster.***