



Breaking the Mold
In Clinical Systems Integrations

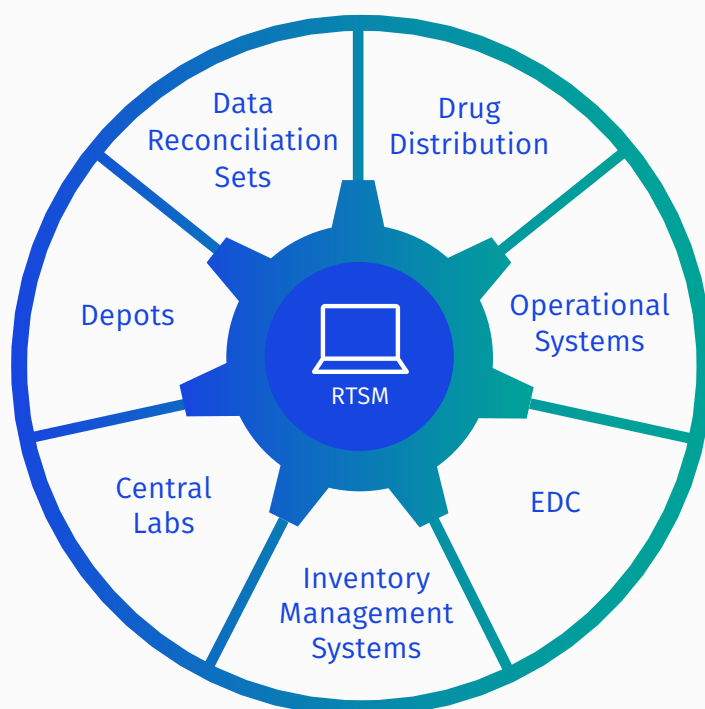
Knowledge Sharing Series

Breaking the Mold

Overview

Leveraging Modern Technology to Seamlessly Integrate with (any) other Platforms

There is a plethora of data points needed to run a successful trial through to approval. Departments (drug supply, clinical, finance) may have different uses for the same data, and therefore the way they track and communicate the data varies. Externally, your vendors and CROs collect, store and analyse data. Your end-users at clinical sites enter data that are fed back through the workflow. With so many systems and so many users, system integrations are critical to avoid redundant data entry, discrepancies and gaps in data.



Breaking the Mold

Overview

ECLINICAL INTEGRATIONS	EXAMPLES
Drug Distribution	Almac, Fisher, PCI, Catalent, Aptuit
Operational Systems	CTMS (Parexel's Impact and Oracle Siebel)
EDC	Inform, Rave, Medrio
Inventory Management Systems	ERP

Value of Integrations to Your Business

As mentioned above, integrations are key to avoid redundant data entry, discrepancies and gaps in data. However, the value of integrations extends well beyond that to inform business decisions. For example, clinical operations professionals use enrollment data (from RTSM) that is transferred to other platforms via integrations (CTMS, etc.) to influence decisions on where to apply recruitment activities, plan upcoming monitoring visits, inform risk-based monitoring, close patient screening at the right time, etc. Having access to the right information at the right time is crucial in clinical trials. Additionally, so is the speed to gather information. Robust integrations enable end-users to avoid searching multiple systems (i.e. inventory shipment requests or lab results).

The Problem

All integrations are not equal

Traditional RTSM vendors custom program each individual integration. Even though some may choose to copy and paste the code from similar integrations for efficiency, the process typically takes 2-3 weeks or longer. Given that many sponsors are unsure of all the integrations needed until closer to go-live, integrations can be a hurdle to overcome to get to FPI.

This challenge has led many sponsors to seek vendors that offer an eClinical suite, regardless if all the technologies would be the best fit for their trial. Many of those systems within the suites have been acquired and are built on separate architectures. They are still exchanging data between two systems, many of which are still custom coded and similar in process as separate products by separate vendors.

So what is the best solution?

Integrations should not determine what technologies you should use in your study, especially when it comes to critical functions with direct patient impact like randomising and dosing patients.

Strong integrations should enable sponsors to choose the best-in-class technology for each function. They should be simple, fast and agile. Modern technology allows us to fully test and release a new integration between 1-3 days. The variance in length is tied to gathering the requirements for the transfer, which includes working with the partner vendor (ex: EDC vendor).




*Once the requirements are established, configurations can be done in as **little as an hour.***

*Modern technology also **enables integrations with any vendor** and any system that works best for your trial.*

Our Approach to Integrations

Modern and Scalable Integration Technologies

In its simplest form, integrations extract data, transform data into the desired format and load it into another system. It shouldn't matter what data is transmitted or what type of system it is coming from or going to. That is the power of modern technology. It enables integrations that are fast, secure and validated without being limited by the vendor, system type or file type.

 eClinical Suite	 Best-in-Class Components	 Best-in-class
<p>X Old Tech</p>	<p>X Old Tech</p>	<p>✓ Modern Tech</p>
<p>X Pre-selected Components</p>	<p>✓ Best-in-Class Components</p>	<p>✓ Best-in-Class Components</p>
<p>✓ Pre-built Integrations</p>	<p>X Disparate Systems, Custom-coded Integrations</p>	<p>✓ Fully Configurable, Seamless Integrations</p>

Modern Technology Enabled Data Flow

Our engineering team designed Prancer RTSM® such that integrations are configurable just like our RTSM features. Configurable systems are designed to adapt to client needs. Flexibility is built into the system itself, and that includes any possible integrations. Integrations are built and tested before the RTSM system goes live.

Once an integration has been built one time by any client, it is now available as a simple configuration. Each integration can have its own nuances due to the inherent flexibility including what triggers the data transfer, what data is extracted, how it is being transformed and transmitted.

4G's integrations are built as Microservices, independent of Prancer RTSM®. Microservices, also known as microservice architecture, is an architectural style that structures an application as a collection of loosely coupled services, which implement business capabilities. It enables the continuous delivery/ deployment of large complex applications.

The benefit of building integrations as Microservices is the ability to decouple certain features from the application so that updating does not require revalidation of your RTSM application.

Simply put, we can upgrade integrations without having to upgrade Prancer RTSM® and vice versa. No down time, no frustration for end-users.

Additionally, the Integration Microservice is constantly listening for real-time notifications from Prancer RTSM® about events and actions performed. Their decoupling means that the RTSM is unaware of what integrations will be performed once the notification is raised and will not be impacted by any communication between the various systems.

The capabilities included in the integration microservice are continually improving. At the time of this publication, data can be sent in the following formats: text file, XML, JSON, and SAS. The data can be transmitted via SFTP and FTP, REST API, SOAP WebServices, and Emails. For example, our system can handle both synchronous and asynchronous API calls, so that we can adapt to any type of vendors (especially EDC which tend to be very rigid). Our system handles any connection type or data type. We advise on best practices and the best option for your business.

Data Strategy Advisory

Capabilities

The hardest part of any integration is determining the requirements because it involves in-depth knowledge of the business of clinical systems. Looking at your overall data story, what data exists where? Is the data terminology consistent, even down to how you are numbering your sites? It can be a pretty complicated process and being able to leverage extensive expertise and best practices for building integrations requirements are key to the business success of an integration.

Two examples of decisions regarding RTSM/EDC integration to consider are:

- Visit dates in RTSM and EDC match OR RTSM holds visit dispensing dates and EDC holds visit dosing dates
- Pass screened patients to EDC, with the possibility of the patient screen failing OR don't pass patients to EDC until they are enrolled/randomised so you have no screen failures in EDC

*4G Clinical's world-wide, **world-class team** has **extensive experience** in clinical systems, and not just with RTSM integrations.*

*Our seasoned team will guide you through best practices and advise on the **best path forward**.*

Delivering Integrations through **Collaborative Engagement**

*Good project management is essential for a **smooth integration** process. Vendors will need to work together, and in many cases, are competitors.*

*This requires a **strong project plan** to work through and align on a specification, build and test the integration before going live.*

Issue Resolution After **Go-Live**

However unlikely, if issues arise it is critical to have an **air-tight issue resolution process** with regards to integrations.

Our integrations have **built-in notifications** for any errors and automatic ticket creation. This allows us to **identify the issue**, immediately **troubleshoot** the issue, **address the rootcause** and resend the failed feed.

Conclusion

Integrations are essential for the trials of today and tomorrow. As with any technology, integrations should adapt to your process and to whatever other platforms work best for your trial. They should be fast, validated and secure, and enable data flow throughout the study.

There is also an enormous amount of knowledge required in choosing the right integrations and the right data. The technology can be sound, but if you are moving the wrong data, your trial is still at risk.

The keys to a successful integration include:

- Combining Best-in-Class components with modern technology for fully configurable, seamless integrations
- Developing sound build requirements that align with your data strategy
- Collaborating with a vendor partner that is both knowledgeable in the business of clinical systems and has deep project management experience

Meet the **Authors**



Phil Woodson 4G Clinical Director, Client Technical Services, has nearly a decade of experience developing RTSM systems across a variety of technologies. In addition to RTSM, Phil has extensive experience developing EDC and ePRO systems as well as a wide variety of data integrations between various clinical trials systems. He is passionate about clinical trial design and loves innovating simple solutions for complex randomisation and drug supply schemes. Phil has a BS in Biomedical Engineering from Drexel University.



Kathleen Greenough Director of Client Solutions at 4G Clinical, has 16 years of experience in life sciences spanning Clinical Operations, Finance, and IT. Her wide range of solutions implementation expertise includes RTSM, CTMS, trial costing tools, OLAP financial suites and patient enrollment planning. Kathleen has also spent many years as a Clinical Financial Planner and Analyst at a major biotech in Cambridge, MA, gaining a broad and deep understanding of the challenges inherent in Clinical Development. Specialising in software adoption and a frequent speaker at industry conferences, Kathleen is most in her element when working within a user community to facilitate solutions that are insightful and truly helpful.

Curious to hear more?
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Still have questions?
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About 4G Clinical

We reduce the time it takes to commercialise vital medications by delivering validated, easily extendable RTSM capabilities to Pharma and CROs faster than anyone in the world.

4G Clinical is driven by a single purpose: bring crucial medicines to those who need them, faster. 4G Clinical believes that the way to accelerate clinical research is by disrupting the way trials are executed. That's why we have revolutionised RTSM (randomisation and trial supply management) and supply forecasting capabilities and services from the ground up.

4G Clinical is committed to helping sponsors and CROs follow the science, wherever it may lead, as quickly and as safely as we can. While we will not discover the next novel compound in the lab, we are doing our part by leveraging our extensive experience and technological innovations to bring speed and agility to clinical trials.

Prancer RTSM®

Our 100% configurable and agile RTSM is built for the clinical trials of today and tomorrow.

4G's RTSM platform, Prancer RTSM®, utilises natural language processing alongside integrated clinical supplies forecasting and management functionality to slash development timelines, increase operational efficiencies and offer exceptional quality.



Bringing crucial medicines to those who need them, *faster*.

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