



Prancer RTSM®

Bringing crucial medicines to those who need them, faster.

[4GCLINICAL.EU](https://4gclinical.eu)

Table of contents

Prancer RTSM®	3
---------------	---

Differentiators	3
------------------------	---

Speed – Natural Language Processing

Agile Design

Flexibility Post Go-Live

Robust Site & Depot Forecasting

Prancer RTSM® Configurable Solutions	5
---	---

Prancer RTSM® Lite

Prancer RTSM® Supply / Rand Only

Prancer RTSM® Platform

4C Supply® Integration	8
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Overview

Prancer RTSM® Real-Time Actuals Integration

Joint Prancer RTSM® & 4C Supply® Solution

PRANCER RTSM®

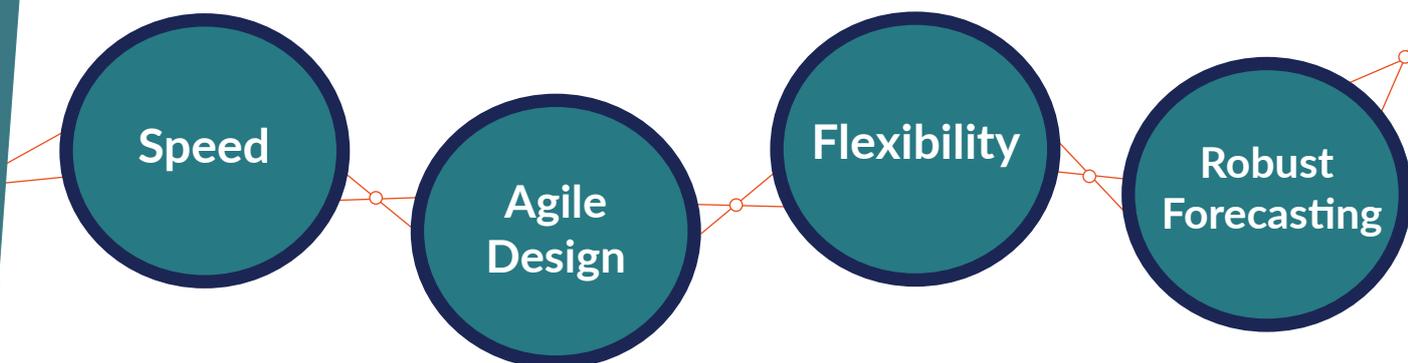
Prancer RTSM® leverages modern technology to enable cutting-edge science.

As a fully cloud-based, 100% configurable and flexible randomisation and supply management solution, Prancer RTSM® uses natural language processing (NLP) and integrated supply forecasting to address the rising complexities and challenges of clinical trials.

Prancer RTSM® is easily configured to meet the needs of the largest pharmaceutical companies to nimble biotechs throughout the drug development life cycle and is able to scale with you from early Phase 1 to post-approval.

DIFFERENTIATORS

Wherever the science leads, we can follow.™



Speed – Natural Language Processing

Prancer RTSM® leverages natural language processing to simplify and accelerate an outdated RTSM build process.

The traditional process for designing RTSM systems requires clinical study teams to sift through hundreds of pages of complex technical requirements to design a study system. As a result, systems are designed by clinical professionals who don't necessarily understand what they are approving. This ultimately leads to increased findings in user acceptance testing (UAT) and further edits to the system, adding additional time before system go-live.

Prancer RTSM® has revolutionised the build process. NLP technology reads and interprets written RTSM specifications, understands them, and builds a deployable system in minutes.

The result? Sponsors approve the system, alongside dramatically shorter specifications (20-30 pages). This can be done significantly earlier in the process, reducing build times to 2-4 weeks from kick-off meeting to spec signature and enabling multiple design reviews before UAT.

Agile Design

4G Clinical utilises an agile, iterative approach to systems delivery. Through several iterations of the system, sponsors collaborate with 4G Clinical experts and make adjustments based on everything from design choices to system flow and study-specific vernacular, in real-time, all before traditional UAT.

This approach ensures there is nothing lost in translation from the written specifications to the system build. Sponsors are able to design and execute the trial they want, without the worry of technology or process limitations.

Flexibility Post Go-Live

We understand that clinical trials may need to adapt along the way and we believe that your RTSM should welcome these adjustments.

Prancer RTSM® is 100% adaptable post study go-live thanks to the use of natural language processing and configurability. Most changes can be incorporated and ready for review and testing within days. Since flexibility is built in, you can shift gears mid-study to follow the science. Your RTSM should never hold you back.

Robust Site & Depot Forecasting

Prancer RTSM® has a fully integrated and intuitive forecasting engine, taking the manual work out of site and depot forecasting. The system calculates the total demand for sites and depots by combining buffer levels with dynamically updated demand for existing patients – allowing you to focus on making decisions based on business need, rather than spending your time on manual calculations or interpreting complex statistical algorithms.

Our platform offers complete transparency and control over the management of your supply strategy, without contacting support to assist and without requiring system changes. Complex algorithms and smart statistical models are leveraged by setting dials in a simple interface, designed to quickly show the impact of changes and find the most appropriate balance for your study's supply needs.

Interested in forecasting throughout the study life cycle? Learn more about our 4C Supply® solution and the real-time actuals integration with Prancer RTSM®.

Prancer RTSM® Lite

Prancer RTSM® Lite is a safer, less error prone way to manage trials currently managed on paper. It is an efficient and affordable solution for studies that only require basic patient screening, enrollment and drug supply management that would have otherwise been managed in Excel sheets. Prancer RTSM® Lite studies are implemented in 20 days from start to finish.

If you find that your study takes off and you need more functionality, the transition to a full RTSM is primarily a contracting exercise. Delivery of the full RTSM is also simplified. Adding features is a configuration change that requires zero customisation and can be completed in weeks, not months. All your data is within the same URL and the transition is seamless to your site users.

Transition to Full RTSM



Lite uses the same product as full RTSM, unused features are dormant

- o No change in study access for site users
- o Simple configuration to add new features as needed in the future (new cohorts etc.)

For more detailed information on Prancer RTSM® Lite, please refer to:
www.4gclinical.com/prancer-rtsm-lite.

Prancer RTSM® Platform

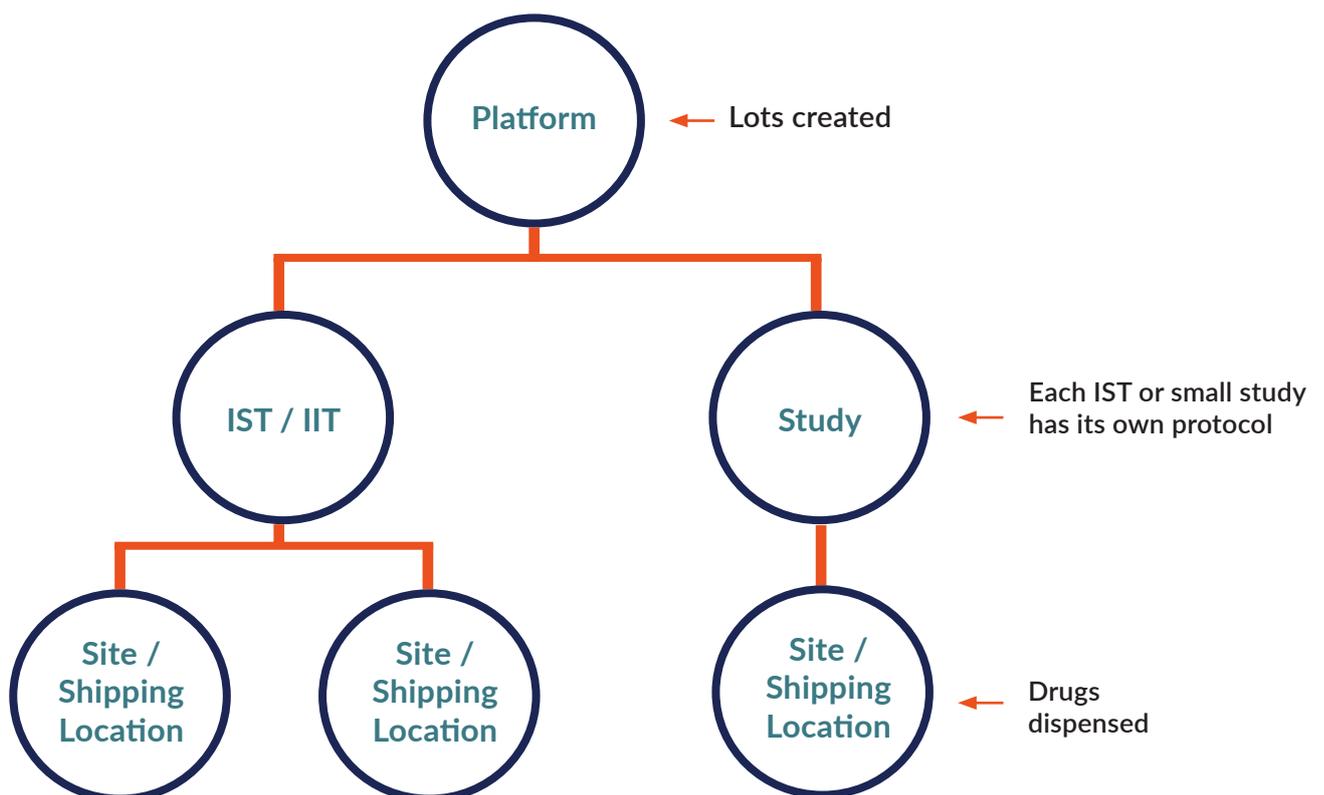
Prancer RTSM® Platform allows you to manage similar studies in a single location. Intended primarily for supply only studies, the Platform contains many protocols and the sites / shipping locations used in each. This solution is frequently used to manage investigator sponsored trials (aka IST or IIT).

4G Clinical builds a single platform where you can manage all the sites across multiple protocols. If all the studies have the same dispensing schedule the Platform can track patients as well, but the configuration is best for studies where there are limited or no patient actions.

In most cases, the platform is used for supply management alone, to offer all the inventory tracking that would otherwise be captured on Excel sheets that quickly get out of date. Clinical sites can receive shipments, submit supply requests, and update inventory statuses as each study progresses. Sponsors can review supply requests, manage available packaged lots, process temperature excursions, and resupply based on thresholds or expiry dates.

The pricing is per platform, the number of studies per platform is unlimited. A full RTSM solution for each of these small studies would be unreasonable, but in aggregate they can be a significant resource drain and difficult to manage. An aggregated platform offers a solution that saves time and offers meaningful value.

Platform Architecture



Prancer RTSM® Platform

Prancer RTSM® Supply or Rand Only configurations are ideal for studies with limited visit schedules or simple supply strategies. They can track only patients, or only supplies, but not both. Pricing is based on feature selection.

Randomisation Only	Supply Only
<ul style="list-style-type: none"> No lots, no inventory Patients randomised in system by unblinded pharmacist OR study is open label Often used when randomisation needed but there are few sites or few visits, making supply calculations very simple 	<ul style="list-style-type: none"> No patients Sites may also order inventory Resupply done manually, based on orders or a fixed schedule, or use min/max thresholds and sites must mark inventory as dispensed Often used when transitioning from paper-based

4C SUPPLY® INTEGRATION

Overview

4C Supply® is an innovative clinical supply optimisation solution leveraging natural language processing (NLP) to turn study parameters from plain English into detailed forecasts, giving you full transparency and complete control of supply decisions. 4C Supply® brings simplicity and speed without the error prone processes of Excel or the need for external SMEs required by existing commercial tools. From early-stage feasibility planning through study completion, informing supply chain decisions has never been easier.

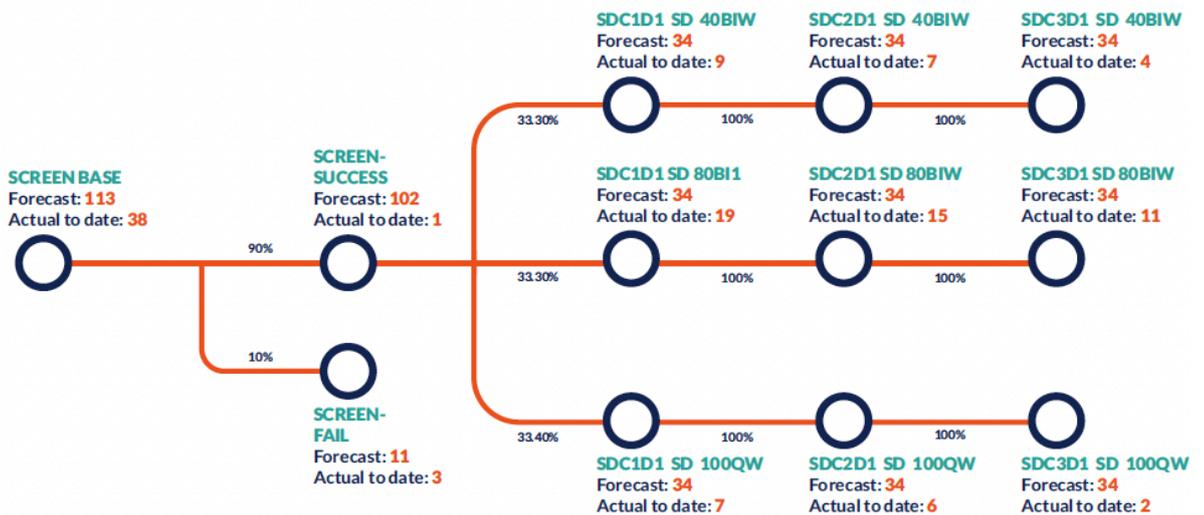
 Excel - The Industry Standard	 Available Commercial Tools	 4C Supply®
<p>X Slow - Manual process</p>	<p>X Slow - Input changes and processing time</p>	<p>✓ Fast - Dynamically adjust forecast in moments</p>
<p>✓ Easy-to-use, known platform</p>	<p>X Complex - Difficult to verify outcome based on inputs</p>	<p>✓ Easy-to-use, intuitive</p>
<p>X Not automated, difficult to scale</p>	<p>X Not automated - Lack of integration, uncertainty applied to study duration</p>	<p>✓ Fully automated, adapts to any level of input</p>
<p>X Risk: Human error</p>	<p>X Risk: Lack of understanding, blindly trust results and expensive</p>	<p>✓ Opportunity: Powerful visualizations, scenario comparisons and real-time reporting</p>
<p>X Labor intensive</p>	<p>✓ Reproducibility at study level</p>	<p>✓ Ability to aggregate to compound and network level</p>

Prancer RTSM® Real Time Actuals Integration

The RTSM supply actuals provide sponsors insight on how the study is progressing, enabling them to compare the actual performance over time against the assumptions included in the previous forecast.

It is extremely important not only to look at the actuals versus assumptions at the study level but also at the regional, country and even site levels to confirm adequate resupply strategies are in place. The sooner deviations of actuals versus assumptions are detected, the sooner corrections can be made to production and/or distribution plans to adapt and prevent scrap or stock-outs.

Prancer RTSM® is now fully integrated with 4C Supply®, enabling sponsors to leverage real-time supply data into their demand and supply planning throughout the study life cycle.



Joint Prancer RTSM® & 4C Supply® Solution

Prancer RTSM® and 4C Supply® are separate solutions. However, together they provide powerful insights to better inform your supply strategy. The seamless integration between the two systems provide real-time adjustments to forecasts for more accurate supply planning. Contact us today for a joint demonstration.

About 4G Clinical

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.

Still have questions?
Contact us today to start a conversation.

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

Contact Us

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