4G CLINICAL

How Prancer RTSM® Enables Complex Studies

The Complex Study is Here to Stay

Knowledge Sharing Series

The Complex Study is **Here to Stay**

Clinical researchers are becoming much more creative in how they explore possible treatments. They are leveraging more adaptive trials where phases can be combined or skipped based on positive results, or where the protocol is amended to explore new treatments or disease states within the same trial. This approach allows researchers to follow the science throughout clinical development, and not waste time and resources on what is not working.

This creativity has led to an increase in clinical trial complexity, creating a cascade of considerations impacting everything from protocol design through the resulting flexible supply chain infrastructure required to support modern trials.

As trial complexity continues to increase, the technology supporting them has responded with intuitive innovative solutions, significantly reducing complex study burden.

What Makes Trials Complex?

When considering complex clinical trials, it is easy to focus on early-phase dose finding/dose escalation oncology studies. When in reality, there is complexity throughout clinical development, no matter what type of study is being conducted.

Protocol complexity arises from a multitude of factors, with one of the main drivers being uncertainty. For example, variability in the patient journey is a major source of uncertainty. This stems from demographic data values including titrations, weight groups and BSA categories, all the way to adapting the protocols to follow the science as certain treatments prove most effective.

As trials progress, complexities within the protocol design have a ripple effect on both the supply chain as well as the end-users of the RTSM. Supply complexity can be introduced as more sites engage in smaller studies, all the way to global expansion. Complexity can also come into play with kit design, not having the correct concentration or formulation for your recommended dose levels, or with your resupply strategies as you incorporate new stability data.

The technology used to support these trials, however, can help simplify the complex and help manage the uncertain. It is more important than ever to partner with an organization that has the depth of experience in complex studies and is powered by modern, flexible RTSM technology.

The Complex Study is **Here to Stay**

Leaders in Complex Trials

Oftentimes technology has limited what is possible in clinical trials. 4G Clinical's Prancer RTSM® has changed that. With a dedicated focus on complex studies since inception, Prancer RTSM®continues to support even the most intricate study designs.

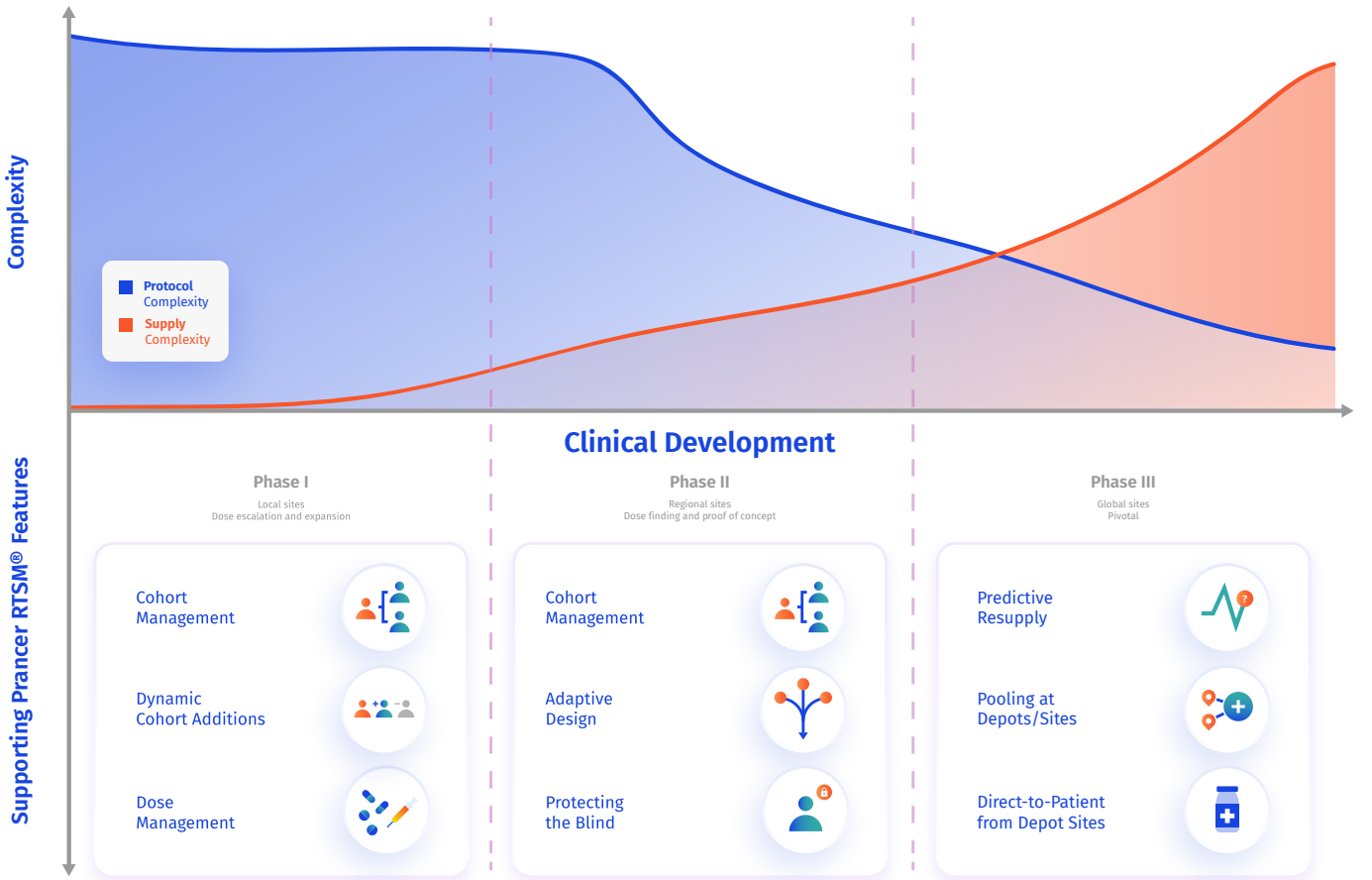
The core functionality within Prancer RTSM® has enormous flexibility to support even the most radical patient flow. Combine that with the ability to add bespoke features and you can be as creative as you need to be in the design and execution of your trials. If bespoke requirements are needed to support future trials, we can incorporate them into the core product as a dedicated feature. This way, Prancer RTSM® continuously evolves to support complex trial needs. Beyond the feature set, Prancer RTSM® supports complex studies through our iterative design process. Our goal is to make building a complex system as simple to review as possible, giving you the opportunity to visualize your protocol in our system and make adjustments prior to spec signature.

While the system design can be complex, the build experience should be straightforward - and you get to iterate on the design to make sure the system is intuitive for your sites. The design can also support many self-service capabilities, removing the burden of contacting support for simple, routine changes as well as more advanced changes including cohort or dose modifications.

According to the ISR IRT Benchmarking and Market Dynamics report released in October 2022, ***39% of trials*** *conducted were moderately complex while* ***36% of trials*** *were highly complex, leaving only* ***25% of trials*** *being deemed as low complexity.*

Complexity throughout **Drug Development**

We understand clinical trial complexity and how it shifts throughout clinical development. Prancer RTSM® supports complex protocol designs in early phases as you are experimenting with the optimal dose and treatment. As you progress to later phases, complexity tends to shift from protocol to supply complexity as you open up your trial to larger patient populations and prepare for regulatory submission. No matter what phase or level of complexity, Prancer RTSM® has you covered.



Depth of Experience

As today's complex trials evolve, it is essential to have a partner who knows how to adapt to change, and how to update the study for optimal outcomes. 4G Clinical's team brings hundreds of years of cumulative experience in clinical trial development to the table, across all therapeutic areas and indications, always keeping the patient at the forefront of our work.

4G Clinical's thought leaders and clinical study experts remain a steadfast resource throughout the clinical trial, providing sound advice for every aspect of your study, no matter where the science leads, or where your patients reside.

*The **largest part of our portfolio** is and always has been complex trials. From basket and umbrella trials to smart trials, we've enabled complex protocols and supply chains while collaborating with our clients to **let the science lead**.*

— **Kathleen Greenough**
VP, Commercial Operations

Meet **Libbi Rickenbacher**

About the Author

Libbi Rickenbacher, Director of Strategy at 4G Clinical, has more than 15 years of experience in the field of life science, and is an e-clinical RTSM solutions subject matter expert.

Her expertise lies at identifying trends and opportunities considering operational business processes, product opportunities and managing partnerships with market leading solutions to drive strategic initiatives.

Libbi is an enthusiastic team player passionate about creating opportunities and innovative direction to improve the clinical trial experience for end user stakeholders and patients. Libbi holds a BA in both Neuroscience and Psychology and a Doctorate (PhD) in Neuroscience.

Curious to hear more?
Explore our Resource Centre

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

About **4G Clinical**

We reduce the time it takes to commercialize 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 revolutionized RTSM (randomization 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®, utilizes 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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