KNOWLEDGE SHARING SERIES

4G CLINICAL

Using Flexible Cohort Management to Enable Creativity in Oncology Designs

Bringing crucial medicines to those who need them, faster.

4GCLINICAL.COM

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 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.

"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."

About 4G's RTSM

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.

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

Using Flexible Cohort Management to Enable Creativity in Oncology Designs

The FDA is making a considerable effort to drive efficiencies in clinical trial research, especially when it comes to oncology studies. In 2017 alone, there were 46 new oncology drugs approved by the FDA, including 18 Fast Track Designated products and 17 Break-Through therapies.

The reason? Regulatory agencies recognise the standard way of conducting studies through rigid phases and designs are limiting drugs from reaching patients fast enough to address the unmet need. They are becoming more flexible about accepting positive results, allowing trial sponsors to be more creative with oncology designs.

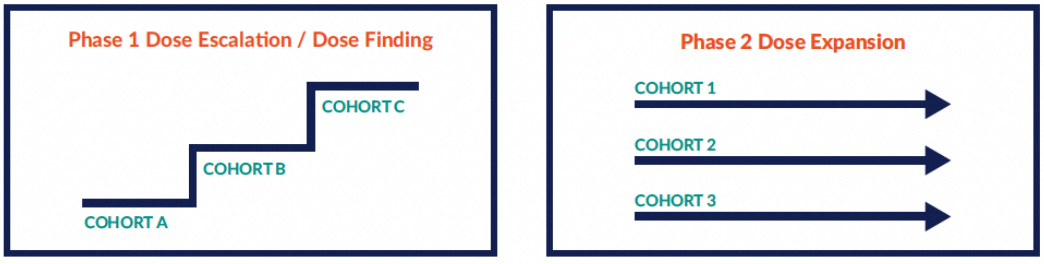
With the support of the FDA, sponsors can follow the science. You should be able to change your protocol based on what is working. Especially with expensive drug. And even more expensive comparators and combination therapies. When you have positive signals, you should be able to pivot direction to build a global programme and gather the required data to prove it.

The challenge is that most clinical systems are not flexible enough to adapt to mid-study changes without trial disruption. To address these challenges, it is crucial for sponsors to have a robust RTSM and specifically cohort management functionality in place.

The use of cohorts allows sponsors to find optimal doses and then expand based on recommended dose. Over the life of the study many things can happen to these cohorts. As dose levels are approved and the escalation progresses, subjects in the lower-dose cohorts may need to be titrated up to the most recent dose level approved. Combination therapies may be added. Alternate dosing schedules may become necessary. New cohorts may test new dose levels.

Depending on where the science leads, there can be several protocol amendments throughout the duration of the study to adapt to new information. This process can be very complicated and there are many variables on how to best manage them.

A robust RTSM should allow for both control and flexibility, with respect to cohort assignments and protocol amendments.



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What are the essential Cohort Management capabilities to support flexible oncology designs?

Ability to support creative designs

As trial designs follow the science, your RTSM needs to enable different methods of assigning, opening/closing and overall managing cohorts. Not every possible outcome is known at the beginning of a study (when in fact most aren't), so the system must be able to allow for changes without waiting for custom coding. A fully configurable RTSM can provide a wide range of options ready to go which can be turned on and off as needed.

Real-time updates

Sponsors should be given the control and flexibility to manage the cohorts themselves, whether it is opening/closing cohorts, grouping cohorts, managing cohort assignments, etc. Having to contact the vendor to make changes can be costly (in both time and resources).

Enrollment and supply management

When you approach the end of a study, you don't want to screen more patients than you can enroll. You need enough patients to get the data, but not so many that you are wasting resources. With cohorts, this process is even trickier since you need to manage enrollment caps and supply for every cohort vs. just the end of the study. Additionally, you have to seed sites with supply for upcoming cohort enrollment. If you have different dispensing rules per cohort this becomes even more complex. It is critical to use a robust RTSM to help manage resupply and forecasting while reducing overage/waste.

Flexibility built into the system

Many traditional RTSMs are rigid and require added time and resources to allow for adjustments during the study. A modern, flexible RTSM is needed to quickly adapt to changes in doses, cohort expansions, protocol amendments.

Full transparency into changes

With so many changes happening during the study to adapt to new information, there needs to be a robust audit trail traced to the protocol version. A robust RTSM shows what cohorts are allowed under which amendments, and which sites are approved for which amendment, for full regulatory transparency.

> *"A robust RTSM should allow for both control and flexibility, with respect to cohort assignments and protocol amendments."*

Conclusion

Your clinical systems should never be a limiting factor and curb innovations in study designs, especially as the FDA is encouraging creativity. If the success of your study depends on being able to follow the science and change your protocol based on what is working, flexible cohort management should be a key factor in choosing your RTSM.

About the Author

Kathleen Greenough, Director of Client Solutions at 4G Clinical, has 21 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. Specializing 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.

Download our White Paper:
Disrupting Study Start-Up

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

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