Designing RTSM for Early Phase Oncology Complexity

How 4G Clinical's Prancer RTSM® enables intricate, flexible designs within an early phase oncology portfolio

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Executive Summary

A Top 10 Global Pharmaceutical Company is exploring new vital science for patients from its robust oncology portfolio. Their pipeline includes investigational therapies across hematologic malignancies and prostate, lung and bladder cancers.
To support the creativity within these protocols, they needed a strategy and supporting technology that is both flexible and manages the unknown that is expected from these types of trials.

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Problem

Complex clinical trials don't follow a linear path. When designing an early phase oncology trial, researchers must try varying dose levels and schedules of administration. The unknown development path may become a roadblock as the entire trial must adapt, especially the technologies that support it.

Their legacy studies, either built manually or with traditional IRT systems, were built with a specific protocol, or path in mind. When that path deviated from the expected, it could take up to 8-12 weeks to make a change in that study. With the magnitude of changes stemming from early phase oncology trials, the nature of the enhancements and the timelines from the legacy IRT didn't coincide.
They needed an IRT that was flexible enough to adjust doses and dose schedules based on incoming data. The team needed a system that could adapt to these changes with ease and efficiency until the data could define the best doses and schedules for the assets. The team also needed an IRT solution that could enable very different approaches to complex clinical trial designs, as no two trials are the same.

They chose 4G Clinical for the power of their core offering, Prancer RTSM®, and their ability to add any bespoke features necessary to support the design as well as their ability to adapt to unforeseen changes as the study progressed.

Every study is unique, and there is no substitute to having an experienced team designing your RTSM implementation

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Solution

With the breadth and scope of early phase oncology studies, the company has two distinct approaches for designing the RTSM to meet the needs of the protocol.

1) Configurable and Flexible

The first approach is to build as much flexibility into the RTSM as possible to allow protocol changes to come in as needed. Mid-study changes are implemented in a very flexible manner.

- Low Complexity - End-user tells the IRT how much IP is required. In the event dose is collected, it is stored for informational purposes only and does not impact medication allocation.
- Medium Complexity - End-user enters the subject's dose and the IRT allows the end-user to select how much IP to allocate based on predefined parameters in the IRT specification.

This approach relies on the site/end-users to calculate the patient's drug needs and enter those values in the system for assignment (versus - IRT performing calculation).

2) Custom Calculations

Another approach is to build in custom calculations at the onset for extremely complex trials. This approach enables intricate designs that have not been done before and pushes the envelope in creative science. This design also provides strict oversight by the sponsor which ensures correct dosing and dispensing to the patient.

4G Clinical's Prancer RTSM® enables both approaches. While the core offering is incredibly powerful, there are instances where custom calculations are necessary. Should there be any key learnings along the way, those custom calculations can be added to future product releases which then become part of the core offering.

4G Clinical has incorporated some of our custom calculations into their core offering. It is great to innovate alongside each other and as those new features are being developed, we have the opportunity to beta test them for future builds.

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Use Cases:
Opportunities, Risks and Timeline Considerations for Each Approach

Use Case #1 - Configurable and Flexible Approach, Low Complexity

The first use case is a Phase 1, open label study for advanced stage prostate cancer. They used a flexible configuration approach (vending machine model) which allowed the selection of vial quantities between two different kit types. This is a low complexity study.

Opportunities

This approach allows site flexibility to handle many different scenarios for dosing. There are fewer high-risk changes needed in the IRT. Additionally, since fewer data points are captured in IRT, there are fewer reconciliation efforts for sites and data managers.

Risks

The main risk of this approach is that the protocol is so open ended. The control is in the study team's hands, but they can circumvent the system. Another risk is that there is more accountability put back on site to select the correct quantity of IP.

Timelines

Within 4G's standard timelines of 9 weeks.

Results

Maximum flexibility for dose escalation/expansion studies; implementing amendments can be done quickly/easily.

Sites can easily and flexibly control the quantity of medication that can be assigned on a kit type level per cohort level. Provides sponsor control on managing how much medication the sites can assign per visit, but site is ultimately responsible for ensuring the correct quantity and therefore dose is administered to the patient for a given visit.

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Use Cases:

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Use Case #2 - Configurable and Flexible Approach, Low Complexity

The second use case is a Phase 1, open label FIH study for Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia. The company used a flexible configuration approach that enabled dose dispensation where the IRT assigns the quantity of vials based on the dose entered. This study is medium complexity.

Opportunities

This approach allows site flexibility to handle many different scenarios for dosing. There are fewer high-risk changes needed in the IRT. Additionally, since fewer data points are captured in IRT, there are fewer reconciliation efforts for sites and data managers.

Risks

Risks of this approach include the need to define all doses upfront because you have to put parameters in there. You need to know what the boundaries are, which oftentimes are not known upfront (so many unknowns in the protocol - number of cohorts, number of subjects, dose levels, visit schedules (number of doses per visit schedule). This approach also adds extra complexity if doses are not known.

Timelines

This approach can be built in standard time of 9 weeks if parameters are known, otherwise can add a few weeks.

Results

IRT system that has more controls but is less rigid than a high complex study – it can move up/ down in dose. IRT system assigns the correct quantity of medication based on the dose entered by the site users. IRT system maintains control of the acceptable dosing range and as a result assigns the correct quantity of medication for dispensation. This minimizes the potential risk of drug wastage and ensure adherence to clinical protocol.

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Use Case #3 - Complex Calculations, High Complexity

The third use case is a Phase 1/1b study in combination with conventional chemotherapy for pediatric and young adults with acute Leukemias. The company used a complex calculations approach that enabled weight-based dispensation, +/- 10% weight change, calculated total
mL dose from cohort dose level (mg/kg), determined kit type & quantity to dispense, and rounding rules. This was a highly complex, intricate design.

Opportunities

The benefit of this approach is you are not limited by the parameters of a configuration. There is quicker visibility for reviewing dosing data, rather than waiting for the site to enter data within EDC. Also, the study team does not need to configure parameters on a cohort by cohort basis.

Risks

This approach is more restrictive and can increase user error when entering a high volume
of information. There is a higher risk of amendments, which can cause lengthy timelines. Amendments are more burdensome since they are not as straightforward as those done with configurations.
More effort is required for reconciliation and data cleanup by the sites and data management team. There is also a higher risk for patient waiting issues and increases in data changes if incorrect data was entered (i.e. weight);

Timelines

This approach can be built in 11-12 weeks if parameters are known, otherwise can add a few weeks.

Results

Sites can't deviate from the protocol; increases study adherence to protocol.
Sponsor ensures that all sites are calculating the dose in the same manner across the trial with the help of the IRT system.

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Summary

This Top 10 Pharmaceutical Company has been able to meet the challenges that are prevalent in the early development oncology space with evermore complex protocol designs becoming the norm. Design solutions that have required to be established for key functionality areas such as cohort management, dynamic visits, and dosing management are required to overcome the challenges. The ED Oncology space has highlighted the need for flexible design solutions to meet the specific needs of a protocol design.

In utilizing modern technology that includes Natural Language Processing (NLP), which enables a highly configurable IRT platform like Prancer RTSM® to design complex functional requirements at speed, at relative cost and to a high degree of quality.

This fits perfectly with ED Oncology trials, that are often extremely time pressured, contain many design elements that are subject to change and have a high degree of complexity.

Learn More About Our Purpose at 4GClinical.com