



What is Agile RTSM, Really?

Not Knowing May Impact Your Study

Knowledge Sharing Series

What is Agile RTSM, Really?

Not all RTSMs that reference being agile are based on the software methodology.

When new buzzwords are introduced, they inspire a new way of thinking. As they are adopted more and more, their meaning is often clouded and we don't know what to think anymore. Just think about the word "innovative". It has been used so much – "we are the most innovative!" that you almost lose trust in the word. Related – shouldn't the customer determine who is innovative?

Suddenly we've been seeing a lot of messaging around agility in Randomization and Trial Supply Management (RTSM) or as some refer to it, Interactive Response Technology (IRT). Is "agile" becoming the new "innovative"?

Does everyone understand what it truly means to be agile with regards to software development? What about project delivery? Both are equally important, but we can argue that agile software enables agile project delivery and not the other way around (which has its limitations). If you didn't know what agile stemmed from you'd automatically equate the term to simply being flexible. But flexible how, with what? The technology? Services? Timelines?

Without context, you are left to your own interpretation. So herein lies the challenge. Our industry is craving flexibility as clinical trials are becoming more complex. How do you cut through the clutter and gain much needed context behind this new wave of agile?

Start with the basics. What is agile, really?

Fundamentally, agile is a software development methodology that:

- Accelerates the delivery of high value projects through iterative development sprints
- Enables continuous feedback and allows for faster changes in system design to meet customer needs
- Produces higher quality, more reliable systems

What is Agile RTSM, Really?

However, **not all RTSMs that reference being agile** are based on the software methodology.

Can you have **agility in project delivery** that is not grounded in agile software development?

Sure. But we can argue there are **limitations to how flexible** you can be, and with the **overall benefits** the customer will receive without it.

What are the Top 5 Questions You Should Ask about an Agile RTSM?

How will you know the difference and how that might impact your study? Arm yourself with a series of questions to weed through all the various interpretations of the term.

Question 1

Was the RTSM developed using agile software methodology and/or are you using “agile” in the context of delivery?

It is critical to understand if the term is being used to describe a software methodology or simply being flexible in delivery. Systems developed using agile methodologies can dramatically accelerate study start-up and mid-stream adjustments because flexibility is literally built into the system. Systems that are not developed based on an agile methodology (and on a modern technology stack/ cloud-based platform) face limitations in terms of flexibility and speed to adapt to a customer’s evolving needs.

Question 2

Is the RTSM 100% configurable? If not, what % is customized vs. configured?

100% configurable RTSM systems are designed to adapt to the customer’s needs. It has the feel of a 100% customizable system without the immense cost, time to build and limited flexibility. Any degree of customization (even as little as 10–20%) involves coding, which follows the traditional waterfall process of designing, developing, testing/ validation and deployment. That has a direct impact on your study agility.

What are the Top 5 Questions You Should Ask about an Agile RTSM?

Question 3

What is the feedback process during system development? When will you see the full, deployable RTSM?

An RTSM developed using cloud-based, agile software methodologies should have the ability to show customers the complete, deployable system before signing off on specifications. Customers then provide feedback and influence system design and development priorities by reviewing and refining several iterations of the system before reaching a traditional timeframe for user acceptance testing (UAT).

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Question 4

Can you quantify the impact of small changes on our study timelines and budget? Do all changes require custom code?

This question ties back to how configurable vs. customizable the RTSM system is. With 100% configurable systems, updates and changes are made without disruption to the customer. Partially configurable systems can range between 2–6 weeks to implement a small change. Changes are unavoidable in the bio/pharmaceutical industry. You should have a clear understanding how changes impact your study progress from a systems perspective.

Question 5

How do your client services team apply agile concepts to delivery?

Agile RTSM delivery should empower client services leads to be problem-solvers, not box checkers. They should be an extension of your trial team and leverage their expertise to solve unexpected issues – feeling ownership and accountability to the solution. Understanding more about the expertise, structure and governance of the client services team is crucial to ensure transparency and collaboration.

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.

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those who need them, *faster*.
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WELLESLEY

370 Washington Street
Wellesley, MA 02481

PORTLAND

1455 SW Broadway, 16th Floor
Portland, OR 97201

AMSTERDAM

Herengracht 124-128, 1015 BT
Amsterdam, The Netherlands

NOTTINGHAM

Office C03, Sir Colin Campbell Building
University of Nottingham Innovation Park
Triumph Road,
Nottingham,
NG7 2TU, United Kingdom

BRUSSELS

Avenue Albert Einstein 2A
1348 Louvain-la-Neuve, Belgium

BONN

Rabinstrasse 1 53111
Bonn, Germany

TOKYO

Crosscoop Shinjuku Avenue Room 702
Forecast-Shinjuku AVENUE 7F,
2-5-12 Shinjuku Shinjuku-ku Tokyo,
160-0022 Japan

BASEL

Lange Gasse 90
4052 Basel, Switzerland

DUBLIN

4-5 Burton Hall Road,
Burton Hall Park, Office # 212,
Sandyford, Dublin 18 D18 A094

COPENHAGEN

Ny Carlsberg Vej 80
Copenhagen, 1760 Denmark