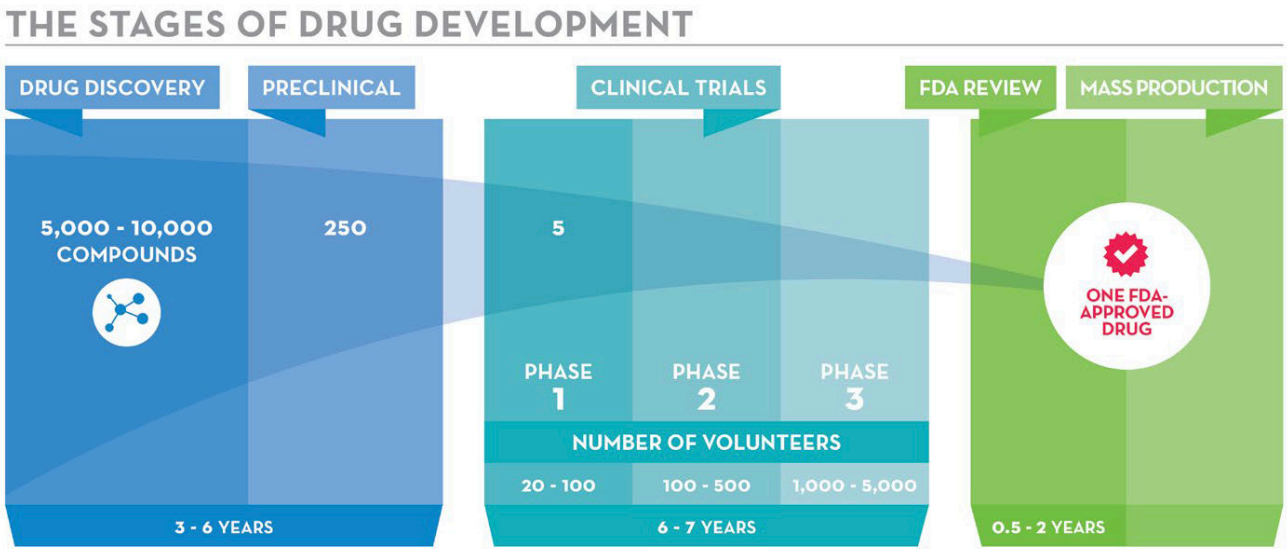
Disrupting Study Start-Up

How Agile RTSM Software Development Accelerates the Clinical Trial Timeline

Knowledge Sharing Series

The **Problem**

In the midst of scientific breakthroughs, new therapies can still take up to 15 years to reachyour medicine cabinet. This figure has not improved in the last 15–20 years. This is simply unacceptable. We need to do better.



Source: World Federation of Science Journalists

For those that do make it through development, it still takes up to 15 years

The **Problem**

Why is that?

We all know there are many challenges and bottlenecks in clinical trials from patient recruitment and retention, to lack of efficacy and safety, to reimbursement and affordability to the patient. What we really don't hear about as often is how the process of study start-up and delivering trials through enabling eClinical technology can by itself accelerate the clinical trial timeline.

According to a **June 2017 press release**, the eClinical Solutions Market is estimated to reach $7.61 Billion by 2020 at a CAGR of 12.4% in the forecast period (2017–2022), including CDMS, EDC, CTMS, eCOA, RTSM, eTMF, Safety, etc.

With the increase in dependence on eClinical solutions to support clinical trials, there is a direct impact on trial timelines based on the efficiency and quality of developing and implementing these systems. For example, for one clinical study a sponsor organisation is reliant on upwards of six (in many cases more!) clinical systems (as referenced in the report above).

If each system had a few days delay because of UAT (user acceptance testing) findings including defects and quality issues, across six systems, the overall delays can be quite costly. More than 80% of clinical trials experience delays ranging on average from one to six months, costing companies upwards of $35,000 per day per trial. Using that data from an **Applied Clinical Trials article**, even a two-day delay across six clinical systems can cost companies upwards of $420,000.

More than 80% of clinical trials experience delays ranging on average from one to six months, costing companies upwards of $35,000 per day per trial.

Moving the Needle in Clinical Trials: **A Case for Leveraging Agile Software Development in Clinical Trials**

Agile software development *is poised to enable a sea-change in the way clinical trial professionals currently leverage software to run their studies.*

This new wave of agile development in clinical trials can ***dramatically accelerate the study start-up process*** *by disrupting the process for building systems, UAT, mid-stream adjustments and its direct impact on system quality.*

This white paper offers insight into ***"how."***

What is Agile RTSM, Really?

Before we dive too far into “how”, it is important to understand what agile truly means and how this methodology came about.

According to Wikipedia, **the definition of agile software development** is a set of principles for software development under which requirements and solutions evolve through the collaborative effort of self-organising **cross-functional teams**. It advocates adaptive planning, evolutionary development, early delivery, and continuous improvement, and it encourages rapid and flexible response to change.

The concept of agile evolved from Just in Time (JIT) Manufacturing principles where your supply was released just in time for manufacturing thereby not wasting any product and still meeting production demands.

In 2001, this concept was adopted by a group of software/engineering pioneers to address the inefficiencies in the traditional waterfall approach. They subsequently published **The Agile Manifesto** outlining 12 principles of agile development. There are countless interpretations of these principles over the years and with that the creation of several agile methodologies including Scrum, Extreme Programming (XP), Crystal, Dynamic Systems Development Method (DSDM), Lean Development, etc. These are not meant to be followed verbatim, but more so offer guidelines to put the manifesto into practice.

“In 2001, this concept was adopted by a group of software/engineering pioneers to address the inefficiencies in the traditional waterfall approach.”

Applying Agile Development to **Clinical Trials**

> *Agile is an iterative process, enabling early and continuous delivery of high-value software through incorporating consistent customer feedback into the development process.*

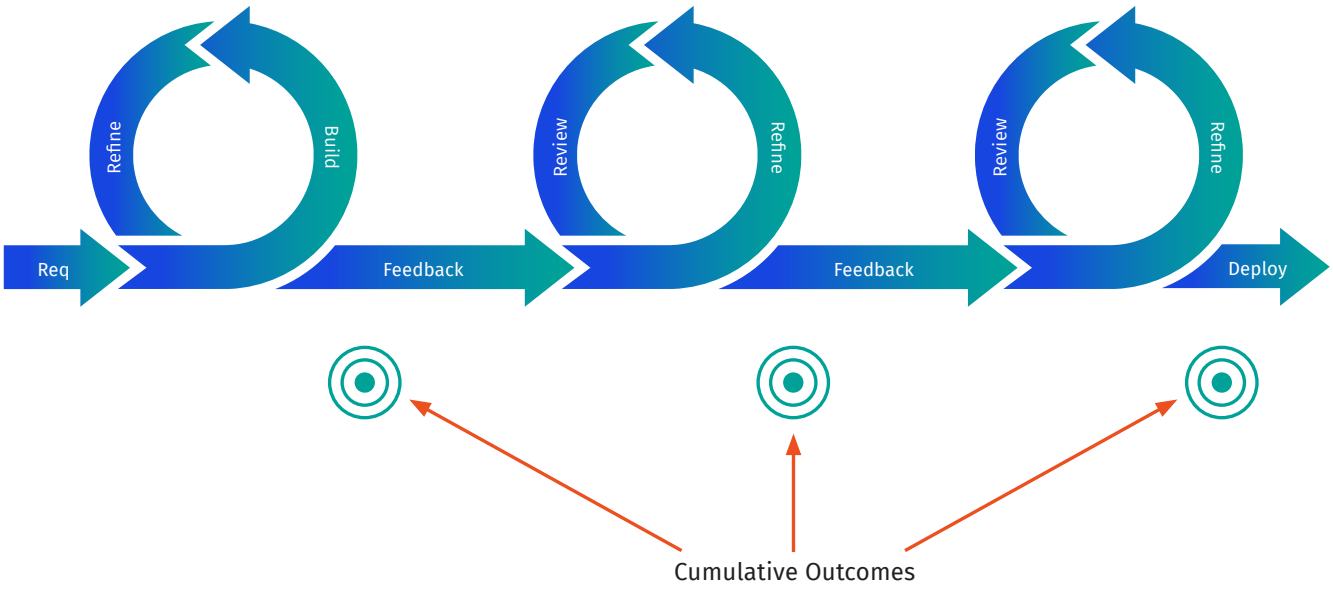
As the complexity of clinical trials increases, so does the need for flexibility to adapt to trial changes. The traditional method of developing clinical software, known as Waterfall, flows through several steps sequentially, without the opportunity for feedback or adjustments to be made during the process. Under this model, adjustments are only made at the conclusion of the entire cycle. This approach simply cannot adapt at the speed necessary to address changes and presents study teams with costly and lengthy change orders.

Agile is an iterative process, enabling early and continuous delivery of high-value software through incorporating consistent customer feedback into the development process. The key is to deliver the full system as fast as possible to the customer and capture customer feedback quickly to increase the speed of each iteration. As a result, changes become more frequent, smaller, less costly, easier.

Applying Agile Development to **Clinical Trials**

Waterfall

Agile



Accelerate Study Start-Up by **Leveraging Agile RTSM Methodologies**

The process for building clinical software is outdated. Clinical study teams, who should be spending their time operationalising a clinical trial, are responsible for sifting through hundreds of pages of complex technical requirements to approve requirements for a system. In essence, clinical software is being designed by clinical professionals that don't necessarily understand what they are approving. The result is unintended issues and surprises during User Acceptance Testing (UAT), causing delays and system rebuilds before study go-live.

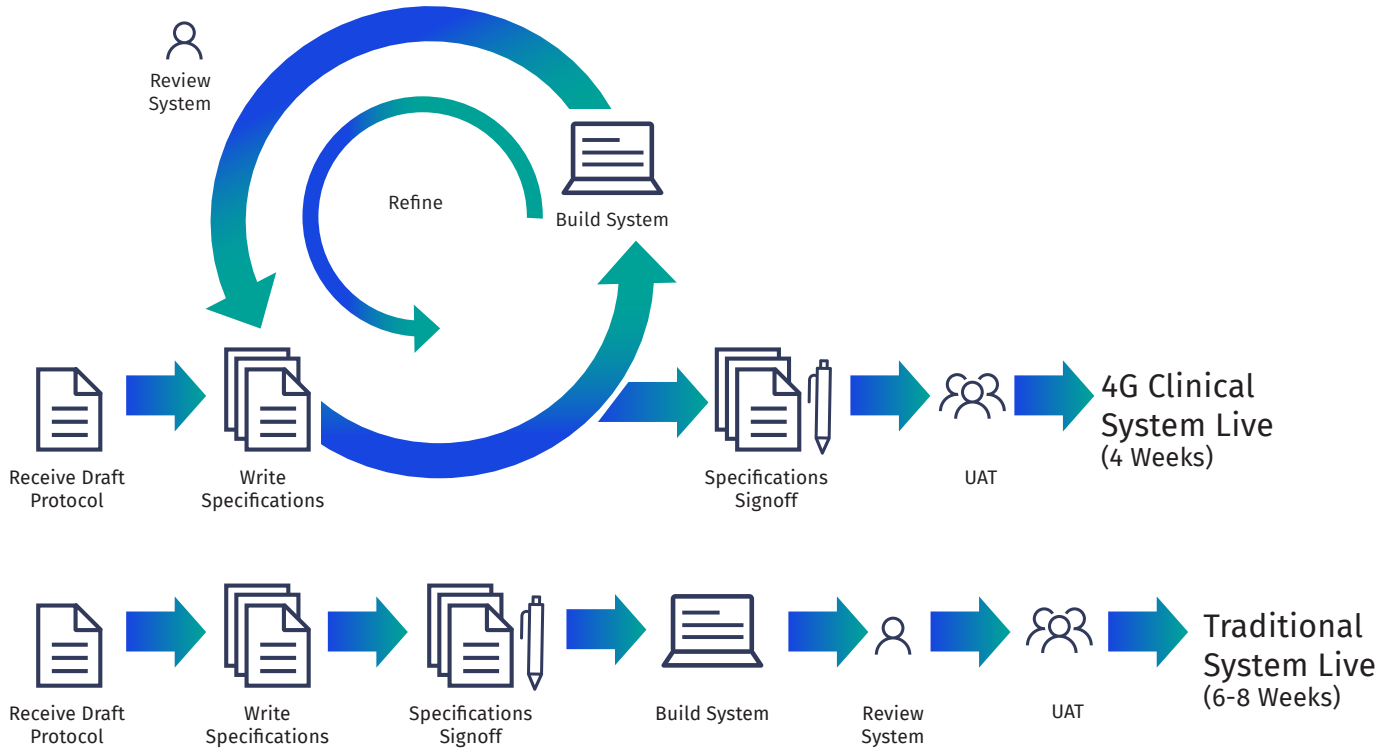
An agile development methodology can be applied to disrupt this process.

The use of Natural Language Processing (NLP) satisfies the first core principle of The Agile Manifesto – to deliver early and continuous valuable software to customers. NLP technology enables software to read and interpret written RTSM specifications and build a deployable system within moments.

Instead of the customer receiving the system right before UAT, the full, deployable system is delivered before the specs are even signed, and in some cases, in a demo before seeing the actual spec for the first time. The benefit to the customer is the ability to interact with the system and provide feedback during several iterative process loops. They know what system they are getting way before they signoff on the specifications. The increased transparency and customer involvement from receipt of the draft protocol ensures UAT will be a final check and there will not be delays to their study.

Traditional RTSM systems take 6–8 weeks to build. Leveraging NLP and an agile methodology reduces the timeline to under 4 weeks.

Accelerate Study Start-Up by **Leveraging Agile RTSM Methodologies**



With this agile methodology, spec sign-off to go-live has been completed in as little as 13 calendar days.

Increase Flexibility and Accelerate RTSM Adjustments **Enabled by 100% Configurability**

According to **Tufts Center for the Study of Drug Development**, "nearly half of all substantial amendments to clinical trials – most often undertaken to modify study volunteer demographics, eligibility criteria, and safety assessment activity – are deemed avoidable by sponsor organisations."

Avoidable changes are typically minor in scope, however they have a major impact on trial timelines and cost.

For each amendment to a protocol, change orders may be required to adjust the RTSM functionality; protocol design changes impacting inclusion criteria, dosing and visit schedules are two common examples of protocol amendments that require a system change. Change orders historically can take weeks to be reflected in an RTSM system since they need to go through a similar waterfall approach of requirements, design, testing, development and validation; 2–3 weeks for simpler changes, up to 6 weeks for more complex. In addition to further delaying a study, change orders are costly to the customer.

Why is that? Let's start by examining the difference between a configurable tool vs. a configurable product/system. Several current RTSM solutions utilise configurable tools.

The system is designed using this tool to adapt to the client's needs which on the surface seems like a satisfactory solution. If we operated in an industry where what you needed on day one was exactly what you needed at day 10, 30, 90, etc., there would be no issue. However, in the pharmaceutical industry, clinical trials are anything but predictable, linear.

Limitations arise when these partially configurable systems need to be changed (from adding functionality to making small adjustments to the navigation) after they are built. If study design and sponsor needs doesn't 'fit' into the pre-defined configurations, any changes needed are now customisations, versus configurations, which require custom coding, testing, etc., hence the waterfall approach mentioned above.

How does **Agile Software Development Solve this Problem?**

When the core product is developed using agile, the process for efficient implementation of small changes is optimised. As a result, it enables a fully configurable system that can adapt to current and evolving customer needs. For example, features currently not in the core product can be development based on the needs of clients in short, iterative, development sprints. It's not custom coded for Client A, and only available for Client A. It is now part of the core product, available to all clients and configured by the RTSM provider for each.

In using agile development based on a modern development stack (similar to platforms used by Spotify, Facebook and Google), updates and enhancements are made frequently without disruption to the customer. Think about how many updates Facebook makes to their platform. Do you feel it as the end-consumer? That is the power of agile development. It enables the flexibility for quick responses to change requests and financial simplicity for customers. It enables clinical trial professionals to focus their efforts on millions of other tasks and not worry about that new feature that the RTSM doesn't have or a report you forget to ask for.

In using agile development based on a modern development stack, updates and enhancements are made frequently without disruption to the customer.

Applying Agile Principles
RTSM Software Delivery

As discussed earlier in this paper, the principles of agile are based on software development methodologies. Core tenets behind the agile manifesto point to the importance of customer collaboration, interactions and response to change over processes, excessive documentation and following a plan. The next focus of this paper is to showcase how applying agile principles to the delivery of software can strengthen the vendor-customer relationship.

There is no doubt the pharmaceutical industry is heavily regulated. As a result, the industry can be risk-averse and have a tendency towards comprehensive, and typically duplicative, documentation to support those regulations. For a detailed view on how agile development enables higher quality systems, **please reference here.**

With that in mind, over-documentation can lead to a culture of box-checking – having a list of things that must be done without a focus on what adds value, what adds to quality vs. what is unnecessary.

The other issue with box-checking is that the bio/pharmaceutical industry is constantly evolving. Clinical trial professionals must balance changing timelines, FPI dates and regulations. They receive new information, analyse and process that information, regroup their efforts and move forward – constantly. Simply following the original plan without adapting to new information ensures wasted resources.

> *Agile RTSM delivery involves empowering the client services team to be problem solvers, not box-checkers.*

Applying Agile Principles
RTSM Software Delivery

This reality underscores why agile RTSM delivery is so critical. Agile RTSM delivery involves empowering the client services team to be problem solvers, not box-checkers. There is a goal in mind at the onset of a clinical trial, but inevitably as stated above there are changes. Client services teams need to adapt to the changes and still deliver on their commitments. For example, if a protocol changes the client services team advises the customer on how to RTSM systems must change to support it – they feel ownership and are accountable for the solution. The management of the change itself sets the tone of the vendor-customer relationship which builds trust through transparency and collaboration.

By delivering projects faster and more often, the lines of communication between vendor and sponsor, data transparency and overall system quality are strengthened. The customer continuously provides input to refine the system to better serve their business and leverage it as a competitive advantage. Conversely, the vendor continuously provides feedback during the build process in realtime thereby closing the iterative loops.

The power of agile is optimised when you combine agile software with a client services team that is empowered to solve unexpected issues. They become an extension of the sponsor's trial team.

*The **power of agile** is optimized when you combine agile software with a client services team that is **empowered to solve unexpected issues**.*

Conclusion

RTSM software developed with an agile methodology and built on a modern technology stack dramatically accelerates the study start-up process and mid-stream adjustments. Customers are able to see and interact with the system before approving specifications and changes can be made quickly, without impacting study progress.

Agile software development is not to be confused with simply being flexible in customer interactions. Systems developed using agile enable the application of its core principles to other areas beyond system development including transparency, speed and enhanced quality.

The use of agile software in clinical trials enables customers to streamline internal processes and spend time on other highvalue activities critical to the success of their studies. For more information, please visit **www.4gclinical.eu**.

RTSM software developed with an agile methodology and built on a modern technology stack dramatically accelerates the study start-up process and mid-stream adjustments.

About 4G Clinical

We reduce the time it takes to commercialise 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 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.

Prancer RTSM®

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

4G's RTSM platform, Prancer RTSM®, utilises natural language processing alongside integrated clinical supplies forecasting and management functionality to slash development timelines, increase operational efficiencies and offer exceptional quality.

Curious to hear more?
Explore our Resource Center

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

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

4gclinical.eu