charles river

RockStep™

From months to minutes

How a leading CRO made its vision for Lab of the Future a reality with Climb™ from RockStep Solutions.

Opportunity

To support its vision "of boldly challenging scientific possibility," Charles River (CR) pursued a strategy to digitalize *in vivo* research study processes as part of its broader efforts to modernize systems. The company viewed the project as a way to give them an edge in the highly competitive CRO market. Their approach centered on three core objectives:

- Efficiency and time savings
- Error reduction throughout the study lifecycle
- Enhancing their client experience by delivering fast, consistent, and comprehensive solutions that helped accelerate time-to-milestones

Solution

Climb™ from RockStep Solutions. Climb is a cloud-native software solution for the *in vivo* lab that comprehensively manages all aspects of a study. RockStep's Climb was the only solution that met CR's objectives: 1) flexibility, allowing it to be customized to specific site needs, 2) standardization that enabled every task to be carried out consistently and comprehensively across multiple sites, and 3) adaptability so CRs teams could manage any type of study regardless of its complexity.

> " A great product is a good start but to get the most out of it you need a great partner who you trust. The collaboration with the RockStep team was invaluable every step of the way. They helped customize and implement Climb to meet our specific needs. "
>
> ~ Jason M. Davis, Product Owner Director, Discovery, Charles River

CHARLES RIVER AT-A-GLANCE

CR is a top 5 CRO delivering products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions accelerate their research and drug development efforts. CR expedites the discovery, early-stage development and safe manufacture of new therapies for the patients who need them.

80%

Of the FDA-approved drugs over the past five years were worked on by CR.

20,000+

Employees are working across 150 facilities in over 20 countries.

Background

Some say the final frontier in designing the Lab of the Future is digitalizing *in vivo* research. The facts are compelling: BioPharma has been slower to embrace digital transformation, with only about 20% of organizations considered to be digitally maturing, according to a Deloitte survey. Remarkably, *in vivo* research lags behind other areas of research even though it is considered the foundation of all scientific breakthroughs.

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It is estimated that about $56.4 billion is spent on preclinical research, with a substantial amount allocated to studies involving animals. When compared to the broader development lifecycle, which leverages automated and data-rich methods, animal research is still performed manually or through outdated systems, leading to high costs, poor reproducibility, and poor data quality.

The reasons behind the slow progress toward innovation in the lab is a study in human behavior. It's well understood that *in vivo* research is complex, data sets are huge and constantly changing, and there is a high degree of variability. Despite all of the challenges, many organizations are reluctant to go through the process of transitioning from unreliable, manual spreadsheets and legacy solutions to become true labs of the future.

That is why CR opted for a top-down approach. Recognizing that digitalizing *in vivo* research would give them an edge in the highly competitive CRO market, CR put a stake in the ground: they were determined to take their broader mission of boldly challenging scientific possibility into drug discovery. The company's digital journey has been focused on modernizing the way it operates across all areas of its business, but bringing innovation into *in vivo* research required deep understanding of discovery processes, the tools scientists needed, and knowledge of the technology landscape.

The company tapped Jason Davis, formerly Associate Director of Technical Operations out of CR's Discovery North Carolina site to transition to Product Owner for the newly envisioned Discovery technology stack. He was tasked with finding a solution that would be flexible enough to meet the needs of their scientists, but importantly, would allow them to scale more quickly and efficiently to get research studies up-and-running without all of the heavy lifting, and help them manage studies without having to rely on outdated processes and technologies.

The Opportunity

In the end, there were three primary drivers to leverage technology to overcome challenges in *in vivo* research and improve the overall quality and efficiency of the services provided by CR.

1

Efficiency and time savings: Streamlining processes such as study design, scheduling, and data capture to save time and improve efficiency in study conduct.

2

Error reduction: Minimizing errors and deviations in study conduct by managing information more effectively and comprehensively throughout the study lifecycle.

3

Client satisfaction: Enhancing client experience by providing quick, consistent, and comprehensive solutions that meet their needs and expectations.

For CR, digitalizing discovery was all about the opportunity. The team was embarking on a journey not many other organizations have started so a "blueprint" on how to transition didn't exist. But Davis knew that the ultimate technology stack that he was helping design needed to meet certain requirements. Chief among them was flexibility. When it came to the *in vivo* study solution in particular, Davis prioritized solutions that could work across sites in different regions, thus meeting the requirements of varying regulations while maintaining a standardized study design. And, given the wide-ranging needs of customers, CR needed a comprehensive yet flexible solution that could ensure consistency and standardization across CR's multiple global sites.

Beyond the flexibility, Davis also knew that he needed to deliver Discovery scientists, technicians, veterinarians – all stakeholders – a solution that eliminated the persistent pain points. He recognized it was a lofty goal, but he set out to find a solution that would allow every action carried out during a study to be managed through a single platform and could straddle both study-based tasks and project management activities.

In the search for a comprehensive solution, one of the challenges CR ran into early on was that most solutions were too rigid to work across its global sites and adapt to the different regulations, guidelines, and animal welfare parameters. The vision was to build a tech stack that could easily handle any study regardless of how complex and help them shave off time in getting a study up-and-running.

The Solution

"We found that the possibilities were pretty endless," Davis says. "We're working on designs that vary depending on the client we're working with. These studies can range from straightforward model development all the way through IND enabling type designs with complex dosing schedules and with multiple individuals involved."

CR turned to RockStep Solutions, a leader in cloud-native software solutions for the *in vivo* lab. RockStep's Climb™ was the only solution that met that objective of flexibility to customize it to the specific site needs, combined with the standardization to enable every task to be carried out consistently and comprehensively across multiple sites.

In evaluating Climb, Davis initially worked with team members at RockStep on workflow analysis. Next, CR North Carolina began using Climb to design studies and modify from the ground up and explore the task sets that could be embedded into the design.

The team has been able to leverage Climb for templating, which allows CR to comprehensively represent its portfolio of tasks on a study, both active study-based tasks and non-operational project management tasks, such as animal welfare reminders, thereby bringing more departments in to use the software.

"We're leveraging Climb to flag project tasks and milestones, for example, flagging the study director three days before a study is due to end so we can reach out to the client for next steps. We're embedding those operational tasks and also working to support our upstream groups in terms of oversight and project management of those studies," Davis says. "This way, everyone is looking at the same study using different dashboards that are specific to their functional roles, but all within Climb."

Process confidence

Once the template is built, users can quickly drag and drop tasks, allowing CR to comprehensively represent its portfolio of tasks on a study and ensuring consistency across study builds. This feature significantly reduces the time required for study setup and ensures uniformity in task execution.

"Having Climb automate resourcing and scheduling to the minute gives us confidence that study tasks are comprehensively accounted for. We can use Climb to generate the work list for the coming week and we can filter it to assign tasks to specific individuals or departments based on task. We can also generate a report in Climb to tell us what we have coming down the pipe."

Consistency with study builds is another feature that helps to reduce the time required for study setup and ensures uniformity in task execution.

"The source of all the power in Climb is templating. We know we can template studies and we know they're going to be consistent," Davis says. "You can have 10 different designers building a study, but by using the template methodology, all of those study builds are going to be consistent for every technician."

# Integration and collaboration

A huge priority for CR is being able to quickly communicate with veterinarians overseeing a study if there are any clinical observations or unexpected events in an animal. To meet Institutional Animal Care and Use Committee (IACUC) requirements on the care of animals, scientists gather and assess key data about animals. For example, body weight data, to determine if an animal has lost weight and, if so, what steps need to be taken for the welfare of that animal. This can be very time consuming when collated manually from spreadsheets and disparate systems.

With Climb, these findings are captured quickly, using a standardized controlled vocabulary, and conveyed to a vet who can see these clinical signs in real time and then, still in Climb, convey to the technician what needs to be done for the welfare of the animal. This makes the quality control for data capture and clinical observations a lot quicker.

"Having these messages from the vet come through in real time is huge for us, since it substantially enhances our animal welfare oversight," Davis notes.

Seamless integration with Dotmatics is also a win for CR and for its clients, contributing to improved turnaround time, study reproducibility, and client communication. The two solutions complement each other in data collection, graphing, and study management.

CR leverages Dotmatics during the study build stage to cost out the study. Once the study becomes active, Dotmatics pulls the referenceable information and graphically presents it.
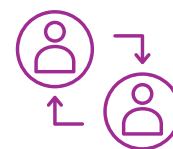
Involving users in the change

Recognizing that the introduction of Climb would require a shift in workflows and processes within the organization, Davis put change management strategies in place to ensure successful adoption of the new technology. As part of the roll-out, CR involved stakeholders from different departments and levels of the organization to ensure buy-in and engagement.

The team took a proactive approach to change management, actively seeking input from those who would be affected by the changes. And they leveraged user-driven feedback and ideas to refine and enhance Climb's configuration, reflecting a collaborative approach to change management where user input was valued and incorporated into the implementation process.

Climb benefit snapshot

HANDLES ANY LEVEL OF COMPLEXITY

Designed to accommodate a wide range of study designs, from simple to highly complex, providing the flexibility to adapt to various research needs and requirements.

STANDARDIZED VOCABULARY FOR CLINICAL OBSERVATIONS

Standardized vocabulary sets for clinical observations, which facilitate quick and objective communication among veterinary teams.

FLEXIBILITY AND CUSTOMIZATION

Climb allows for comprehensive representation of a portfolio, enabling users to design and modify studies on the fly to suit specific needs. It accommodates both customized work and the ability to adapt studies even within a small team setting.

TEMPLATING

Climb introduces game-changing templating that streamlines study design by allowing users to quickly drag and drop tasks, ensuring consistency across study builds. This significantly reduces the time required for study setup and ensures uniformity in task execution.

PROJECT MANAGEMENT INTEGRATION

Users can incorporate non-operational tasks, such as animal welfare reminders and project management tasks, into study designs. This integration expands Climb's utility beyond operational groups, attracting more departments to utilize the software.

DYNAMIC SCHEDULING

Climb offers granular resourcing and scheduling options, allowing users to dynamically schedule tasks down to the minute, date, and individual. This enhances efficiency by optimizing task allocation based on individual skills and expertise.

Results

From months to minutes

Prior to the adoption of Climb, tasks such as study design and scheduling were time-consuming and involved manual coordination across various platforms, including legacy systems, Excel, and Outlook calendars. These tasks required significant effort and could take a considerable amount of time to complete.

However, with the introduction of Climb, these processes have been streamlined and automated. For example, study design, which previously involved manual input and coordination, can now be completed rapidly using templates and standardized workflows. Similarly, scheduling tasks have been automated based on start dates and task counts, allowing for quick and efficient allocation of resources.

By leveraging Climb's capabilities, tasks that once took months to complete can now be accomplished in a matter of minutes, representing a significant improvement in efficiency and time savings for the team at CR. This transformation highlights the tangible benefits of the new system, accelerating workflows and enhancing productivity.

"You can really do anything in Climb as long as you define the task you are asking it to do," Davis says. "We can build studies that capture tasks spanning the pre-activated study phases, such as animal welfare and project management. Once we get into the study phase, Climb's comprehensive landscape lets us convey tasks down to our operational groups to complete the study, supporting standardization. And it supports strong compliance, study-to-study, which enables us to demonstrate strong scientific integrity and repeatability of scientific results."

Outcomes

Study design

45%

REDUCTION IN
STUDY DESIGN TIMES

Efficiency

~500 hours

SAVED BY
AUTOMATING DRUG
FORMULATIONS

90%

REDUCTION IN
PAPER USAGE

Task visibility

100%

VISIBILITY OF STUDY
DESIGNS AND TASKS

Scheduling

0

HOURS OF MANUAL
CALENDARING

What's next?

CR is continuing the digital journey at pace with the deployment of Climb globally for *in vivo* via lighthouse sites in North Carolina US, Finland, Germany, and the UK.

"Our clients view Charles River as an extension of themselves or an extension of their lab," Davis says. "So being able to showcase how Climb allows us to fluidly assign tasks and studies to ensure they're carried out on time, by proficient individuals, and they're done consistently study after study is big. Being able to show our clients that studies will be run with integrity, that the data will be clean, and that it will be run on time helps us to set ourselves apart."

Climb is checking all the boxes for CR, or as Davis says: ***"If you can dream a task or action, we've yet to experience a situation where we can't have Climb visualize it right for the individual in the system."***

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