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How No-Code Can Transform Clinical Trial Management

COVID-19 has created urgency for the digital transformation of clinical trial processes. No-code is an ideal platform for rapidly developing robust digital applications in complex and heavily regulated industries such as healthcare.

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Even before COVID-19 prompted an unprecedented rush for new vaccines and therapeutics, it was clear that many existing clinical trial processes were technologically outmoded.

Now that the world is depending on the life sciences industry to lead the way out from this pandemic, the need to move away from in-person engagements, on-site monitoring, paper documentation, and other manual checkpoints has taken on a new urgency.

In response to today's challenges, the industry has made many changes and regulators have appropriately updated rules to decentralize processes and move towards trial virtualization. Now, it is time to accelerate these efforts.

There are many valid reasons for the sector's traditional resistance to transformation: Tight controls are required so that safety and efficacy can be properly assessed; high variability requires any software be tailored to address the specific needs of an individual trial, which isn't always economically feasible (at least, not using traditional development approaches—see "Why No-Code for Clinical Trial Transformation" on page 7); and as trials involve human participants there is a general hesitance to introducing any known-unknowns to the process.

In addition to the challenges of conducting trials while adhering to COVID-era social distancing guidelines, maintaining the technological status quo comes with many inherent drawbacks such as:

- **Increased potential for error:** Whenever processes rely on manual checkpoints, rather than digital ones, you introduce the potential for human error, which could lead to protocol deviations, delays, and patient risks.

- **Inefficient coordination of systems:** One recent landscape study noted that (emphasis added) "inefficient encounter-driven system[s] that relied on manual intervention **... could pose institutional risk at all stages.**"

- **Wasted or duplicated work:** Clinical measurements, for example, are typically written by hand, re-entered into multiple systems, and then reviewed by a third-party monitor to ensure accuracy between written and electronic data.

- **Additional burdens placed on patients:** In most trials, participants are required to come on-site frequently, and they may also be subject to in-person questionnaires and other forms of data gathering. Which takes on additional challenges in the age of social distancing.

While the shortfalls of current "analog" practices are well known, the industry has been reluctant to make changes for the reasons detailed above. If only one positive thing comes out of this pandemic, it might be that the urgency of the moment compels the industry and its regulating bodies to finally implement some long-overdue technical upgrades, which could have benefits beyond the current crisis.

Digital transformation however, is no easy undertaking—particularly in complex, highly-regulated sectors such as life sciences. The good news is the industry has access to powerful technologies that weren't available even a decade ago.

Enterprise no-code application platforms like Unqork empower organizations to build complex, scalable digital solutions with a fraction of the resources it would take using a traditional code-based approach. In this eBook we will explore two key ways no-code is being used to accelerate transformation in this vital sector, in this crucial time.

Digital Transformation Opportunities for Clinical Trials Using No-Code Right Now

Advanced Trial Monitoring

Monitor trials efficiently and remotely while maintaining patient privacy.

Clinical trials incorporate a number of processes to ensure high-quality data collection. During one key process known as Source Document Verification (SDV), clinical trial monitors review and validate source documents from a trial site against the data collected in Electronic Data Capture (EDC) systems to ensure accuracy. This is often a highly manual, paper-based process, that can take focus and resources away from other critical areas.

Typically, SDV takes place at the trial site in order to protect patient privacy and limit the opportunity for sensitive Patient Health Information (PHI) to be exposed. However, with the onset of COVID-19, the ability of trial monitors to visit trial sites was greatly restricted, which meant a new, innovative SDV approach was needed.

Unqork empowers organizations to rapidly build and effectively manage custom trial monitoring software. These solutions allow trial managers to efficiently and securely conduct SDV—either remotely or on-site. Advanced technologies such as automated document scanning and NLP-driven redaction automate key tasks with machine efficiency, while robust Role-Based Access Control (RBAC) functionality ensures that trial data will only be reviewed by the relevant trial monitor before they are purged from the system.

Benefits

Accelerated trial timelines: Realize faster paths to revenue

Greater operational efficiencies: Streamline processes and free-up capacity for mission-critical or high-touch processes

Enhanced compliance: Mitigate risk and penalties with proper workflow documentation and highly auditable digital trials

Capabilities

Secure integrations: Built an application that seamlessly and securely integrates with legacy systems and external third-party solutions

Advanced document management: Efficiently manage documents and make them available to all stakeholders

Easy (re)configurability: Easily build (and re-build) systems and re-use for new trials

Study Start-Up & Site Activation

Optimize and automate processes in order to accelerate site activation, leading to a faster path to revenue.

Onboarding a new clinical study requires clinical research organizations (CROs) and life sciences organizations to navigate a highly regulated landscape and coordinate complex workflows across multiple sites, stakeholders, and business functions. Currently, start-up processes consist of high volumes of manual and paper-based tasks across dozens—if not hundreds—of locations. In addition to necessitating a huge investment in administrative resources, addressing these operational challenges can lead to lengthy delays that can prolong the time-to-market and negatively impact the bottom line.

Due to the high variability of clinical trials, life sciences companies find it challenging to build a digital solution capable of addressing the needs of an individual trial—at least it would be using a traditional code-based approach. As a result, many processes remain overly reliant on "analog" tasks. This is where no-code technologies can be a game-changer.

Unqork empowers life sciences organizations and CROs to rapidly build and effectively manage a custom digital onboarding application for every trial they manage. With Unqork, organizations are able to automate, optimize, and coordinate complex back-end processes, leading to greatly accelerated onboarding times. These solutions will allow trial sponsors to rapidly survey sites for feasibility information and seamlessly integrate them with downstream applications, such as eTMF or CTMS. Digitalization allows trial managers to reduce errors and apply compliance measures at scale while increasing visibility, traceability, and audibility across those teams involved.

Benefits

Greater operational efficiencies: Streamline processes and free-up capacity for mission-critical or high-touch processes

Enhanced compliance: Unqork's native compliance engines keep your processes up-to-date with state and federal regulations and avoid regulatory penalties and fines

Increased visibility: Provide highly auditable digital trails

Accelerated onboarding: Realize a faster path to revenue

Capabilities

Seamless integrations: Freely (but securely) exchange data between existing legacy systems and external solutions

Document management: Generate, manage, and store documents and make them available to all stakeholders

Easy configurations: Easy to reconfigure systems and re-use for new studies

Why No-Code for Clinical Trial Transformation

No-Code Vs. Traditional Code-Based Development

A bespoke management solution from the ground-up for each new trial would be infeasible using traditional code-based development methodologies.

Custom enterprise-grade software requires the digitization of analog processes[1], upgrading and integrating legacy systems, implementing air-tight privacy controls, complying with an evolving patchwork of regulatory demands, and competing for scarce IT talent. Factoring all these challenges together, it's little wonder that enterprise development (regardless of industry) is such a painfully inefficient affair with **85% of projects going over schedule** and 70% of large-scale digital IT programs **failing to even reach their stated goals**.

It would take too long and be too expensive, and the resulting software may not have a life beyond the trial.

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[1] Consider this year's strange **rush on COBOL-literate programmers** to update long-untouched government systems built on a mostly-forgotten language.

No-Code vs. Pre-Built Solutions

Off-the-shelf, technologies have introduced efficiencies and automation ton specific parts of trials, e.g., Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC), Electronic Patient-Reported Outcomes (ePRO), but they aren't able to overcome the challenges of transformation alone because:

- **These solutions automate some components of trials but not others.** Many pre-built solutions are area-specific. However, trials are complex processes involving multiple parts and true transformation can only happen when change is realized throughout the process.

- **It's difficult to securely integrate prebuilt, area-specific solutions into a legacy tech stack.** Trial processes need to function seamlessly with disparate legacy systems, which isn't always easy. They require multiple users with strict controls around who can access what data when, and the transfer of sensitive information across parties.

- **Code is often still needed to configure off-the-shelf software anyway, defeating the point.** Trial solutions require tailored document management, complex logic and decisions triggered by actions and/or changes in data, and high-fidelity user interfaces for patients, physicians, and doctors. Many software vendors can handle some or all of these requirements, but for organizations creating their modules or solutions with code, it's challenging to build these capabilities for disease- or therapy-specific requirements across hundreds of trials, often with very short time windows from trial design to First Patient In (FPI).

What About "Low-Code'?

Despite their similar sounding names, low-code and no-code couldn't be more different. Low-code was developed in the early 2000s to amplify developer productivity. These solutions work by inserting repeatable scripts into specific parts of the platform. Some of these tools may have drag-and-drop functionality, but to achieve complex—or unique—custom functionality, coding is still necessary. Most low-code platforms focus only on internal, back-end workflows and few have any consumer-focused capabilities that would help organizations develop robust user/patient experiences (e.g., styling, anonymous users).

The Technology

	Low-Code	No-Code
Front-end development	Basic functionality can be configured in a visual editor, but complex operations (e.g. form data validation) requires scripting	Both basic layouts and and complex operations can be configured without the need for scripting
Back end processes and workflow	Application workflow can be configured visually, executing either pre-built modules or scripting	Application workflow can be configured visually, executing either pre-built modules or scripting
Integrations	Modern integrations done with configuration, but legacy systems or more complex data transformations require code	Modern and legacy integrations can be configured without scripting
Data transformations	Data transformations and logic requires complex code and data transformation	Conduct data transformations with a completely visual ETL tool that incorporates visual import

The Results

	Low-Code	No-Code
Time to first build	**Faster**: typically a low-code application of equal complexity can be completed in 3-6 months relative to 9-12 for a typical enterprise application	**Much Faster**: typically a no-code application of equal complexity can be completed in 2-3 months
Ease of making material changes	**Difficult**: because code is involved an engineer must decipher and debug often idiosyncratic lines of code	**Easy**: all configuration takes place within the confines of business logic, only changes to business logic are required to change the application
Ease of hiring and training	**Difficult**: requires either consultants trained in specific language or seasoned developers that already understand code	**Easy**: anyone versed in business logic and decisioning can configure on a no-code platform
Total cost of ownership	**Slightly less**: basic elements of code maintenance and support still required	**None**: no legacy, no editable codebase to maintain or upgrade

No-Code Is the Way to Go

No-code eliminates the need to compromise on speed, security, functionality, or flexibility. Designing trial workflows with no-code bypasses many of the usual challenges of traditional software development by providing:

- **Accelerated development:** No-code platforms automate many high-volume coding tasks, which allows developers to focus on process logic and UX rather than syntax and codebases. Overall, this greatly accelerates the development process.

- **Enhanced collaboration:** Programmers are still central to the no-code development process, but it also opens access to a wide range of internal stakeholders. With a little bit of training, non-technical personnel (legal, accounting, research teams, etc.) can directly apply their knowledge to relevant areas of the application(s), instead of relying on IT as an intermediary.

- **Advanced data functionality:** Advanced systems like Unqork have the ability to ingest data (from both physical and electronic sources) as well as create new structured data, which is invaluable in clinical trial operations. With this integration layer in place, everything associated with tailoring the trial process to specific cases becomes easier and faster. Designers can easily load datasets directly into the platform to pull into data transformations or custom calculations.

- **Seamless integration:** Companies won't necessarily use no-code to create a new telemedicine platform, but they will use them to integrate legacy and external technologies into systems and processes already in place including existing CTMSs or Clinical Research Information Systems (CRISs) that they've used previously.

- **Enterprise-grade standards:** Advanced no-code platforms such as Unqork come with industry-grade security and privacy functionally baked in (e.g., adherence to all HIPAA security standards, encryption of data in transit and at rest, automatic back-up, enterprise-strength disaster recovery, cloud instance isolation, robust access and integrity controls, multi-factor authentication, and more).

Curious about how no-code can be applied within your organization? Get in touch to **schedule a demonstration** from one of our no-code experts.

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Enterprise application development, reimagined