

How No-Code Accelerates Transformation in Life Sciences

No-code empowers life sciences organizations to rapidly transform their operations and realize new efficiencies and flexibility.

Contents

Introduction	3
3 Opportunities for Digital Transformation in Life Sciences Using No-Code	4
Site Selection & Activation	4
Patient Recruitment & Screening	5
Personalized Patient & Provider Services Centers	7
Ungork: The World's First Enterprise No-Code Application Platform	10

oo often, life sciences organizations have lagged behind other sectors when it comes to digital transformation¹. Even before COVID-19 prompted an unprecedented rush for new vaccines and treatments, it was clear that crucial processes involving everything from clinical trial startup to provider services were technologically outmoded2. With the world depending on the sector to forge a way "back to normal," the time is now to implement some long-overdue technical and process upgrades.

Going digital, however, is no easy undertaking—particularly in complex and highly regulated sectors such as life sciences. Custom enterprise-grade software requires digitizing analog processes, upgrading and integrating legacy systems³, implementing air-tight privacy controls, complying with an evolving patchwork of regulatory demands, and competing for scarce tech 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 projects failing to even reach their stated goals.

This is why leading companies are increasingly embracing no-code. This new class of cloudbased development platforms eliminates traditional friction points and accelerates the building of scalable, sophisticated solutions.

No-code offers a number of inherent advantages over other development approaches. For one, no-code platforms come "out-of-the-box" (or, out of the virtual SaaS box) with all the toolsets and industry-specific elements necessary to build and manage a robust application (e.g., front end UX, workflow, rules engine, analytics, visualizations, integrations, and maintenance). Since they're all components of the same unified platform, everything works together in instant harmony. By streamlining development, organizations are able to focus their resources on addressing business challenges and enacting long-term strategies.

Also, by eliminating the need to write code from the building process, no-code expands the scope of who is doing the development. In a no-code platform, users (or "Creators," as we refer to them at Ungork) build applications by dragging and dropping configurable elements representing userfacing elements, back-end application logic, and integrations with third-party services. While modern programming languages (Java, Python, etc.) can take a year to learn and a decade to master, no-code can usually be mastered in just three weeks. With no-code, business and science leaders can take a direct role in the development process, which can increase collaboration.

The Takeaway: No-code empowers organizations to readily explore and expand digital opportunities that would have been inaccessible just a few years ago. In this eBook, we'll explore how today's most innovative leaders are using no-code to supercharge their digital transformation and inject operational efficiencies and flexibility throughout the life sciences value chain.

¹A 2018 Deloitte survey of biopharma companies found that only 20% of respondents considered their organizations to be "maturing," while 55% considered themselves "developing," and 25% were only "in early stages" of their digital journey.

²According to a <u>research report by Accenture</u>, "86% of clinical trials do not meet enrollment timelines due to issues with recruitment." Paperless management systems are recommended to speed up this process.

³Consider this year's strange <u>rush on COBOL-literate programmers</u> to update long-untouched government systems built on a mostly-forgotten language.

3 Opportunities for Digital Transformation in Life Sciences Using No-Code

While we highlight only three key life sciences use cases below, the beauty of a no-code application building platform is that there are endless possibilities. No-code enables you to rapidly build and effectively manage just about any custom solution your team can imagine.

1. Site Selection & Activation

Activities to support site selection are often spread across a patchwork of legacy systems. Even organizations with strong Electronic Data Capture (EDC) functionality and Clinical Trial Management Systems (CTMS's) often rely on tools such as Teams, Sharepoint, Outlook, and Excel to support critical "in-between" workflows. These ad-hoc, manual processes result in duplication of efforts, lack of visibility, and sub-optimal decision-making, ultimately increasing both time-to-First Subject In (FSI) and trial costs.

To date, there has not been a practical alternative to the status quo—R&D leaders would either have to implement generic point solutions or undertake a 12+ month internal development effort. With Ungork, however, sponsors and CROs can now rapidly stand up a custom solution that simplifies the end-to-end process and integrates with existing systems.

Ungork's Site Selection & Activation solution automates workflows and data exchange, enabling Clinical Research Managers and Associates to select and activate trial sites more efficiently. Leadership can then monitor progress against recruitment goals in real-time through the same unified application. The solution can be easily integrated with existing systems (e.g., CTMS, EDC, SIP) and stood up in as little as three months. It enables CRMs and CRAs to:

- Short-list sites based on consolidated views separated by disease area and featuring past performance (from internal & external sources), capacity, and conflicts of interest.
- Deploy tailored questionnaires to assess each site's capabilities and patient "funnel," which can drive automated inclusion/exclusion decisions.
- Understand each site's likely contribution (and the timing thereof) to overall targets and optimize the portfolio of selected sites accordingly.
- Access real-time recruitment performance updates by site, which are automatically pulled from the EDC system into sponsor dashboards that are tailored by role/seniority.
- Following trial, provide & capture feedback on site performance that can be used in future trials.



10-25%

Reduction in CRA & CRM workloads through the elimination of manual data entry and other workflow bottlenecks.

Faster Time-to-FSI

Quickly identify the right sites for the trial and stay close to the recruitment progress.

Lower Costs

Reduce the need to "overactivate" sites initially and rescue underperforming sites later on.

Increased Visibility

Equip key internal stakeholders with role-appropriate views of recruitment progress, allowing them to intervene on a timely basis.

KEY CAPABILITIES

- Seamless Integrations: Efficiently integrate and exchange data with existing systems, such as legacy EDC platforms and CTMS's.
- Rapid Surveys: Customize site evaluation and patient funnel templates based on the trial at hand, which can be deployed to each site.
- Automated Business Logic: Automatically generate recommendations to include or exclude a given site and quantify likely impact on overall trial recruitment and timelines.
- Tailored Dashboards & Alerts: Monitor and receive omnichannel alerts as to each site's realtime performance against recruitment targets and whether or not they are on track.

2. Patient Recruitment & Screening

Clinical trial recruitment and screening processes are painful for both patients and site staff. For patients, initial screening—even when conducted digitally—is difficult and time-consuming to navigate, especially when questions around medical history need to be researched. As a result, a significant swath of patients drop out prematurely and/or provide inaccurate information. Subsequent rounds of screening often occur at the site, which may take weeks or months to schedule and require travel on the part of the patient—often before eligibility is even confirmed.

Even when CROs are involved, site staff must often shoulder some upstream responsibility for recruitment and upfront screening. Therefore, they are compelled to spend time on outreach, assessment, manual re-entering into an EDC system, and even ordering full medical records for patients who could—and in many cases should—have been disqualified well before the site got involved. These low-value tasks take time away from more impactful activities and can contribute to site burnout over the long term.

Current point solutions may digitize specific components, but aren't often integrated with end-to-end processes or legacy systems (e.g., EDC). Internally-led software development allows for more robust integrations, but tends to take 12+ months and is difficult to update by trial or as the market evolves.

Unqork's **Patient Recruitment & Screening** solution solves all of these pain points. Patients go through an intuitive, omnichannel intake experience to learn about and see if they might qualify for trial; those that do can then share medical records with the click of a button. Unqork automatically parses these records and maps them against the trial's inclusion/exclusion criteria to flag patients whose clinical history renders them ineligible. This information is routed to the closest site (or first to the CRO, if one is involved) for staff to conduct further screening and schedule a virtual consultation with the patient. Site staff can then trigger digital informed consent to be sent to eligible patients and review the forms with them virtually as helpful. Ultimately, the trial portal is "turned on" for these patients, and the data that has been collected so far is automatically pushed to the EDC to eliminate duplicate entries.

Faster to First-Patient-In

Mitigate bottlenecks stemming from scheduling in-person visits and manual, labor-intensive documentation/ assessment of clinical history.

Stronger Recruitment Volumes

Reduce premature attrition and ensure that sites and qualifying patients are motivated to make it through the end-toend process.

Less Site Fatigue

Significantly streamline the patient funnel by sparing site staff from having to spend time evaluating "false positives."

Lower Operational Expenses

Conduct virtual screening and onboarding to reduce patient travel expenses and reduce CRO/site staffing ratios.

Enhanced Data Capture

Seed relationship with patients (even those ineligible for the trial at hand) for future trials and/or ongoing contribution of medical records for RWE generation.

KEY CAPABILITIES

- Tailored User Experience: Responsive omnichannel interfaces with pixel-perfect, role-specific workflows for patients, sites, CROs, and sponsors.
- ✓ Upfront Screening: Custom screening logic and site routing based on the protocol and active sites for any given trial.
- Clinical Data Sourcing: Instantaneous patient access to medical records from one or multiple providers, as well as nationwide health information exchanges.
- Triaging Recommendations: Automatic mapping of patient medical history to trial inclusion/ exclusion criteria to flag potential eligibility issues.
- Seamless Integrations: Efficient integration and data exchange with existing systems (e.g., EDC, CTMS) and third-party services (e.g., clinical data, virtual connectivity, eConsent).
- Tailored Dashboards & Alerts: Monitor and receive omnichannel alerts as to each site's realtime performance against recruitment targets and whether or not they are on track.

3. Personalized Patient & Provider Services Centers

New therapies and devices that are coming to market are increasingly complex. Meaningful engagement from patients, clinicians, and caregivers is needed to drive initiation, adherence, and positive outcomes. Furthermore, growing competitive intensity in many therapeutic areas means that providers must offer valuable, fit-to-purpose support services to differentiate themselves.

Patient and Provider services hubs, which support education, access, and adherence, play a valuable role. However, each vendor in this space has strengths and weaknesses. For example, one might have stellar co-pay solutions, but a poor case management infrastructure in its call center; for another, the opposite is true. Many existing hub solutions are difficult to tailor to specific patient segments, let alone down to the individual patient—a sophisticated adherence application, for example, may work well for younger, digitally-oriented users, but frustrate older patients. The lack of personalization is particularly acute in conditions with small patient populations (e.g., rare disease, gene therapy), where there is a need for customization, but the investment is difficult to justify. Ultimately, these obstacles lead to missed opportunities for education, initiation, and adherence along the patient journey.

Manufacturer and third-party support services (e.g., web resources, call centers, field reimbursement personnel) facilitate key activities such as patient intake, benefits verification, prior authorization, billing/coding, and more. However, the resources that are optimal for one therapy may be vastly different for another—even within the same indication. Furthermore, even in the context of a single therapy, providers have different needs and preferences based on experience, comfort with technology, patient mix, etc.



Ideally, biopharma and device companies could mix-and-match different third-party services and internal capabilities, as well as personalize them based on what will work best for each individual HCP. Unfortunately, hub vendors are generally unable to accommodate this type of best-of-breed approach, which falls outside their standard offerings. When they do, it exceeds the budget and timeframe allocated for development and still often results in a disjointed experience for the patient as well as the HCP.

Unqork's **Personalized Patient & Provider Services Centers** equips biopharma and device companies (as well as hub providers themselves) with a chassis on top of which therapy, segment, and even patient- and provider-specific service centers can be rapidly and cost-effectively stood up without code. Manufacturers can unify all support for a given therapy into a single portal—typically a combination of services across hub providers, internal capabilities, and Unqork-native applications.

Services, which can be integrated and unified across different hub providers, enable fit-to-purpose:

- Knowledge gathering, such as disease and treatment background, patient networking, and information on relevant clinical trials.
- · Logistics coordination, such as insurance navigation, provider search, and provider scheduling.
- Access to care, such as telehealth, connected devices, transportation support, adherence support, and digital therapeutics.
- Data sharing, such as EHR and patient-reported outcomes.
- Education, such as details on the treatment itself, guidance on new processes (e.g., buy-and-bill), and tools to interact with Medical Affairs and network with other physicians in real-time.
- Logistics support, such as tools and templates to ensure insurance coverage, find highquality and cost-effective specialist referrals, and even for procurement.
- Care delivery, such as ongoing access to patient clinical data from other providers or connected devices and patient-reported outcomes, and tools to order and direct ancillary care (e.g., labs).

3 Months

Number of months it takes to rapidly and cost-effectively stand up a fully-functioning portal (including integrations)—often even faster for subsequent launches, given the ability to leverage "connected health" chassis.

Higher Patient & Provider Satisfaction

Equip patients and providers with a unified set of best-in-class support services, making for a smooth and tailored care journey.

Better Patient Outcomes

Make it easy for patients to educate, initiate, and adhere over time while enabling providers to help patients initiate and adhere.

More Robust Data Collection

Incentivize patients to share clinical data and PROMs for strategic initiatives around registry creation, market access, etc.

Stronger Business Performance

Maximize uptake throughout the product life cycle and use Ungork to rapidly adapt portals and offerings based on changing market dynamics.

KEY CAPABILITIES

- Seamless Integrations: Unqork's platform supports robust integrations with hub provider offerings, point solutions, and manufacturer systems/capabilities.
- Custom Logic: Easily personalize support services by patient/provider segment, and use a dynamic intake process to ensure patients/providers are "assigned" to the proper category.
- Flexible Web & Mobile Design: Deliver pixel-perfect, modern interface to all users regardless of channel or device.
- Authentication & Security: Enable enterprise-grade authentication functionality across users while remaining compliant with key regulatory requirements, such as HIPAA.
- 玄 Dynamic Intake Process: Generate custom recommendations and access to services based on provider readiness, needs, and attitudes.
- 玄 Surveys & Data Sharing: Rapidly create and deploy questionnaires to solicit critical information on patient outcomes and experiences; enable patient access to EHR data.
- <u>~</u> End-to-End Analytics: Understand how both providers and patients are interacting with and benefiting from the platform.



he leaders of tomorrow will be the organizations that can digitize their processes most thoroughly and adapt their infrastructure most rapidly around a wide variety of shifting challenges. With no-code, companies are empowered to build scalable, secure, complex, compliant, custom applications with unprecedented speed and flexibility.

That's why many of the most innovative players in healthcare and beyond are partnering with Ungork, the first enterprise no-code development platform specifically designed for the world's most complex and regulated industries. Our platform represents an entirely new paradigm that optimizes every aspect of enterprise development through:

A UNIFIED SAAS PLATFORM

Ungork is a completely unified SaaS platform, which means it provides all the components and capabilities related to crucial areas like compliance (up-to-date regulatory and enterprise rules engines for FATCA, CRS, UK CDOT, Dodd-Frank, EMIR, and MiFID II, etc.), security (native encryption both in transit and rest, custom RBAC capabilities, and crowd-sourced penetration tests), and application management (SDLC governance, application versioning, and module management)4.

A VISUAL UI:

Applications are built via an intuitive, visual User Interface (UI) featuring drag-and-drop components representing user-facing elements, backend processes, data transformations, third-party integrations, and a growing library of industry-specific templates.

ENTERPRISE-GRADE STANDARDS:

While there are several business-area-specific or consumer-level no-code systems on the market, Ungork is the only no-code platform designed specifically to build scalable healthcare applications 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).

⁴While Unqork is a SaaS platform, our customers operate in single-tenant environments, which means there is never a mixing of client data between Unqork customers.

Unqork takes on the "heavy lifting" of development and frees companies to shift their focus and resources towards building operational efficiencies, perfecting the user experience, and enacting long-term strategies. By tapping into the power of Unqork's no-code application platform, organizations can realize:



Accelerated speed-to-market: No-code automates many high-volume development tasks so new applications can be built and deployed much faster. In many cases, applications that would take months or years to reach the market can be built in a matter of weeks, or even days.



The elimination of legacy code: Code becomes legacy nearly instantly. With no-code, organizations only need to be concerned with building business logic; even if there is a technical change, the platform handles all that on the backend.



Ease of updates and maintenance: Large enterprises can spend up to 75% of the total technology budget maintaining existing systems. One of the reasons is the complexity of making a change in one area requires changes throughout the process. A no-code platform automates many of these cascading tasks and therefore reduces the complexity of making changes.



Business agility: Whether it is a pandemic, new or changing regulations, or disruptions of a smaller scale, no-code can provide organizations with a way to address events quickly.

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.

unqork

Enterprise application development, reimagined

Unqork is a no-code application platform that helps large enterprises build complex custom software faster, with higher quality, and lower costs than conventional approaches.

Request a Demo

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