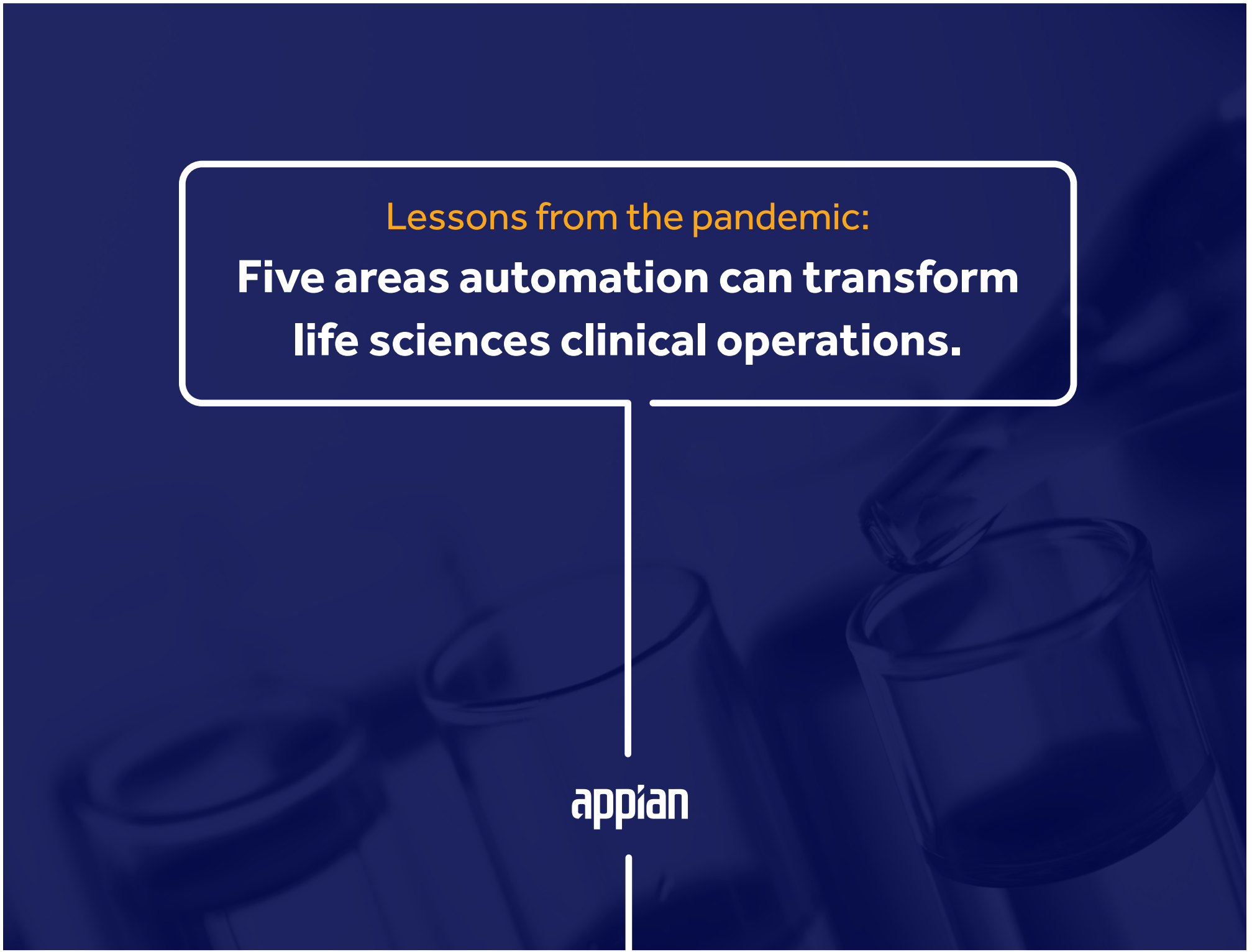

Lessons from the pandemic:

Five areas automation can transform life sciences clinical operations.

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Table of Contents

Introduction

How did the prioritization of vaccine development impact other medical innovations patients need? Beyond COVID-19, there are still many drug and device development programs with key impacts on patients' lives, health, and well being.

Over the past year we've seen amazing scientific breakthroughs with the COVID-19 vaccine coming to market swiftly and safely, as well as the development and evaluation of innovative COVID-19 treatments. This process was both lauded and met with skepticism as leaders across the globe worked to get safe and effective vaccines to the most vulnerable. Now we're seeing patients worldwide obtain vaccinations, in fact, the number of individuals in the United States who have received at least one dose of the vaccine outnumber those infected with the virus in the country, bringing reason for hope. [1]

Organizations previously balancing vaccine development with projects already in place pre-pandemic are now shifting their focus back to those paused programs. Drug and device development stalled or hampered by the pandemic–including R&D operations, clinical sites, and patient trials–have returned to center stage.

The COVID-19 pandemic didn't necessarily bring about all new challenges to the clinical operations process, but those obstacles organizations had been facing for years are now being acutely recognized.

1. www.bloomberg.com/news/articles/2021-02-01/u-s-hits-milestone-in-pandemic-with-more-vaccinated-than-cases

Here are five areas of clinical operations in ripe for advancement.

1

Study Design and Execution Lifecycle.

The complex protocol development process involves multiple stakeholders and subject matter experts and is frequently amended during the clinical trials due to unforeseen variables. Add the impact of the global pandemic and accomplishing study goals faced even further obstacles. Between efforts to maintain trial subjects' safety, and subjects making significant lifestyle changes, organizations were challenged to obtain quality data. Many completely paused clinical trials and now face steeper challenges to resume them.

2

Study Start Up.

Getting a clinical trial study and associated sites up and running effectively is often a laborious, disjointed undertaking. To identify problems before they occur, ensure regulatory compliance, and prioritize the safety of patients involved in the study, study managers want a clear, complete understanding of their process.

3

Global Contracting Agreements RFPs and Tender Management.

The competitive nature of tender management did not disappear in the wake of the pandemic, if anything, the crisis heightened its urgency. To succeed in this space, life sciences organizations are seeking real-time updates that serve as a single source of information, rather than less efficient and error prone spreadsheets or other ad hoc, manual solutions. They need a way to collect, track, and analyze data without the risk and increased errors of manual methods.

Hyperautomation has the potential to advance clinical innovation, improve patient outcomes, and get products to patients faster.

4

Centralized Site and Study Monitoring.
For clinical trials' leaders, visibility into individual trials, and across multiple trials simultaneously, is of critical importance. With the right platform solution, the centralized monitoring process provides multiple on-site monitoring capabilities, as well as additional for rapid data evaluation methods, alerting these leaders to any anomalies in real-time. These capabilities avert problems before they occur, and help products get to market faster.

5

Clinician Onboarding and Credentialing Management.
Staff at hospitals, clinics, and other locations who conduct clinical studies are critically important. Therefore life sciences companies must ensure they're onboarding the best people, properly confirming credentials, and onboarding new staff quickly and thoroughly. Often this process is disjointed and cumbersome, stretching across multiple systems and ultimately slowing study initiation and progress.

Automation and low-code for clinical operations' future

We're now seeing an increased number of successful global life sciences organizations turn to low-code automation to improve their clinical operations.

COVID-19 brought increased attention and urgency to areas that already needed improvement within the clinical operations space, including:

- **End-to-end process visibility**
- **Adherence to new and evolving regulations**
- **Exception handling**
- **Unforeseen costs**
- **Accelerated timelines**
- **Enhanced quality**

By combining people, process, bots, and machine learning technology with enterprise-grade automation workflow capabilities, organizations can break down the barriers between data silos and functional areas. This unites technical disciplines, helps create end-to-end visibility, and enables life sciences organizations to work faster and smarter, even during challenging times. Automation equipped with key exception handling can also help organizations handle regulations that vary by country, ensuring clinical trials stay on track.

Automation and low-code for clinical operations' future

At Appian, we've worked with several of these organizations to advance their clinical operations processes, including these specific use cases:

A multinational pharmaceutical company

This drug maker utilizes low-code automation to improve business operations and collaboration, reduce avoidable study amendments and cycle time, and decrease the risks associated with manual data entry and the review and approval of study ideas.

Because the study protocol design life cycle often extends over many months, the goal of capturing tacit knowledge was critical, as was enabling seamless remote collaboration. The team also wanted to automate the planning stages of clinical development, including integration of the evidence plans that show the value of the team's work.

Leading international clinical trial and health data company

This organization needed to eliminate manual processes that were slowing their trial startup and execution time, along with creating risk for tracking regulatory and legal requirements across geographies.

Using low-code automation they have been able to streamline their on-demand process tracking and tailor their processes to comply with varying international regulations.

A large multinational life sciences company

This organization built their clinical operations application in eight weeks using low-code automation. Through design principles that ensure workflow automation, while minimizing the number of necessary touches, they have enhanced the overall user experience and are now developing additional process improvements and workflow automation.

The organization continues to use Appian to automate numerous processes and sub-processes and develop "blueprints" for predictable and dynamic steps. Through design principles that ensure workflow automation, while minimizing the number of necessary touches, they have enhanced the overall user experience and are now developing additional process improvements and workflow automation.

Large multinational pharmaceutical company with over 100,000 employees

This leading drug maker was using a largely paper-based clinical trial management system that operated in silos, lacked visibility, and was ripe for error when it came to filing deadlines for global regulations.

Their goals included merging all of their clinical operations across multiple geographies and systems on a single platform and to accelerate time to submission and ultimately time to market. Using low-code automation they reduced start-up cycle times by 60%, reduced cycle time by 32%, and Increased regulatory compliance to nearly 100%.

Summary

Industry leading life sciences organizations trust Appian, including nine of the world's Top 10 largest Drug and biotech companies[1].

astellas

Boehringer Ingelheim

MERCK

Medtronic

SANOFI

GRIFOLS

BAYER

gsk

Learn more about Appian's work in life sciences at appian.com/lifesciences.

1. List according to Forbes Middle East.

Appian provides a low-code automation platform that accelerates the creation of high-impact business applications. Many of the world's largest organizations use Appian solutions to improve customer experience, achieve operational excellence, and simplify global risk management and compliance.


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