UiPath The Foundation of Innovation™

Intelligent automation in life sciences R&D

Accelerating time to market for life-saving therapies

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Introduction

"Science and technology are advancing at an unprecedented pace, and we have more knowledge at our fingertips than ever before."

- Vasant Narasimhan, CEO of Novartis, The Future of Medicine is Here

Never before has humankind had access to both knowledge and technology that is accelerating our understanding of science in ways that we are only beginning to understand. Many of us may remember that the mapping of the human genome project was completed in 2003, several years ahead of schedule because of the increase in computing power that accelerated the analysis.

Fast forward twenty years to 2023 and we are only now beginning to fully understand how little we knew about human biology and disease. The creation of new drug development platforms like MRNA have allowed researchers to develop life-saving vaccines and therapeutics that, for example, use a patient's own immune system to produce antibodies that protect a patient from viruses and/or diseases.

Conversely, this technological innovation has also significantly increased the complexity of research and development processes. Cloud-based networks, leveraging high performance computing to provide molecular modeling of millions of complex proteins, have become much faster and more accurate, but processing the data is complex and costly to create, curate and maintain.

Further, research data may reside in a variety of locations and states. For example, a researcher's electronic lab notebook could reside at a clinical trial site that is administered by a clinical research organization using their internal network and may require days, weeks or even months to aggregate, validate and compile the data for analysis. These efforts will take the researcher away from science and require them to spend significant amounts of time to capture, move and validate the data from their research and/or trials.

"The average R&D efficiency of big pharma was $6.16 billion total R&D expenditures per new drug. Almost half of the leading companies needed to compensate for their negative R&D productivity through mergers and acquisitions."[1]

- Analysis of pharma R&D productivity - a new perspective needed

[1]*Alexander Schuhmacher, Markus Hinder, Alexander von Stegmann und Stein, Dominik Hartl, Oliver Gassmann, Analysis of pharma R&D productivity – a new perspective needed, Drug Discovery Today, Volume 28, Issue 10, 2023, 103726, ISSN 1359-6446, https://doi.org/10.1016/j.drudis.2023.103726.*

Automation as an enabler

UiPath was launched in 2005 in Bucharest, Romania by ten people in an apartment. Their goal was to create automation libraries. It was clear to our founders that organizations needed the ability to automate repetitive and mundane processes, but it was also early in the development of technology. The UiPath teams continued to evolve and improve the product to its current state as the market-leading platform for AI-enabled intelligent automation for healthcare, life sciences, and many other industries around the globe.

Users across the globe began to see the importance of intelligent automation as a way of helping researchers stay focused on their science rather than on the systems and technologies that enable science. Why would we waste the time of one of the top oncology researchers in the world on organizing and centralizing their research data from one system to another for analysis? Life sciences organizations recognize the importance of having a researcher focus on their research, as opposed to the technology, to provide scientific breakthroughs for patients waiting for these life-saving therapies.

Consequently, R&D is an area that sees the benefits and importance of AI-enabled intelligent automation. From clinical data management to capturing and indexing assay tests to completing clinical regulatory forms for submission to global agencies, automation has had a significant impact on improving productivity, reducing time to market, and transforming the experience of clinical researchers. This white paper will highlight some of the many ways AI-enabled automation has impacted the research and development business area starting with clinical data management.

"Automation is not a silver bullet or a one-size-fits-all fix, but full automation can bring numerous benefits to R&D labs. Specifically, it has significant potential to contribute to improvements across all primary laboratory KPIs."

- McKinsey: From bench to bedside: Transforming R&D labs through automation. March, 2023.

Clinical data management*

Hours saved per year by automating clinical data management use cases

100s of hours	1000s of hours	3,000+ hours	5,000+ hours	8,000+ hours	2,500+ hours
Provisioning & migration of data	Migration of data from regulatory sites	Corporate dispatch and submissions	Upload of submission information into the RIM	E-submissions	Publication of the electronic master file

* Benefits are estimates based on customer deployments

Managing clinical research data can be a significant challenge. Data may reside in a variety of locations, including but not limited to company research sites, clinical research organizations, cloud-based data repositories, electronic lab notebooks and university research institutions. Simply organizing, validating, and analyzing data can be a very cumbersome, difficult, and timely process. Ensuring the access, accuracy and integrity of the data is also one of the most important tasks within a research project, and AI-enabled automation can simplify, improve, and accelerate this process in a variety of ways that, based on our experience, could provide a significant reduction in employee and researcher cycle times including but not limited to:

- **Provisioning & migration of data:** Provisioning of researcher accounts including creation and updates of those accounts based on role and location. Also, once a user is no longer involved or active in research or study, they must be deactivated. High level estimates in this area suggest a 65% reduction in time with savings of hundreds of hours per year while improving data quality.
- **Migration of data from regulatory sites:** Organizations may be required to download data from regulatory sites like the European Medicines Agency website to their regulatory information management (RIM) system. Automating this process could save thousands of hours a year.
- **Corporate dispatch and submissions:** Organizations spend considerable time creating, editing, and submitting clinical documentation to regulatory agencies for review. Global life sciences organizations have dozens of employees allocated to this effort. Implementing AI-powered automation and reallocating resources could save upwards of 3,000 hours per year and, more importantly, reduce the time to market for new products by as much as three months.
- **Upload of submission information into the organization's RIM:** Typically, organizations will upload the submission data into their RIM systems that may include a workflow process. This process is difficult but could save over 5,000 hours per year while improving accuracy, compliance, and timelines.
- **E-submissions:** Life sciences organizations will interact with the FDA website to load e-submissions and subsequently archive those same documents into your corporate RIM system. This effort could be automated and reduce the workload on the business by upwards of 8,000 hours per year while improving accuracy, compliance, and cycle times.
- **Publication of the electronic master file:** Automation can enable publishing of the approved documents from your Documentum, Veeva Vault or other document management solutions to your electronic master file system for review. This effort will help save upwards of 2,500 hours per year while improving compliance with GXP compliant automation.

Clinical reporting and audits*

Annual benefits of automating clinical reporting and audits

* Benefits are estimates based on customer deployments

Life sciences organizations will spend a considerable amount of time reviewing, generating, validating, and reporting the data in and around clinical research. Researchers must ensure the data is collected from patients and ensure that the protocol has been correctly administered. Trial data is reviewed to ensure accuracy while the trial data will be aggregated across multiple study sites from a trial execution perspective. Automation will be key throughout this process as we would expect a global life sciences organization to reduce their effort by over 110,000 hours annually, including the following areas of automation:

- **Producing studies & reports:** Life sciences organizations will have multiple repositories for studies, typically 350+ studies with 10-50 reports each, shared via document solutions such as SharePoint with e-mail notification. This could save an average of 50+ people required to execute these reports on a regular basis.
- **Email routing of request creation:** Classify emails for downstream processing based on the content included in the body of the email. The estimated savings are over 675 hours per year while reducing processing time and improving accuracy.
- **Email request creation:** Process email data received via e-mail forms, attachments or included in the body of the email that create new requests into a workflow application. This process avoids considerable manual processing and results in savings estimated at over 5,500 hours annually.
- **Lab reporting:** Automation can enable an end-to-end experiment management automation via a desktop widget for the end user. These automations enable the experiment team to modernize their testing platform to reduce manual labor, allowing scientists to focus on analysis of data while providing insights into data processing. This area is estimated to save over 1,000 hours annually while improving visibility across lab operations.

- **Regulatory reporting:** Regulatory reporting is one of the most pervasive areas of opportunity for global life sciences companies given the variety of burden of reporting requirements. Automation of case report forms (CRFs), regulatory compliance checks to ensure documentation accuracy, and automated submissions of regulatory reports, including adverse events, are just some of the many requirements needed in this area. The automation works in coordination with the broader supply chain management and workflow platforms to identify organizations that may require auditing. Automation of regulatory reporting is estimated to save over 2,500 hours annually.
- **Clinical document types:** The electronic trial master file contains over 500 document types required for submission in a single clinical trial, and organizations may have dozens, if not hundreds, of trials running worldwide simultaneously. Automation of just one of those document types can free up as many as three full time equivalent (FTE) personnel while eliminating errors and lengthy processing times.
- **Patient safety narratives:** Automated solutions build an intelligent starting point for the narrative to significantly reduce the upfront preparation time. Intelligent mapping of various sources into the patient safety narrative template accelerates the process and reduces the cycle time. Our experience suggests a reduction of approximately 60% of project QC personnel resulting in savings of over 1,500 hours annually, 80% improvement in accuracy, and a 100% audit capacity.

Clinical supply chain

"Ultimately, better visibility will be a key enabler for evolving more sophisticated digitally driven supply chains of the future, which will build in automation, artificial intelligence (AI), and end-to-end process integration. As such, supply chain visibility will be a critical focus for industry investment into improved resilience."

- EY: Why digital supply chain visibility should be a pharma priority

Leveraging AI-enabled automation will help life sciences organizations better plan, execute and report on their clinical trial operations. Automation will help reduce the cycle times and improve the efficiency of the operations in and around the clinical supply chain. This is enabled through improved transparency where the automation can capture, calculate, and notify the appropriate participants in the clinical supply chain processes. This improved transparency extends beyond the traditional processes and includes clinical planning, study enrollment, and drug dispensing processes, while also allowing for greater collaboration across the clinical ecosystem.

Specifically, automation can streamline and extend clinical trial supply processes including the following:

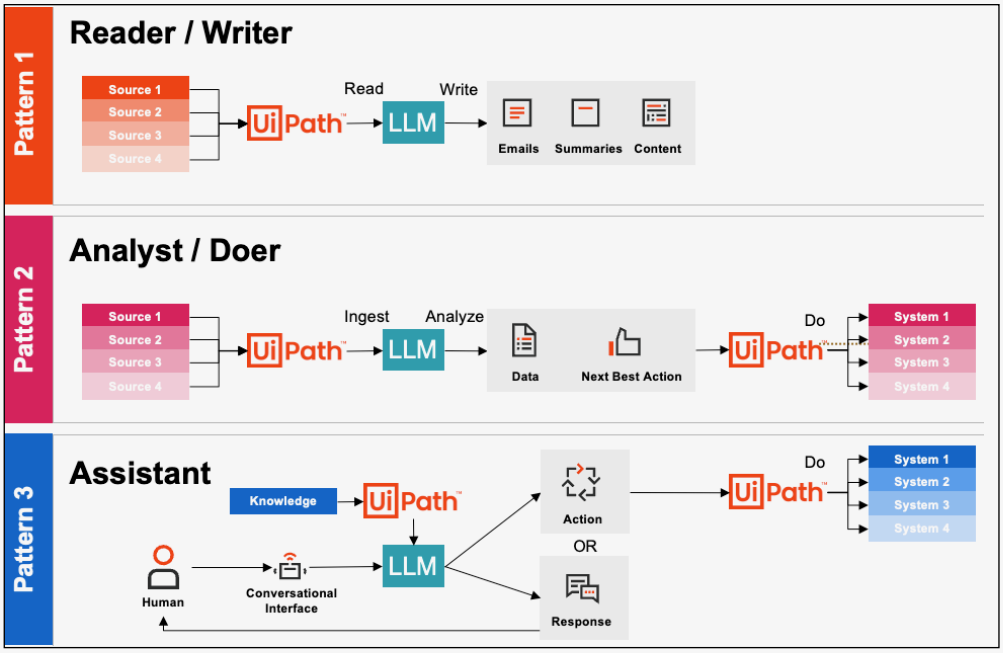
- **Data collection:** Automation can capture both patient vital signs and process specific information for the study. This data can be time and date stamped in an electronic format that is validated and auditable.
- **Identification of outliers:** Real time data capture will allow for immediate notification for any participants who may be outliers from a data perspective. The outliers can be contacted early in the process to correct, for example, any protocol execution issues that are causing data anomalies and eliminate the loss of a trial participant due to site execution and/or administration errors.
- **Aggregate clinical data:** Given all the data silos that occur during a clinical trial, automation can ensure that the data is tracked, validated, and aggregated into a central repository at regular intervals to ensure transparency and availability for timely analysis.
- **Decentralized trials:** Given the complexities around streaming data, AI-enabled automation can ingest, standardize, and aggregate the massive amounts of data that is accumulated from a device or sensor. Alerts and workflows can also be automated and include, when necessary, a human in the loop to ensure real time notification of researchers for any exception scenario.
- **Adaptive clinical trials:** Automation can assist researchers by aggregating, validating, and analyzing the trial data to identify patterns that may allow the researchers to, for example, adjust the dosage, in accordance with the protocol, to account for improved efficacy levels for any patient groups and/or biomarkers.
- **Ordering clinical supplies:** Based on trial requirements, AI-enabled automation can process the ordering of the clinical supplies required by clinical researchers, sites and organizations. The purchase order process can include validations that would allow for a touchless order placement or route to a human for review, prior to placement, based on parameters, such as order size.
- **Request clinical service providers:** AI-enabled automation can ensure that service providers like 3PL, diagnostic laboratory organization, contract manufacturing organization (CMO), or clinical research organization (CRO) will receive event-based service requests to ensure the respective service is reserved, including cold chain transportation and/or clinical manufacturing assets.

Impact of Generative AI

In 2023, no intelligent automation document would be complete without including a section on Generative AI (Gen AI). Prior to 2023, AI was a core competency of global life sciences companies. AI is used extensively to develop new drug and device therapies. Generative AI is a type of artificial intelligence capable of creating new data, such as images, text, and music, which exploded onto the industry landscape in late 2022. It's created tremendous interest in accelerating drug discovery and development in the life sciences industry.

Gen AI is quickly demonstrating its ability to dramatically accelerate new product development given its ability to create content. Gen AI leverages large language models (LLMs) that can review, for example, the clinical data captured during a pharmacovigilance investigation or a clinical trial and complete a narrative of that information. This would include a written description of numeric data included in charts or spreadsheets that could then be reviewed and edited by a human. The ability to synthesize the numeric and quantitative data into a concise and clear summary saves considerable time for the researcher in compiling their data for review.

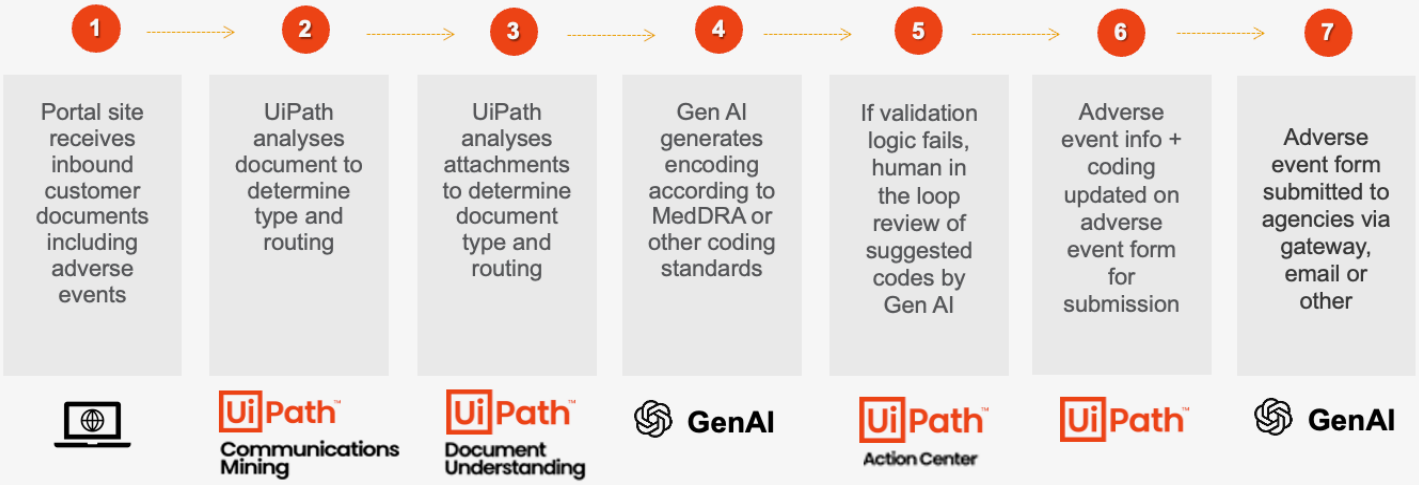
When Gen AI is combined with automation, the process will not only generate the content, but it can act and react to the data through the automation. At UiPath, we see three specific patterns of Gen AI emerging are summarized below in the graphic.



In **pattern 1**, the user can gather context from multiple sources to generate and distribute personalized messages across a range of responses. This could be as simple as crafting an email or a more complex response, such as completing a regulatory form like an adverse event form, to a regulatory agency like the FDA or EMA.

For **pattern 2**, the automation can ingest data from a variety of sources and use the LLM to analyze the next best action based on the information provided. The automation can embed the business context into the response and can present this action to a user directly or in the context of a workflow that is defined in conjunction with that next best action.

Lastly, **pattern 3** illustrates how automation can add context and action to conversational assistants. Users can query a repository either verbally or with text, and automation can enable an action or response based on the nature of the query and business context. This is still in its initial stages of a use case, but we expect to see this grow rapidly given the simplicity of the verbal query interface.



Organizations are excited to see the synergistic impact of combining intelligent automation and Gen AI that not only orchestrates but automates the response. The combination of the intelligent automation process combined with the content generating abilities of Gen AI are extremely powerful and can enable a variety of use cases including but not limited to:

- **Pharmacovigilance process (PV):** PV is a systematic process that is used to collect, monitor, and analyze data, usually through a complaint, on the safety of medicines. Complaints can come from a variety of sources, and Gen AI-enabled automation can analyze the data to determine if a submission is required. It can then update the regulatory document and submit the form to the appropriate regulatory agency either directly or after the review of an employee. The intertwining of the automation combined with the Gen AI capabilities increases the value of the scenario by making it more intuitive and responsive for the user.
- **Patient/donor screening:** Many newer therapies are personalized based on an individual's genetic makeup. Consequently, these therapies require a screening and/or diagnostic test to ensure the patient is eligible to take the treatment. Automation can coordinate the appointment for the patient, ensure the machine required for the diagnostic is available at a specific time and guide the patient and/or employee through the questionnaire that is based on a decision tree approach to the questions. The Gen AI capabilities can be used to generate any number of follow-up documents that summarize the results of the tests, confirm the appointments, and provide any other relevant information for the patient.
- **Regulatory submissions, including new drug application (NDA) and biologics license application (BLA):** Earlier we discussed the potential for Gen AI to update the information required for regulatory reporting across a variety of operational and/or clinical use cases. One of the areas currently under analysis is the potential to point the Gen AI LLM at the clinical trial data and have the Gen AI make the first pass on completing an NDA or BLA new product submission.

This process could take many months to complete as the data is organized and assembled in a clear and comprehensive manner for regulatory agencies to review. Gen AI could generate the data in a matter of a few hours and allow researchers to edit the data for accuracy and completeness rather than having to draft the report from a blank sheet of paper. Initial estimates indicate that organizations could save between 10-20 weeks by preparing documents which, at a revenue estimate of between $1M - $3M per day for a new drug, could provide a significant benefit of between $70M - $420M in accelerated revenue for global pharmaceuticals.

- **Narrative ability:** Regardless of the scenario, Gen AI's ability to generate a narrative from large collections of text and/or numeric datasets will have a massive impact on almost any type of study that will significantly reduce the time required to assess and analyze the research data. This could dramatically impact clinical data summaries and could be extended into more complex scientific and/or genomic scenarios where it may be a challenge to summarize the insights in a concise and accurate manner.
- **Query standard operating procedure (SOP) documentation:** One of the most remarkable aspects of Gen AI is its ability to review vast amounts of data. Many life sciences organizations have extensive libraries of SOPs that define the steps required to successfully execute a process. For example, Gen AI will allow a user to query an SOP library of documents to answer any questions the user may have in executing a specific process. Further, the query could be either a text or voice statement that would provide a response to the user in real time.

UiPath is excited to see the combination of intelligent automation and Gen AI come together to create and accelerate the AI and automation synergies across R&D. This AI-enabled automation is helping organizations reduce cycle times, including time to market for life-saving therapies, while also accelerating time to revenue for global life sciences organizations. We are truly living in remarkable times.

"Life sciences companies are using artificial intelligence (AI) to transform drug discovery by extracting concepts and relationships from data. By 2030, the time required for screening to preclinical testing will be reduced only a few months, and new potential drug candidates would be identified at more affordable prices."

– Deloitte: 2023 Global Life Sciences Outlook

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