

Fully Automated Safety

IQVIA's Safety Automation Maturity Matrix (SAMM) offers a step-by-step roadmap for automating safety surveillance

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Every pharmaceutical company must have a safety surveillance organization — it is a non-negotiable part of the business. It is also a labor-intensive cost-center where teams often juggle more work than they have time for, and struggle to attract and retain talent.

Automation can alleviate many of these time, cost, and labor challenges, but only if companies are willing to embrace automation, and to do the hard work required to support a digital transformation.

Most industry professionals recognize that automation and artificial intelligence (AI) can add significant value to the safety workflow. When deployed successfully, AI can automate many elements in the safety environment including management of non-electronic data, processing inbound data, and triaging data based on its source. These applications deliver higher levels of productivity with lower technology costs and lessens the reliance on manual labor to get tasks completed.

So why are pharma companies slow to make the transition? For many, uncertainty about how to proceed can paralyze

progress. Senior stakeholders may be able to envision a future state of total safety automation, but they lack a roadmap to lead them there, and they often jump ahead without doing the necessary due diligence. That leads to project planning mistakes, which can cause even the simplest digital transformation efforts to fail.

They set unrealistic expectations, choose the wrong vendors, launch projects without linking them to measurable performance outcomes, or fail to support change management efforts. These are all common missteps on the journey to safety automation.

They can all also be avoided when companies follow the roadmap laid out in IQVIA's Safety Automation Maturity Matrix.

CHALLENGES AND SUCCESSES



Where does our organization experience land and why?

Welcome to the matrix

The Automation Maturity Matrix provides pharma companies with an honest assessment of where they are versus where they would like to be, and offers a step-by-step guide to achievable, scalable automation.

Each of the four phases outlines specific criteria for progress, giving decision-makers clear guidance on:

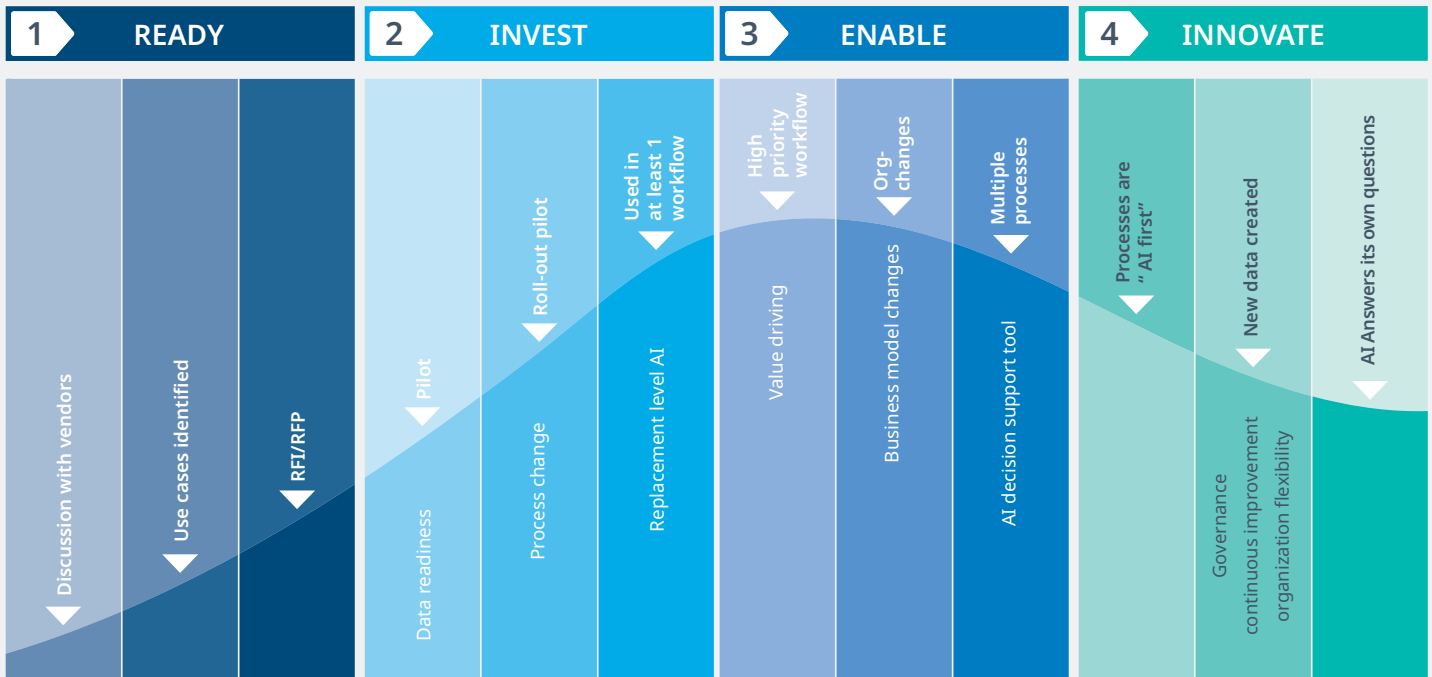
- How to vet their readiness for each step of automation
- How to choose the next best project
- How to identify obstacles that could slow their progress

These stage-gates ensure companies can stay on a consistent path, continuously monitor benefits, and avoid pursuing projects that will not deliver value.

The details of this automation journey will vary for every company. While some might have the resources and ambition to rapidly move to phase 4 (innovate); others may find that completing phase 3 (enable) delivers enough benefits, or that their culture is not ready to go beyond phase 2 (invest). The key is to figure out where you are today, and where you want to go.

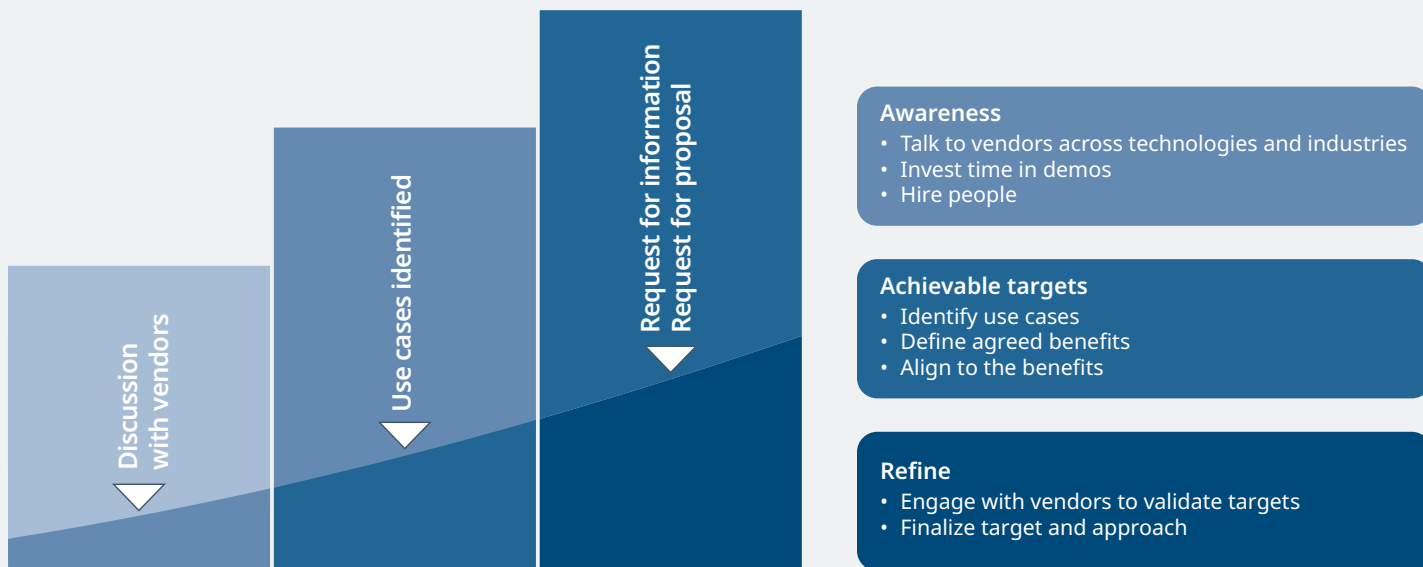
Regardless of the final destination, the matrix will help you chart the right course forward.

FIGURE 1: IQVIA'S SAFETY AUTOMATION MATURITY MATRIX



Phase 1: Are you ready?

READY FOR AI



Phase one focuses on education. Before picking technology or rolling out a project, you need to educate yourself about what's possible today, where benefits can be achieved, and what big obstacles your teams face. These insights will help you choose a low-risk project with tangible outcomes to start with, and to identify the best vendor to help you achieve your goals.

TALK TO VENDORS

Speaking with vendors is the most important step in phase one. Vendors are the experts in their technology. They can educate you about what's possible and what's practical in your safety environment, time frame and budget. This will help you hone in on the best first use case for automation in safety based on needs and challenges in your safety processes, and where you can gain the most benefits with the least amount of risk.

Talking to multiple vendors in this step will help you build a broad picture of what's possible and find partners who align with your culture and technology needs. This is critical, as you will be relying on your vendor to make this transformation possible. They will understand the technology, but they may not have your safety expertise.

Tip: Do not rush this process!

Many companies skip this step, or they delay vendor engagement until they've already picked a use case, which opens them up to unnecessary risk and bias. Without the early education that vendors can provide, those first projects are often not the right places to start. They may be overly complicated, companies lack the data or infrastructure to make them work, or they won't deliver significant cost or time savings. And when companies do finally connect with vendors, coming with a pre-selected use case shifts the conversation from discussing what is possible, to focusing only on how the vendor can make that chosen project happen.

To get the most value from vendors, use them to educate your team about how automation can be deployed in safety, and what use cases they think will add the most value.

THE TROUBLE WITH TRIAGE

One of the most common mistakes companies make when they fail to educate themselves about the best first step in this journey is selecting automated triage as their initial project. Triage can be a troublesome element of safety, but problems are often due to poorly designed processes rather than the need for automation.

Many vendors also lack the ontologies to effectively automate this safety surveillance step. If you have no experience automating other elements of safety, it is easy to partner with a vendor who won't be able to meet your needs. Even if they get the triage system working, the business benefits will be small since manual triage represents a small element of the workflow.

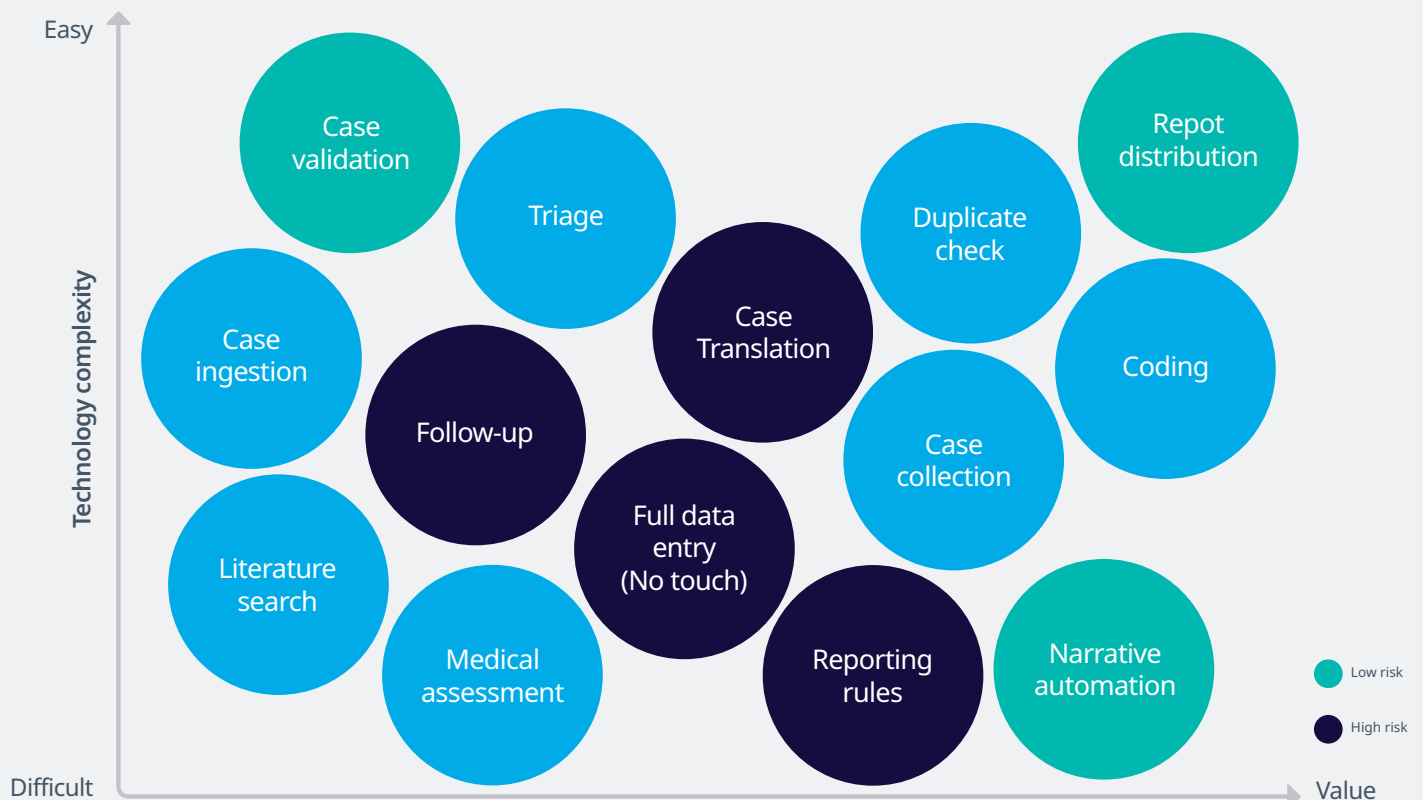
IDENTIFY YOUR USE CASE

Once you've had a few of these vendor conversations it will be time to pick a project.

The goal at this stage is to find a project that delivers high value with low risk, and to map the process for deploying it. That choice will vary based on the needs of the surveillance team, the goals of the business, your budget and timeframe, and advice from vendors. It should be relatively easy to deploy, with low associated risk, and include measurable key performance indicators (KPIs), like time saved, or improved data quality.

For many companies, this first project isn't what they expected. For example, at first glance you might think automating intake is a great place to start. But once you start talking to vendors about where to deploy it and how the data flows, you might realize that it makes more sense to start automation at the patient or HCP level.

AI IN SAFETY SURVEILLANCE: EASE, VALUE AND RISK



Tip: Every automation project will follow the same three steps: map the process, define the cost and timeline, and identify KPIs.

Talking with vendors will lead you to a project that has tangible achievable benefits, and help you chose the partner who is the best fit for your team from a culture and technology perspective. tomation can be deployed in safety, and what use cases they think will add the most value.

PUT OUT A REQUEST FOR PROPOSALS (RFP)

The RFP process will tell you which vendor is capable of handling your project and setting you on the course for successful safety automation. This is the time to be critical. A proposal is an indicator of how a vendor communicates, how they will accommodate your needs, and their ability to explain the technology in terms that are relevant to your business.

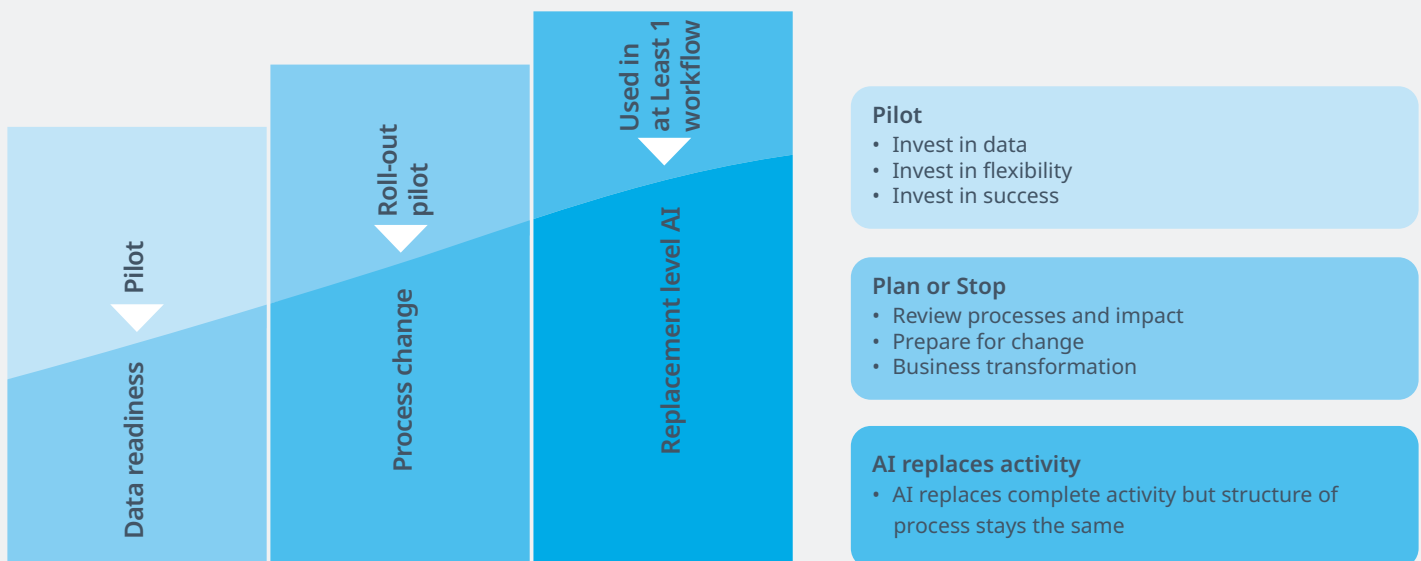
Tip: If a proposal doesn't fill you with confidence, they aren't the right vendor.

Many project owners think that if they can't understand a proposal, it is a reflection of their own lack of knowledge about the technology. But in reality, it's a red flag. If a proposal is full of jargon you don't understand, glosses over key business elements or is difficult to follow, don't assume it makes sense. It is the vendor's way of telling you that your needs are not something they understand.

The right proposal will explain the project in terms that are meaningful to your team in a way that makes you feel confident that they can deliver what you need when you need it. If you can't trust them to communicate effectively, don't move forward because the project is likely to fail.

Phase 2: Time to invest

STRUCTURED INVESTMENT - NO QUICK WINS



Once you have selected a proposal, it's time to plan for your first safety automation pilot project.

READY YOUR DATA

For any automation project to work, the safety team will need to prepare the data for AI application. This step needs to be conducted by your company's internal data experts, or with support from your case processing vendor to ensure the data is clean, consistent, relevant, and follows all data governance rules.

Tip: No matter how good the technology is, if your data isn't properly formatted and accessible to the new AI system, the project will fail.

This step includes mapping how the data will move through the system. As part of this process, you need to determine what jobs will be impacted, the tasks that will be changed or eliminated, and the KPIs you will use to monitor value. Process mapping will help your safety team prepare for the change and will make it easy for them to see the positive impact of automation.

This can be a difficult step in the Matrix, especially when it leads to staff reductions or job changes. But these issues need to be considered before the pilot roll-out or the automation journey can get stuck. Preparing your team for change is key to any project success.

Tip: If you automate manual tasks, but fail to reassign talent or change the workflow, it will have zero impact on productivity or performance.

ROLL OUT THE PILOT

With the data and workflow in place, you are ready to deploy the technology. Continuous measurement throughout will be crucial to proving the project is working.

Ideally you will begin this process with a clear measurable end goal in mind. *For example: automating narratives will*

cut 100 percent of the hours spent transforming structured data to a human readable format — if the business uses the automation. That requires a baseline measure (e.g., we now spend 100 hours per month on narrative), and KPIs to track weekly reductions and to validate that change is being embedded in the organization.

If you prepared the data effectively and the vendor's technology works as promised, the KPIs should show the results you were expecting. If they don't, the measures should make it easy to understand where you fell short.

Tip: Don't make perfect the enemy of Good.

Even if the pilot isn't a perfect success, it's important to assess its impact in the context of the value it delivered. For example, if the automated narrative system only cuts 80 hours from the process but still requires some manual oversight for complex narratives, can that still be considered success? If you lack flexibility in measuring value, that project could be deemed a failure causing you to revert back to the original highly manual process, losing all of that time saved.

However, if the pilot failed to deliver meaningful value, or it's so buggy that you spend just as many hours fixing problems, the next step is to determine why. Failed pilots can be caused by poor data, insufficient technology, and/or lack of commitment to process change within your internal team. Identifying obstacles will help you determine if the project can be saved, or if you aren't ready for this stage of automation.

This is not a time to be overly optimistic. The outcomes of the pilot (good or bad) should trigger important conversations among key decision-makers about whether you are equipped to move forward, whether your vendor is meeting your needs, and whether your organization is ready to continue the journey to automating the safety surveillance environment.

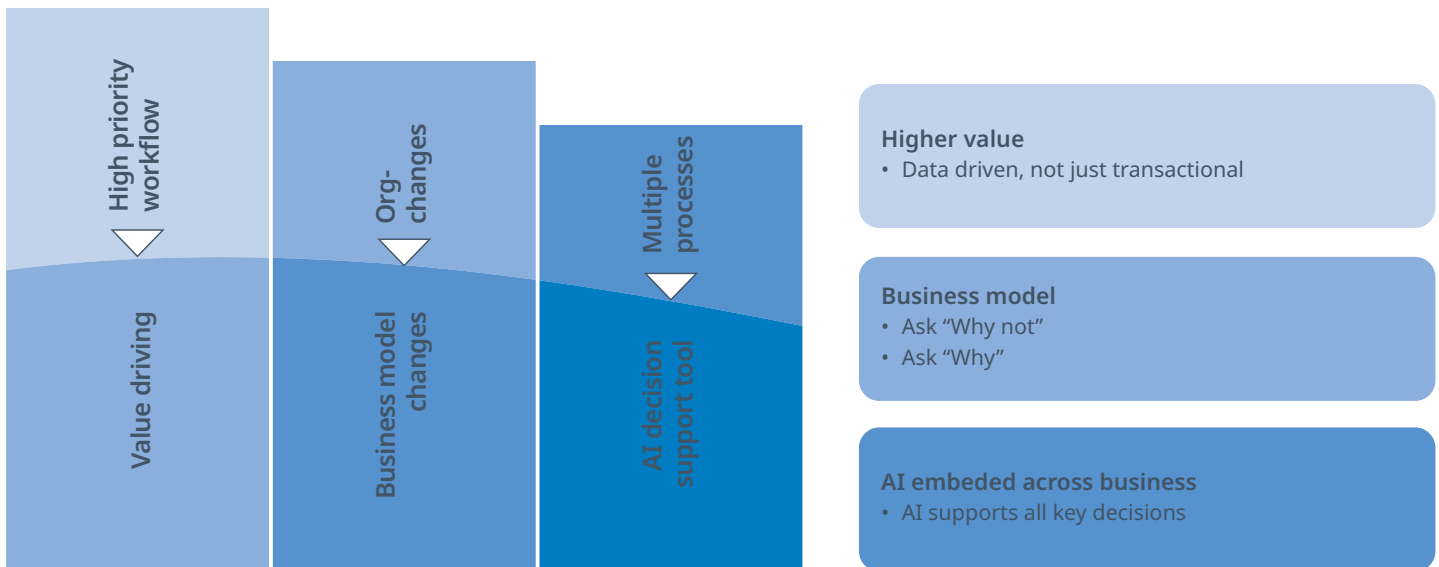
REPLACE A WORKFLOW

If the pilot was a success, congratulations. You have officially demonstrated that your team has the capability to successfully deploy AI and that you are ready for the cultural change that comes with it. This first success will help you build the business case for future projects and establish a foundation for the use of AI across the safety environment.

Consider it a major milestone in your safety automation journey. The next step is to use that AI technology to fully replace a manual process in the workflow.

Phase 3: Enable AI

ENABLE AI ACROSS THE ORGANIZATION



If you have entered the enable phase of the matrix it means you are ready to consider where AI can add value in more high-risk high-reward applications.

FOCUS ON HIGH PRIORITY WORKFLOWS

The pilot targeted a low-risk step so that if it failed, it wouldn't be dangerous and highly disruptive. But now that you proved that you can successfully deploy AI in your safety environment, it's time to focus on projects that you wouldn't have considered at the beginning.

These are no longer nice to have novelty applications. The Enable Phase is about delivering significant time, cost and quality benefits through automation of data driven steps in your workflow.

Some companies ease into the pilot process by running the automation in one area of safety, or in parallel with the original process for several months. This gives them the benchmark data to compare the impact of manual vs. automation, while providing the team with enough time to adapt to the change.

If you took this route, or only deployed AI in one smaller element of your workflow, Step 6 is when you go all in. It is time to transition those team members out of their roles and/or expand the technology across the safety environment.

If you're not willing to take this leap of faith, then your automation journey ends at low-risk projects. But if you are willing to evaluate the entire safety workflow, it's time to focus on more high value, high risk projects.

This is also the point when you begin building a project framework and governance model for all future AI deployments. Capturing best practices related to timelines, stakeholder support, vendor management, and change efforts will help your streamline these projects, reduce the time to deployment, and prevent the same mistakes from reoccurring.

CHANGE THE BUSINESS MODEL

To achieve success in this phase of transformation it is time to start thinking about safety as a tech-driven process, not just a place where AI could replace a few transactional steps and ease the burden on your team.

Tip: Instead of saying ‘where can AI help?’ Start asking ‘why am I not using AI in this application?’

When you embrace a tech-focused business model it becomes easier to identify all of the activities that should be converted to AI, and to select technology that will eliminate bottlenecks rather than seeking solutions to those bottlenecks. For example, if you normally convert adverse event emails to electronic data formats before submitting them instead of thinking about how to automate the formatting, you should ask ‘why aren’t these submissions coming in as electronic data in the first place?’

The later question considers the entire workflow through a tech-enabled lens allowing you to identify the real obstacle (email submissions) so you can figure out how to use technology to eliminate that problem all together via web forms or physicians’ apps.

Expect to spend the majority of your digital transformation efforts in the Enable Phase, rolling out several high value automation projects, and reinventing the culture of your safety team to be technology focused.

DECISION SUPPORT

You will reach the final step in the Enable Phase when you are ready to use AI to support all key decisions in the safety workflow. At this point AI should be embedded across the department, impacting most/every step in the process.

You should be able to achieve fully automated data entry, have built-in reporting rules governed by machine learning algorithms, and a suite of applications that enable automated case translation, data analysis, and decision-making as part of the safety workflow.

Some companies aren’t able to make it this far — and that’s okay. You need to have total confidence in the technology, your vendor, and your organization to be able to replicate every safety practice in an automated environment.

It also has to continue delivering business value. Every project – from the first pilot to the final automation — must have measurable KPIs that can be tracked and verified. If an automation project won’t deliver relevant business benefits, it’s just not worth doing.

Phase 4: Innovate

If you have made it to the final phase of your AI transformation journey, congratulations, you are ready to consider what could be possible in the future.

THINK AI FIRST

You are an AI-first safety organization, and you now actively seek new ways to use AI to enhance, accelerate, and act on safety data. You are no longer thinking about what’s possible today, but what could be possible in the future.

In this phase, you should focus on supporting a continuous state of improvement. Ideally you will have a dedicated team who monitor digital innovations and constantly question how, when and where new technologies could add value for your organization — even if they are not ready today. This team will push your vendors to create new solutions and reimagine their own technology roadmaps to improve processes within the safety environment.

Tip: Stop asking ‘what else can I do with AI?’ and start asking ‘why do we need humans to complete these tasks?’

THINK ABOUT NEW DATA CREATED

The pharma industry has seen an explosion of data, much of it from devices and sources that didn't impact safety in the past. Data flowing from wearable devices, social media, audio recordings, and shared images can now be used to monitor the safety of products.

This transformation will only continue, which means your safety organization must continue to reimagine what data is relevant to the safety workflow, and how AI can be used to capture, translate and interpret it in meaningful ways.

AI can be taught to continuously look for new data insights in huge volumes of data. Creating digital pathways that enable that interpretation will make it possible for your team to stay abreast of all information relevant to the safety of your products.

AI TAKES OVER

Eventually, the AI will start doing the research for you. In a perfect automation environment, AI technology will be trained to alert the humans on your team when a trend is discovered, a signal is detected, or a process could be improved. Safety surveillance will never be without human guides, but for companies that make it this far, it will be far more streamlined and largely automated, where humans validate decisions made after the technology does all of the work.

This will not only lower costs and speed access to insights, it will eliminate the constant challenge of hiring, training, and retaining staff for safety data tasks.

There are never enough talented applicants to fill these positions, and younger generations with these skills are looking for more innovate roles. Replacing data entry and safety analytics jobs with automation will ease the burden on pharma companies, and free them to use those talented resources in more high-value jobs.

Time to get started

Safety is a pre-requisite for this industry, and these departments are getting more complicated and expensive to run. Automation can make this workflow more efficient and cost effective while eliminating the hiring headaches that constantly plagues safety teams.

But to get there you have to be willing to follow the steps in the Matrix, and to be brutally honest about what your organization is willing and able to do to make automation in the safety environment a reality.

The Safety Automation Maturity Matrix not only offers a roadmap to AI transformation, it can help you see where you are today, where you want to go, and how missteps in the past may have derailed your progress. Using the steps laid out in IQVIA's Safety Automation Maturity Matrix, you should be able to chart a successful course forward and accelerate your path to a fully automated future.

To learn more about IQVIA's Safety Automation Maturity Matrix, or to learn how IQVIA can help you on this journey, contact Safetypv@iqvia.com or visit iqvia.com.



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