FREE WHITEPAPER

The Burning Challenges in the Pharma Industry and

Why Is Organizational Agility the Key to a Successful Digital Transformation?

businessmap

Table of Contents

Executive Summary

There's no doubt that we live in a world where the only constant is change. A world where companies must be agile to survive, and where digital transformation is not an option anymore, but a necessity. This is the world that the pharmaceutical industry finds itself in today.

Due to the highly unpredictable business landscape because of constantly emerging market disruptors and, most recently, the COVID-19 pandemic, pharma companies are increasingly under pressure to speed up time to market to ensure their survivability.

Combined with the long-lasting challenges in the industry, having a first-to-market advantage has never been more prominent for pharmaceutical companies.

In this whitepaper, we take a look at the burning challenges in the pharma industry and why achieving organizational agility as part of a digital transformation strategy is key for business survivability.

Finally, we will move forward to exploring some industry real-life use cases to see how companies can actually take advantage of embracing Lean/Agile operating models.

01

Challenges in the Pharma Industry

Before we explore the state of digital transformation across the pharma sector, we must pay attention to the challenges driving the need for change.

In fact, due to the nature of the work within the pharmaceutical industry, those challenges have long been a matter of discussion. Based on our in-depth research, we've identified 3 main ones.

- **Long Lead Times/Slow Time to Market**
- **Eroom's Law (Or Moore's Law Backwards)**
- **Falling Internal Rate of Return & Ultimately Higher Risk**

Long Lead Times/Slow Time to Market

Numerous studies over the last decade (2010/11-2020) indicate that the average time for a Phase I asset to go through regulatory approval is 10.5 years. Often, this doesn't include the time for drug discovery and pre-clinical research which is estimated to be between 1-3 years.

On average, it can take between 10-15 years for a novel drug to reach the market.

And that's just one part of the story because in the US, for example, drug patents last for about 20 years. This means that in most cases, a drug patent is valid for only 10 years.

At the same time, the costs of developing new drugs keep rising. According to the National Library of Medicine, estimates for more recent drug development projects indicate spendings of around $2 billion to bring a new product to the market.

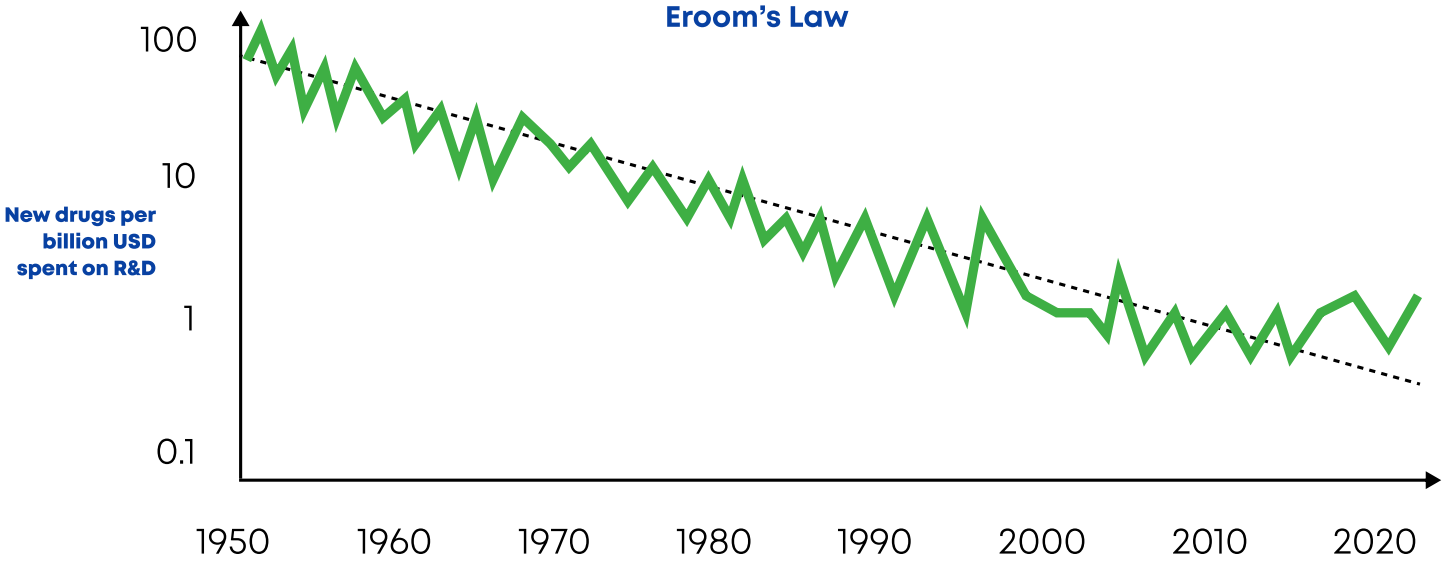
Eroom's Law (Or Moore's Law Backwards)

Over the years, there's been an interesting observation in the pharma industry regarding the opposite trend of the famous Moore's Law. In case you're not familiar with it, here's a short summary.

"Moore's Law is an observation by Gordon Moore (co-founder of Intel) stating that the number of transistors per semiconductor chip doubles every two years while the cost of developing computers is decreasing".

In the pharma sector, apparently, the inflation-adjusted cost of developing a new drug roughly doubles every 2 years. The graph below shows that the number of drugs approved by the U.S. Food and Drug Administration (FDA) per billion dollars of R&D spending has been mostly pointing downwards since the 1950s.

In other words, while the overarching trend has been for less drugs to reach the market, at the same time, it becomes more expensive for that to happen. So, what does that mean?



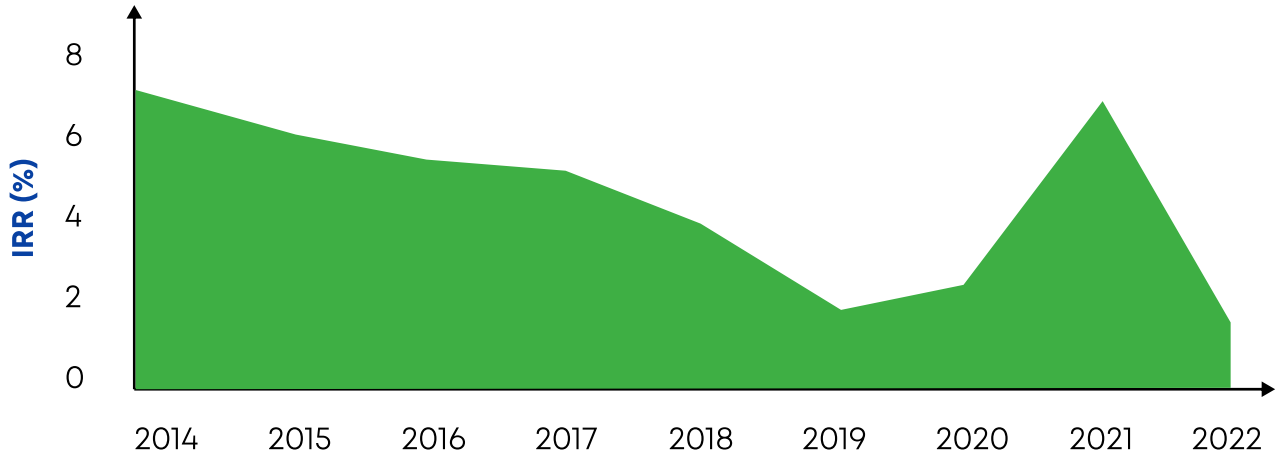
Falling Internal Rate of Return & Ultimately Higher Risk

Despite a surge in the internal rate of return (IRR) on investment that the pharma industry saw in 2021 (largely due to the COVID-19 pandemic), recent data shows that the overall IRR for companies in the sector has been sloping downward. In fact, a recent study by Deloitte found that from an increase to 6.8% in 2021, **the IRR rate returned to pre-pandemic levels**, and it currently stands at a little above 1%.

The same study also found that despite a dip in 2021, **the number of terminated drug assets is once again on the rise**.

This isn't new information as pharma companies have long been fighting significant failure rates of products across clinical trials. In general, all of this data shows that the development of a novel drug is time-consuming, extremely costly, and comes with a low probability of success. Obviously, the accumulation of these challenges significantly increases risks in the industry and drives away potential new investments in research and development.

R&D returns have returned to the declining trend evident pre-pandemic



**Deloitte Report - Seize the digital momentum 2022*

What's The Pharmaceutical Industry's Response?

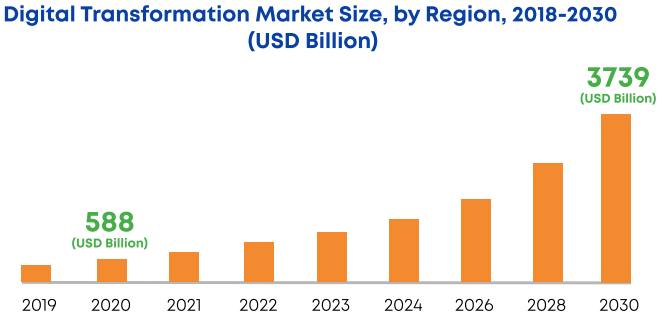
The above-mentioned problems are well-recognized by the industry and to alleviate them, more and more companies hop on the race to adopt the latest technologies to increase operational efficiency. At the end of the day, the advantage of being first-to-market has never been more crucial for businesses, especially pharmaceutical companies. That's why digital transformation initiatives are on the rise, even in one of the highest regulated industries in the world.

02

The Growing Digital Transformation Trend

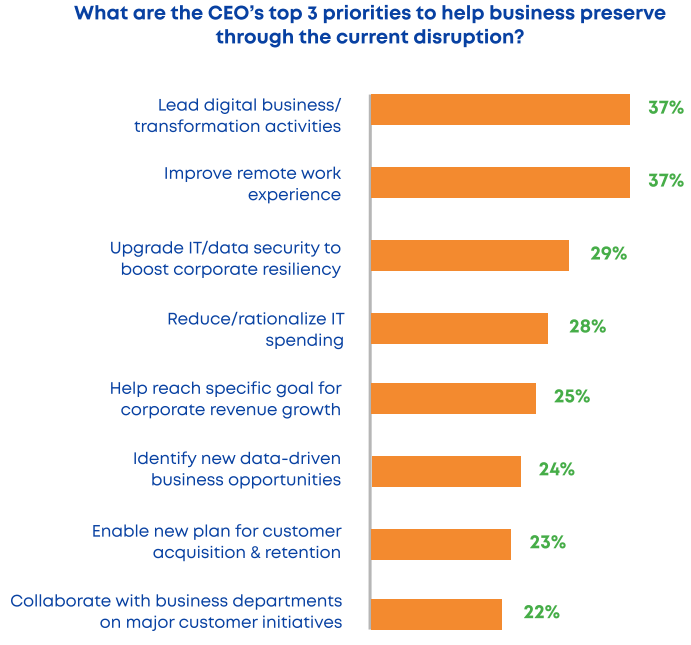
To support our statement, let's look at some data regarding the uprising digital trend.

According to Statista.com, global **spending on digital transformation is going to reach 3.4 trillion dollars** by 2026. Other studies (Source: Polaris Market Research) show that it is expected for the digital transformation market to grow at a 23.6% CAGR (Compound Annual Growth Rate) until 2030.



Polaris Market Research - Digital Transformation Market Share 2022

At the same time, in another report by Statista.com it's evident that the main goal for executives amidst the COVID-19 pandemic is leading a successful digital transformation initiative.



Statista- CEOs' top priorities to preserve business amid COVID-19 2020

What About The Pharma Sector?

The pharmaceutical sector is not an exception to this trend.

In an attempt to deal with its pressing challenges, a recent survey by Deloitte across pharma companies shows that 70% of respondents treat digital innovation as a competitive differentiator. On the other hand, 82% agree that the adoption of a digital operating model will keep rising after the pandemic.

Generally speaking, there's no denying that digital transformation is on the rise.

70% of pharma companies treat digital innovation as a competitive differentiator. On the other hand, 82% agree that the adoption of a digital operating model will keep rising after the pandemic.

But at the same time, it's also true that **the failure rate for digital transformation attempts remains high with an average of 87.5%** (Source: Harvard Business Review).

So why does that happen?

While there isn't a single reason we can point out, it seems that culture and overall organizational agility are an important piece of the puzzle.

Let's see why.

03

Business Agility as an Enabler & Supporter of Digital Transformation

At its core, digital transformation doesn't just mean adopting the latest technological advancements. It's also about the evolving pursuit of a digital culture and Agile ways of working with the goal of creating new value for customers.

In fact, a study from BCG (Boston Consulting Group) based on 40 digital transformation attempts found that the organizations which focused on the cultural aspect of the transformation had 5 times greater results. The report emphasizes **5 key aspects of a digital culture**:

- An external rather than internal orientation
- Delegation over control
- Experimentation over caution
- Short-term actions over extensive planning
- Collaboration over individual effort

What's interesting here is that those aspects closely coincide with the values from the Agile manifesto. If you're not familiar with them, they're:

- Individuals and interactions over processes & tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

To support these values, the authors of the manifesto also agreed on 12 principles which you can read more about here. Both values and principles form the Agile mindset, which is the building block of an Agile operating model.

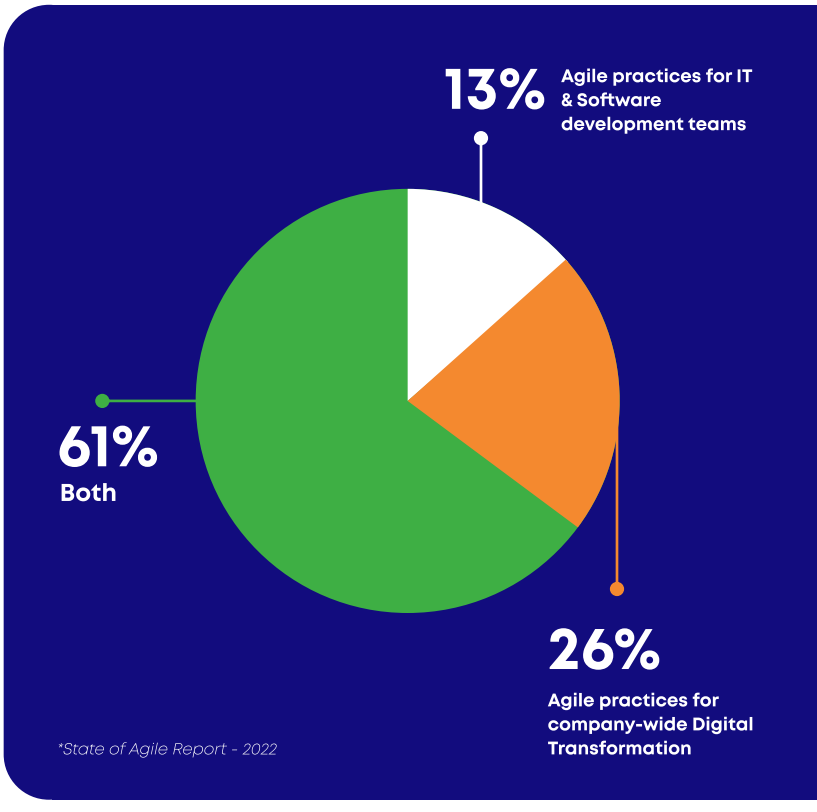
At the same time, did you know what the most reported benefits of digital transformation are?

According to a study from Parametric Technology Corporation, organizations mainly look to **improve operational efficiency (40%), achieve faster time to market (36%), and meet changing customer expectations (35%).**

Meanwhile, more and more companies agree that they use Agile practices to optimize the entire delivery cycle and support company-wide objectives such as digital transformation (Source: State of Agile, 2022).

In turn, this mostly results in better operational efficiency, which feeds into accelerated time to market.

Putting all the findings together, it seems that everything revolves around the wider topic of business agility.



While digital transformation can certainly help companies improve their operational efficiency, embracing agility alongside the transformational journey can stipulate better odds for organizations to achieve a first-to-market advantage and reduce risks.

The Pillars of Agility: Key Ingredients to a Transformation in Pharma

What we've discussed above is applicable to any industry, including the pharmaceutical sector. But just like anyone looking to initiate something new, it's important for pharma companies to do it gradually without revolutionizing what's already in place.

Instead of blindly adopting digital tools and reorganizing existing structures for the sake of cross-functionality, true business agility comes from:

- **Organizational transparency**
- **Strategic alignment (coupled with autonomous teams)**
- **Reduction of process waste and data-driven continuous improvement**

Combined, they form the foundation of organizational agility, which can help pharma companies propel adaptability across the entire drug development lifecycle and even beyond that.

The Question Is: How to Put Them into Practice?

Today, pharma companies have more choices than ever. From iteration-based frameworks such as Scrum to flow-based methods like Kanban, there is a plethora of approaches to agility that have been tested over the years.

Take the Kanban method, for example.

According to one of the recent "State of Kanban" reports, out of all surveyed companies in the healthcare and pharmaceutical sector:

70% **of respondents indicate that they find Kanban more effective than previous ways of working.**

**State of Kanban Report - 2022*

But in reality, it's not about picking an iterations-based over a flow-based model or vice versa because there are processes suitable for both. Instead, it's about taking an evolutionary approach to an Agile transformation, starting from understanding how you deliver work throughout the value stream and then experimenting with the different operating models.

At the end of the day, the first-to-market advantage comes from embracing the agility pillars regardless of how organizations decide to do it.

And yet, as Benjamin Franklin remarks: **"A good example is the best sermon"**, we've collected several real-life use cases from a pharmaceutical and biomedical environment which we're presenting below.

04

A Practical Approach to Lean/Agile Transformation in Pharma.

5 Real-Life Use Cases

For the purpose of this paper, we've interviewed several pharmaceutical companies to better understand where, why, and how they're using a Lean/Agile operating model.

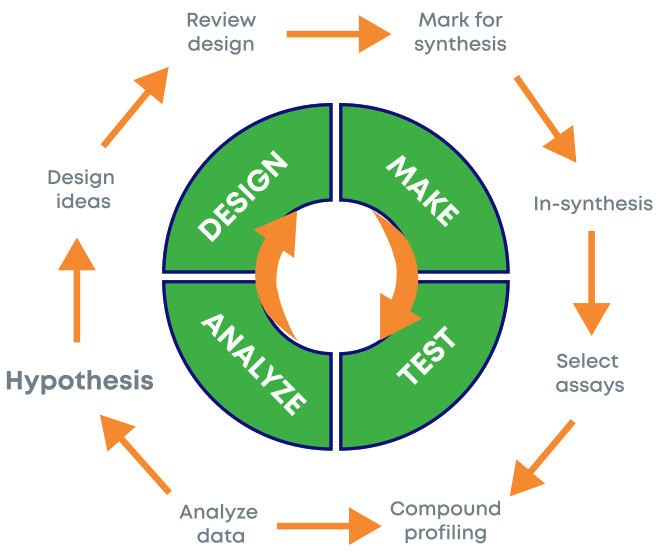
We've found that Lean/Agile practices get the most support across scientific and knowledge work teams.

Let's explore more.

01

Faster Drug Discovery Through Iterative Cycles & Visual Flow Management

The initial drug discovery work of scientific teams, such as reagent provision, antibody generation, biophysics, computational biochemistry, etc., is often characterized by cycles to prove hypotheses for prospective molecules. This naturally makes iteration-based ways of working suitable.



A common challenge, however, appears when those drug discovery teams need to coordinate their efforts and achieve a high-level overview of their flow.

This is what one of the pharma corporations we interviewed shared with us.

While implementing an iteration-based model (such as Scrum) on the team level, soon enough, they realized the need for complete transparency across the end-to-end drug discovery process.

To do this, they combined their iterative ways of working with a flow-based approach such as Kanban.

While teams kept using Scrum to move their work in cycles, they also visualized its status with the help of Kanban boards. The management, on the other hand, started building Portfolio boards to visualize the flow of work across the wider value stream and put on display the project portfolio. Eventually, all teams connected their boards to the Portfolio one, which allowed them to start using cadences to coordinate who is working on what and prioritize what's next in line.

To better understand key results with these ways of working, we ran a poll among some of the company's representatives. We found out that managers now have a much better understanding of their workflows and iterations. Most respondents remark that this enables lead time communication and better management of handoffs between teams/groups.

An interesting insight came from the Novel Biological Entity (NBE) managers, who responded that the addition of a Portfolio board on top of their iterations helps them to communicate project increments more efficiently than before. **As a result, they can get a better overview of the progress of all drug discovery projects, transmit incoming priorities in a timely manner, and ultimately shorten the experimentation cycles.**

02

Value Stream Mapping to Understand Demand & Manage Capacity Across Clinical Trial Processes

Another relevant use case for Lean/Agile ways of working in pharma is the clinical trials phase. Except for the huge lead times that this stage is characterized by, we found that a lot of pharma companies need to deal with many dependencies between data scientists inside the organizations and external medical entities which perform the actual trials.

To overcome such challenges, one of the interviewees shared with us their intention to better understand the entire value stream.

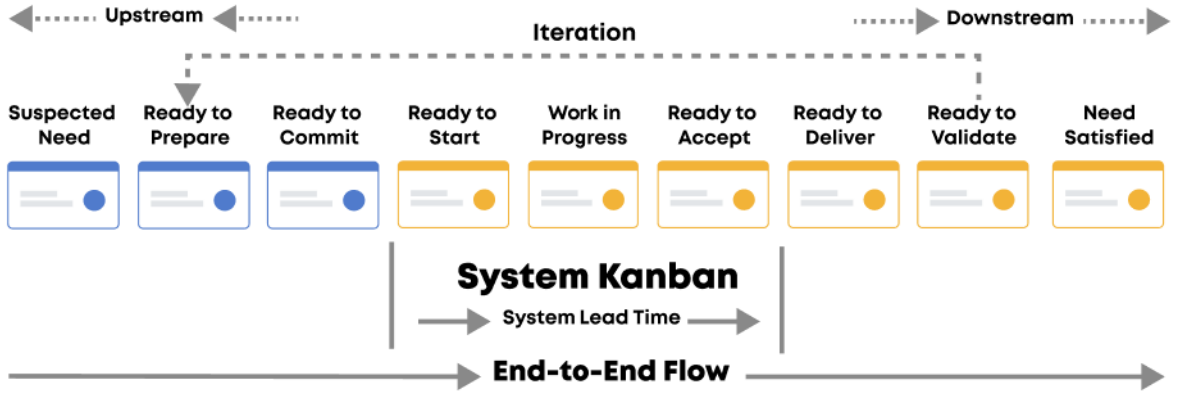
In their case, this means everything from creating trial protocols and gathering data from external entities to submitting inputs to medical documents. The pharma company aims to gain clarity over how work is handed off between teams for the preparation of a clinical trial, where their constraints are (both internal and external), and what parts of the workflow could be optimized to speed up the entire process.

This is how they found the Lean practice of value stream mapping, which they decided to implement through a flow-based approach like Kanban. All teams involved in the preparation and statistical analysis of a trial currently visualize their processes from beginning to end on digital Kanban boards.

While this includes the value-adding steps, the company was more interested in visualizing the non-value-adding activities (queues) to uncover bottlenecks.

This approach helps them understand where work is waiting, so they can implement policies (such as negotiating expectations for delivery times) to streamline their process. In addition, the company is also looking to experiment with other flow-based practices, such as limiting WIP (work in progress) to manage capacity and better match it with incoming demand.

By visualizing parts of the value stream, **the company already reports a better understanding of existing capacity levels and where dependencies form between the teams. As a result, they can begin alleviating bottlenecks and optimizing the flow of clinical trial work.**



03
Improved Planning in Lab Testing Through Lean/Agile Ways of Working

Moving forward, testing procedures in labs turn out to be another area that can benefit from a Lean/Agile operating model. Different representatives from pharmaceutical organizations have shared with us that from analytical processes such as method development to physical tests in labs, the work at this stage of the drug development can yield a lot of volatility due to changes in time or scope from the product/project side.

This was the case with the management in the lab testing area of another pharmaceutical organization we talked to.

Looking to handle the challenge of frequent scope/timeline changes, they embraced both an iterative and flow-based model.

Instead of working on big batches, they created a "Flight-Levels"* structure through a network of hierarchical Kanban boards.

**Flight Levels is a business agility concept for visualization and improvement of the workflow across different hierarchical level in the organization.*

While using a top-level board to map out the roadmap of long-term projects, the company implemented an "Epics" coordination board where they visualized the shorter-term deliverables and their distribution across teams.

Moving further down, the team-level Kanban boards are where the actual method development or physical testing work happens.

And while the product owners embrace a flow-based model for the management of demand on an epics/portfolio level, the teams use iterations to develop test protocols as soon as possible.

Due to the iterative ways of working, the management of the lab testing area shared with us that teams developed more predictable cycles for work delivery. As a result, they can now communicate with confidence what can be done in a given period.

Meanwhile, the implementation of flow on an epics/portfolio level helps product owners understand how bigger work packages move across various testing procedures.

Due to the hierarchical network of Kanban boards, they gained the ability to quickly communicate changes in scope or time with the teams. Ultimately, this results in faster re-planning and better adaptability to new requirements.

04

Identifying Waste & Improving Flow Across Multiple Departments

Other than the scientific process, the successful delivery of a drug to the market often requires coordination between multiple functions such as software development, IT, QA, technical support, etc. This creates complex interactions between many departments, which could lead to the accumulation of process waste and low-efficiency levels.

Throughout our conversations with one biotech company, we discovered that excessive process waste was the main challenge they were facing. Due to the complexity of their value stream, they were looking for a solution to better understand how knowledge work moves across external labs, product development, IT departments, etc.

This called for a flow-based approach, which the company started implementing. The initial goal was to reveal bottlenecks by visualizing where work spends time. This was done through a network of Kanban boards, which helped the company identify that their work spends almost 95% of the time sitting idle in queues instead of moving across the value chain. The network also allowed the company to gain a bird's eye view of how smaller work items are connected to bigger projects.

The main key result that the company shared with us is the improved awareness of how work moves all the way from lab work to a complete software solution. This allows them to start optimizing weak spots of the value stream and ultimately accelerate delivery cycles.

The network of Kanban boards helped the company identify that their work spends almost 95% of the time sitting idle in queues instead of moving across the value chain.

05

Lean/Agile Portfolio Management of R&D Projects & Goals Visualization

So far, we've focused our discussion on separate processes across the drug development lifecycle. But are Lean/Agile practices applicable across the wider R&D portfolio and strategy management inside pharmaceutical corporations?

In fact, throughout all of the interviews we conducted, most organizations shared with us one common challenge – difficulties dealing with constantly incoming demand from the portfolio side. And while most companies' response to this is usually to hire new people without realizing this can create too much overhead, Lean/Agile portfolio management proposes limiting how many projects can be in progress simultaneously.

In our interviewing process, we discovered that for most companies, this is the next phase of their Lean/Agile transformation journey. And while we don't have specific examples to share yet, we learned how one biotech company aims to scale its Lean/Agile operating model to the portfolio and strategy levels.

To do this, they're currently visualizing their so-called "Must Win" battles on a central Master board. Below it, they're planning to use the "Flight Levels" concept and tie in:

- **the top-level strategy**
- **the long-term projects that support it**
- **and the actual daily initiatives that teams are working on**

Through this structure, they're looking to understand how different types of projects from the portfolio are linked to the strategic goals. Based on this, the idea is to pick a limited number of long-term projects that contribute to the company's "battles" and ensure that they're done before moving to the next ones. Further down, teams are currently visualizing their initiatives and work items, so the management can stay aware of the status of work and reprioritize if necessary.

At the end of the day, no matter what the actual structure is, what's important is that it revolves around the agility pillars. The high-level transparency of work coupled with strategic alignment and optimization of the delivery processes can enable complete symbiosis within the organization and unlock its ability to react to changing market conditions in a timely manner.

05

The Strategic & Evolutionary Path Toward Digital & Agile Transformation in the Pharma Industry

Although it might be hard to imagine how a wide-scale transformation in one of the highest-regulated industries in the world can work, data shows that more and more pharma companies are hopping on the digital trend. And yet, many digital transformations still fail.

That's why investing in different technologies with the hope of gaining a fast route to operational efficiency is not enough. Instead, the key ingredient for a successful transformation lies in the organizational culture and the entire operating model. Enabling agility there means (1) promoting transparency, (2) aligning strategy with execution, (3) uncovering deficiencies, and (4) continuously improving.

So, our best advice is twofold.

First, make sure that there is support for the transformation at the executive level.

No matter if you approach it from a top-down or bottom-up perspective, our practice shows that executive leadership's involvement is absolutely vital.

Think of business agility as a global strategy instead of a practice that you apply to improve local flaws.

After all, just like the famous leadership consultant Dr. Russel Ackoff remarks **"A system is never a sum of its parts, it's the product of their interactions".**

Second, start with what you do now.

Understand how your organization manages work, gain an overview of the interdependent services across your organization, and then gradually evolve. Just don't go rushing into reorganizing what's currently in place without having context first. That's the definition of "doing Agile" without "being Agile".

And finally, if you're going to commit to one thing, let it be continuous improvement.

Because remember, every transformation (Agile or Digital) is never a sprint but a continuous journey toward excellence.

businessmap

Businessmap offers the most flexible software platform for outcomes-driven enterprise agility.

The unmatched functionality consolidates multiple tools into one, enabling affordable deployment at scale, visibility across all projects/portfolios and alignment on goals, to deliver quality work faster.

Pairing it with the proprietary consulting program creates a tailored solution that ensures lasting value and exceptional ROI.

Book a free consultation