White Paper Summaries

EMEA Thought Leadership
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For further information, please contact
ThoughtLeadershipGroup@iqvia.com

EMEA Thought Leadership: Our 7 Focus Areas

Contents

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Go-to-market

Published: July 2023

Launch Excellence VIII

Report summary

Launch Excellence VIII picks up the post-Pandemic story for innovative prescription medicine launches, taking the story right up to the end of 2022 across specialty and non-specialty launches from all therapy classes with innovative launches in 8 key markets: the US, Germany, France, Italy, Spain, UK, China and Japan.

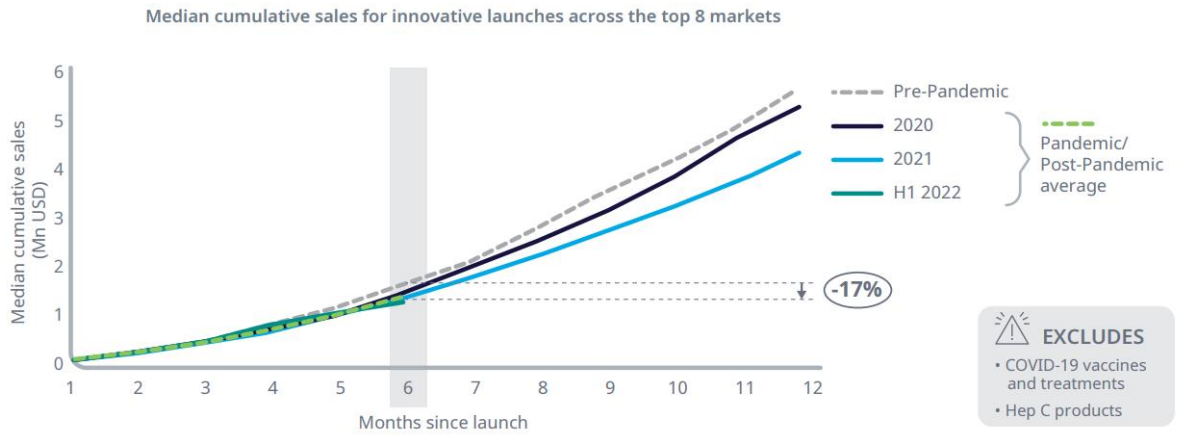
We examine how the fundamental rules of Launch Excellence have changed for the launches of 2020 onwards: the Pandemic added incremental challenges to achieving Excellent launch performance, and caused system changes to healthcare provision, healthcare professional engagement and healthcare budgets.

IQVIA previously identified three areas for incremental launch focus in the new environment as the “Three Pillars of Post-Pandemic Launch Excellence”. These pillars continue, but also evolve: early preparation of health systems to adopt new launches becomes even more important in resource constrained environments. Pharma must broaden its value proposition and engagement for new launches to meet wider health system needs.

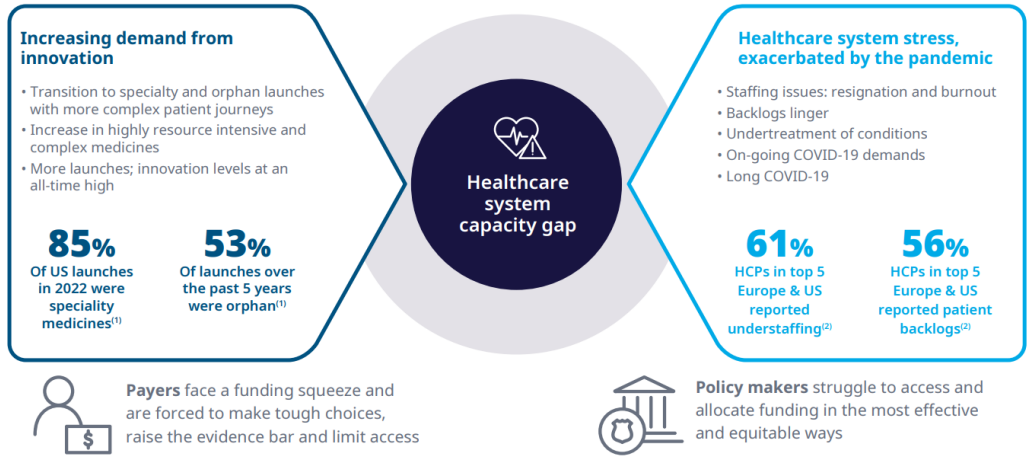
Key findings

- Launch sales uptake in the first six months and beyond is still below that of pre-Pandemic launches – in fact, for the 2022 launches, it is lower than for the 2020 and 2021 launches
- The six month window, the rule we have consistently found that 20% or fewer of launches make a significant uptake improvement after 6 months on the market, still holds for the launches from 2020 onwards, with only a slightly better prognosis
- Launches see lowered interactive engagement volumes with HCPs in most markets; however, the launches which are commercially Excellent by our criteria achieve higher interactive engagement volumes than non-Excellent launches

Performance of innovative launches pre- versus post-COVID-19



There is a gap in health system capacity which must be addressed to allow new launches to reach their full potential



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Published: February 2023

Success multiplied: Launch Excellence for Multi-Indication Assets

Report summary

Multi-indicationality offers commercial opportunities, but also presents strategic and operational challenges, such as deciding which indications to prioritise, optimal pricing strategies, and resource allocation. Despite these challenges, multi-indicationality has significant benefits, such as long-term revenue potential and leverage in payer negotiations or pan-indication synergies..

Launching a drug in multiple indications requires consideration of the "narrow-first" vs. "broad-first" sequencing strategies. The former approach allows for demonstrating superior outcomes in defined patient segments, generating real-world evidence and securing favourable pricing, while the latter maximises early revenue opportunities.

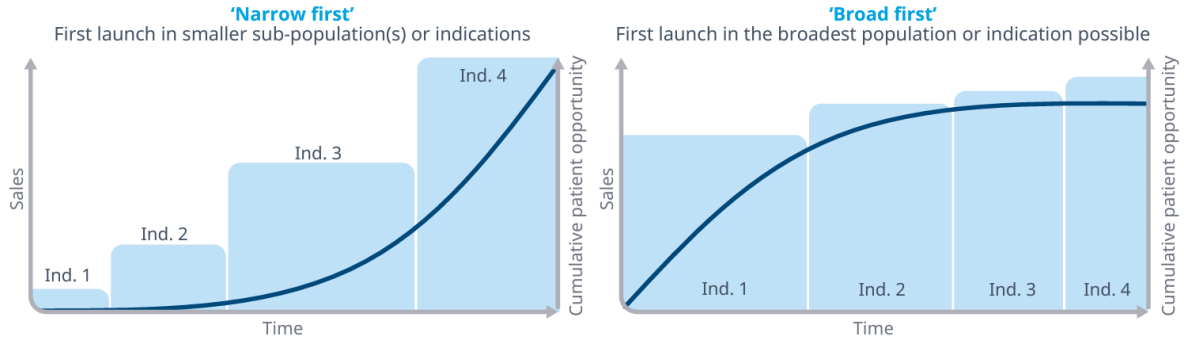
Getting the indication rollout right is crucial, with considerations towards unmet needs, differentiation of benefits, supporting evidence, market competition, speed of indication and launch consistency.

Pharma companies must aim for high performance consistency across the rollout of subsequent indications and countries to maximise the potential of a pipeline in a products.

Key findings

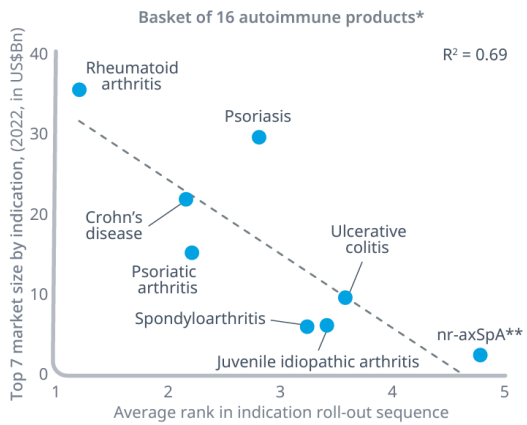
- Indications: launching in rapid succession without overstretching the organisation
- Pricing: innovative approaches anticipating impact of future rollouts
- Compelling evidence: sustained evidence generation and dissemination across all launches
- Adequate resourcing: competitive investments sustained across all launches
- Focused organisation: Maintaining momentum through optimal governance structure to enable consistent execution

Sequencing strategy archetypes for multi-indication launches

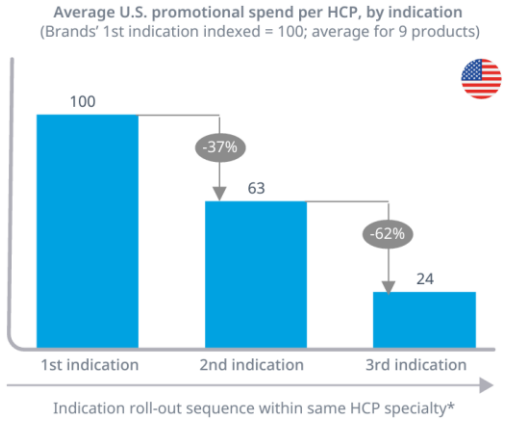


Case examples: What multi-indication launches have done

Indications sequencing



Promotional synergies



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Published: January 2023

Transcending the Traditional Focus of Oncology Commercialisation: How to succeed in an increasingly unforgiving oncology marketplace

Report summary

The oncology market is expected to continue growing at a rapid pace, driven by a high level of innovation and competition. At the same time, the space is characterised by significant complexity and challenges, including fragmentation of the market, shorter exclusivity periods, and the need for more complex, integrated launches. Additionally, post-pandemic customer expectations have changed, and healthcare systems are under significant budgetary and resource strain.

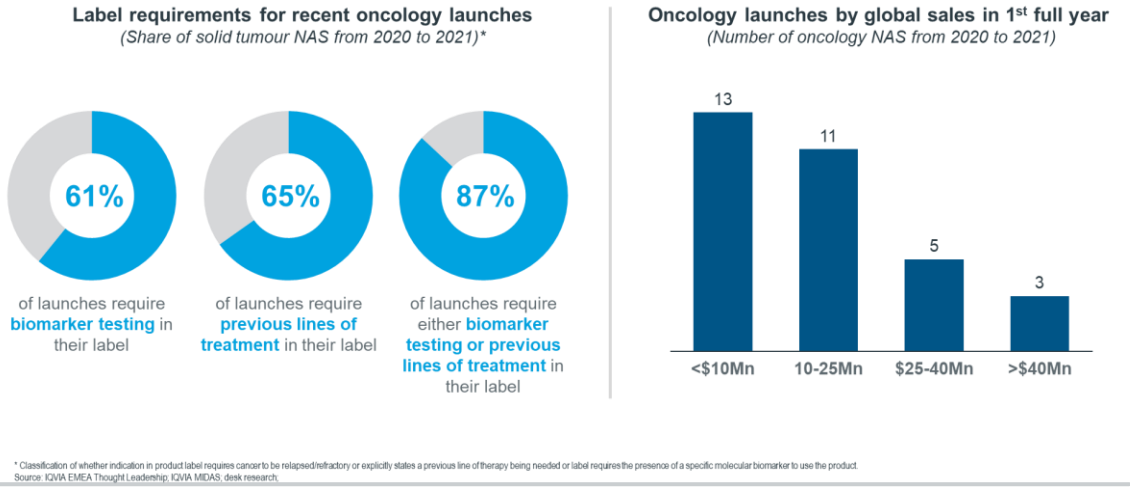
To succeed in this environment, companies must master the four key pillars of the new go-to-market model and crucially must understand in which specific market context they operate to determine how to apply these four key pillars. The market context is categorised into two archetypes primarily defined by their maturity: 'hypercompetitive' and 'underdeveloped'.

The four pillars consist of personalised insights, content and journeys, continuous, integrated evidence generation, solutions to optimise care pathways, and empowered and orchestrated engagement. In hypercompetitive markets, companies must activate demand while in underdeveloped markets, companies must invest in market shaping.

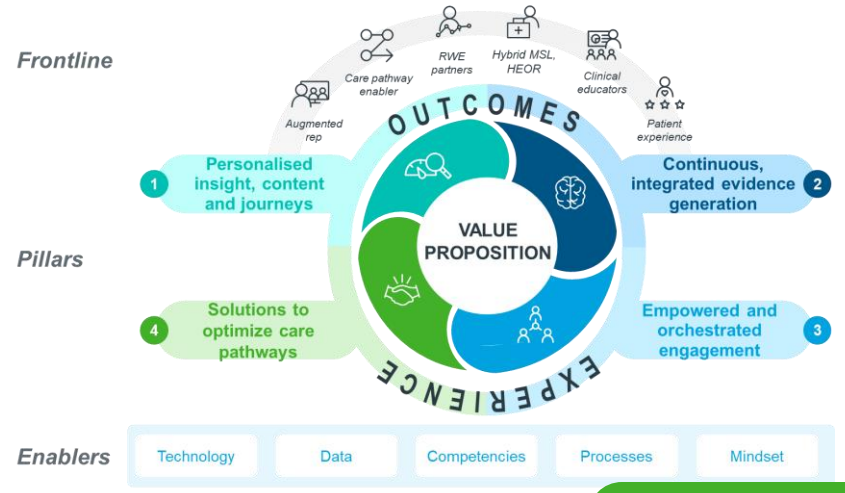
Key findings

- Commercial success in today's highly fluid and competitive oncology environment requires a new go-to-market model which transcends the traditional narrow focus.
- To succeed, innovators must understand in which of two market archetypes they operate: Hypercompetitive markets with an entrenched standard of care and/or a highly crowded marketplace or underdeveloped markets with high unmet needs and limited innovation.
- They must then master the four pillars of the new go-to-market model as they apply to the respective market archetype

Opportunity fragmentation and smaller oncology launches



The four pillars of the oncology go-to-market model



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Published: October 2022

Overcoming Pharma's Launch Performance Problem

Report summary

More than two years since the pandemic began, most non-COVID innovative launches are still not achieving their commercial potential in the major markets.

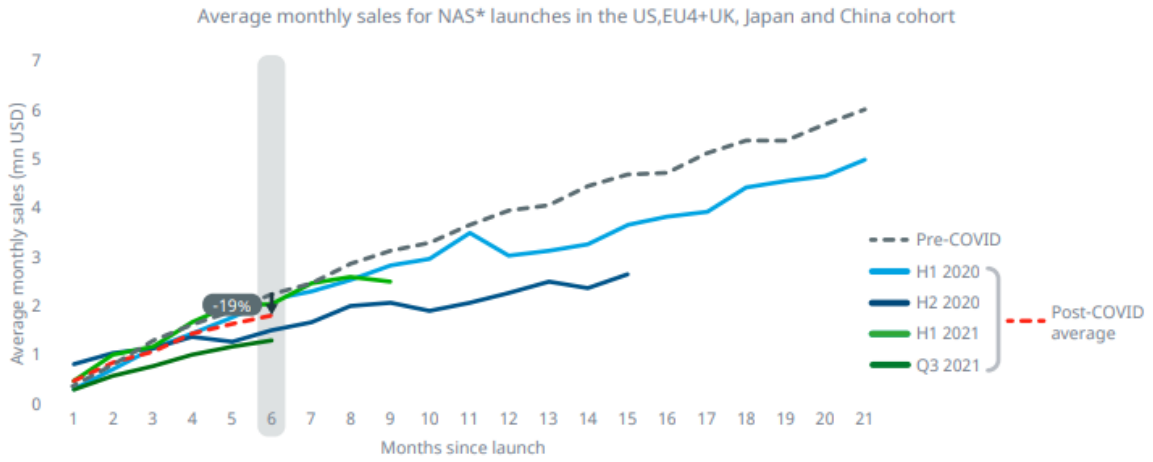
A storm of pandemic-accelerated factors combined, and continue to combine, to create an environment that hurts the sales performance of launches more than inline medicines. The pandemic made the patient journey to diagnosis and treatment more complex, reduced opportunities for pharma to engage with doctors on newly launched products, and worsened an already challenging economic situation, leading to payer constraints and a hardening market access environment.

There are non-COVID launches that have been resilient to the challenging environment, which demonstrate emerging common themes such as a combination of strong patient pipeline, strong clinical story and reduced healthcare burden (e.g. decreasing hospital visits, at home or rapid administration). From now on, it is critical that companies with launches understand the persistent challenges of the new environment and learn every lesson from the resilient pandemic launches to achieve launch success.

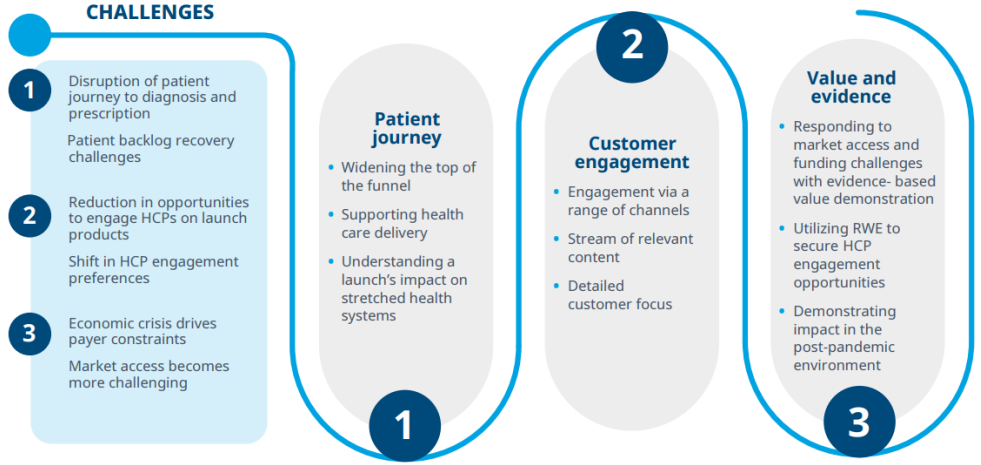
Key findings

- In 2021, innovative medicines were approved, launched and granted market access at rates above or closely similar to pre-pandemic benchmarks.
- Average sales for post-pandemic launches at month six are down by 19% on pre-pandemic benchmarks.
- Underperforming 2020 launches have not recovered from a slow start.
- Generally, orphan medicines are the most resilient group due to unmet need in small and well-defined patient populations.

Performance of innovative launches pre- versus post-COVID-19



The three pillars of launch excellence to achieve post-pandemic success



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Published: February 2022

Realising The Commercial Promise Of Europe For Emerging Biopharma

Report summary

Emerging biopharma companies (EBPs) have steadily expanded their role as key drivers of biomedical innovation over the past 15 years. Today, many EBPs choose to commercialise their assets themselves, to capture a larger share of the value. To maximise an asset's potential, it is important to enter the European market, the second-largest in the world after the US.

EBPs launching their products into Europe face significant challenges. The market landscape is complex, requiring EBPs to navigate different healthcare systems, regulatory, market access and reimbursement environments.

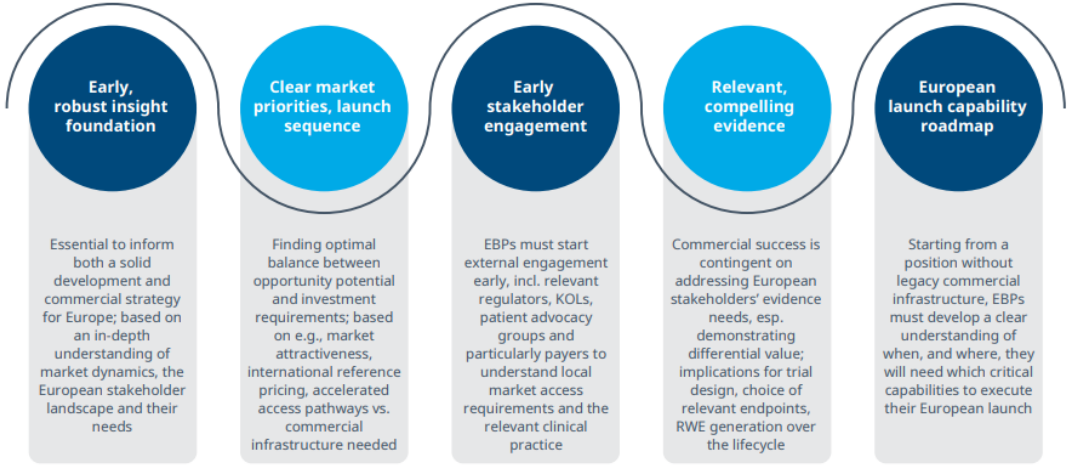
Many EBPs have never launched a product before. As such, they must fundamentally change their organisational mindset, from focus on science and clinical development to driving business results.

Establishing a successful commercial organisation in Europe requires careful trade-offs. EBPs need to make a number of strategic choices that define the optimal configuration and scale of their launch infrastructure. These choices often involve deciding between building capabilities in-house and when to find external partners.

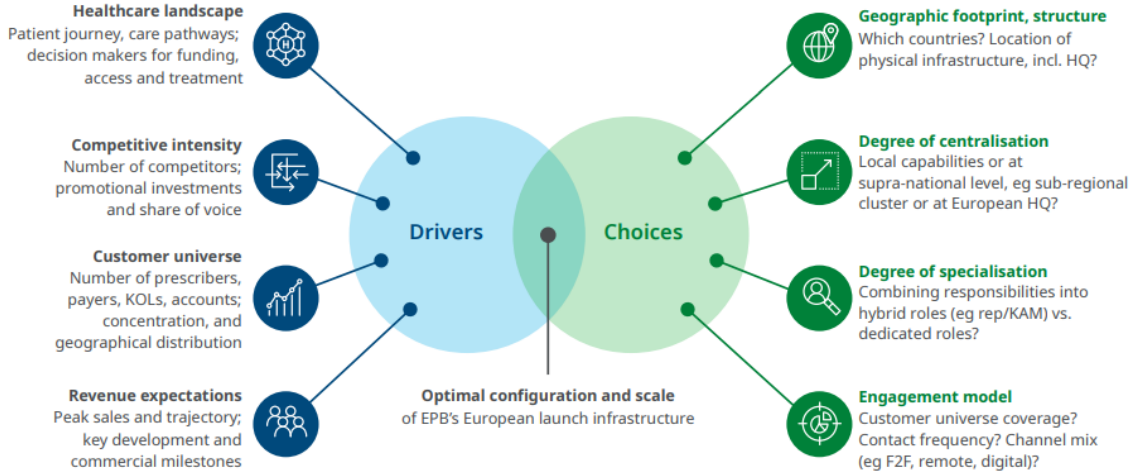
Key findings

- In the last decade, 42% of all new active substances commercialised by EBP originators were launched by those same EBPs in Europe.
- EBPs launching in Europe must focus on 5 CSFs: insight foundation, country sequencing, stakeholder engagement, evidence, capability roadmap
- Case study outcome: By tapping into IQVIA scale, technology and domain expertise, the EBP was able to rapidly close critical capability gaps and dramatically accelerate timelines for evidence generation and launch readiness.

Five critical success factors for EBPs launching in Europe



Drivers of European commercial infrastructure and key choices



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Published: September 2021

Launch Excellence: Escaping the Complexity Trap

Report summary

The pharmaceutical industry has seen an increasingly complex environment for launching new products over the past decade, driven by trends such as the introduction of new types of innovative products, a shift from primary to specialty care, and the need to target smaller patient populations.

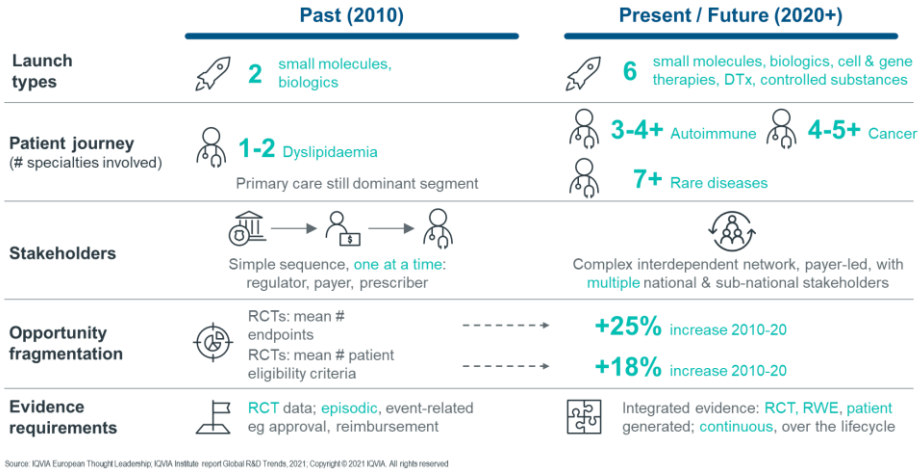
Consistency of launch performance across countries has been a perennial challenge, and the COVID-19 pandemic has added further complexity. Launches show wide variations in local performance and even excellent launches still exhibit considerable variance in market share attainment. Improving launch consistency is imperative for pharmaceutical companies to maximise the value of their assets, yet IQVIA has found that there is an inverse relationship between the number of launches a company has in a given time period and the proportion of those launches that are excellent.

Mergers in the pharmaceutical industry can also cause disruption and complexity, leading to lower launch performance during the "peri-merger period." Companies must assess specific complexity challenges for a given launch and focus on ways of working, structure and governance, and resource ownership to mitigate the negative impact of complexity on launch performance.

Key findings

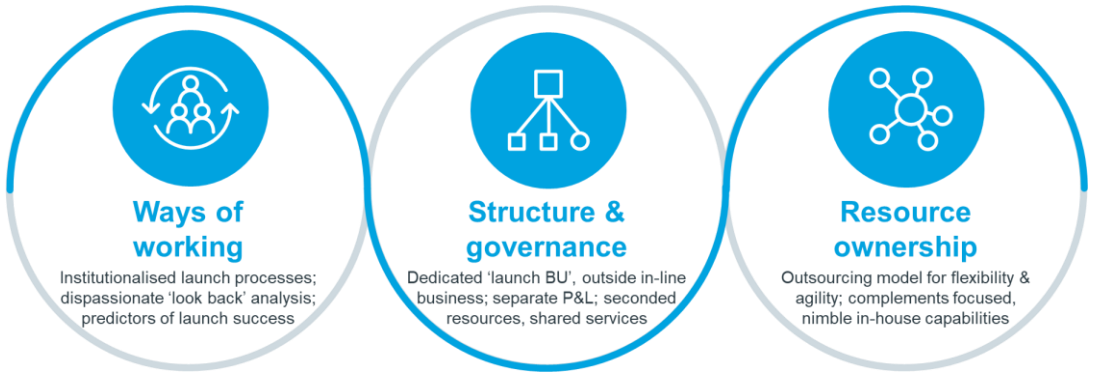
- Complexity is on the rise, driven by novel therapies, more complex patient journeys and stakeholder networks, opportunity fragmentation, and higher evidence demands
- When it comes to multi-launch performance consistency, three proficiency tiers can be identified, with companies in the top tier able to handle three times as many launches as companies in the bottom tier and still achieve 10% excellent launches
- To escape the complexity trap, companies must focus on three areas: ways of working, structure and governance, and resource ownership. Temporary dedicated launch business units and outsourcing critical capabilities can be potential solutions.

The increasingly complex external launch environment



Source: IQVIA European Thought Leadership, IQVIA Institute report Global R&D Trends, 2021.

Escaping the complexity trap – three focus areas



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Published: September 2021

Launch Excellence VII: The three pillars of post-Pandemic Launch Excellence

Report summary

We apply our established launch excellence methodology to the latest pre-pandemic cohort of launches and find that launch excellence remains exclusive for most, with 6% of specialty and 4% of primary care launches excellent internationally.

Whilst the launch landscape has evolved dramatically, there's some consistent launch principles holding true for the latest pre-pandemic launches. First, eight country markets are responsible for 90% of launch success in the first five years on the market. Second, less than 20% of launches significantly improve their launch trajectory beyond 6-months. Third, we find a tiered inverse relationship between the number of launches by a company and launch performance, suggesting the complexity of handling multiple launches outweighs the potential advantages of a greater level of experience.

Importantly, new analyses demonstrate the pandemic had a negative impact on the first 6-months sales of launches since 2020, due to substantial changes in aspects of the healthcare environment critical to launch.

We identify three critical pillars of post-pandemic launch success for achieving launch excellence in the new environment: patient centricity, customer re-engagement and integrated evidence strategy.

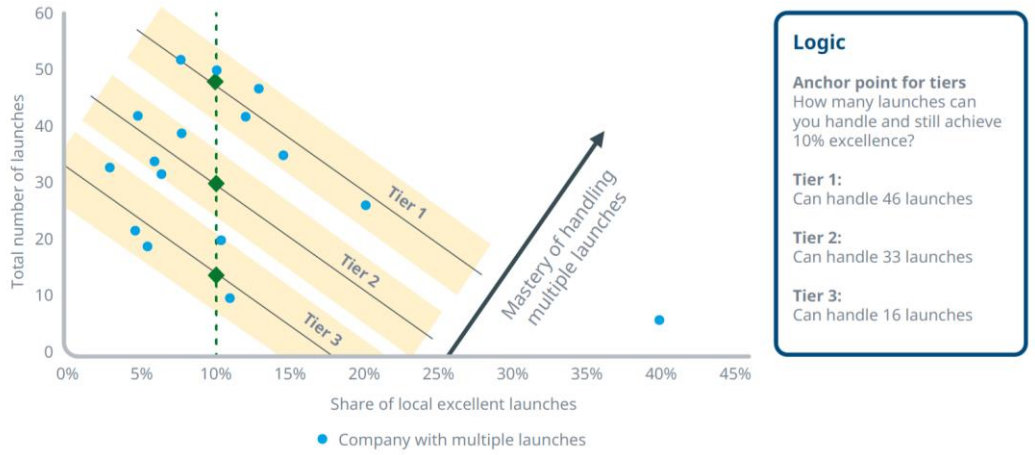
Key findings

- 6% of specialty launches and 4% of primary care launches are excellent internationally
- Only 20% of launches significantly improve on their trajectory beyond 6-months (with only minor exceptions to this rule since the Launch Excellence series began in 2007)
- First 6-month sales of Pandemic-impacted launches are generally down relative to pre-COVID benchmarks.
- Resilient launches that succeed post-pandemic enter areas of high unmet need, offer self/home administration, provide low-cost options or treat a later stage of disease.

Evolution, then disruption in the Launch Environment

	Past (2010–2013)	2014–2019	Future (without Pandemic)	Future disrupted (post-Pandemic)
Stakeholder environment	Simple- payers then prescribers	Complex- web of stakeholders, payer-led	Personalised and patient journey based	Patient journey complexity increased
Customer engagement model	Share of voice, rep-led	Multichannel, digital share higher for successful launches	Orchestrated for individual prescriber journeys	More remote, hybrid model, engagement and impact challenge
Payer priorities	Price	Value based, health technology assessment	Outcomes, RWE, new funding approaches	Budgets tighten, evidence bar raised
Launch positioning	First line, mass market	Later line, segmentation	Companion diagnostic, biomarker, genotype	Challenging in complex, uncertain environment
Launch type	Small molecule and biologic increasingly specialty	High cost specialty Orphan Medicines Cell and gene therapies	Further diversification: digital therapeutics, diagnostics	Launches self/home administrable have new advantage
Company type	Top 20 Pharma	Small, mid-sized pharma launch success	Non-conventional pharma companies enter	Digital players surge

Launch Excellence Consistency by Company



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Published: June 2021

No more surprises: Understanding predictors of launch success

Report summary

Launch represents the single-most important event in a product's lifecycle, and the stakes for getting it right could not be higher. 10% of launches achieve launch excellence, and further, 80% of launch trajectories are determined in the first six months. The Forxiga DECLARE launch was a landmark indication expansion in diabetes, and was used as an exemplar to help answer two key questions:

1. What local pre-launch metrics correlate with launch success at country level?
2. What physician-level metrics correlate with greater post-launch brand usage?

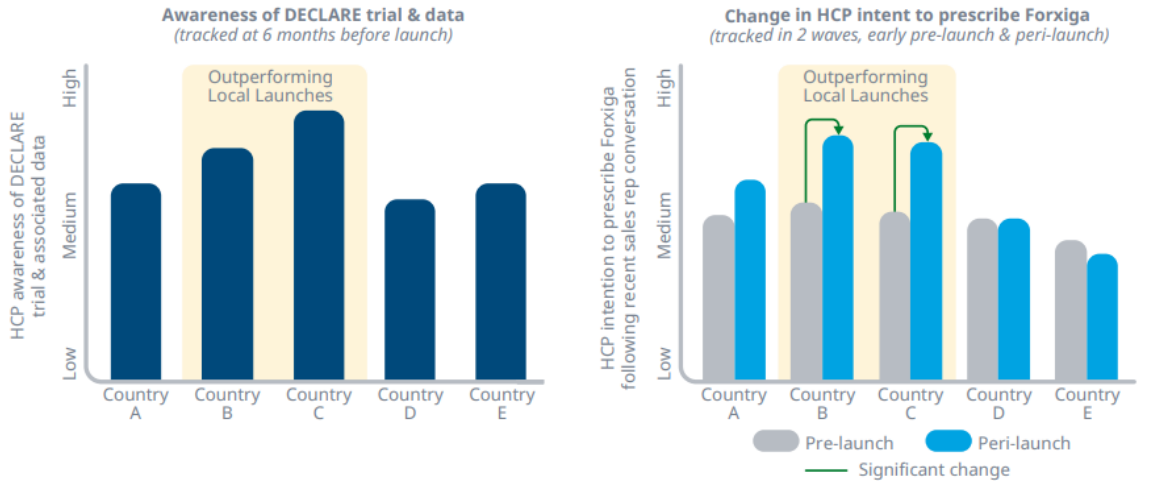
Four external, pre-launch metrics have shown strong correlations with more successful Forxiga DECLARE launches at a country level. Three pre-launch and three post-launch HCP perceptions of Forxiga were identified, which corresponded to high prescribers of Forxiga.

Understanding these early predictors of success will equip teams with actionable foresight to avoid surprises and keep their launch on track.

Key findings

- Four country-level pre-launch indicators of Forxiga success: HCP awareness of the DECLARE clinical trial, increased willingness of HCPs to recommend and prescribe the brand, a strong Net Promoter Score vs. competitors, multichannel engagement.
- HCP-level drivers of Forxiga launch success found among high prescribers:
  - Pre-launch: perceptions of quality of rep engagement, number of rep visits, brand attributes, eg efficacy and safety.
  - Post-launch: perceptions of quality of rep engagement, number of rep visits, tangible hard-outcome benefits of the brand.

Early predictors of local success: awareness and intent to prescribe



Key post-launch drivers found among high prescribers of Forxiga

Source: IQVIA Channel Dynamics; AZ | GIACE - IQVIA Launch Excellence Partnership, 2021

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Published: March 2021

Editing the DNA of pharma go-to-market models

Report summary

The COVID-19 pandemic has led to a significant shift in the way organisations operate, with a heightened focus on technology adoption and agile working practices. The pharmaceutical industry has not been immune to these changes, with the pandemic having a negative impact on product launches and growth due to reduced face-to-face interactions between patients and healthcare professionals. To address these challenges, companies must evolve their go-to-market model (GtM), considering rising pressures on margins, increased competition, and the need for digital engagement.

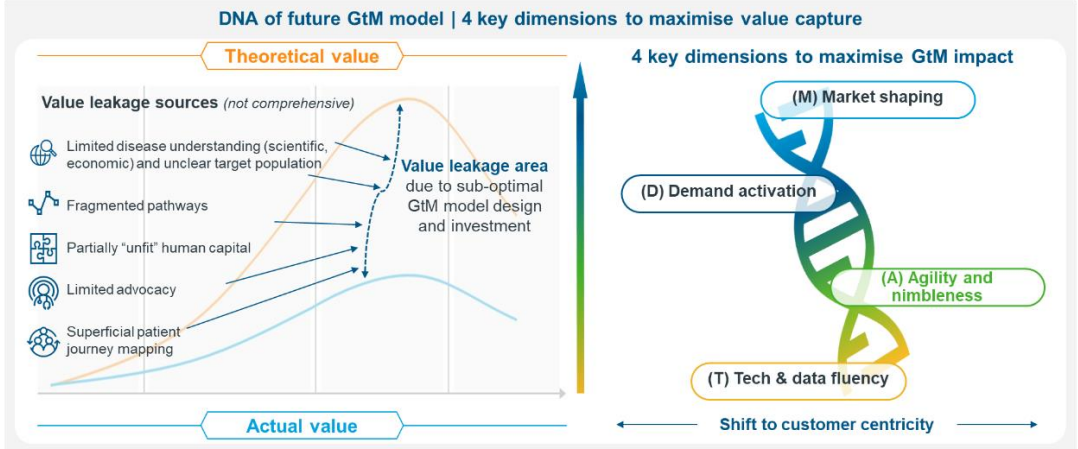
The GtM value compass is a four-part model designed to maximise product adoption and create a superior customer experience.

This model includes market shaping, demand activation, tech and data fluency, and agility and nimbleness as key dimensions. Companies must tailor their transformation roadmap to align with the relevant GtM archetype defined by product differentiation and market maturity.

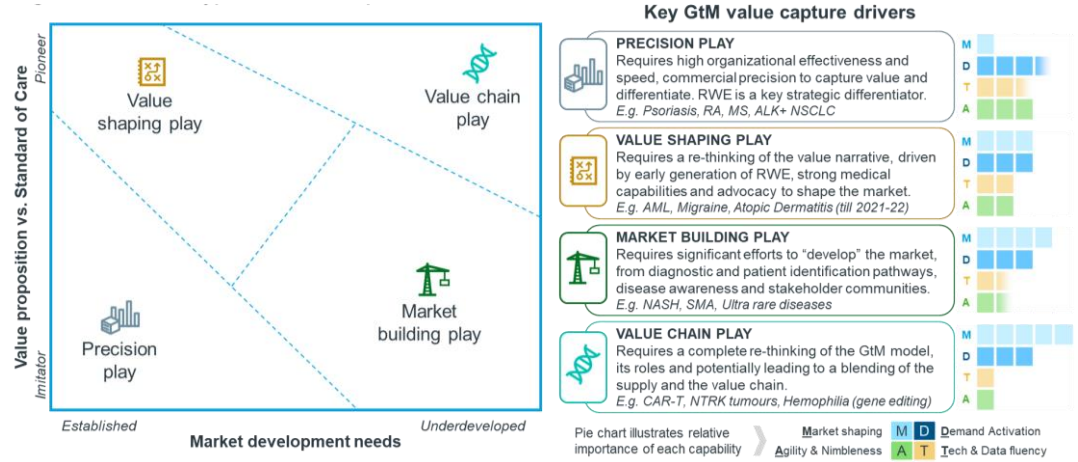
Key findings

- Increasingly accustomed to more personalised, on-demand services and less tolerant of poor or fragmented experiences, customers will demand significantly more of manufacturers.
- To remain relevant and prepare for the future, pharma companies need to focus on four transformation priorities: Envision, Design, Fund, and Rewire.
- Companies must seize the transformation momentum unleashed by the pandemic and establish a future-proof go-to-market model for a post-pandemic world to deliver superior customer experiences and achieve commercial success.

Value leakage sources and DNA of the Go-to-Market (GtM) model of the future



GtM archetypes and value capture drivers



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Published: October 2022

Re-defining OPEX modelling for a competitive future

Report summary

Pharmaceutical companies need to update their operating expense (OPEX) assumptions as outdated strategies are no longer applicable in today's post-pandemic landscape. Companies must adapt to changing market dynamics and stakeholders' needs, shift their go-to-market models and channel mix, and evaluate and prioritise early-stage assets with precision to ensure commercial success.

To maximise launch potential, OPEX spending must be rebalanced to accurately reflect shifting trends, enabling smarter decision-making for optimal asset or franchise value. Many companies partner with IQVIA to inform their investment and launch strategies, combining deep market expertise with practical experience in commercial strategy and launch. A more robust approach to OPEX modelling helps companies create targeted asset plans that better align with the complexities of the current healthcare environment.

OPEX modelling won't guarantee a successful launch, but it can give pharma leaders greater confidence in their investment decisions and go-to market plans, thus minimizing the risk of over/under-investment in an ever-changing environment.

Key findings

- Despite significant changes to launching in a post-pandemic world, many companies still plan OPEX with traditional assumptions, such as OPEX = 15-20% of revenue.
- In order to succeed in today's changing launch environment companies need to challenge the way they plan OPEX, helping to build rigour and consistency into launch planning.
- Leveraging industry benchmarks, launch expertise and Launch performance Indicators gives pharma the insight they need to model scenarios and optimise investment decisions for better market results.

Increasing cost and complexity of launches

Increasing frequency of new launches (number of NAS launches, '21 vs. '16)[1]

2x

Increase in New Active Substance launches (84 in '21 vs 41 in '16)

Growth of innovative MOAs and orphan launches (share of FIC and orphan launches, '21 vs. '18)[1]

+18% *Increase in share of first-in-class drug launches* **&** **+10%** *Increase in share of orphan drug launches*

Rising pressure on margins & intensified competition (CAGR, '15-'19)[2]

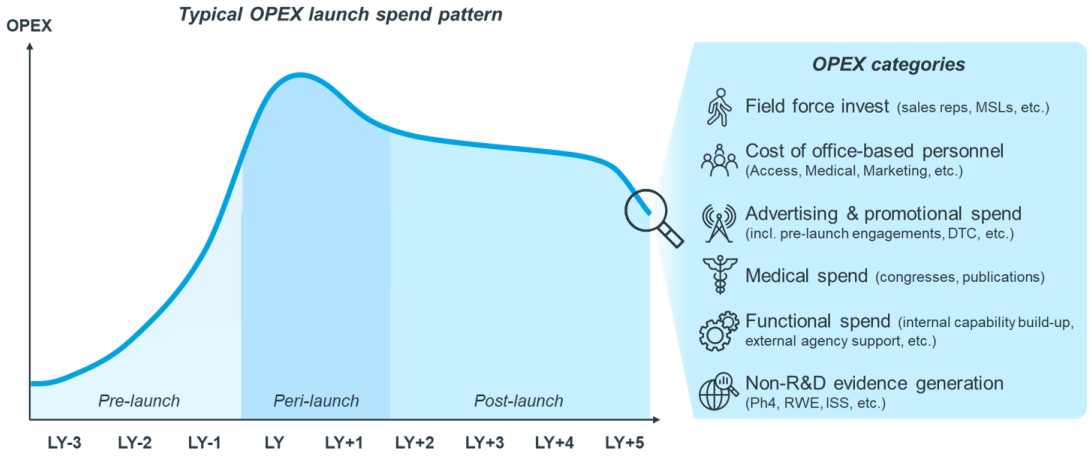
+6.2% *COGS* **vs.** **+3.9%** *Sales*

Fundamental change to HCP engagement (share of remote engagement)[3]

12% *2010* **vs.** **51%** *2020*

Yet many companies still plan OPEX with traditional assumptions such as OPEX = 15-20% of peak sales

Typical OPEX launch spend pattern and categories



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Published: December 2021

HCP Channel Preference in an Increasingly Complex Promotional Landscape

Report summary

Traditional promotional channels were significantly affected due to the imposition of in-person restrictions during the pandemic. As a result, across major global markets, the way Healthcare Professionals (HCPs) interact with industry has changed and many now choose to use digital channels for updates on new products and treatment options.

Balancing the mix of promotional channels to achieve maximum impact is crucial, with companies needing to identify the most effective channels for each HCP type and allocate resources accordingly. Different channels must be integrated seamlessly and used in a complementary way to provide an optimal experience for HCPs.

Winning engagement strategies will need focus on three key priorities:

• Identifying the **right customer** through granular segmentation based on a deep understanding of their information needs and channel preference.

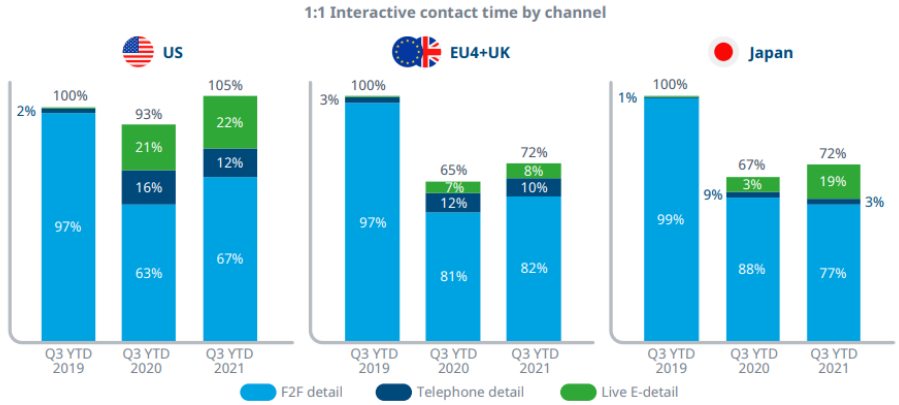
• Delivering the **right value** by creating an individualised customer experience.

• Building the **right orchestration** through an intelligent hybrid model supported by data-driven insights.

Key findings

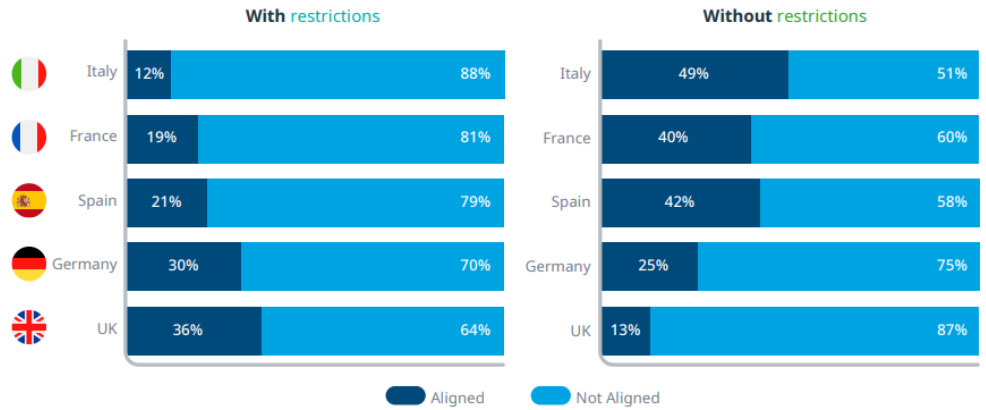
- In the EU4+UK, where digital share rose to 14% of total spend in 2021, only 8% of interactive time was delivered by live e-detailing.
- HCP responses to how satisfied they are by virtual interactions varied significantly between regions. In the EU4+UK and Japan, around 40% of HCPs agreed that virtual interactions could be completely sufficient in meeting their needs.
- In reality, either with or without COVID-19 restrictions in place, there is <50% alignment between what HCPs want in terms of channel preference and the channel through which they receive information.

The amount of interactive time with HCPs is still well below pre-pandemic levels in Japan and Europe



Source: IQVIA EMEA Thought Leadership; ChannelDynamics Sept 2021

There is low alignment between preferred channel and actual received channel



Source: IQVIA ChannelDynamics Channel Preference Survey July 2021; IQVIA ChannelDynamics Daily Diary Survey information Jan 2020 to June 2021

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Published: March 2020

Excellent Launches are Winning the Evidence Battle

Report summary

In an increasingly unforgiving launch environment, Real-World Evidence (RWE) has emerged as a strategic differentiator for launch success.

A product's success depends on regulatory approval, market access, and adoption. RWE is crucial in convincing stakeholders of its benefits and safety, while enabling is adoption and optimal use in routine practice. Compelling RWE-based news flow must address demands for more information and proof points along the product lifecycle, while creating engagement opportunities for capturing HCPs share of mind.

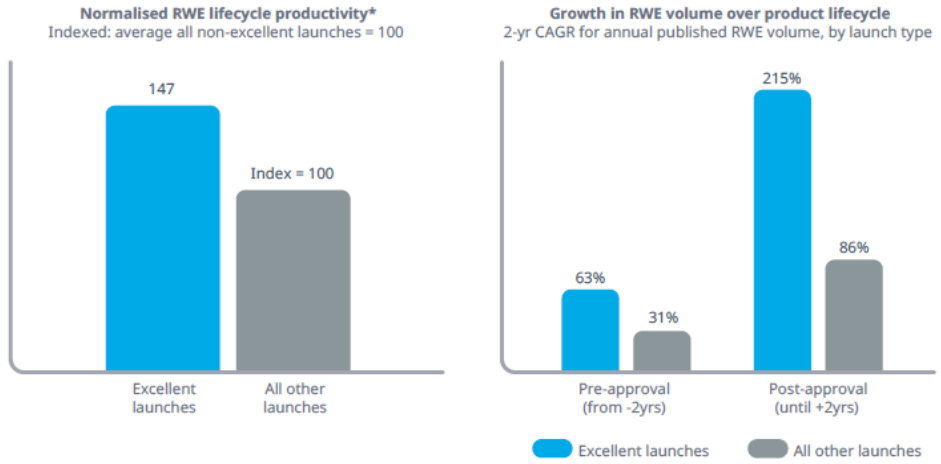
The are several key findings: excellent product launches generate more published RWE and faster, and sustain high levels of RWE productivity throughout their lifecycle. Crucially, the focus of RWE publications must evolve over the product lifecycle to reflect healthcare stakeholders' different evidence demands at different points in time. It typically shifts from generating insight to demonstrating real world outcomes. Additionally, the analysis highlights therapy area-specific trends in the use and focus of RWE.

In conclusion, companies must embrace RWE as a true strategic asset and novel source of competitive advantage to achieve launch success.

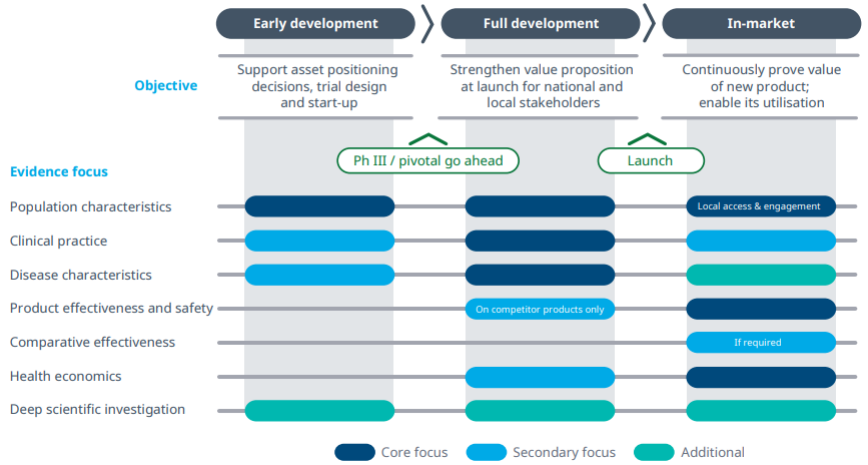
Key findings

- RWE plays a crucial role in addressing healthcare stakeholders' growing evidence demands
- RWE dissemination typically starts two years before product approval, with RWE volumes doubling year after year. This requires a committed and proactive approach
- Excellent launches generate more RWE volume and do so faster than non-excellent launches, and they also maintain competitive levels many years after launch
- Excellent followers make greater use of early RWE to generate insight on incumbents

Excellent launches generate more RWE, faster



Systematic RWE planning must start early and anticipate future needs



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Technology

Published: December 2023

At the Cutting Edge: The Rise of AI and Technology-enhanced Customer Engagement in the Life Sciences Industry

Report summary

The life sciences industry is undergoing a significant transformation, with artificial intelligence (AI) enhancing engagement with HCPs.

This white paper highlights the evolving engagement landscape, including the changing HCP demographics and the need for integrated customer engagement ecosystems. Ideally, these must include AI-enabled Next Best recommendations to inform the optimal interactive approach for individual HCPs.

The paper explores the use of technology across a variety of use cases from acting on real-time analysis produced by AI, building intelligent and dynamic customer personae and enhancing the speed of business operations.

Content creation is also a key area of opportunity, helping life sciences companies to quickly build a bank of pre-approved materials, taking advantages of the benefits that a large language model brings.

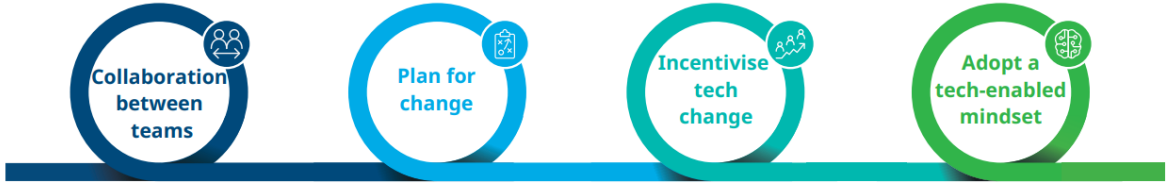
The paper concludes by referencing the importance of managing tech-orientated business change. Companies need to appreciate that it is people who will drive processes and workflows improvements that allow organisations to make the most of operational efficiencies through technology.

Key findings

- Only 12% of interactions across the EU4+UK involve sharing digital content using a portable handheld device
- AI regulations and the quality of prompt engineering (i.e., the preciseness of the question that is fed into a platform like ChatGPT) must be carefully considered to achieve an accurate desired output derived from AI.
- Three overarching themes lead to best practice: building a precise customer insights foundation, accelerating operations through AI-driven algorithms and managing tech-orientated business change through competent and capable people who are open to new processes and ways of working.

Set of IQVIA Next Best algorithms to support engagement with HCPs

Change enablers to embrace technology



- Encourage collaboration among stakeholders
- Bring together strong technical expertise

- Plan for change resistance by consulting cross-functional teams to understand tech-focused tech enhancements

- Incentivise uptake of tech
- Reward tech-enhanced changes

- Instill a tech mindset to develop new skills
- Upskill existing talent

Download here

Published: February 2023

From Surviving to Thriving: Changing the Paradigm of HCP Interactions

Report summary

The COVID-19 pandemic changed how HCPs and biopharma industry engage with each other. Commercial models are shifting to become increasingly digital and there is a clear need for personalised and valuable interactions across a variety of channels.

Many life sciences companies are making the transition towards omnichannel engagement but change management and people are perceived as the largest obstacles to overcome. It is crucial to take people on the journey, ensuring change transcends individuals, teams and the entire organisation.

To enable successful business transformation, companies must adopt a next best mindset approach, bringing together customer insights, an openness to change and digital capabilities to deliver an optimal and seamless experience across all touchpoints.

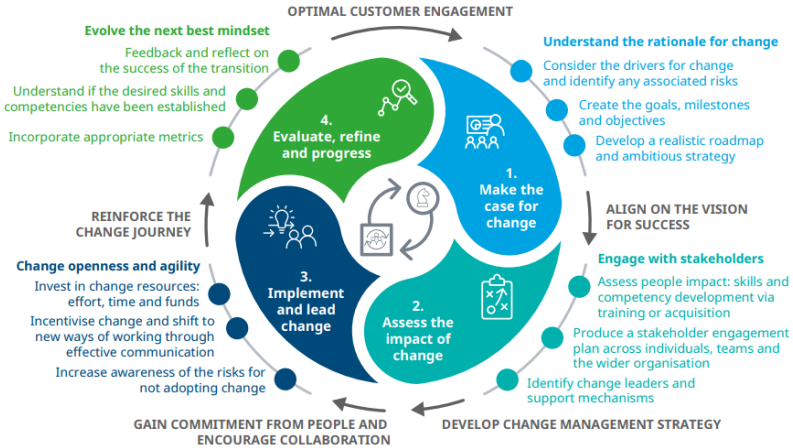
Implementing the omnichannel shift is perceived by many companies as challenging and the 'people-focused model for change' breaks down the transition to omnichannel engagement into 4 manageable steps, aiming to help facilitate and simplify the process.

Key findings

- IQVIA survey showed 82% of respondents are transitioning to omnichannel
- 67% perceive change management to be the most important challenge
- Face-to-face interactions are most appropriate to discuss a newly launched drug, new data/clinical trials, info on a new licensed indication or formulation
- Successful change management programs have a clear vision from senior leadership, high stakeholder engagement and appropriate investment of resources.

Setting out the elements that feed into the Next Best Mindset

A people-focused change model, aiming to progress hybrid and omnichannel customer engagement for life sciences organisations



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Published: July 2022

Riding out the storm: the future of post-pandemic customer engagement

Report summary

The COVID-19 pandemic greatly disrupted customer behaviours and how HCPs engaged with the life sciences industry. In particular, face-to-face interactions decreased across the EU4+UK during the peri-pandemic period and many companies reactively turned to using digital channels.

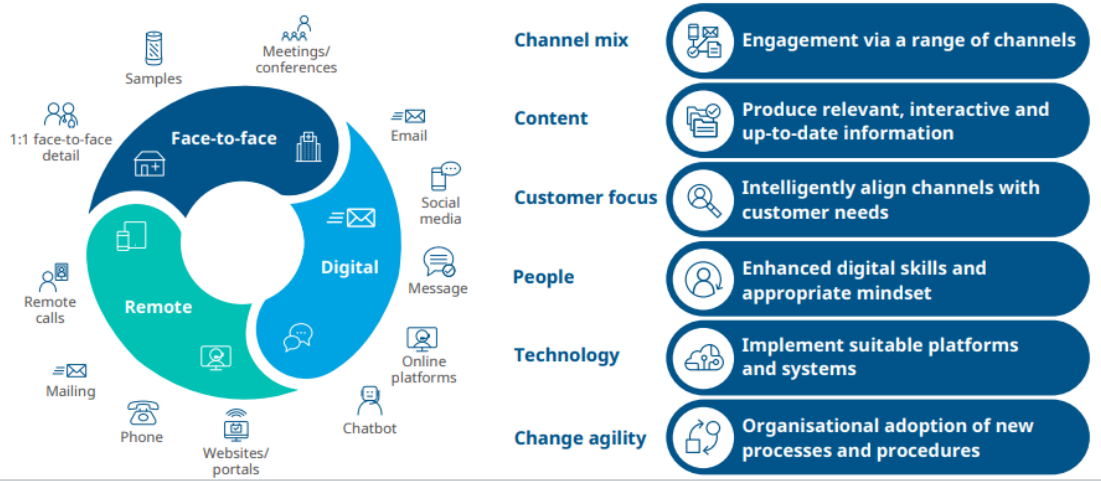
As the promotional environment stabilises across major markets, companies must adapt to the new reality of customer engagement. This involves developing future-proof commercial approaches that are flexible and strike an appropriate balance between digital and traditional methods. In addition, organisations that develop digital capabilities and invest in technology infrastructure will build a strong competitive advantage.

Companies must endeavour to create a customer journey that is joined up across all touchpoints and an omnichannel experience that aligns with HCP preferences. The aim is to ensure lasting and strong relationships are established and maintained when operating in a post-pandemic landscape.

Key findings

- Total promotional spending on remote 1:1 detailing experienced a four-fold uplift between Q4 2019 and Q4 2021.
- The total time that industry spent digitally interacting with HCPs increased by almost 700% between 2019 and 2021 across the EU4+UK.
- Companies must focus on 6 key enablers when deciding on an optimal commercial approach and, from a channel perspective, orchestrated, hybrid and omnichannel operating models are central to success in the post-pandemic world.

Circular customer engagement flow and six enablers for future success



Future attributes of people in customer facing roles

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RWE, Market Access & Medical

Published: November 2023

In pursuit of Medical Launch Excellence

Report summary

Medical affairs can make or break a successful launch. Here, we discuss the critical role of Medical Affairs in driving launch success building on IQVIA's legacy Launch Excellence research, which studies the performance of innovative product launches to understand the drivers of success.

The role of medical during launch is pivotal in driving success against the three pillars of Launch Excellence: Healthcare System Readiness, Content-Driven Interactive Engagement, and Timely and Compelling Evidence. Medical Affairs is positioned as a key enabler in all three of these areas, providing deep insights into healthcare stakeholders, patients, and disease areas.

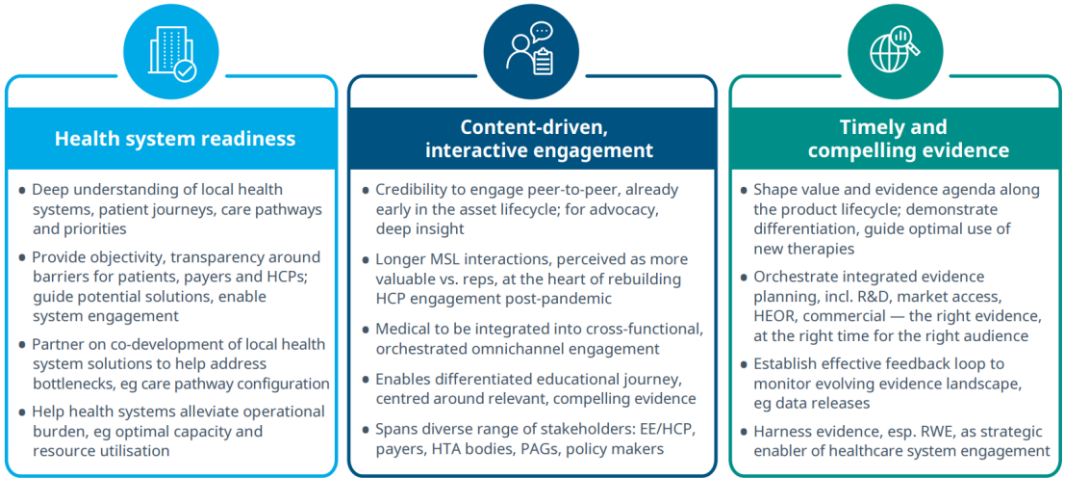
Medical must be part of early launch preparations, cross-functional collaboration, with its deep understanding of the practical realities experienced by health systems. Moreover, medical affairs is important in shaping an integrated evidence strategy to secure approval, access, and adoption of new therapies.

The unique insight of medical affairs is a key prerequisite for making optimal decisions about the brand strategy which positions the function as the ideal orchestrator planning activities from pre-launch to commercial execution.

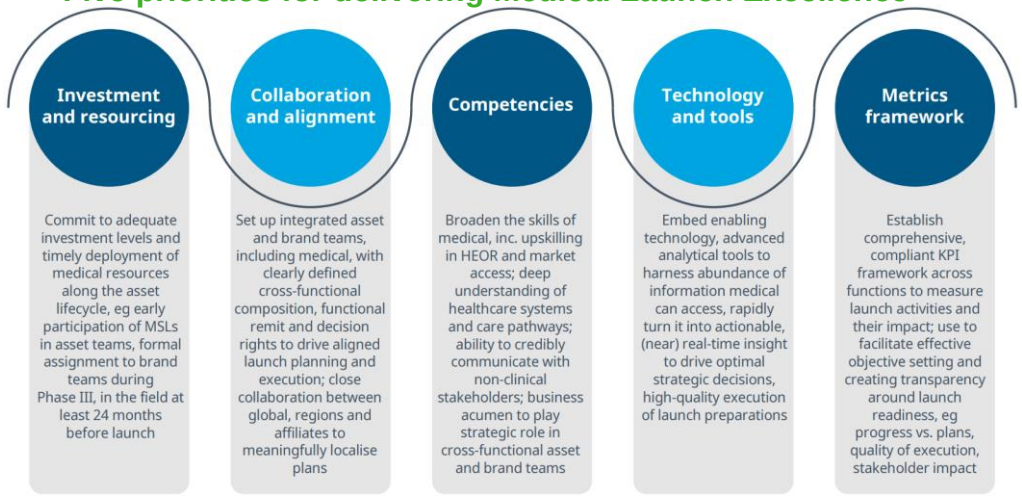
Key findings

- The strategic pillars of Launch Excellence (Healthcare System Readiness, Content-Driven Interactive Engagement, and Timely and Compelling Evidence) have evolved due to post-pandemic trends, which has led to a growing gap between the requirements to adopt innovation and health system capacity
- Medical affairs plays a pivotal role in driving launch success against these three pillars and must be adequately resourced to enable early, pre-launch engagement.
- The five priorities do deliver medical launch excellence are investment and resourcing, collaboration and alignment, competencies, technology and tools, and metrics.

Three pillars of Launch Excellence and the pivotal role of Medical



Five priorities for delivering Medical Launch Excellence



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Published: June 2023

In the thick of it: Medical Affairs, strategic partner to other functions

Report summary

Beyond its externally focused remit, Medical Affairs has an equally invaluable, yet often underutilised, internal role to play as a strategic partner to other functions. The unique value of medical as internal partner along the asset lifecycle derives from its deep insight and relationships with healthcare stakeholders while being in tune with the real world.

As asset lifecycle partner, from development through to commercialisation, medical has valuable, specific contributions to make at each key lifecycle stage, e.g. supporting the development of an asset's target product profile; providing input on trial designs to ensure practice- and payer-relevant endpoints; refining the product strategy and helping to sharpen an asset's differentiation; orchestrating integrated evidence planning across functions; sharing intelligence on competitive activities, e.g., new data releases, and interpreting their implications to inform how to respond; or making introductions to EEs to support commercial in proposing and briefing speakers for a speakers' bureau.

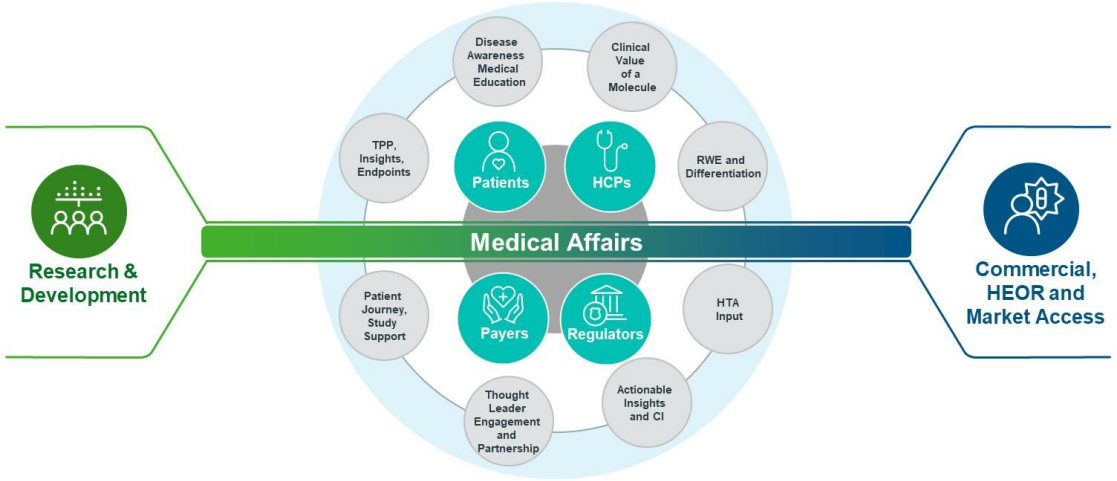
Biopharmaceutical companies must fundamentally re-evaluate the way medical affairs is positioned within their organisations to capture its tremendous potential as a strategic partner, with focus on 5 priorities: cross-functional governance, formalised processes, technology, resourcing, skills and mindset.

Key findings

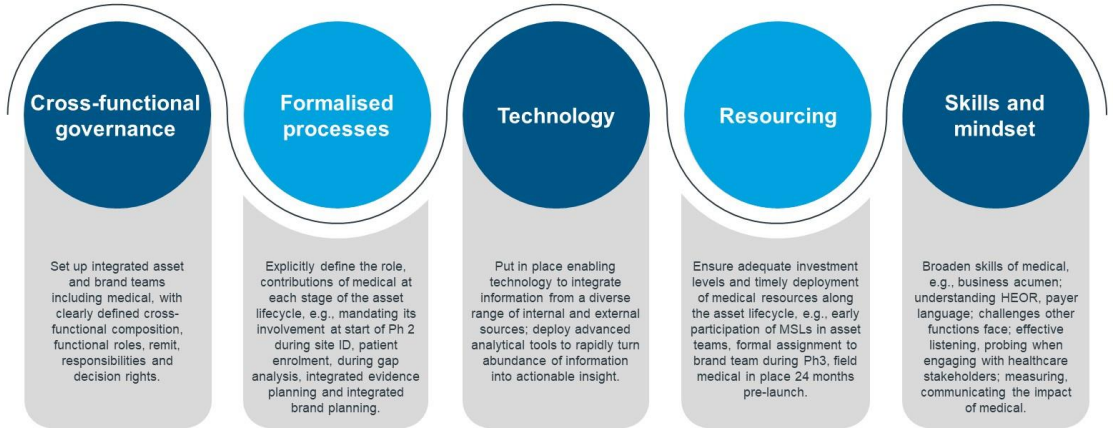
Medical affairs adds internal value as a partner to other functions in three ways:

1. Enabling better strategic decisions and operational execution, by providing deep insights
2. Driving alignment around a common agenda focussed on optimal patient and health systems outcomes, by acting as a bridge to connect different functional stakeholders
3. Leveraging its unique relationships with key healthcare stakeholders to support other functions in achieving their objectives

Expanding remit of medical affairs as bridge between functions



Systematically embedding medical affairs as strategic partner: Five priorities



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Published: December 2022

Medical Affairs' Next Frontier: Unlocking Omnichannel Engagement

Report summary

The COVID-19 pandemic caused biopharma companies to rapidly pivot to remote customer engagement and accelerated the use of digital channels. HCPs are now looking for personalised experiences that reflect their needs and preferences.

The role of medical affairs teams is evolving alongside and must also reflect the shift in customer engagement preferences when providing scientific education and evidence to healthcare providers, payers and regulators.

Medical affairs professionals must now use a variety of channels such as webinars, emails or video calls, aligned with customer needs and preferences to provide the right content at the right time via the right channels and format.

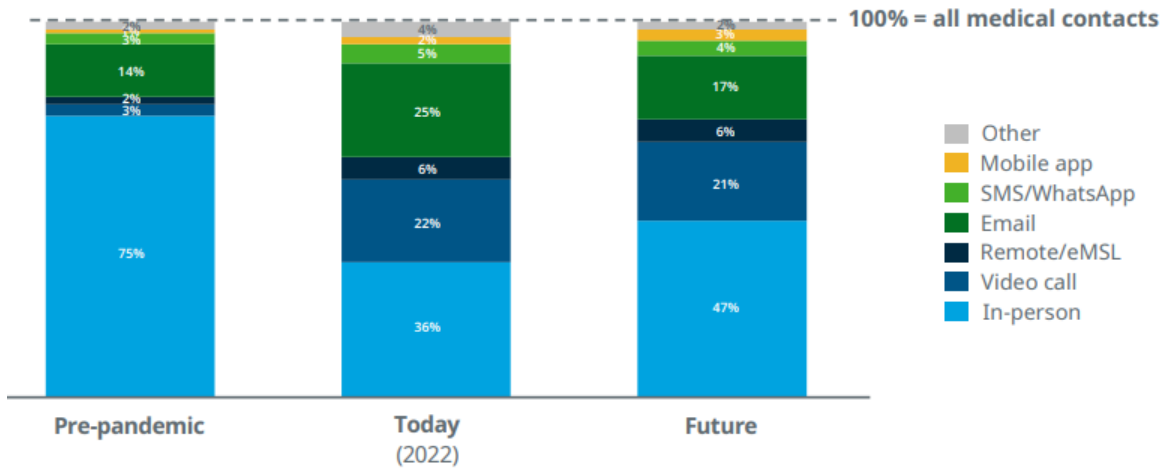
Delivering this in practice is challenging, requiring a clear customer-centric strategy, joined-up planning, enabling technology infrastructure, while ensuring unwavering regulatory compliance.

Omnichannel is the next frontier for medical engagement and the dissemination of scientific and medical content. Companies that do this well will stand out in an increasingly competitive world and will build deeper, lasting customer relationships.

Key findings

- 7-fold increase in share of MSL video calls as proportion of all HCP medical contacts, pre-pandemic vs. today (2022)
- 61% of physicians identify greater personalisation as the main differentiator for making medical engagement more valuable
- Enablers for omnichannel engagement: Insight, Planning, Content, Technology, Metrics
- Organisational priorities: Vision, Commitment, Collaboration, Mindset and Skills.

A hybrid model for medical engagement is here to stay



Five priorities to realise the full potential of medical omnichannel engagement

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Published: September 2022

Their finest hour: Medical Affairs in a disrupted world

Report summary

Medical affairs (MA) has evolved from a supporting function to playing a critical and strategic role. It leads the value and evidence agenda, provides insight on therapy areas and patient journeys, and engages with external stakeholders to educate on the value of innovative products.

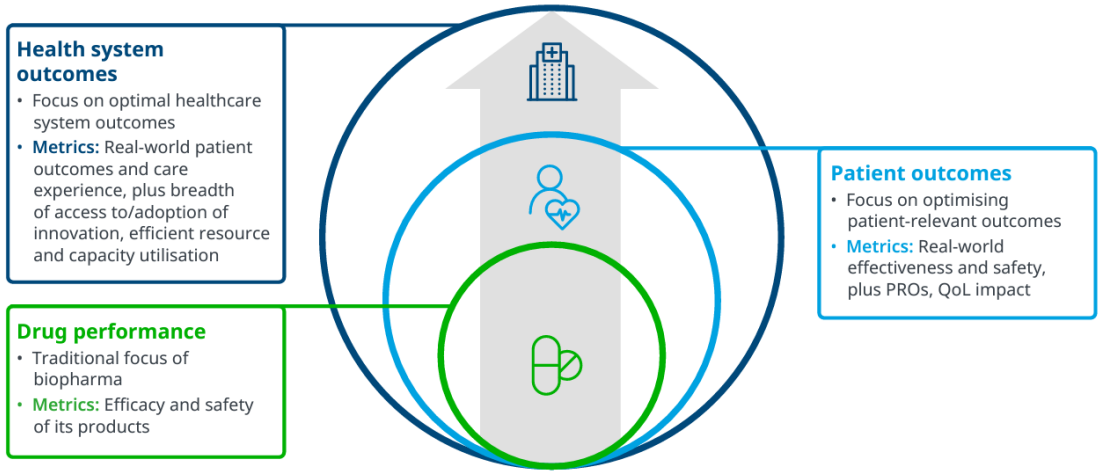
The role of medical affairs has been further elevated due to recent trends in healthcare, such as increased financial pressures on healthcare systems, a higher evidence burden for regulatory approval and market access. More demanding HCPs seek customer-centric experiences. The pharma business model is being disrupted by the rise of patients as key stakeholders, faster innovation cycles, and new players in healthcare.

Healthcare system partnering is critical for future success, with MA being instrumental in facilitating trusted, mutually beneficial partnerships. Companies have a choice: being part of shaping the new model or being swallowed by it. The imperative to seize this opportunity is now.

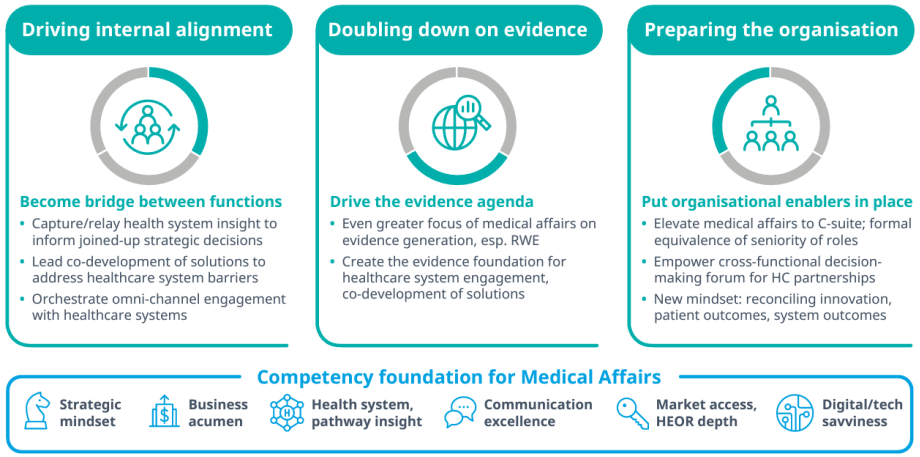
Key findings

- Medical affairs has moved centre-stage to increasingly play a strategic and pro-active role. Post-pandemic realities are now taking hold which further elevate the role of medical affairs and accelerate the need to expand its remit.
- To fulfil its promise, medical affairs must transform from being a third pillar alongside R&D and commercial to becoming the bridge between key functions, including R&D, commercial, market access and HEOR, and drive alignment around a common agenda focussed on optimal patient- and healthcare system outcomes.

Broadening the basis of biopharma–healthcare engagement



Implications for the future of Medical Affairs – key priorities



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Published: October 2021

Capturing Value at Scale: The $4 Billion RWE Imperative

Report summary

The COVID-19 pandemic has accelerated the need for effective evidence generation and the use of Real-World Evidence (RWE) in the pharmaceutical industry. Companies can capture $4 billion in value from RWE along the value chain by embedding RWE operationally across their business.

The opportunities presented by RWE in the post-pandemic world are vast, including de-risking clinical trials, accelerating regulatory decisions, pinpointing unmet needs in specific patient sub-segments, and streamlining diagnosis and treatment.

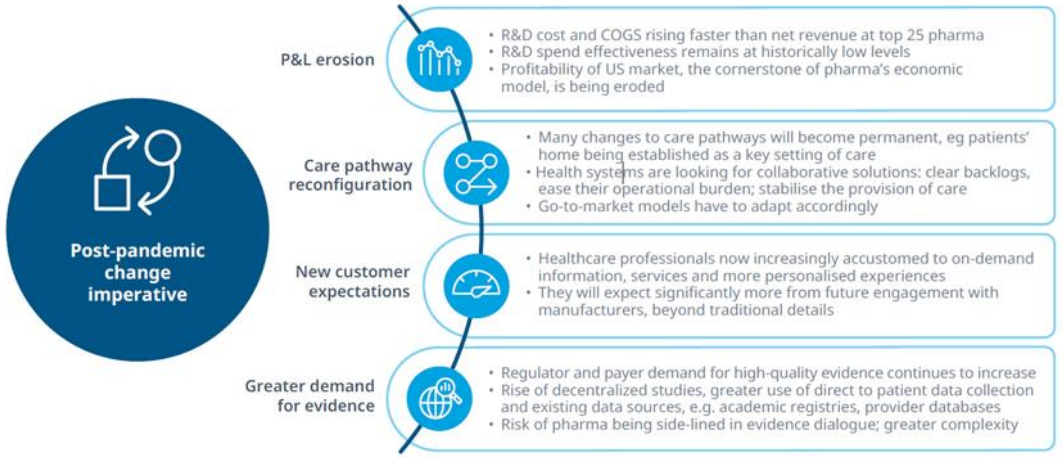
Faced with post-pandemic headwinds and margin pressures, the imperative to capture the $4 billion RWE opportunity is now.

Pharmaceutical companies must flexibly access critical RWE capabilities and transform their model to become a power node connecting the broad network of healthcare stakeholders, spanning regulators, payers, providers and academia. Facilitating trusted, mutually beneficial partnerships with health system is key to unlocking the full potential of RWE.

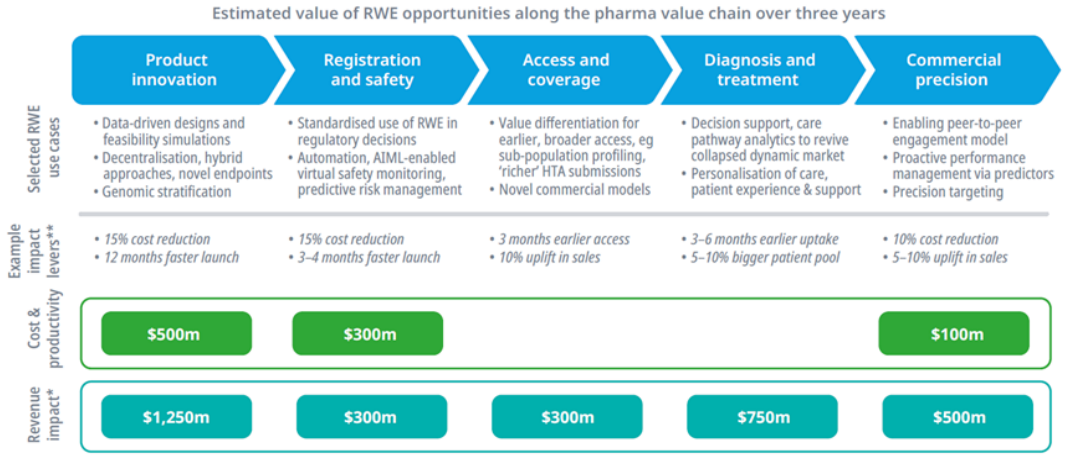
Key findings

- The pharmaceutical industry can capture up to $4 billion in value by systematically embedding RWE operationally across the business.
- Companies typically realise only 30-40% of their total RWE opportunity potential due to various barriers and must transition to a new model
- To capture value from RWE at scale, pharmaceutical companies must consider different capability ownership models to balance three objectives: flexible access, economies of scale, and agility.

Post-pandemic Challenges Demand a New Model



The Post-pandemic $4 Billion RWE Opportunity



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Published: August 2021

Making real-world evidence meaningful and actionable

Report summary

Real-world evidence (RWE) is increasingly important in healthcare decision-making, providing a 360-degree view of product performance that complements traditional clinical trials. RWE generates new insights to inform decision-making throughout a product's life cycle, from clinical trial design to regulatory approval and market access decisions. Effective communication of evidence is crucial to ensure that it is understood, meaningful, and actionable for different audiences, including regulators, payers, healthcare professionals, and patients

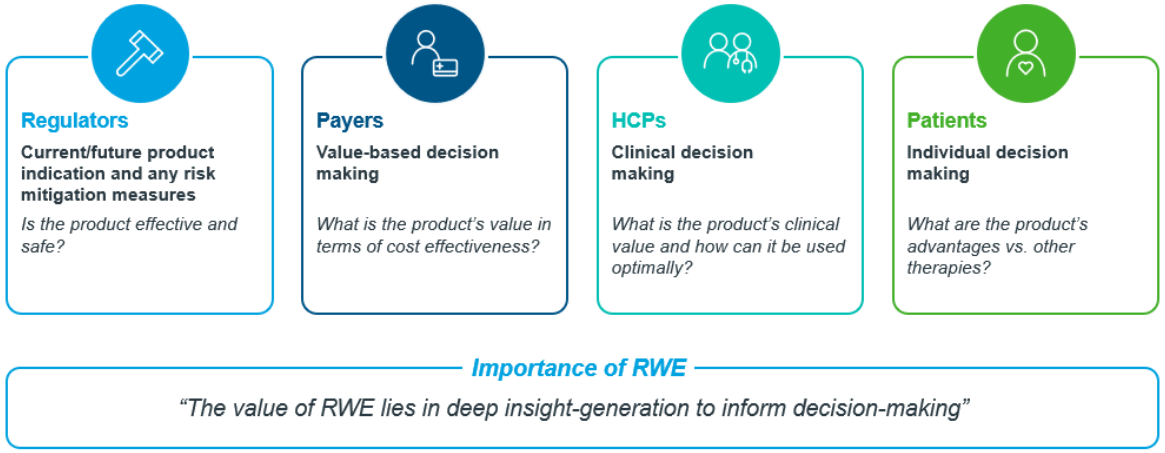
Medical communications experts play a crucial role in bridging the gap between evidence generation and its final users by developing engagement plans tailored to stakeholder needs and utilizing innovative tools to reach audiences more efficiently. The involvement of Steering Committees and Communications Advisory Groups can aid in planning engagement with external stakeholders, while digital enhancements such as visual abstracts, videos, and data visualization can be used to disseminate research findings effectively.

The key to the success is integrating effective communication strategies from the start, making it an integral part of both the RWE programmes and individual studies.

Key findings

- RWE has become increasingly important in healthcare decision-making as it is used ever more frequently in regulatory approvals, clinical guidelines, health technology assessments, and market access decisions
- To fulfil the potential of RWE relevant, clear and actionable insights must reach healthcare stakeholders to enable evidence-based decisions
- Integrating effective communication strategies into RWE programmes from the start is key.

RWE audiences and their different decision-making needs



RWE audiences and their different decision-making needs

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Therapeutic Innovation

Published: March 2024

Sticking Point: Developing and Retaining Value with Parenteral Products

Report summary

Parenteral delivery is a critical method of administering medicines, with nearly half of global Rx value coming from products that are administered parenterally. Comparatively, the global Rx volume of parenterals is around 1% excluding vaccines, indicating the parenteral market consists of high-value, low volume products.

With such significant value comes significant competition, both from external product classes – notably orals – and between parenteral delivery modes. Oral products can be more easily stored and administered than many parenterals although are generally not suitable for biologics, whereas within parenterals, devices that allow for self-administration such as autoinjectors are typically preferred.

With healthcare systems under considerable strain, formulations that can reduce impact on hospitals by allowing for greater efficiencies, or that allow care to be moved out of the hospital, are being looked upon favourably.

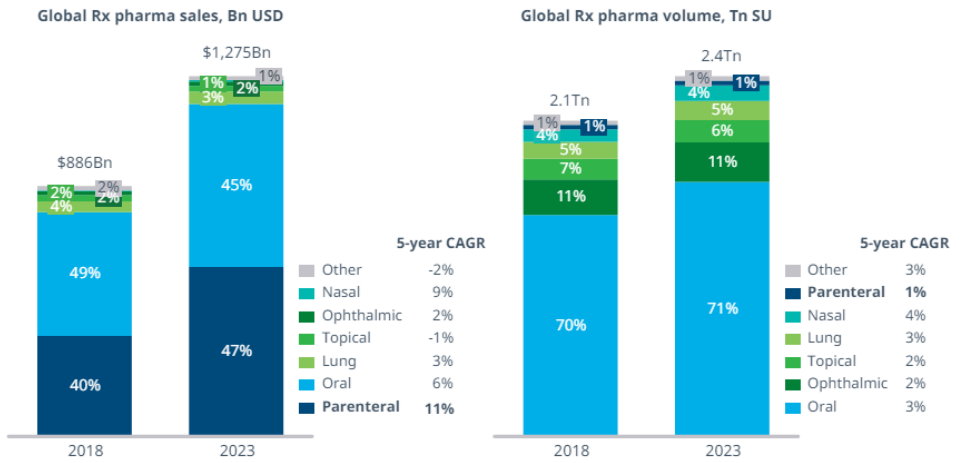
As a result, it is vital for manufacturers to consider the formulation used and design of the device, alongside aspects concerning the supply chain and disposal of products.

There is also notable innovation occurring in parenterals with the development of large-volume autoinjectors and the opportunity to move into new markets.

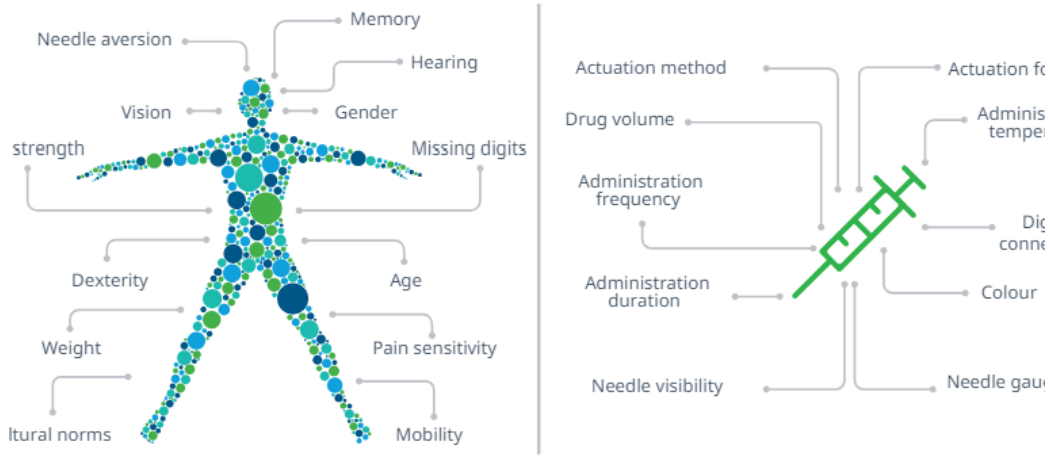
Key findings

- Sales from parenteral products made up nearly half of global Rx sales value at list prices and excluding vaccines; slightly more than sales from oral products.
- Parenterals make up a sales majority in the top 3 therapy areas (oncology, diabetes, immunology), with more than 90% of sales in immunology from parenterals.
- Within parenterals, formulations that could be self-administered are growing at twice the rate of those that require hospital admission (15% vs. 7%).
- The parenteral market is expected to grow globally at a CAGR of 9.4% over the next five years.

Global Rx market split (excl. COVID-19 vaccines)



Patient characteristics and device design elements



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Published: January 2024

Emerging from the Shadows: A New Era for NASH

Report summary

NASH (non-alcoholic steatohepatitis) is a leading cause of liver-related morbidity and mortality. The unmet need remains high in the absence of any approved, disease-specific therapies to date; however, 2024 may see the first-ever approval of a NASH-specific treatment.

Despite significant R&D efforts, innovation in NASH treatments has faced many setbacks. The barriers to NASH innovation include its complex pathophysiology, low diagnosis rates, and regulatory requirements. Non-invasive diagnostic tests will play a key role in overcoming many of those barriers and will be critical to unlock the commercial opportunity.

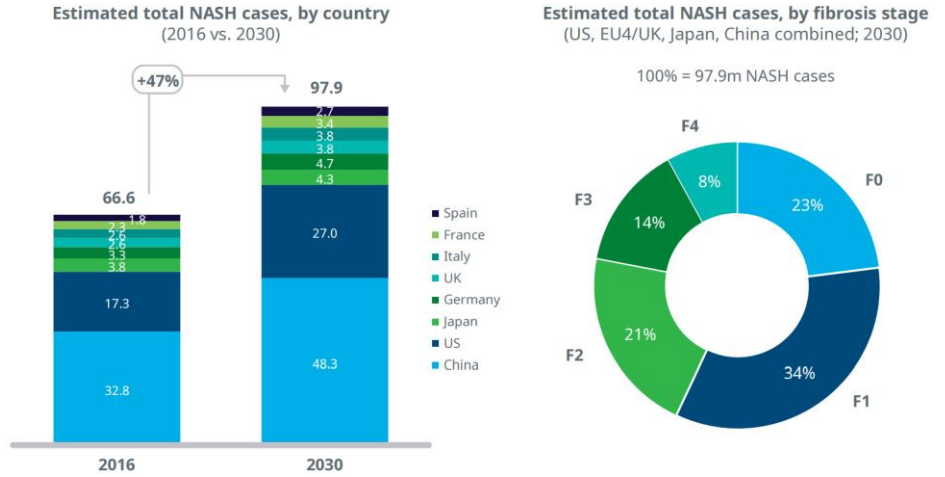
Pipeline momentum is accelerating, with novel GLP-1-based obesity therapies also being investigated for NASH, given the high overlap of co-morbidities.

There are five factors that innovators must consider to achieve commercial success in NASH: disease awareness and advocacy, care pathway readiness, an integrated evidence program, reassured payers, and public health priority.

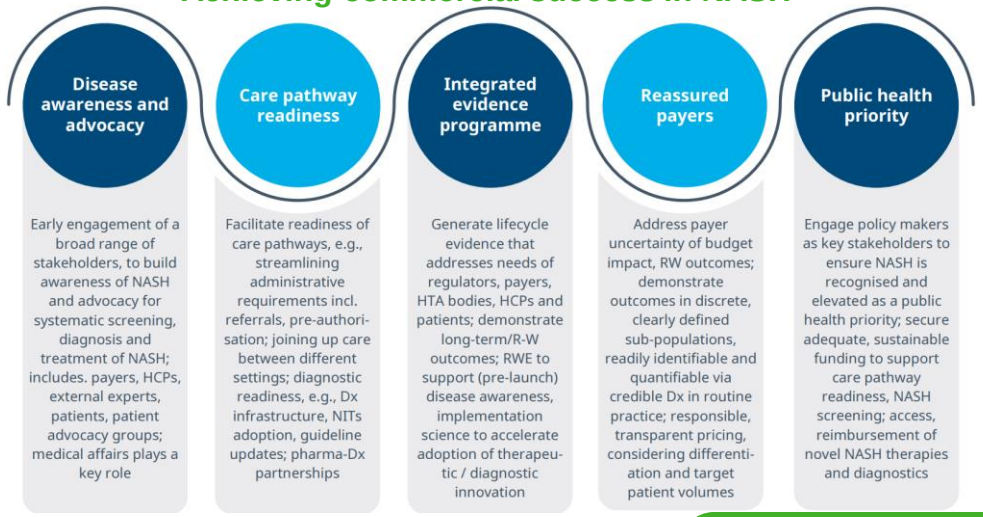
Key findings

- NASH is a significant global health concern. By 2030, the total number of NASH cases is estimated to reach ~100 million in 8 countries, including the US, EU4/UK, Japan, and China.
- There are no disease-specific treatments approved to date, but 2024 might see the first-ever approval.
- Uncertainty remains high around how the disease burden will translate into a global market, resulting in estimates ranging between tens to over $100 billion by 2030.

NASH represents a large and growing public health burden



Achieving commercial success in NASH



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Published: September 2023

Race for immunity: Exploring the evolving landscape of the vaccines market

Report summary

Vaccines are available for most of the highest-burden infectious diseases. Still, significant unmet need persists within vaccine-preventable diseases (VPDs), such as tuberculosis. Climate change, antimicrobial resistance, and pandemic readiness challenges also underscore the necessity for new and improved vaccines.

However, the number of approved vaccines has risen steadily in the last decade; there are now 54 EMA- and 104 FDA-approved vaccines, for over 20 infectious diseases. Despite COVID-19 vaccines dominating recently, innovation in other indications has continued; the first RSV vaccine approvals in 2023 marked a significant breakthrough.

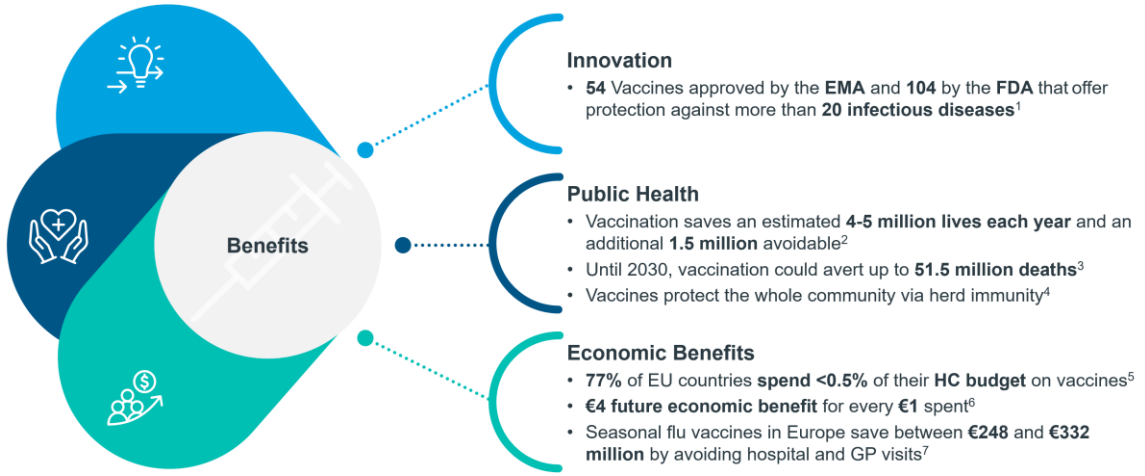
The approval of COVID-19 mRNA vaccines was pivotal. RNA's rapid computational design and synthesis in cell-free systems offer huge advantages over other platforms. mRNA has the potential to disrupt established markets like influenza, pioneer first-to-market opportunities in latent viral infections like CMV and EBV, and expand in scope to personalised cancer vaccines. Challenges around manufacturing, logistics and duration of protection must be overcome for mRNA success outside of COVID-19.

The global vaccine market landscape is inherently complex, but the future holds immense promise. Vaccine companies must help to foster a healthy vaccines market that can sustain innovation while addressing public health needs.

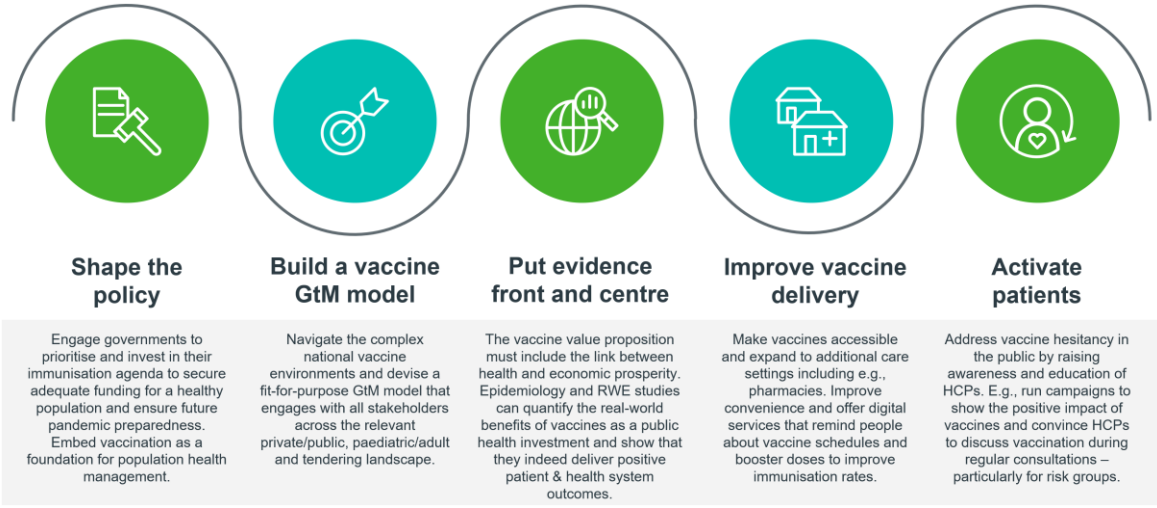
Key findings

- Future vaccine innovation must look beyond improving efficacy, e.g., elicit stronger, longer-lasting immunity, or be universal against multiple viruses or bacterial strains.
- The full vaccine pipeline has 442 assets out of which 67 are mRNA – exclusive of COVID-19. One third of the prophylactic vaccines in the mRNA pipeline are for diseases which currently have no approved vaccines.
- The global vaccines market reached $39 bn in 2022, excluding COVID-19, and is forecast to grow at a future 5-year CAGR (2022-27) of 5-10%.

Vaccines – an unparalleled success story with massive benefits



How to succeed with vaccines



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Published: June 2023

A renaissance for cardiometabolic innovation

Report summary

Cardiometabolic risk factors are still among the leading drivers of both global mortality and morbidity. Managing these conditions becomes a public health imperative but bringing innovation to patients was challenged by high generics utilisation, high evidence bars from payers and low success rates for clinical trials.

In the past five years, cardiometabolic assets in the pharmaceutical industry have increased by 13%, comprising 7% of the total R&D pipeline. Leading indications include diabetes, NASH, hypertension, obesity, and heart failure, accounting for approximately 50% of phase 1-3 assets. Furthermore, cardiometabolic innovation leverages advanced technology platforms such as cell, gene, and RNA therapeutics.

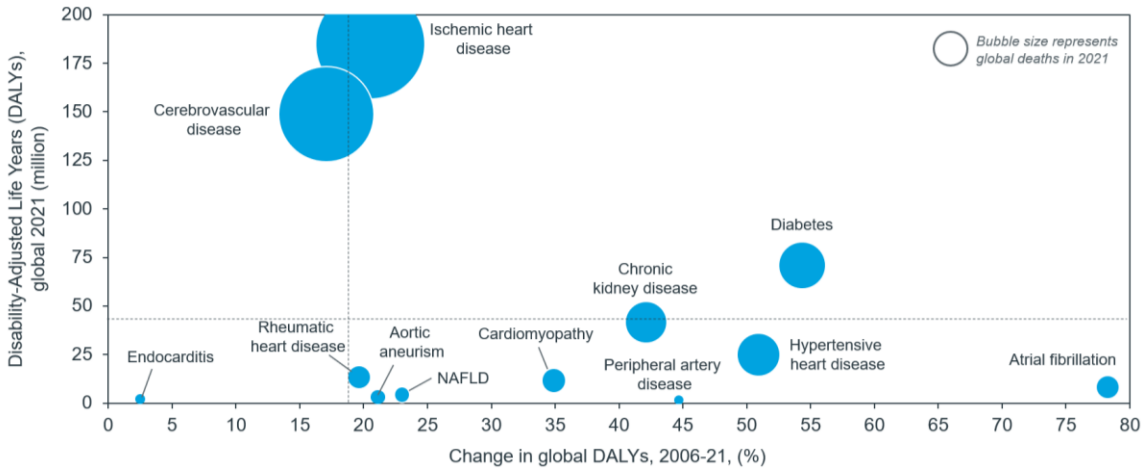
Cardiometabolic innovators face challenges in achieving commercial success, including the need for early engagement with stakeholders, generating long-term outcomes data, addressing payer concerns, preparing health systems for novel therapies, and engaging patients through digital health solutions.

Despite these challenges, there is significant potential for innovation in the field of cardiometabolic diseases, which are a global public health priority, offer opportunities for therapeutic breakthroughs and commercial success.

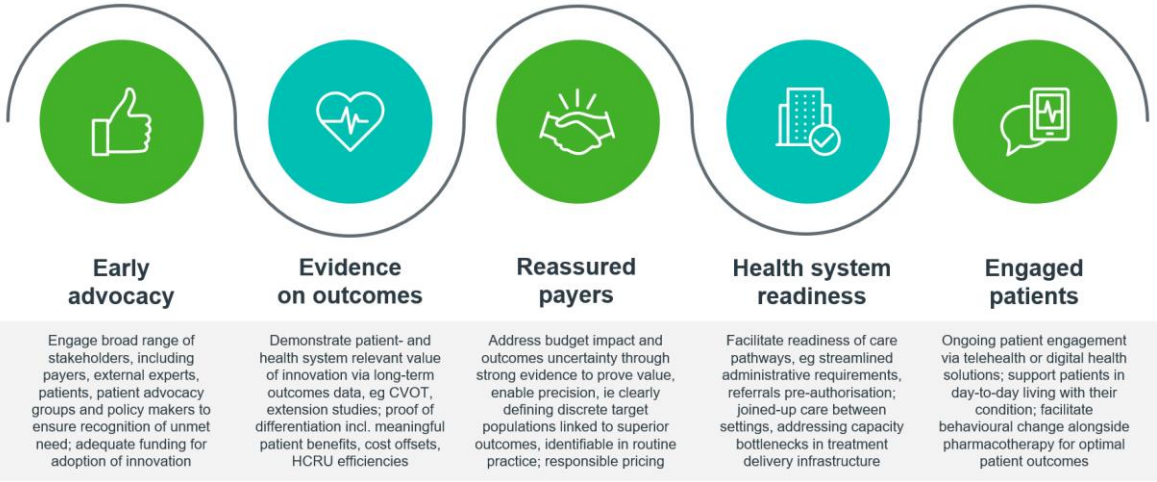
Key findings

- Metabolic risk factors are key drivers of global mortality and burden of disease. In 2019, they collectively accounted for 34% of deaths and 500 million DALYs globally.
- Cardiometabolic innovation was challenged by high generics utilisation post LoE events, low perceived need for innovation, low clinical trial success rates and high costs to run the demanded large-scale studies.
- With GLP-1 agonists, the global obesity market is at the cusp of major expansion
- The cardiometabolic disease market reached $264 billion in 2022 and is expected to reach $370 billion globally by 2027

The global burden of cardiometabolic diseases is high and growing fast



Succeeding with cardiometabolic innovation



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Published: March 2023

Bigger on the inside: the expanding world of microbiome therapeutics

Report summary

The microbiome refers to the community of microorganisms that live in and on the human body, including bacteria, viruses, and fungi. These microorganisms play a crucial role in maintaining our overall health and well-being. Inversely, the microbiome was linked to various disease including neurodegenerative disorders and also cancer.

Faecal matter transplants (FMTs) transfer the whole gut microbiome ecosystem form a donor to a patient and are the first approved microbiome therapeutics whilst innovators work towards donor-independent and more specific approaches. Inflammatory bowel disease and oncology are amongst the major areas of interest and here were are only at the beginning to fully comprehend the role of the microbiome. Thus, more translational research is needed to fill the evidence gap for the successful development of future therapeutics.

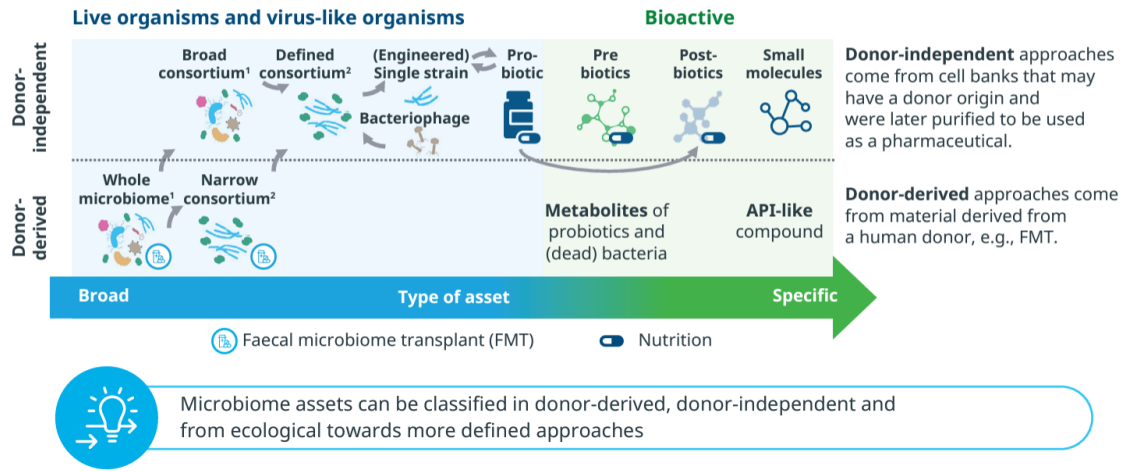
Pharmaceutical companies invested in microbiome assets depending on the fit with their existing portfolio whilst agro-alimentary players focused more on technology platforms that they can leverage in their core business areas.

To succeed as a microbiome innovator it will be important to diversify your portfolio, work closely with regulators, prepare the market and focus on RWE generation.

Key findings

- Microbiome-based products are a viable consumer health market (CH) as probiotics reached $4.6 billion in value in 2022 and outperformed the overall CH market growth
- Autoimmune disease oncology and *C.diff.* infections are focus areas for microbiome innovators and account for 35%, 20% and 12% of the R&D pipeline
- It is not just pharma that are actively investing in microbiome therapeutics or microbiome-based technology. Agro alimentary players also made big bets.
- 1st generation microbiome Tx must convince all relevant stakeholders to successfully define and create a new market that can be built on in the future

Spectrum of microbiome therapeutics



Future scenarios for the microbiome market

Download here

Published: March 2023

Two steps forward, one step back: the long road to success in CNS

Report summary

Mental health and neurological disorders are growing in prevalence and impact on people's quality of life, and despite some innovation, many CNS conditions lack disease-modifying treatments (DMTs). However, digital biomarkers, AI tools, novel trial designs, and diagnostics are improving the fundamentals of CNS innovation, while a better under standing of the biology of CNS diseases opens up new drug development targets.

CNS innovation is predominantly driven by smaller players, but big pharma has also discovered CNS as an attractive area of high potential. Setting a new standard of care with novel DMTs, esp in Alzheimer's, Parkinson's and rare neurological disorders with high unmet need, will drive CNS market growth dynamics in the future.

Alzheimer, Parkinson, psychedelics-derived and digital therapeutics are exemplars of the promise of cutting-edge CNS innovation and are explored in four deep dive sections.

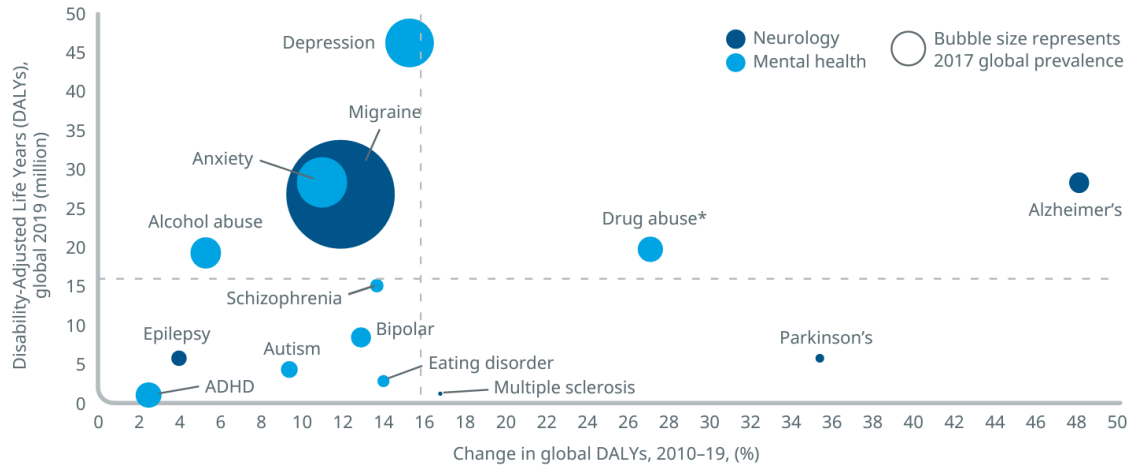
To succeed as a CNS innovator, it is important to address five critical priorities: embracing the power of digital, putting evidence front and centre, helping health systems get ready, reassuring payers, and shaping public policy debate.

As the fundamental for CNS are improving, innovators should feel emboldened to stay the course.

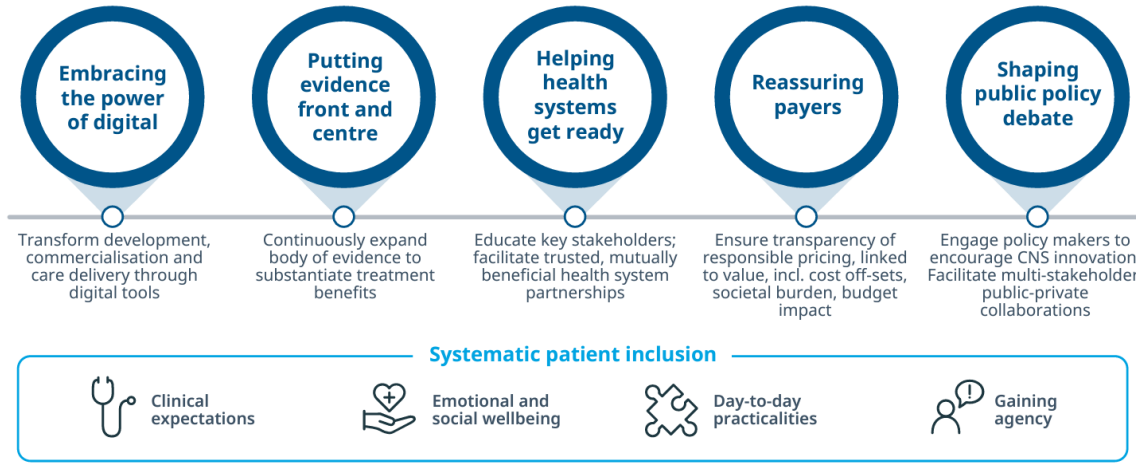
Key findings

- The global disease burden of CNS conditions is high and has reached 256 million disability-adjusted life years (DALYs) in 2019, an increase of 16% since 2010
- Digital health technology has seen dramatic developments while its adoption in neurological trials has grown at a 36% CAGR between 2010 and 2021
- The CNS pipeline has expanded by 31% between 2017-2022 and accounts for 14% of the overall industry R&D pipeline
- New DMTs will drive the CNS market which is forecast to reach $167 billion by 2027

The global disease burden of CNS is high and is growing fast



How to succeed as a CNS innovator



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Published: January 2023

Pharma’s frozen assets: cold chain medicines

Report summary

A huge and lingering logistical challenge in delivering vaccines globally during the pandemic has been in scaling up the refrigerated networks that make up part of the global ‘cold chain’, the uninterrupted process of maintaining end-to-end temperature-controlled conditions from the manufacturing site to the point of care.

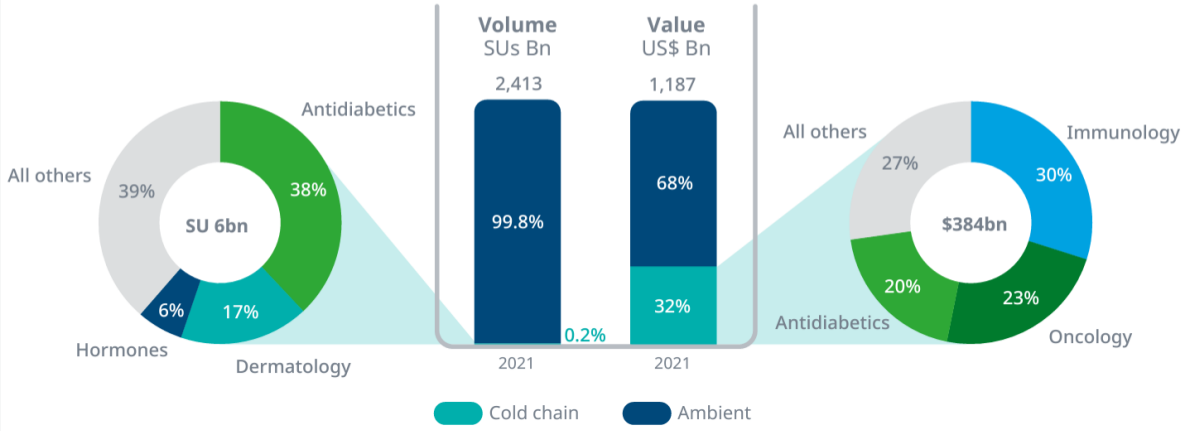
Cold chain medicines require more energy than their ambient temperature counterparts. Biologics and advanced medicinal therapy products (ATMPs) in high-income countries and vaccines in middle- and low-income countries will continue to drive cold chain medicine value and volume growth respectively.

If pharmaceutical companies want to live up to their ambitious environmental, social and governance (ESG) targets, they will need to understand current and future trends and work closely with logistics companies to ensure delivery of often live-saving cold chain medicines whilst having their CO_2 footprint in mind.

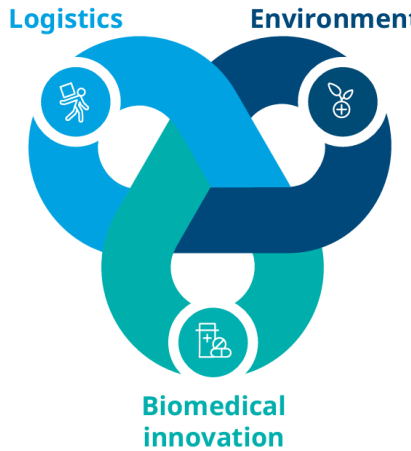
Key findings

- The pharmaceutical supply chain including logistics was impacted by an increase in gas prices, container costs, API precursors prices and moreover a shortage of raw materials and labour forces
- Cold chain medicines grew more than twice as fast at 13% compared to 6% for the total market between 2017 and 2022
- Mastering the logistical challenges to ensure end-to-end cold chain integrity is paramount for success in this market segment

Global cold chain market exclusive of COVID-19 vaccines & therapeutics



Considerations for pharma and logistics companies



Master cold chain logistic complexity
- Capture the value in a rapidly growing market segment
- Limit temperature fluctuation during last mile delivery

Reduce environmental impact
- Use of greener fuels and passive cooling when possible
- Manufacture closer to patients

Explore ambient temperature alternatives
- Optimise drug formulation to improve stability
- Explore new drug delivery systems

Download here

Published: May 2022

In the eye of the storm: PD-(L)1 inhibitors weathering turbulence

Report summary

The advent of PD-(L)1/ checkpoint inhibitors has transformed the oncology treatment landscape and created blockbuster products in the process. The checkpoint inhibitor market has grown at a CAGR of 45% between 2016 and 2021 to reach $36 billion globally and is expected to continue growing at a CAGR of 15% through to 2026.

Keytruda is the dominant player in the market, with a 54% market share, and is used across 13 indications. There are seven globally competing PD-1/PD-L1 inhibitors that find use across 17 different tumour types, with non-small cell lung cancer being the biggest indication.

Clinical trials have shifted from monotherapies to testing combinations of checkpoint inhibitors with other therapies to achieve better outcomes.

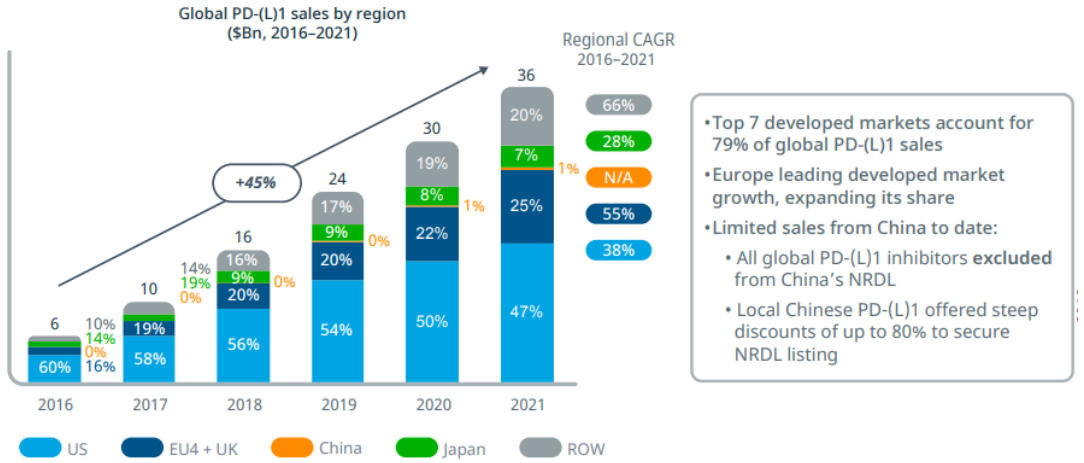
The confluence of intense competitive dynamics and a surge in innovation has created strong headwinds for the future PD-(L)1 market, including complexity, fragmentation, regulatory and payer pressure.

However with the right approach and an open mindset for embracing partnerships, innovators will be able to find success in the market.

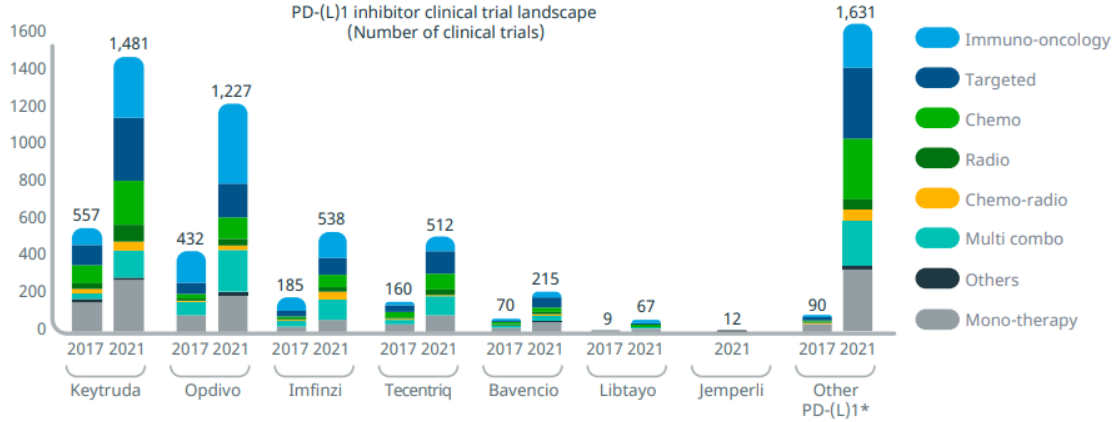
Key findings

- The global checkpoint inhibitor market reached $36 billion in 2021, and is expected to grow at a CAGR of 15% through to 2026
- Brand-level dynamics of the PD-(L)1 market are shaped by four defining themes: multi-indicationality, biomarkers, market maturity and Keytruda dominance
- Finding differentiation is paramount for success in the crowded PD-(L)1 landscape with its prevailing competitive dynamics, such as by targeting unmet need

Global PD-(L)1 sales



PD-(L)1 combination clinical trials



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Published: April 2022

Promise fulfilled? The next decade of cell, gene and RNA therapies

Report summary

The development of Advanced Therapies, including cell, gene, and RNA treatments, has become increasingly popular in recent years. The COVID-19 pandemic has had a major impact, as it has accelerated the growth of mRNA vaccines and RNA therapy, leading to billions of dollars in sales and investment from pharmaceutical companies.

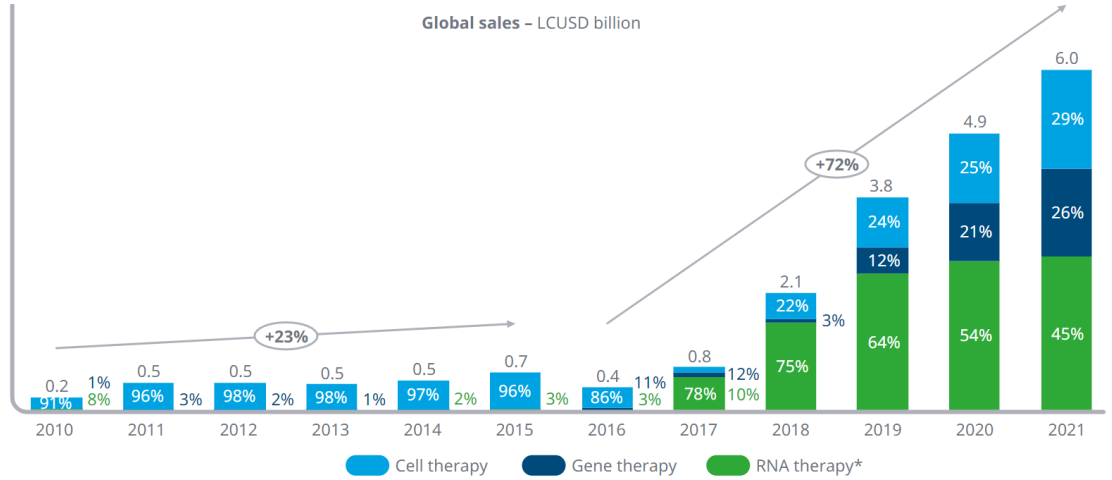
The success of mRNA COVID-19 vaccines has also brought a revival of interest in RNA therapies and gene therapy, with companies entering the field and recent gene therapies showing commercial viability.

However, funding and delivery challenges still need to be addressed for the success of future advanced therapies. The growth of advanced therapies is driven by factors such as increasing investment in R&D, regulatory support, growing patient awareness, and partnerships between biopharmaceutical companies and academic institutions. Personalised medicine and innovative technologies are expected to continue to drive the growth of the advanced therapies market in the coming years.

Key findings

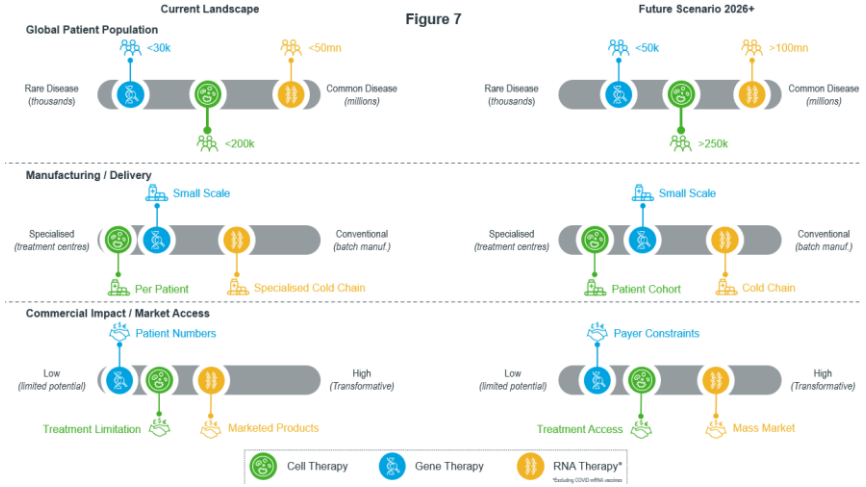
- The cell, gene and RNA market has reached $6 billion in sales in 2021 and is expected to reach $20 billion by 2026
- Revival of interest as companies made significant investment in advanced therapies and usher the field from rare to increasingly more common indications
- Future commercial success is not guaranteed and challenges around market access, pricing and competition as they enter therapeutic areas with well-established and cost-efficient treatment options

Cell, gene and RNA revenues – exclusive of COIVD-19 vaccines



Future of cell, gene and RNA therapy scenarios

Figure 7



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Published: November 2021

Paving the Path in Haematological Cancers

Report summary

Haematological cancers represent 7% of new cancer cases globally and have a disproportionate impact on the paediatric population, accounting for 43% of new cases. These cancers share unique traits, such as slow and fast growing types, and chromosomal translocations that are more commonly present in haem vs solid cancers.

Many breakthrough technologies have been developed for these cancers and have revolutionised treatment, e.g. haematopoietic stem cells in the 1950s, targeted therapies, such as kinase inhibitors, in the 1990s, and the novel CAR-T technology in the 2010s. Despite these advances, unmet needs persist such as identifying new targets, efficiencies in manufacturing, and better management of side-effects

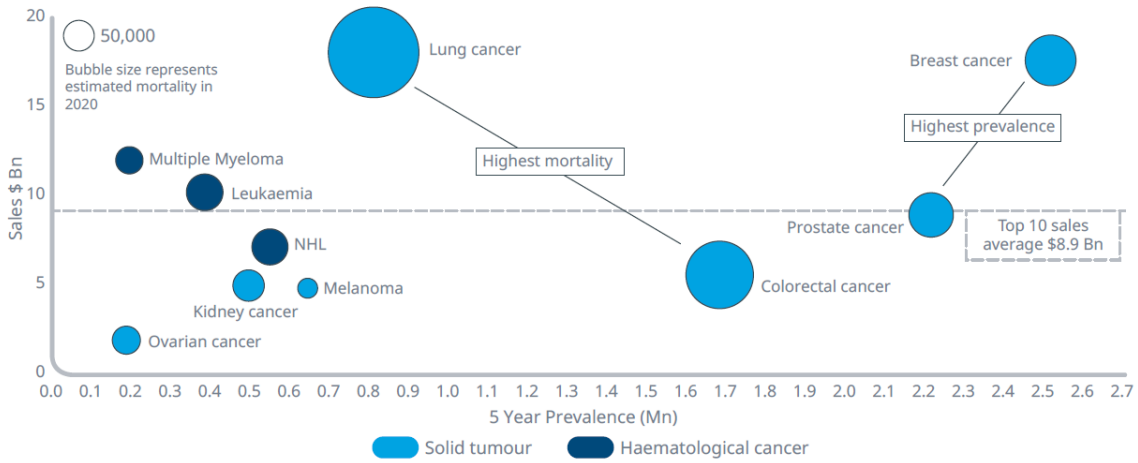
There are hundreds of new assets in the late-stage pipeline and with a scarcity of patients, success for pharma and biotech will rely on Real-World Evidence (RWE) to meet the high evidence demand.

The haem cancer landscape is complex and challenging, presenting several difficulties for pharma. However, with continuous investment and innovation, the future looks promising and still presents an attractive commercial opportunity.

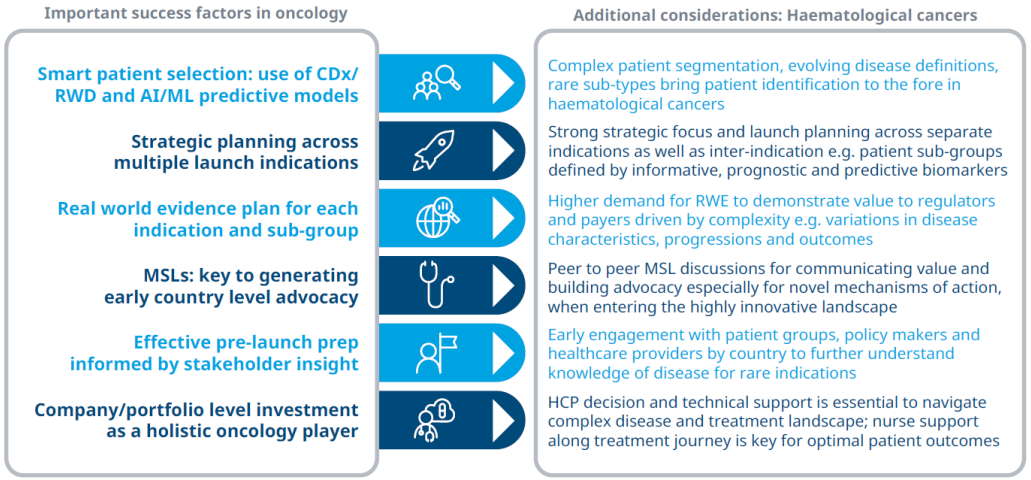
Key findings

- Commercial success requires insights into the following 4 areas:
  - **Disease.** Classify and track progression in overlapping and similar indications
  - **Patient.** Diverse demographics requires characterisation. Biomarkers usefulness can be limited
  - **Patient journey**. Complex care pathways require stakeholder mapping
  - **Competitor.** Keep up with pace of innovation and guidelines to position asset
- RWE external comparator arms can be more efficient than placebo or SOC arms

Prevalence and mortality (2020, USD, US, EU4+UK, JP)



Critical success factors in haematological cancers



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Healthcare Policy

Published: August 2023

EU Revision of the Pharmaceutical Legislation

Report summary

Five key areas of the European Commission's proposed revision to the EU's pharmaceutical legislation were analysed, these were:

- Regulatory Data Protection (RDP) amendments
- Orphan Market Exclusivity amendments
- RDP incentive for launching in all EU 27 member states
- Antimicrobial resistance (AMR) vouchers
- RDP incentive for Repurposed medicines

The proposal relies heavily on RDP as an instrument to achieve its aims of more available, accessible and affordable medicines. This includes RDP incentives for faster and greater access across Europe, developing medicines which address High Unmet Medical Need (including AMR), the use of comparative trials, repurposed medicines and additional indications.

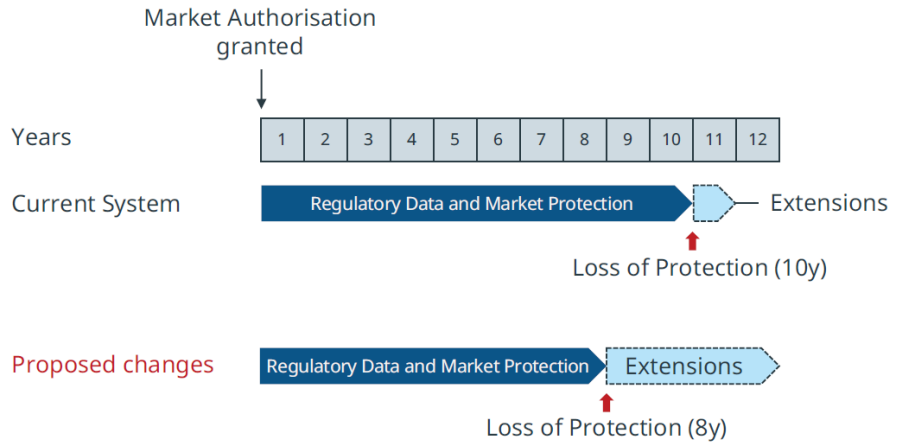
The aims of this proposal are benevolent; however, these incentives may not succeed to stimulate the majority of pharma: RDP only protects around a third of medicines.

Furthermore, launching across all EU member states within two years is not possible in the current environment, and vouchers for AMR development are unproven.

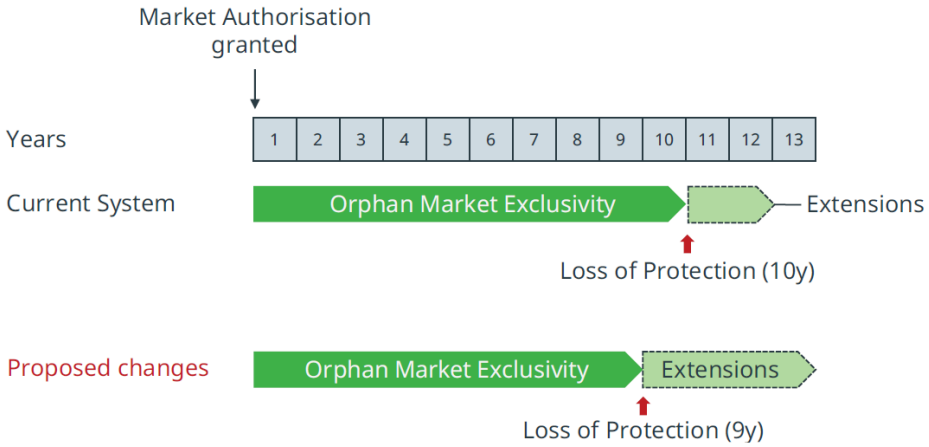
Key findings

- Pharmaceutical companies will be impacted depending on their size and portfolio
- The proposal incentivises launching across all EU member states within 2 years, but currently no companies achieve this.
- Low competition will limit the impact of the changes in Orphan Market Exclusivity
- The proposal includes transferable data exclusivity vouchers to incentivise antimicrobial R&D, but their impact is not clear and may be limited
- The proposal grants 4 years of RDP to repurposed medicines, but questions remain about achieving price premiums to incentivise activity in this area.

Proposed changes to Regulatory Data and Market Protection



Proposed changes to Orphan Market Exclusivity



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Published: January 2023

Remedy of the Commons: Addressing Pharma's Carbon Footprint

Report summary

A rapidly changing climate will have a significant impact on human health and this is beginning to be felt on a global level. The healthcare sector has a responsibility to act as a stewards and reduce its carbon footprint to mitigate the very problem it will have to increasingly tackle.

International policies and initiatives are being introduced to reduce carbon emissions, with some healthcare systems committing to net-zero emissions. Medicines make up a large proportion of healthcare's carbon footprint, calculated between a third to a half of all its emissions. It is likely that focus will turn on medicines and pharma will need to address this before regulatory action forces the industry to change.

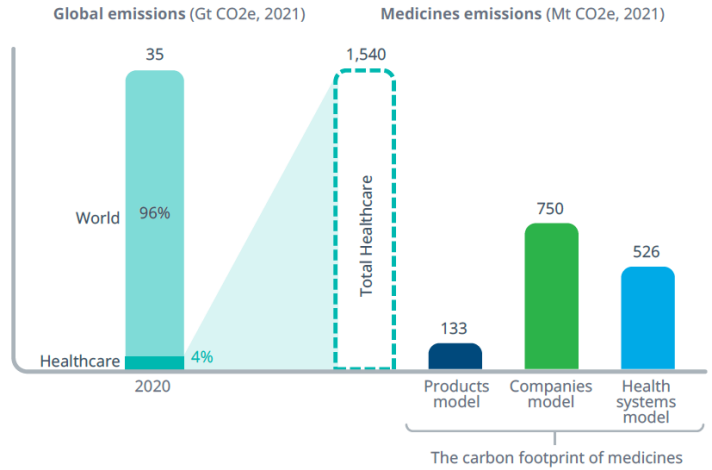
So far, corporate disclosures shows that less than half of the top 100 pharma companies have reported time-bound commitments and only 8 are committed to net-zero. Western public companies lead on commitments and will need to promote greener practices to their Eastern counterparts, where manufacturing dominates.

In order to investigate the drivers of emissions in pharma, we use three distinct models to bring greater quantitative insight on the carbon footprint of the industry.

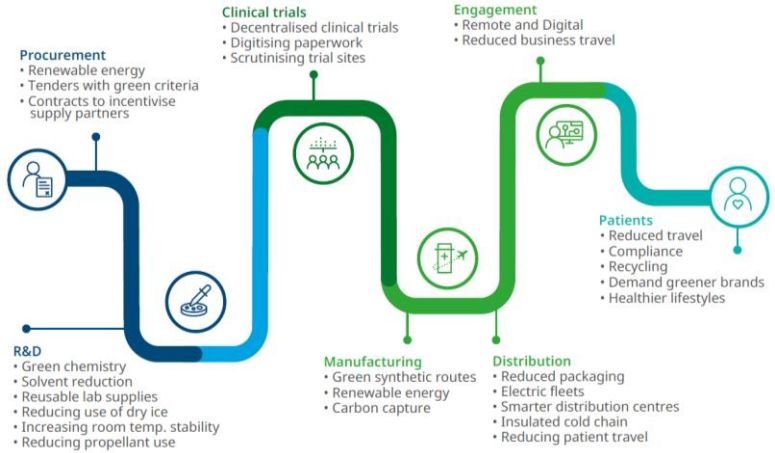
Key findings

- There is a lack of transparency and data making estimations difficult
- Emissions from Inhalers and anaesthetic gases can be audited with greater precision
- The carbon footprint of pharma is estimated at 750 $MtCO_2e$ or 49% of all healthcare
- Healthcare systems, led by NHS England, will drive greater data generation
- Collaboration across sector boundaries and accountability across the value chain are necessary to address pharma's carbon footprint

Estimates for the carbon footprint of medicines



Areas of focus along the value chain



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Published: July 2022

Attracting Investment in Clinical Development

Report summary

Deciding where to locate clinical trials is a critical and multi-layered investment decision for pharmaceutical companies. Understanding the country selection criteria pharmaceutical companies use is essential for policy makers and regulators to attract investments in clinical trials and generate economic and societal value from these.

Research based on analyses of industry trends and interviews with senior managers from big and mid-sized pharma as well as emerging biopharma suggest that the main selection criteria for country location of trials are prevalence, trial performance, expertise network, and regulatory framework. Cost is not a top priority selection criterion.

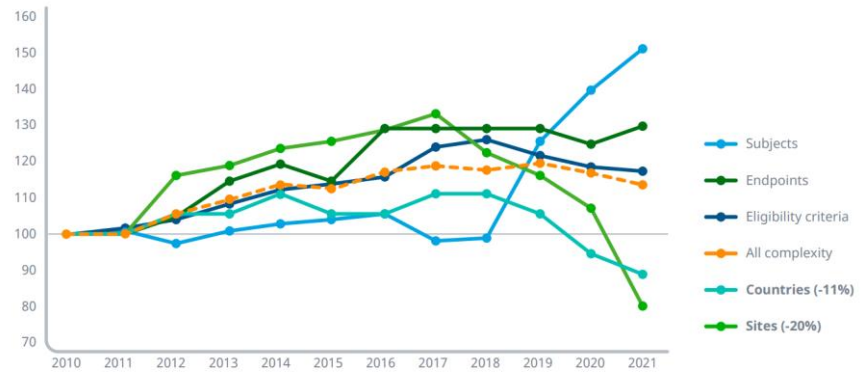
Based on strategic objectives and internal policies, three country archetypes can be identified: “Cornerstone” countries are a commercial and strategic priority and include the largest global pharma markets (US, EU4, UK, Japan, and China), “growth” countries include more than 150 countries which are considered as optional locations, and “out-of-scope” countries are those where no clinical trials are conducted due to ethical concerns or geopolitical factors. An Investment Criteria Framework incorporating these three archetypes provides strategic recommendations for policy makers and pharma.

Key findings

- Trial activity and commercial opportunity are highly concentrated in a small number of countries. Eight “Cornerstone” countries (US, EU4, UK, Japan, and China) hosted 60% of global clinical trials and generated 77% of global sales in 2021.
- Three country archetypes (cornerstone, growth and out-of-scope) were identified and policy makers wanting to attract investment in clinical trials should base their strategies on the recommendations for the respective archetype
- Pharma can influence the development of country environments by a range of activities such as proactive collaboration with agencies and associations

Elements of complexity

Figure 4: Clinical trial’s elements of complexity indexed to 2010 values, all phases, 2010–2021



Source: Citeline Trialtrove, IQVIA Institute, Jan 2022.
Global Trends in R&D: Overview through 2021. Report by the IQVIA Institute for Human Data.

Investment Criteria Framework: Country Archetypes

Archetype	Description	Examples
“Cornerstone” countries	• 8 “Cornerstone” countries prioritised by **commercial priority:** 60% of total CT, 77% of global prescription medicine sales in 2021 (List price, IQVIA MIDAS) • Highly competitive and saturated markets. Diversity regulations apply. Changes in their share of inward investment captured	E.g.; US, EU4, UK, Japan, and China
“Growth” countries	• **+150 countries.** 40% of global CT in clinicaltrials.gov. • Three tiers identified by number of clinical trials in 2022 • Multiple local agencies and regulations, creating need for global cooperation initiatives	E.g.,: Canada, South Korea, Australia, Belgium, Netherlands, Denmark, Sweden, Poland, other Eastern European countries
“Out-of-scope” countries	• **Ethical concerns:** No CT in countries with no commercial intent (few exceptions for rare diseases, or those largely prevalent in these countries), (for some) high corruption index, etc. • **Geopolitical factors:** Issues affecting CT stability and continuity.	E.g.: Most low income countries in Africa, Asia, South America

Source: Clinicaltrials.gov, March 2022, IQVIA MIDAS Quarterly Sales 2021 (List price, Rx Only), IQVIA VII Launch Excellence 2022.

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Published: January 2022

Switching on the lights: Benchmarking digital health systems across EMEA

Report summary

As digital technologies have become more embedded in our daily lives, their role within health systems has been increasingly explored. However, their integration within health systems is not uniform across countries, with disparate levels of initiatives, infrastructure and implementation across even the more sophisticated countries.

We examined the state of digital health systems within EMEA, by scoring countries based on a set of 12 elements from survey responses from IQVIA in-country experts. This allowed for a quantitative comparison between countries and identifying common trends to build out archetypes.

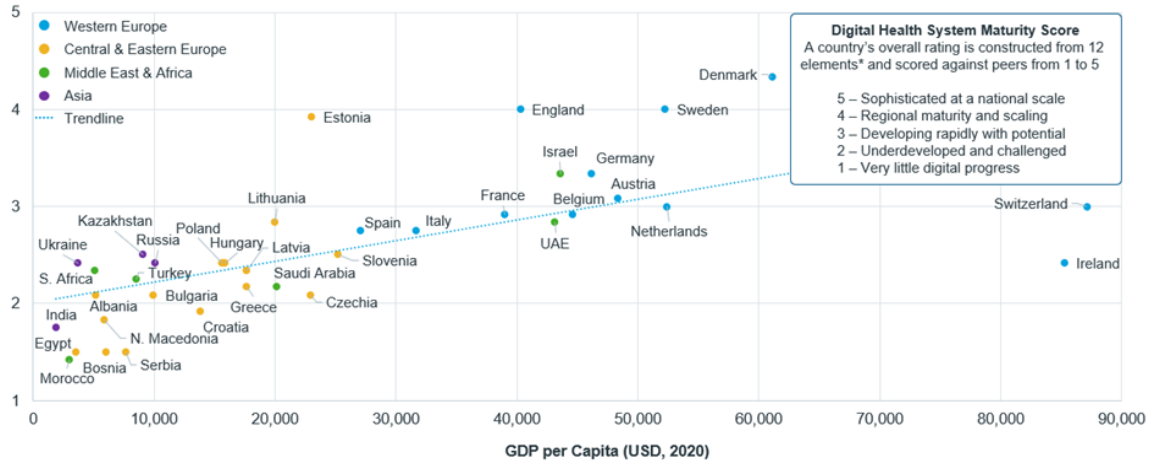
Multiple factors affect the state of technological implementation, and these follow a waterfall structure, with most countries scoring highest in their initiatives, followed by infrastructure and finally implementation, which would be expected from a progression towards maturity.

We also find that certain countries can be considered as standouts for specific elements, particularly driven by their wealth, centralisation, history and cultural attitude towards digital progress at scale.

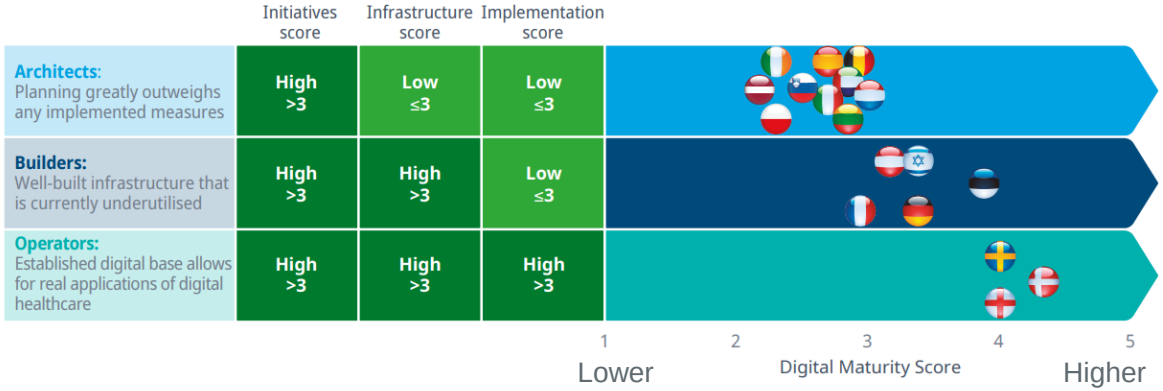
Key findings

- There is a noticeable correlation between GDP per Capita and a country's Digital Health Maturity Score, with both positive and negative outliers.
- There are other factors that influence a country's score, such as its history of digitisation, degree of healthcare centralisation, and cultural acceptance of mass technological shifts.
- Countries can be grouped into three archetypes based on stage of maturity: Architects, Builders and Operators.

Digital Health System Maturity Scores



Digital Maturity Archetypes



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Health Systems

Published: February 2024

Harnessing the Power of Patient Organisations: A Case Study of PO-Driven Drug Development in Ultra-Rare Disease

Report summary

Rare and ultra-rare diseases are an area with significant unmet need but also much development activity. While overall, R&D in rare diseases performs slightly better than R&D overall, there is considerable volatility reflecting the special challenges in this area.

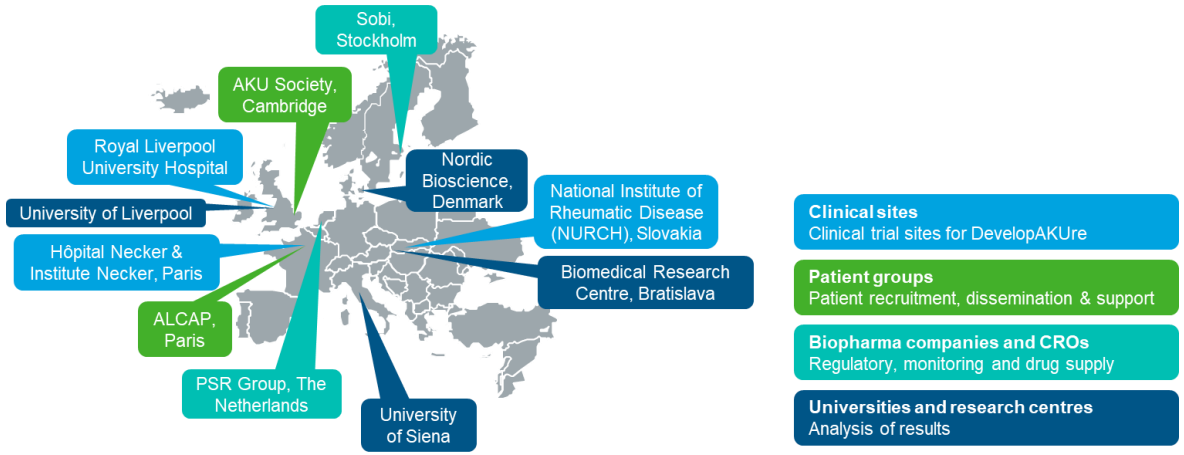
As the example of the development of nitisinone as a treatment for Alkaptonuria (AKU) shows, patient organisations can be powerful drivers of drug development. Because of their personal involvement, they have an intimate understanding of the unmet needs of their patient communities as well as unrivalled access to these communities. They can provide invaluable input into trial design and understand how to genuinely prioritise patient concerns and needs. Their main limitations are usually financial. In this instance, the patient organisation also took on the role of instigator of the drug development process, putting together a research consortium and coordinating the stakeholders involved.

Especially in rare disease development, close alignment with patient needs and expectations is indispensable and patient organisations are able to provide this connection. For pharma companies, seeking out collaborations with patient organisations is therefore an advisable approach but requires careful and consistent management to succeed.

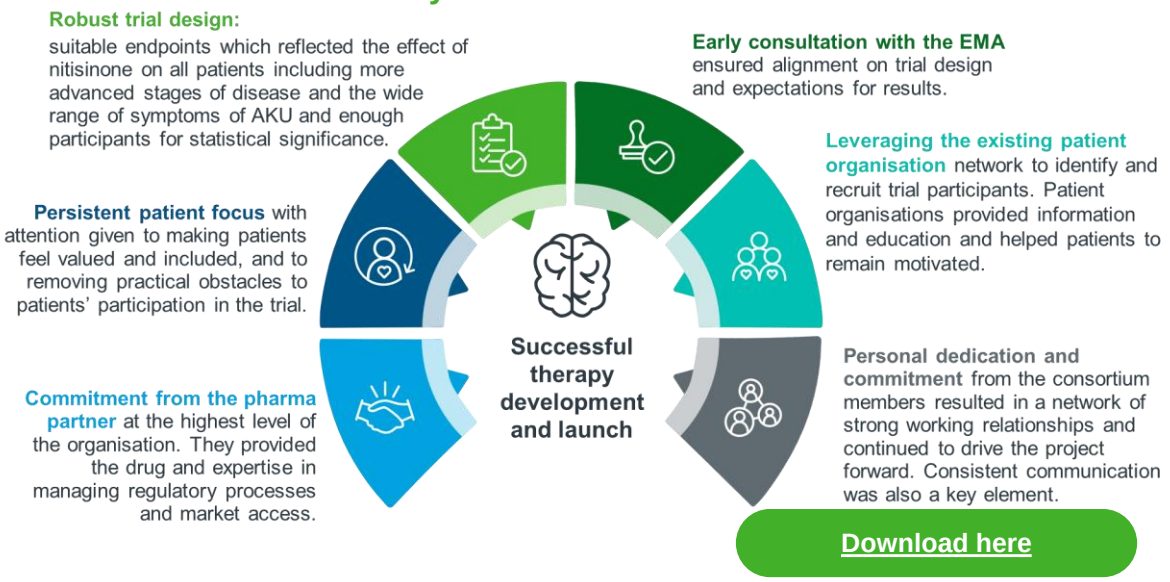
Key findings

- To improve R&D efficiency in rare and ultra-rare diseases and bring much-needed treatments to patients, collaboration between pharma and patient organisations is a promising approach, but to succeed, it is crucial to consider some key success factors.
- Pharma must have a good understanding of patient organisations and adopt a respectful approach – patient organisations are not just another supplier.
- Patient organisations for their part will benefit from embracing an entrepreneurial and pragmatic mindset in engaging with pharmaceutical companies.

Geographic distribution of the research consortium



Key success factors



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Published: August 2023

Firestorm to Burnout: The Impact of the Pandemic on Healthcare Professionals

Report summary

During the pandemic, healthcare professionals have demonstrated extraordinary tenacity, resilience, and dedication. Although the pandemic is now largely behind us, both healthcare systems and healthcare professionals (HCPs) are currently facing huge stresses, many of which have been exacerbated rather than caused by the pandemic and are unlikely to be resolved soon.

In early 2023, IQVIA conducted a survey of 720 primary care and specialist physicians across six countries to better understand how healthcare providers and their patients are affected by the COVID-19 pandemic and its aftermath, what their expectations for future developments are, and how other healthcare stakeholders can support them.

From their responses, it is clear that the aftermath of the pandemic is still with us and is likely to be so for some time to come. Many are reporting an increase in patient caseload as a consequence of the COVID-19 pandemic, with patient backlogs and remote management of patients the leading causes of the increase.

The survey confirmed that pharmaceutical companies have a role to play in providing resources and support that will ease the burden COVID-19 at several points in a product's lifecycle, especially during and post-launch.

Key findings

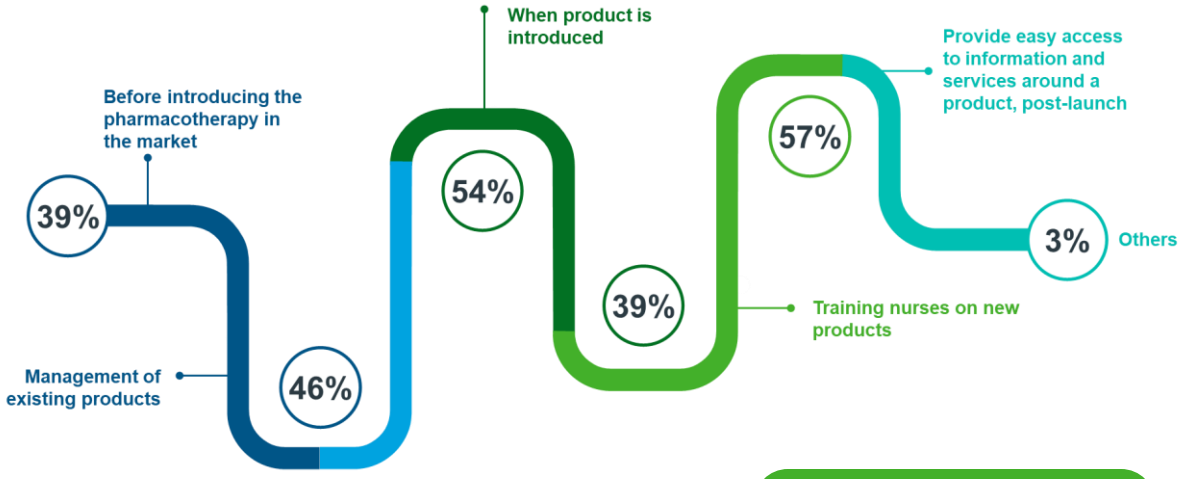
- To ensure the future resilience of healthcare professionals, continuous support is needed from the government, policy makers and employers in providing the resources needed to alleviate the post-COVID-19 burden, especially around improving the work environment and increasing the health workforce.
- For pharma, there is considerable scope for engaging with HCPs by providing support throughout the product lifecycle, provided it is tailored to HCPs' needs and preferences. Expectations of support include a wide range of potential measures, from patient support programs to insights on managing patients and provision of innovative products which reduces time requirements for patient care.

Ongoing impact of COVID-19 on non-COVID-19 health services

	(n=120)	(n=120)	(n=120)	(n=120)	(n=120)	(n=120)
Understaffing due to resignation and burnout	56%	57%	63%	53%	**74%**	64%
Patient backlogs	55%	64%	30%	68%	**79%**	41%
Increased healthcare demand due to infectious disease waves	59%	53%	40%	**63%**	48%	39%
Under-treatment of conditions due to lockdowns	41%	45%	22%	53%	**71%**	43%
Load of long COVID-19 cases and other complications of COVID-19	58%	38%	36%	41%	43%	37%
Higher healthcare expenditure mainly for cleaning equipment and PPE	43%	38%	33%	28%	28%	47%
Lack of comfort in using digital platforms	20%	23%	21%	30%	27%	16%
Others	7%	3%	4%	3%	3%	4%

61% 56% 51% 46% 42% 36% 23% 4%

Stages of the product lifecycle where HCPs expect support from pharma



n = 720

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Published: July 2023

Hospital Capacity Management: Making Best Use of Available Resources

Report summary

Hospitals and hospital workers are facing an increasingly harsh healthcare environment. Underlying long-term trends of demographic change and more advanced, but also more expensive, therapies test the affordability of healthcare systems, and the post-pandemic fallout along with a global economic downturn mean healthcare budgets will be tight for years to come. Healthcare workers, too, are becoming a rare resource, with more workers leaving the profession than entering it, and with those who remain struggling with burn out, overwork, and physical and mental fatigue.

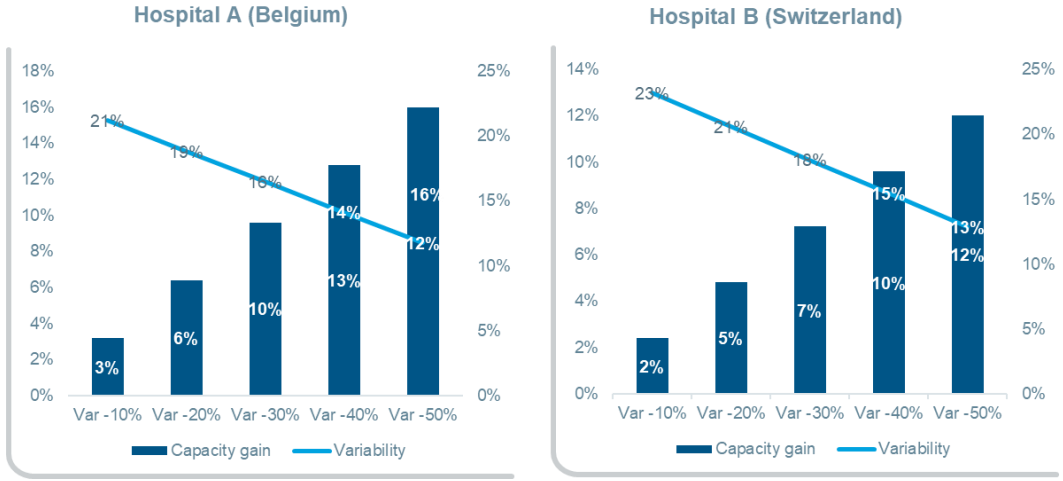
Hospitals will have to learn to meet rising demands without a concomitant increase in resources and will have to contend with higher expectations not only of the quality of treatment and care, but also increasingly of the quality of the patient experience and workplace environment.

Effective capacity management is therefore an essential part of the operational and strategic toolkit for individual hospitals of all sizes and networks of multiple providers alike. Capacity management enables achieving optimum resource utilization through aligning resources, processes, and planning across individual providers and networks and is a fundamental component in any strategy to future-proof hospitals in a world of scarcer resources and higher demands.

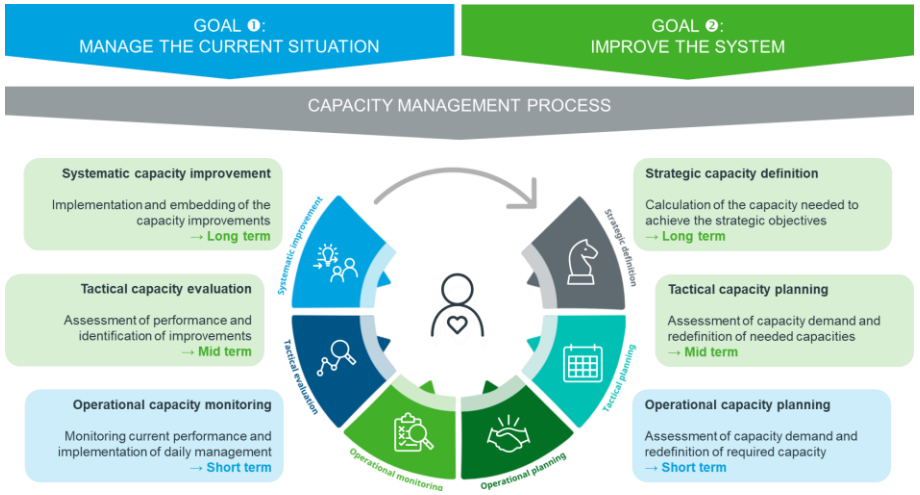
Key findings

- Hospitals will have to get better at managing capacity since “doing more with less” will be the maxim for the foreseeable future. Effective capacity planning is a key pillar in hospitals’ toolkits to master the ongoing and future challenges of the changing healthcare environment
- Capacity management enables shorter patient stays and higher numbers of treated cases with the same level of resources.
- It also leads to a less stressful working environment for staff and a better patient experience, helping hospitals to position themselves in an increasingly competitive market.

Reducing variability leads to capacity gains



Capacity management enables operational, tactical, and strategic planning



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Published: May 2023

Your Order has Been Dispatched: Opportunities in Moving Care Nearer the Patient

Report summary

The healthcare sector has increasingly moved towards treating patients at an individual level, both in terms of patient centricity and personalised medicine.

As part of this phenomenon there is a growing focus on providing patients with greater flexibility with where and when they receive care. It is important to stress that this movement is not merely looking to increase at-home delivery of medicines, but instead to introduce structural changes to healthcare systems, focusing on treating patients outside of the hospital where feasible.

There is no one-size-fits-all approach to near-to-patient care, which features various care delivery endpoints ranging from outpatient centres to homecare, alongside increased telehealth usage and patient-friendly drug formulations and devices.

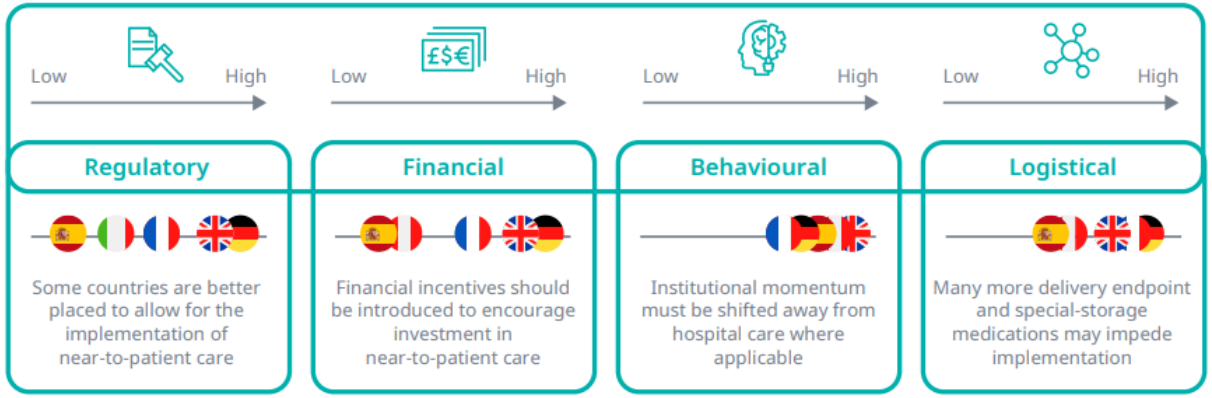
Whilst many strides have been made, there remain challenges to overcome, which can be grouped into four main categories: Regulatory, financial, behavioural and logistical. These challenges must be addressed collaboratively by all stakeholders to maximise the potential of a near-to-patient system.

For those that successfully navigate these challenges, significant opportunities arise, from new markets to increased control over one's own healthcare.

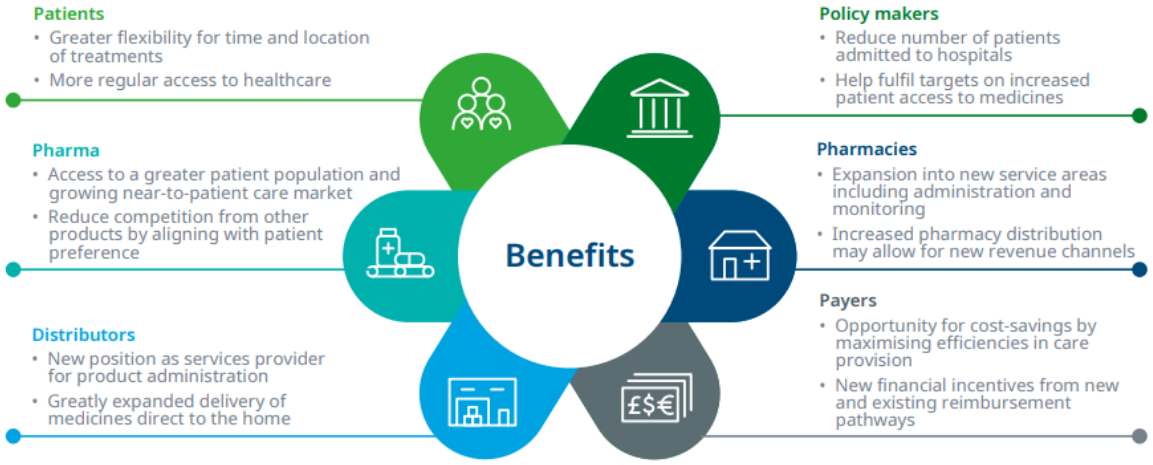
Key findings

- There is a growing focus on providing patients with greater flexibility with how, where and when they receive care.
- A near-to-patient care system involves moving healthcare closer to the patient through more delivery endpoints, telehealth usage and patient friendly formulations and devices, bringing a range of benefits to stakeholders.
- To maximise these benefits, stakeholders must navigate four challenge areas: behaviour, regulatory, financial and logistics

Qualification of readiness for near-to-patient care by country, EU4 & UK



A breakdown of benefits to the stakeholders in near-to-patient care



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Published: April 2023

Making Best Bets: Prioritizing Expenditure for Maximizing Impact on Patient Communities

Report summary

Balancing the competing priorities of investing in research, patient services, fundraising, and running an effective organization has long been a challenge for patient organizations. To effectively prioritize resources, patient organizations take a structured, systematic approach that involves analyzing the research pipeline and the entire space related to the focus disease(s) to identify areas where the organization can make the biggest difference.

As research progresses and the understanding of the disease and patient needs evolves, patient organizations readjust their priorities, including shifting focus to developing therapies, tackling particularly bothersome symptoms, or lobbying for access to new therapies. Patient-driven prioritization of goals is becoming increasingly important, as organizations survey patients to gain insight into their experiences and identify areas where research is lacking. Patient organizations play an important role in amplifying the voice of patients and providing insights to policy makers, private investors, regulators, and industry, and gain considerable leverage this way.

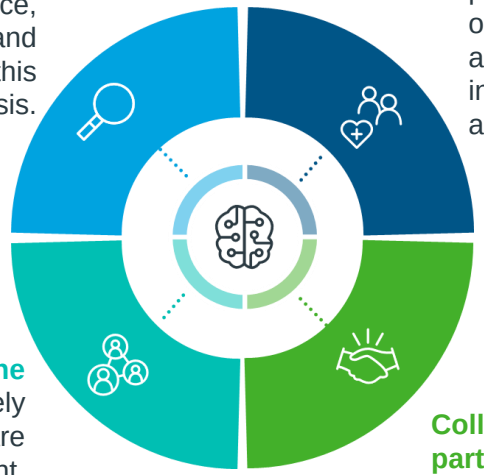
Key findings

- Focus and prioritization are key for all patient organizations irrespective of size.
- Leveraging the power of collaboration and partnerships with all stakeholders in healthcare is key for enabling patient organizations to punch above their weight.
- Patient organizations are the ultimate source of knowledge about their patient communities, and they should not hesitate to use this lever.
- Patient organizations should not be afraid to invest in their organization since an adequately resourced organization will be more powerful, more efficient, and better able to support the mission goals.

Key factors for successful patient organizations

Focus and prioritization are key for all organizations irrespective of size. Organizations must decide which outcomes they are trying to achieve, what will make the biggest difference, for whom and how fast, and base strategy on this analysis.

Patient communities: Patient organizations are the ultimate source of knowledge about and access to their patient communities and can participate as peers and opinion leaders with academics, with the industry, with regulators, and policymakers.



Investment in the organization: Adequately resourced organizations are more powerful, more efficient, and better able to support the mission goals. Investing in people by building out internal capacity and expertise will allow them to fully leverage their potential

Collaboration and partnerships with all stakeholders in the healthcare space enable patient organizations to punch above their weight.

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Published: February 2023

Planning to Engage: A Holistic Approach to Patient Inclusion

Report summary

For pharma, patient centricity has become a strategic imperative as the rise of individualised medicine, a trend towards remote treatments including self- or home administrable drug formulations collide with the post-pandemic fallout of disrupted patient journeys and severely constrained healthcare resources. This necessitates a patient-inclusive approach across the entire pharma value chain.

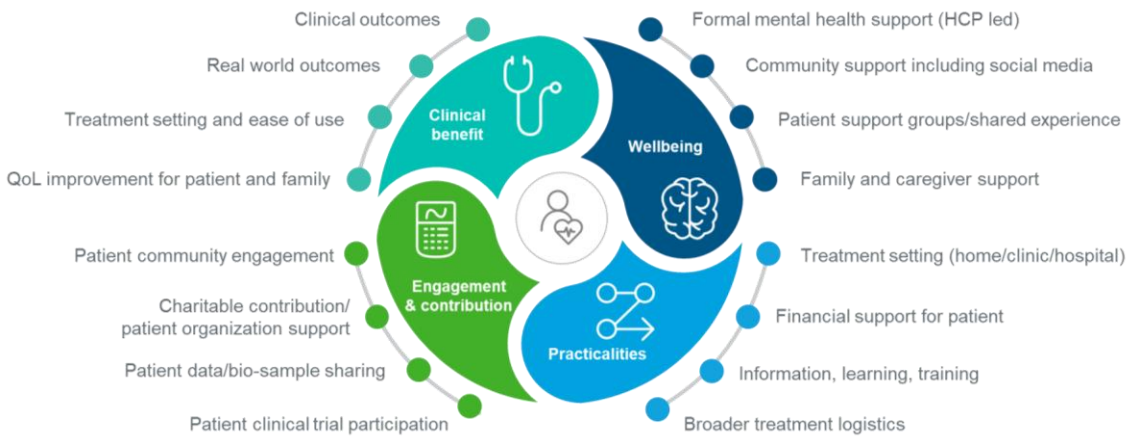
To fully reap the benefits of patient centricity, a complete, 360-degree view of the fundamental components of patient-centred asset strategies, clinical trial design, pre-launch planning and patient support programs from the perspective of patients is needed. This view must include direct input from patients and patient organisations to ensure it reflects a true understanding of the patient perspective. This in turn necessitates a common framework and language as foundation for effective communication between all stakeholders.

To meet this need, IQVIA has developed a Patient Engagement Framework in collaboration with patient organisations and pharma to support comprehensive and consistent assessment and planning for the inclusion of patient needs and preferences.

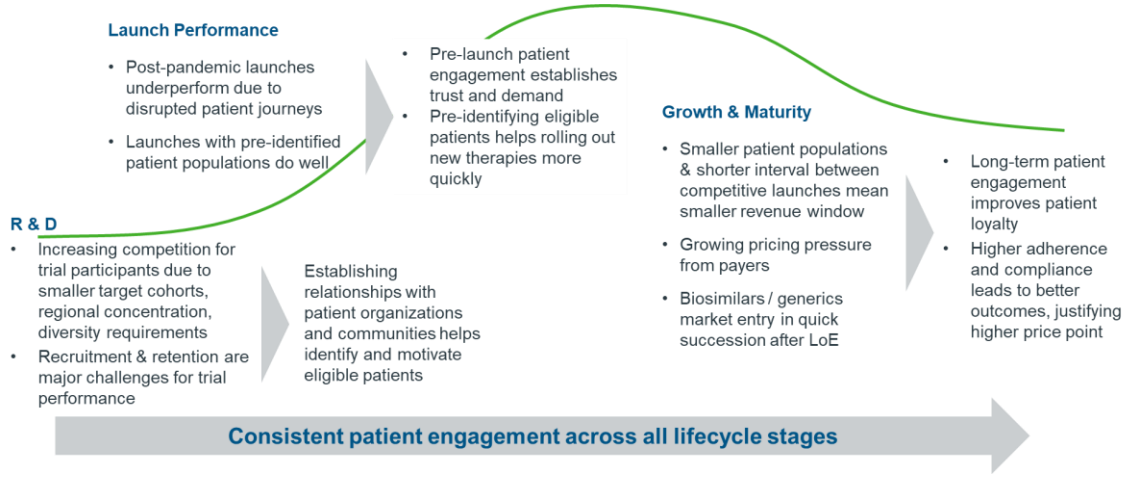
Key findings

- Patient engagement is the key to maximising benefits of new therapies for patients, the healthcare system, and the industry. Stakeholders including pharma, regulators & policy makers and patient organisations have recognised this.
- For successful patient engagement, direct input from patients and patient organisations is vital to ensure the patient perspective is truly understood.
- To reap maximum benefits, all stakeholders must find a common language and understanding. The IQVIA Patient Engagement Framework is designed to support and enable this understanding.

IQVIA's Patient Engagement Framework



Benefits from patient engagement across the entire lifecycle



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Published: September 2022

Finding All the Needles in the Haystack: Technology-Enabled Patient Identification for Clinical Trials

Report summary

While trial activity and the number of participants globally are on the increase, trial productivity is dropping. One factor for this is the large number of studies which fail to enrol enough participants. The overall increase in demand for trial participants, geographic concentration of trial activity, complex inclusion and exclusion criteria, and diversity requirements are some of the contributing factors.

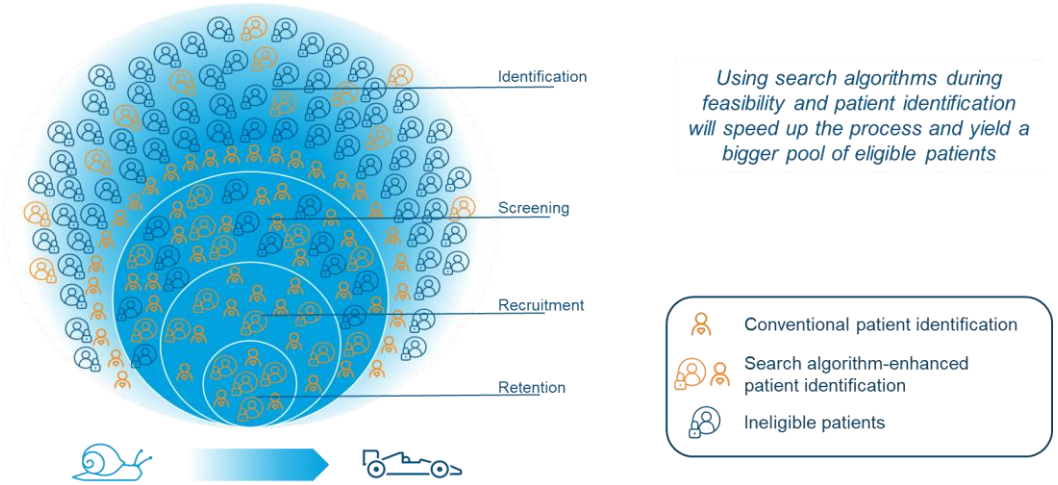
The use of technology-assisted approaches such as query-driven search algorithms and centralised data management systems can help overcome the challenge of patient under-enrolment. The use of algorithms to search electronic healthcare records (EHR) has been shown to be effective in identifying eligible patients and extracting relevant data points. Using these algorithms during the feasibility and recruitment phases will ensure efficient and effective patient identification and minimise the number of low-enrolling sites. For best results, the use of search algorithms should already be considered when drawing up the study protocol.

Incorporating technology-assisted solutions will also result in significant time savings for healthcare workers and free up resources in the health system.

Key findings

- Identifying eligible patients during the feasibility and recruitment phases of clinical trials is key to successful product development since under-enrolment is a major factor in underperforming clinical trials.
- Using customisable query-driven algorithms to search electronic health records has been demonstrated to be a fast and reliable method for identifying eligible patient even for very large numbers of records and complex cohort criteria.
- A technology-driven approach is also very resource-efficient and will relieve pressure on overstretched healthcare providers.

More efficient feasibility and patient identification using search algorithms



Direct and indirect costs of under-enrolment to trial sponsors and research sites

Loss of revenue through delayed time to market

Under-enrollment leads to longer R&D times, resulting in delayed time-to-market, and ultimately lost revenue due to shorter time in the market before LOE or competitor entry

Cost of non-enrolling sites

Many initiated sites do not enroll any or very few patients, delivering no or very low return on the cost of initiation

Adjustments to study protocol

Eligibility criteria or other aspects of the study protocol may have to be adjusted, resulting in further delay and additional costs

Loss of revenue to trial sites

Revenue from trials can form a significant part of research sites' revenue stream. Underperforming trials therefore have a real economic impact for research institutions

Opportunity cost to trial sites and sponsors

Due to financial and staffing resources committed to under-enrolling and therefore potentially under-performing studies, other studies may not be able to be conducted

Limited scientific benefits

Low patient numbers result in too few data points for statistically significant conclusions

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Global Public Health

Published: October 2023

Climbing the Mountain One Step at a Time: How patient organizations in Africa are advancing healthcare

Report summary

The African healthcare landscape is rapidly evolving, and patient organizations have a significant role to play in this development. They provide education and support to their patient communities, raise awareness, and advocate for their communities' unmet needs with governments, healthcare systems, and international organizations. In doing so, they highlight where the most urgent needs are and often demonstrate how these can be met in the most resource-efficient way.

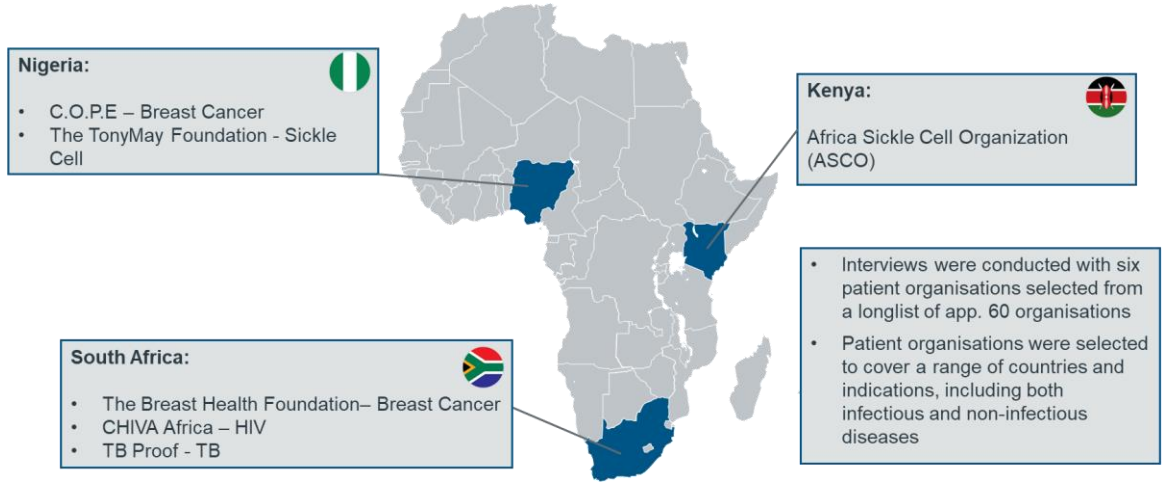
This white paper takes a closer look at the current situation of patient organizations in Africa, the challenges they and their patient communities face, and their impact, based on in-depth interviews with representatives from six organizations. These organizations are based in Nigeria, Kenya, and South Africa and are active in HIV, sickle cell disease, breast cancer, and tuberculosis.

Because they build close relationships with their communities, they are uniquely placed to understand the most immediate unmet needs and develop unique, creative solutions. They also bring these unmet needs to the attention of healthcare stakeholders. Their main limitation is that of financial and personal resources. If governments and healthcare systems aim to improve healthcare delivery on the ground, seeking out partnerships with and providing support to patient organizations is one avenue towards this goal.

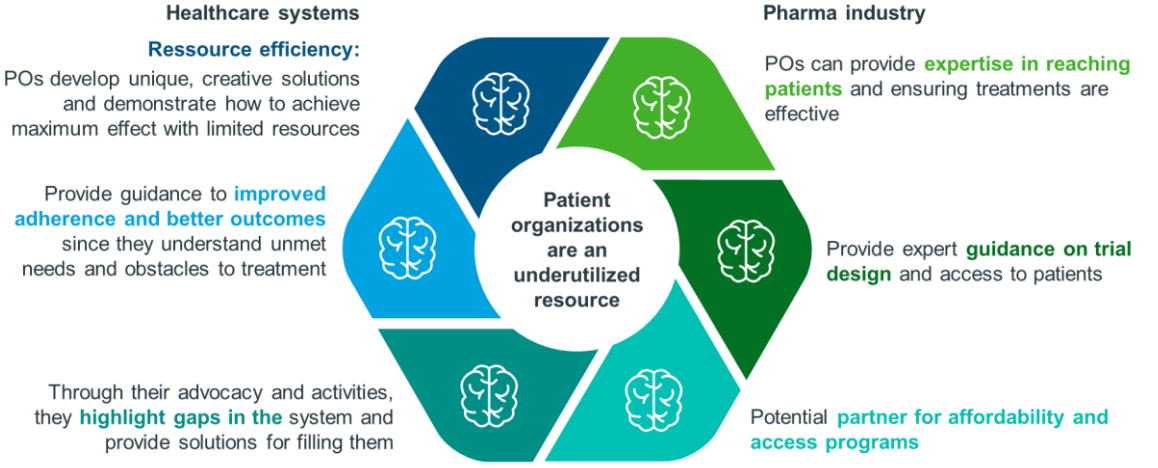
Key findings

- Patient organizations in Africa have unique insights into the needs of their communities as well as developing creative solutions on a shoestring. Their limitations are largely financial, and they represent an underused resource.
- Healthcare systems can benefit from co-operating with and learning from patient organizations to improve patient outcomes and resource efficiency
- There is also potential for pharma to cooperate with patient organizations to gain access and insights into patient communities, but this will require relationships built on trust and transparency, putting patients' and patient organizations' needs first

The paper is informed by interviews with six patient organizations



Healthcare systems and pharma can benefit from co-operating with and supporting patient organizations



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Published: September 2023

Digital Health Systems in Africa: A convergence of opportunities

Report summary

Africa's young tech-savvy population, combined with a rise in non-communicable diseases and a threat from climate change, is creating a convergence in health challenges that can be unlocked by digital technologies.

The needs for digitisation faced by Africa are borne from similar causes as highly developed regions but opportunities manifest themselves differently due to unique features such as:

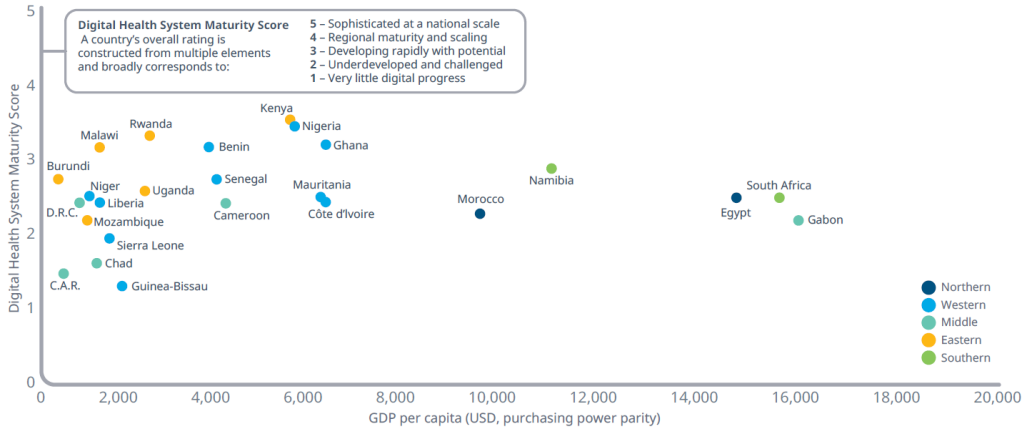
- **Timing**. Many open-source technologies are maturing right now.
- **Leapfrogging**. Bypassing systemic challenges in infrastructure development.
- **Collaboration**. Opportunity to build pan-African standards and regulations.
- **Open source**. Collaborative approaches are cost-effective solutions and scalable.
- **Determination**. International multi-donor funded initiatives.

Africa stands at a transformative juncture in its healthcare evolution and is increasingly ready to capitalise on greater digitisation. These advancements will allow Africa to prepare for novel challenges in the evolving healthcare landscape, from shifting disease patterns to the health impacts of a changing climate.

Key findings

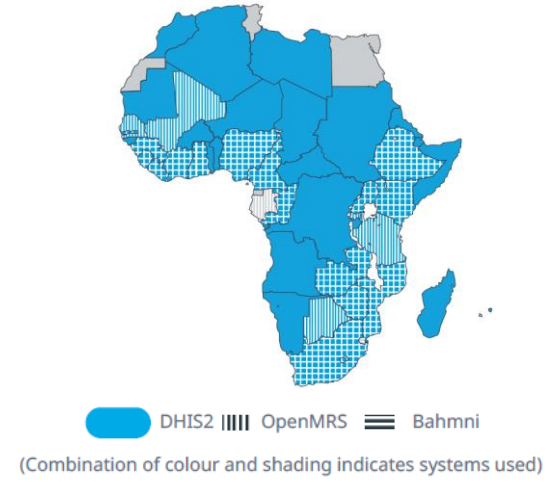
- **Private/Public sector disparity**. Private sector funding is often greater than public.
- **Underdeveloped Electronic Health Records.** There is no consistency across countries concerning operational EHR networks.
- **Mobile Health prominent but not universal.** There are substantial variations in mHealth implementation across countries.
- **Scalability and long-term commitment.** Impact from many projects are minor.
- **Future-fit systems.** Emphasis on addressing infectious diseases. However, there is a steady continental shift occurring, from acute diseases to chronic conditions.

Level of digital health system maturity across Africa



Source: IQVIA EMEA Thought Leadership; Based on interviews, surveys and scores from the Global Digital Health Monitor May 2023.
Notes: D.R.C. = Democratic Republic of the Congo; C.A.R. = Central African Republic

EHR system country coverage



(Combination of colour and shading indicates systems used)

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