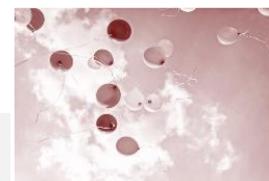


THE LAUNCH LEADERS' GUIDE

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LAUNCH LEADERS' GUIDE PART 1

To Delay or Not to Delay the Launch – 'That is the Question' Nowadays

Welcome to the Launch Leaders' Guide! Hot on the heels of the wild success (in the author's mind, at least) of the Brand Planners' Guide in 2019, here we have a new launch excellence series on launch leadership in pharma and biotech.

Having had the privilege of working on a number of UK, European and global launches over the years in different capacities, I had thought about starting this series with an examination of what makes a launch excellent or, at least, jolly good news for patients, prescribers and the pharma industry. However, in light of COVID-19, we have seen an unimaginable series of events impacting the planning and implementation of pharma launches: delays in clinical trial recruitment, transfer of field-based medical, access and sales teams into virtual working settings, delays in regulatory approval timings, cancellation or postponement of major congresses and much more.

And at this time, never have I felt more proud to work in this life sciences industry where we are researching, developing, testing, collaborating and doing so much more to find a solution to the global coronavirus pandemic, as well as to many other rare and not so rare diseases.

Working across the industry with different teams and in different therapy areas, there are so many questions to address:

- **How** will my launch timelines be impacted?
- **How** will the post COVID-19 situation impact physicians, payers and patients' attitudes, behaviours and priorities?
- **How** do I move my engagement and promotional mix to more virtual / digital activities?
- **How** do I plan my launch across countries and functions in the virtual environment?
- **What** will the impact be on launch uptake in the short and medium term?

Wherever you are in your launch planning, it is worth going back to revisit your launch assumptions, timings, channel mix, tactics and forecasts – and probably much more. The good news is that cross-functional launch teams can work productively and virtually with a common goal and set of priorities. Here are ten immediate areas to review for your launch:

- Are your clinical trial, submission, approval and reimbursement timing assumptions still valid?
- What kind of changes are there to your patient, physician and payer insights and the external environment in which they will be operating in 2021?
- How is the competition being affected by COVID-19?
- What are the key internal and external assumptions that you are making as a team and what are the two or three alternative scenarios that you can foresee?
- Can you still guarantee your launch supply volumes will be on time and get to your key centres?
- What are the new scientific engagement / promotional channels for your target customer groups across the pre-launch / post-launch timings?
- How will the national and local access, health economic and formulary decisions be impacted?
- How will these changes impact your needs for resourcing (teams, spend, timings)?
- What will the impact be on your launch uptake vs. your previous forecasts?
- How will you continue to engage your entire organisation in your launch to make it a success from a belief, mindset and innovation perspective?

There is a lot to think through, including some bigger strategic decisions on whether to delay the launch, launch 'softly' and then deliver a high profile launch down the line or push forward and launch with the highest profile digital, PR and virtual set of activities available. If I was a potential patient for some of our industry's newest medicines, I know what my vote would be for.



LAUNCH LEADERS' GUIDE PART 2

What Does the Launch Environment Look Like In the 'Next Normal'?

If you're leading or working on a launch – whether it's a new indication, formulation or a completely new molecule and brand – you may be thinking carefully about what you are able to do both pre-launch and post-launch as the months progress in 2021.

It has never been more important to create different launch scenarios with supporting strategies and tactics. We have talked a lot about 'agility' but now is the time to truly implement this. As a specialist in pharma / biotech launch excellence, I feel so proud to be working at the forefront of the industry's new medicines, but I appreciate it's a super tough environment to launch into.

Some companies are moving forward boldly with their launches, using a strong digital engagement strategy – usually with heavy early investment across key stakeholder groups. Some are delaying or are being delayed from a clinical trial, regulatory, access or internal operational perspective.

Taking a look at what's been happening in our industry over recent weeks and months, here are some encouraging reports and pieces of analysis from across our industry:

- **Digital channels** have had a massive boost for 1:1 interactions, group sessions and of course email (with an increase of 482% according to Veeva), website, webinars and much more – our IT teams have been busy! But other reports show that physician satisfaction with some of these channels is low
- **Face-to-face interactions** are making a comeback (after live events decreased by 41%, according to Veeva) but this is highly dependent on which country you are working in and of course may change with any future second wave of COVID-19.

In my work with launch teams across the industry, teams are keen to understand the tactical options and best practices for pre-launch and post-launch in the current environment. Of course, this depends on the current government guidelines and the therapy areas they operate in.

It's been really exciting to see how different teams across the industry have 'flipped', 'pivoted', 'flexed' and 'adapted' their launch strategies and tactics to the current world we are operating in – keeping the patient and physician at the centre of their thinking. It will be great to see examples of this agility in the coming months as we share best practices and build further skills in virtual working.

So more than ever, it's worth looking at the latest economic and health statistics to help you make some clear assumptions for your launch: in classical terms, a base case, the upside and the downside. Global economic forecasters warn of a full global recession, and health forecasters warn of a second wave, or multiple minor waves, that may impact healthcare systems in the coming months. There appear to be three key potential scenarios to consider for your launch (*New York Times, This is the future of the pandemic, 8 May 2020*):

1. **Peaks and valleys in 2020-21** – minor ups and downs, some having a major impact on regions / countries
2. **Fall / Winter burn 2020-2021** – major impact during the winter period in many countries
3. **Slow burn** – minor ups and downs during 2020 and 2021.

Scenario 1 is a mixed bag in which 'next normal' operations will need to be carefully orchestrated according to the timing and region and will therefore be dependent on virtual / digital interactions for continuity. **Scenario 2** is a more seasonal scenario, and the key question here is how to manage a future lockdown environment.

Scenario 3 consists of minor ups and downs with minimal impact on normal operations.

It's worth taking these three scenarios and translating them to your country and therapeutic area, as there is such a difference depending on the area you are involved in, ranging, for example, from oncology or severe asthma to fungal nail ointments. Most importantly, as a launch team define and align on the key assumptions for your scenarios and be ready to leap into another scenario if needed.

So, if you're in the middle of creating a global or local launch plan, it may need to look quite different from previous launches, in both structure and content – showing the impact of COVID-19, your scenarios and assumptions, as well as the capabilities and internal ways of working that are needed to be successful. This is no small 'ask' for large pharma companies that are used to operating in a more stable environment.

And finally, while times may feel tough and we may feel 'cooped up' in our virtual working environment, what better way to refresh our insights and thinking than by trawling online patient and physician community discussions to see what's changing. For example, patients are embracing telemedicine, internet sources and online pharmacy now more than ever and, as launch leaders, we need to do the same to achieve launch excellence.



LAUNCH LEADERS' GUIDE PART 3

What Makes a Great Launch Leader and Launch Team?

In our industry we have spent much time building launch excellence frameworks, processes and tools to help bring some structure, rigour and coordination to the complex and risky process of launching a new medicine globally. In this part, I'd like to focus on the launch leader and the launch team, the people who are the driving force behind the thinking, strategies, planning and execution of the launch over a number of years.

Having launched a number of medicines in different companies, I reflect that my launch roles were some of the most challenging, exciting, frustrating, exhausting and exhilarating moments in my career! Whether it was receiving a regulatory 'no' after a year of planning a respiratory launch in the UK or a European-wide successful cardiology launch that exceeded everyone's expectations.

As a launch leader and now consultant to launch teams and leaders, I have come to the conclusion that there is a special set of skills and behaviours that launch leaders and teams need in order to be successful. Building these skills and practising these behaviours can really make the difference between commercial success and failure, and also how the launch team feels, works and engages with important external stakeholders.

I'm often asked about the one key skill that a launch leader must have and I am quick to reply that there really isn't one. There are a whole range of skills that a launch leader must have and this ideal blend of skills can change across the pre-launch time frame and across different companies, markets and therapy areas. This lack of a nice 'cookie cutter' approach to launch is so important to embrace – a successful launch makes us think carefully about the specific blend of skills, processes and strategies we need.

From my research over the years with senior launch leaders across our industry, a few key skills have emerged:

1. **Attracting, motivating and developing cross-functional launch team members** – getting the right blend of personalities, experience, values and commitment from your team is generally cited as the most important of launch leader skills
2. **Strategic decision-making and alignment** – the ability to create a compelling launch excellence strategy adapted to the local market, therapy area, competitive context and external environment ensuring critical success factors for the launch are identified
3. **Effective engagement with external and internal stakeholders** – the ability to build credible, sustainable relationships with scientific thought leaders, pricing and access stakeholders, regulators and patient group leaders, as well as key internal stakeholders to get decisions made and resources in place
4. There are also a host of **other skills** related to planning, project management, tracking launch readiness, anticipating future issues and monitoring, that speak to the discipline needed to lead an effective launch
5. **Technical skills** are also important of course: a deep understanding of the science, experience in the therapy area, and an ability to create a strong operational launch plan.

Some of the most successful launch leaders I have observed have many of these skills but not all. That's where the first skill in building a cohesive, complementary launch team comes in.

Ultimately the most successful launch leaders I have come across demonstrate an authentic commitment and inspirational style in the way they translate what their launch will bring to patients. They invest in building the right team, creating the right roles, culture, ambition and ways of working before jumping into the tasks at hand. They will include their key strategic partners – agencies, suppliers and consultancies – in key meetings and planning sessions. And when the going gets tough with a regulatory delay, a supply chain issue or a tough internal business review, they keep calm and positive, with a focus on the end goal of a successful launch.

There are some great practical tools and techniques to support a successful launch leader and team: creation of a launch team charter and ambition, deep dive

planning sessions, celebrations at key milestones, launch team temperature checks, launch excellence training sessions, innovation competitions and much more!

It's been wonderful to see launch excellence at work in recent times – shifting to digital or hybrid programmes, changing to a host of new ways of working, flexing strategies, working across different locations and time zones, using technology to run launch planning sessions and not only connecting regularly with daily and weekly check-ins, but supporting fellow team members if they are feeling overwhelmed with a 'virtual cup of coffee' or finding a 'virtual hot desk buddy' for the day.

I'm excited to see how launch plans, strategies and teams evolve even further in the future so we can keep up the pace of launches of innovative medicines, devices and services to benefit the people who need it most.



LAUNCH LEADERS' GUIDE PART 4

Praising the Medical Team for an Excellent Launch

Finding great medics to work on a launch team is a tough challenge, but definitely worth the effort

In this part, I'd like to recognise a group of wonderful people who have become more and more important in guiding and delivering a successful launch. It's the medical team!

In recent years, the number and range of medical roles has increased significantly when other more traditional sales or commercial roles have been in decline. There are now medical roles covering medical affairs, medical information, scientific communications, R&D, clinical trials, compliance, scientific advice, medical science liaison and a number of new hybrid roles to manage relationships with thought leaders, patient groups, national payer and guideline bodies, and to support large multichannel engagement campaign content. And in the context of launch, the medical team are often some of the first roles in place to shape early new product planning at a global or local level.

In my experience of working as part of a launch team, I've been guided and inspired by my medical colleagues who are able to build strong relationships with scientific / clinical thought leaders, analyse and interpret complex clinical trial results and publications, and operate as a true strategic partner for key decisions relating to the target patient, differentiation and to explain how physicians think, feel and behave in a particular therapy area. Medical roles have evolved light years away from a more passive, signatory function to ensure compliance with industry codes of practice.

Finding great medics to work on a launch team is a tough challenge. It's a big jump for a physician to move from clinical practice into the pharma industry and there is often a lack of clear role descriptions, defined competencies, onboarding and training in the many organisational processes relating to launch. Some medics struggle with the move to a corporate environment with a whole host of new processes – internal communication, reporting, financial, planning, compliance,

management review, readiness, cross-functional brand team – that are involved in a pharma / biotech launch. Some industry medics can be left bewildered, unsupported and unhappy without the right support, guidance and encouragement from their team leaders.

When building a launch team, it's so important to define the key roles needed, their technical skills, as well as the softer skills needed, and to consider the personalities and fit of the individuals. When forming a launch team, I like to take the team away for a day or so and invest time in some team building, personality profiling and then to map out the team's vision for success for the launch and ways of working. It's so important that the medical roles are clearly defined at each phase of the launch and that the medics and the rest of the cross-functional brand team are all on the same page. Otherwise, this can lead to disconnects, missed deadlines, grumpiness, stress and worse within a launch team. A few stories and anecdotes come to mind as I write this...

When planning a global launch, I've seen some great industry practice from the medical leadership in clearly defining the structure and roles of the medical function at a global and local level. This may vary depending on the company culture and processes, disease area / speciality and launch archetype – a rare disease medical organisation will look very different from one in vaccines or cardiology. Other examples of industry medical excellence to support launch include:

- **Creating medical competency frameworks** for different medical roles and levels of seniority, with specific reference to launch excellence processes and tools / resources for core medical activities
- **Defining the softer and leadership skills needed** for key medical roles and providing these roles with development tools, training and coaching by senior medics with practical launch experience
- **Creating training programmes** to support medics with their capabilities in launch planning, strategy, creating a winning medical affairs launch plan, project management and reporting, working with agencies, innovation, multichannel engagement and industry trends in technology, market access, evidence generation and even AI, data and analytics
- **Setting up processes** for medical teams across brands and launches, to share internal best practices and leverage external industry best practice.

Finding a true medical launch leader can have an enormous impact on the planning and ways of working of a launch team, as well as creating strong relationships with external experts and thought leaders to shape the launch strategy and investment in major programmes of evidence generation.

The best medics I remember from launch teams in recent years all have a strong focus on the launch team (vs. the medical function), the treating physician and the target patient, and a sense of positivity and resilience even in the face of change or setbacks in the launch. They are not afraid to roll up their sleeves and help out and can frequently be found right by the side of their commercial colleagues, a true leader in the launch team. Thank you, magnificent medical team!



LAUNCH LEADERS' GUIDE PART 5

How Can Launch Leaders Innovate?

2020 was a tumultuous year on so many fronts and has also stimulated so much innovation across different teams, functions and disease areas as our industry jumps into a new way of working in the 'next normal'.

There are some wonderful examples of multi-brand, multi-country innovation across our industry as we strive to do things better and solve problems, with the ultimate goal of improving the lives of patients. In recent months I have been doing a good deal of work with teams who are working on how to innovate, evolve and transform in different ways to launch their medicines successfully. It's really thought-provoking and rewarding work!

So what do we mean by innovation? I like to think of three different types of innovation:

1. **Incremental innovation** – utilising existing technology, processes and capabilities to deliver small stepwise improvements
2. **Disruptive innovation** – where a smaller company / player with fewer resources is able to successfully challenge incumbent businesses
3. **Radical innovation** – new industries, products, services or processes that are transformative.

A launch leader will be best served to deliver an innovative launch with the right internal environment. In his book *'Be Less Zombie'*, Elvin Turner identifies that organisations which are highly innovative will have processes, capabilities, leadership, culture and resourcing dedicated to supporting innovation.¹

¹ "Be less Zombie" Elvin Turner

We could all do with being a bit 'less zombie' in our launches, but in practice that's easier to say than to carry out in reality. Tight timelines, low levels of resourcing, complicated external environments, changing product profiles and complex internal stakeholders are just a few of the challenges that a launch leader has to navigate.

So which companies are winning at innovation in 2020? Forbes' most innovative companies in 2020 has Siemens, J&J, Bayer and Novartis in its top 50. However, if we look at the other companies across tech, social media, devices, diagnostics and more, many of the top 50 companies have a significant interest in healthcare.

So, if you're a launch leader and thinking about how you can innovate across the different strategic elements of launch, I'd like to propose a **'ten Ps' framework** (yes, Ps are well used in business practice). Consider the following ten Ps to give you some stimulus to identify two or three (but no more) areas to innovate across your launch: Price, Partnership, Physical Evidence, Patient, Place, People, Processes, Product, Personalisation, Promotion. Run a workshop with your cross-functional launch team and see where their collective creativity, expertise and energy takes you!

I'm also asked other questions, such as 'Are there truly innovative people and less innovative people?' and 'How do we build innovation skills within our launch team?' Research into innovation highlights the **five key skills of an innovator**: associating, observing, experimenting, questioning, networking (The Innovators' DNA, INSEAD). The recommendation in this great study into innovation is that we can all rehearse, hone and use our innovation skills in our roles with a little bit of discipline and effort.

So what does this mean in practice? If you're a launch leader and keen to foster capabilities and a culture of innovation, there are lots of things you can do:

1. **Spend some time as a cross-functional launch team** to reflect, plan and implement innovation initiatives
2. **Track what the competition is doing** to be innovative in your therapy area, category or sector
3. **Create reward / recognition schemes** for the innovators in your launch team
4. **Plug into internal and external networks** for practical sources of ideas on innovation

5. **Give yourself some protected time to 'be innovative'** – to think, plan, read, play around with an idea or problem
6. **Hire great agencies and partners** that offer new ideas and capabilities, and be careful not to shut down their innovative ideas.

I'm so excited to see brand and launch teams across countries defining problems or pain points, devising solutions and then testing / evaluating them. Whether you have a company innovation team or hub, retreat or hackathon – just go for it! Innovation is a core ingredient of launch excellence.

There are some great models, articles and resources if you are inspired to be more innovative. My favourites are Frugal Innovation and 'Be Less Zombie'.



LAUNCH LEADERS' GUIDE PART 6

What Should Launch Leaders Be Measuring?

Challenging a few norms in our industry so we don't become fixated on the wrong type of metrics

I would now like to explore what launch leaders should (ideally) be measuring at different phases of their launch – pre-, peri- and post-launch. I'd like to challenge a few norms in our industry as we can sometimes become fixated on the wrong type of metrics: what's the peak year sales figure? What market and class share can we expect? What's the likely uptake vs. previous launches in our company or in the class?

When working with global or local launch leaders, I've come across two distinct 'personas':

- 1. The strategic and numerical experts** run a tight project management ship, are immersed in the analysis, derive strategy from the numbers they see and will set a fully quantified set of KPIs adapted to different phases of the launch.

Are you one of these people? If so, you are in high demand! But don't forget the qualitative, intuitive insights that can come from real-life observation, interactions and 'gut feelings', based on healthcare and patient-centricity.

- 2. The number-phobic launch leaders** who delegate analytics, forecasting and measurement to finance, business analysis, competitor intelligence and sales force colleagues.

These launch leaders are much more comfortable immersed in the patient experience journey, insight generation, branding, team dynamics and thought leader interactions. Are you one of these people? If so, you're in high demand too!

Ideally launch leaders should combine these two profiles but often launch leaders come from either a quantitative or a qualitative background, which informs their experience and confidence.

So, the questions that a launch leader needs to consider are: what matters at each key stage of my launch? What information will help me make better strategic and operational decisions as the launch progresses to achieve launch excellence? Which KPIs do my senior management need to see?

Which KPIs are truly important from a patient, prescriber, payer, competitive and internal team perspective? Are we truly engaging and changing the knowledge, attitudes and behaviours of target customers in order to improve patient outcomes?

In my experience, some of the most important KPIs for the **pre-launch phase** are:

- Tracking to the critical launch path timeline – i.e. speed to market for regulatory, pricing / access, supply and commercial operations, and mapped vs. the competition
- Probability of success for hitting clinical trial primary endpoints and showing an improvement or differentiating benefit from alternative treatments
- Scientific thought leader engagement with the launch, active input to the clinical programme and strategy, active readiness with media and peer-to-peer activity, indicators of proactivity from thought leaders as 'extended' members of the launch team * Pricing, formulary and percentage open access to key territories or patient populations within a geography
- Prescriber understanding of the mechanism of action, published clinical studies and degree of unmet need, along with motivation to act in the future
- Engagement and support of the patient advocacy community and media
- Internal launch team belief in the success of the launch, and senior management support for the launch.

In the **peri-launch phase**, the focus is on implementation, communication and coordination on a daily and weekly basis. If you are in a global or regional team, my strong recommendation is to back off and let the local teams deliver the launch and engage with their local customers!

I know this is easier said than done. Some local launch teams create a 'global request triage manager' to process and respond to multiple requests for a variety of information across different functions.

But not all teams have the resources to do this. If your company has business analysts to manage your market research, performance analysis and reporting and launch excellence KPIs, they are an invaluable part of your launch team, helping to identify the issues that need decisions or management attention.

In the **post-launch phase**, this is the time to identify learnings, 'fast failures', share best practices with the next countries about to launch and, of course, to recognise the heroic work of the members of the launch team. In this post-launch phase, it's worth tracking:

- The highest performing launch tactics and how to measure their operational effectiveness
- The competitive response – strategically and operationally to the launch
- Who the early 'hot spot' prescribers and patients initiated in the first instance are
- Any lesser performing tactics, channels, content, messages – 'course correct' fast
- Payer, formulary and pricing / value discussions with how best to demonstrate the value of the new product
- How the media – medical and general – is covering the launch, disease area, access, policy
- Internal organisational learnings – processes that don't quite work or don't work fast enough, new capabilities needed for success
- Who the highest performing members of the launch team are – across territories and functions and ensuring their great work is shared and recognised.



LAUNCH LEADERS' GUIDE PART 7

How to Lead a Successful Launch In the Future

Some themes and questions that may help the next wave of launch teams and leaders

As we navigate through 2021 with continued uncertainty in our healthcare, economic and operating environment, I'd like to tackle the question of how to lead a successful launch in the future – across different therapy areas, different types of company and different countries.

There are many articles signalling further waves of the global coronavirus pandemic, new variants, new vaccines and new government regulations on businesses, healthcare professionals and the general public. It's difficult to make any firm predictions or specific recommendations on the future ingredients of launch excellence, but I'd like to present some themes and questions that may help the next wave of launch teams and leaders.

1. Be people focused, be kind

Here I mean 'people' in the context of patients, healthcare professionals, payers, decision-makers, carers and a host of internal stakeholders across the launch team, customer-facing teams and senior management. 2020 was a tumultuous year for us all and has impacted our daily lives, how we work, how and where we seek medical care and how we feel about our health.

Successful launch leaders will map the 'new normal' in their therapy area and local country and will capture these insights in careful patient journey maps, experience maps, conversations and decision-making processes. Mapping the practical steps and interactions between patients and healthcare professionals will be key, along with the emotional needs, motivations and frustrations. Being kind will elicit strong listening, empathy, understanding and a team-based approach to planning and problem-solving as a virtual launch team.

Successful launch leaders of the future will need a whole host of softer skills, around a culture based on kindness, in order to be successful – to effectively engage healthcare professionals operating in highly stressful situations and to lead virtual launch teams in a changing and complex environment.

2. Create a strong launch plan

Launch teams will need to invest more time in creating a really strong launch plan – working through the launch plan structure as a cross-functional team to define and align on key elements: the launch vision, objectives, specific areas of success or focus, the target patient, positioning, key messages, content and story flow as well as a series of flexible tactics pre- and post-launch with the right groups of stakeholders.

There's so much to think about, including the definition of key assumptions about the external environment and then the creation of alternative scenarios if (or when) the competitor, customer or market situation changes. These launch-planning skills are not just about mapping the launch critical path and timelines and project managing the key tasks; the 'new normal' of launch planning will consist of intense bursts of planning sessions creating a concise but high quality launch excellence plan to support decision-making, internal communication and coordination of activities. Successful launch teams may need to create concise, flexible plans – consisting of 20 pages or slides rather than 100!

3. Adopt a 'challenger mindset'

This is more easily said than done! I'm a big believer in Adam Morgan's Eating the Big Fish approach, adopting a 'challenger mindset' in order to change the norms of a particular market. This can involve doing something bold, different and consumer-focused to accelerate the growth of a new product or service.

This is an area that really excites me as the pharma / biotech industry has so much opportunity to innovate – across wearables / devices, digital technology that can track, communicate and alert, new biomarkers, new delivery systems and the creation of digital communities to share and collate data, and much more. Successful launch leaders will keep asking the questions to help identify potential ways to 'change the game' and make a positive impact on their therapy area.

4. New roles and tactics

In recent months, I've seen a number of new roles and tactics emerge across the industry – possibly all part of the new commercial model in pharma – but I prefer to think very practically about how new medical roles are emerging to address changes in care pathways, solicit scientific input and map budgetary implications of a new pharma product or guideline.

New digital customer-facing roles are emerging with flexible and shorter hours to engage with healthcare professionals using digital technology. There are also new hybrid roles to manage congresses and meetings virtually or in person using new technology platforms or working in partnership with professional organisations. Creating a series of launch tactics that can be flexed to local / regional conditions and priorities will be key. Successful launch leaders will also need to define the key capabilities of their launch team and the roles needed to succeed and may potentially reconfigure the 'usual' team.

5. Check the numbers

And last but not least, a successful launch plan, team and leader will need to have a series of numbers to help guide resource, tactical investment, timings, innovation, market potential, uptake curves and more. We're often being asked to do more with less, but I predict that in the near future successful launches will need strong investment recognising the current global environment. Could we do more with more?

Wishing everyone a happy and healthy year and I am looking forward to charting how launch leadership evolves throughout 2021.

Acknowledgements

The author, **Stephanie Hall**, is MD of the award-winning brand planning healthcare consultancy Uptake Strategies.