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The Launch Rollercoaster:

Riding the highs and lows

> *There is more pressure than ever to get a launch right first time, but the odds of this happening are diminishing. Very few launches exceed expectations, while many aspects of asset development are complex and fraught with challenge. This puts more emphasis on planning for success.*
>
> **Jane Shirley,**
> Global Practice Head, Asset Optimization and Commercialization – Lumanity

What does it take to ride the highs and lows and deliver launch success? That's what Lumanity set out to answer in its live Q4 2022 webinar, The Launch Rollercoaster. The three-part session focused on:

- The importance of developing trust
- Managing stakeholders' expectations across the launch timeframe
- How collaboration is essential to optimizing a business' resources
- Why an agile mindset is important for success when launching assets
- Finally, a panel of industry experts and a patient shared their experiences and opinions on launch success

Jane Shirley
Global Practice Lead, Asset Optimization & Commercialization, Lumanity

Mike Kelly
Principal, Commercial Consulting, Lumanity

Andrew Wood
Head of Behavioral Science, Insight, Lumanity

Alex Adams
Digital Marketing Excellence Lead, Roche

Louise Sheppard, PhD
Global Head of Launch Capabilities Centre of Excellence, Astellas

Graeme Johnston
Board Member, Patient Focused Medicines Development (PFMD)

Tracey Barnes
VP, Launch Excellence, Lumanity

John Crick
Launch Excellence Project Lead, Lumanity

Industry statistics suggest almost 50% of launches fail to meet expectations in their first six months. And in today's post-pandemic world, pipelines are under intense pressure and the stakes have increased dramatically. So, what can pharma do to better ride the ups and downs of launch?

Jane set the scene, "The value proposition is obviously crucial, but that needs to be combined with strong, high-quality strategy and organizational alignment. It is so important that stakeholder groups understand the interdependence of decisions and actions and the potential ramifications on different parts of the launch strategy. We need to be able to adapt to changing circumstances, because nothing ever goes exactly to plan."

Reshaping perceptions by nurturing trust

Andrew Wood is Lumanity's Head of Behavioral Science, leading a dedicated team whose sole focus is to find ways to find ways to drive behavior change in physicians and patients. Andrew set out to answer the question of how the industry can make product launch a success in the eyes of physicians and nurture trust.

Prior to the webinar, Andrew and his team conducted research to uncover what it might be about product launches that don't always hit the right note. To do this, they held in-depth telephone interviews with 20 healthcare professionals (HCPs). All experts in their fields across different specialties in the US and Europe (primarily those with a high frequency of new pharma launches) plus four pharma industry personnel. So, where is pharma getting things wrong in the eyes of HCPs?

It's not simply about providing information

"By not doing enough research into an HCP's unmet needs and what frustrates them, there's no emotional connection built and no real trigger to act," said Andrew. "Often there's an HCP population who might have been working in the same therapy area, perfectly happy with their existing standard of care for years. One thing we know in the behavioral science team is that doctors are loss averse, they're not necessarily out there striving for a new solution."

Trial design was consistently cited as the hardest element to get right and most common mistake. This is often due to over-optimistic trial data setting expectations too high, underestimating side-effects or getting the trial population wrong.

Meanwhile, execution is another area for improvement. According to the team's research, launches fail because HCPs can't access information about the product or don't feel reps are being transparent - a sure-fire way to lose trust.

Andrew referenced a popular behavioral science model, ***Cialdini's Principles of Persuasion***. This identifies seven core principles that affect decision-making shortcuts, particularly in relation to purchasing decisions - or in the case of HCPs, when it comes to prescribing a brand to a patient. Andrew applied it to eight key rules to building trust in the pre-, during and post-launch stages.

Figure 1
Behavioral science gives us the tools to harness trust and change behavior

Pre-launch

Rule 1: Stimulate curiosity, but don’t over-promise

If the product is game-changing, HCPs indicated that they want to know about it one to two years in advance. For launch that might mean getting the planning underway earlier than anticipated.

“A good pre-launch is like a coming attraction at the movies and, if there’s a new mechanism of action, getting people excited about it. By the time the drug launches, you feel like you’re comfortable with it already - getting people to fall in love with the drug before it arrives.” Hematologist, US

Creating a buzz, building excitement, cutting through the noise… all these are important to pique the interest of HCPs, but there are risks, warned Andrew:

“You want to create that excitement, comfort and discussion, but it’s got to be grounded in reality. Don’t set them up for disappointment. Do your research, know your product and know the market.”

Figure 2
Stimulate curiosity pre-launch

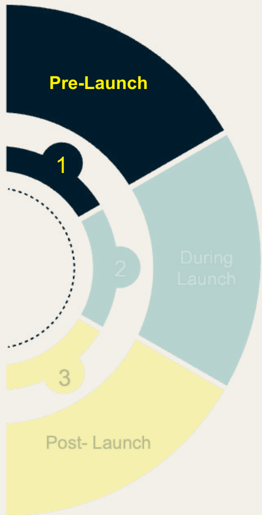
Rule 2: It all comes back to trial design

"From the beginning the study set up should be discussed with clinical physicians. It shouldn't be a solo effort by the manufacturer to present something sensational" – Oncologist, Germany

A unanimous rule of thumb picked up by the research was the need for advance planning. It's no surprise that ensuring the appropriate scale, correct geographical coverage and relevance to HCPs' patient populations are important to clinicians. But collaboration is key – working with HCPs to ensure clinical trial success and positioning results together.

"Pharma needs to recognize HCPs' needs, so they can learn about the product, give their buy-in and tell their colleagues about it. Collaboration is vital so that physicians feel like you're taking them with you, because if the conversation is one-sided, if it feels like pharma is talking and not consulting physicians, then you're not going to get that buy-in," said Andrew.

Figure 3
It all comes back to trial design



'Ideal' means:

- **Appropriate** size, multiple sites
- Relevant to their **patient population**
- Consideration of how SoC may **evolve** by launch
- **Patient-centred endpoints**

Collaborate with pharma in study design and interpretation

Pharma learns how to best meet HCP needs ⇄ **HCPs learn**, buy-in and share with colleagues

Pre-launch

Rule 3: Raise the profile with peer and expert insights

"KOL endorsement is very important. I always try to get their opinion. Some of them are being paid by the pharmaceutical company, but they still have that expertise, the vast background to put it in the context"
– Oncologist, US

Getting key opinion leader (KOL) endorsement early-on can create anticipation pre-launch and build confidence in the trial. This hits two different behavioral science principles, authority and consensus. Authority because we defer to experts or those in a position of authority and Consensus – essentially: 'If the prevailing voices endorse this new product, and I think the voices are like me, I am more likely to use it.'

KOL endorsement creates pre-launch anticipation and confidence in the trial, both of which are key to launch success. COVID-19 may have curtailed in-person training and conferences attended by KOLs, but the importance of these trusted learning platforms, whether in-person or virtual, remains. It's a matter of knowing the customer to decide the best form of engagement.

"Training events are so valued because the interaction between the pharma company and physicians doesn't feel one-sided and the pharma industry really shared that view on collaboration and co-creation. Yes, you're selling to us, but it's more factual and sincere," explained Andrew. "Collaboration within the company and across US, EU and other regions is essential to ensure they are all aligned to meet the needs of patients, HCPs, payers and regulators."

During launch

Rule 4: Create credibility by sharing honest data insights

The research found that 'credibility' was the word that cropped up most frequently when discussing the launch itself, namely a commitment to being credible by sharing honest data. In fact, overstating a product was the number one reason HCPs gave for losing trust in the pharma company as a whole and not just the individual product.

"The presentation of the product needs to at least give the impression that it is objective. Side effects or negative aspects also need to be mentioned. I will need to be able to judge if the benefits outweigh the drawbacks"
– Endocrinologist, Germany

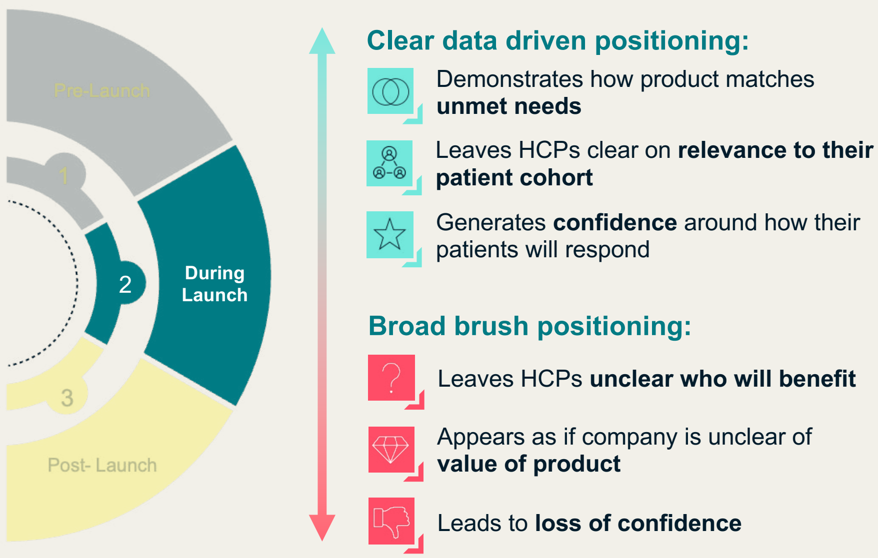
"When the drug actually hits the market, all this emotion, all this commitment, the excitement we've created… it now needs to be complemented by data," said Andrew. "Presenting the information in really clear scientific language, having honest and data-driven conversations by highlighting the benefits and being upfront about negative data, helps the clinician feel they are making an informed evaluation," said Andrew.

Rule 5: Be clear on positioning – what does it mean for patients?

"The product didn't work in a third of patients. I put my hand up and asked if there were any particular subsets of the population, or was there anything predictive they could tell me about why it didn't work? And what disappointed me is that they didn't know"
– Nephrologist, UK

Andrew explained how important it was to have a clear value proposition and positioning and to provide clear direction about how and when to use the drug. Backing all this up with data helps doctors know exactly how the product meets their unmet needs and those of their patients.

Figure 4
Be clear on positioning – what does it mean for patients?



Rule 6: Tailored engagement and support at launch

A multi-channel strategy is a pre-requisite nowadays, but the rep is still central to it all. Ultimately, they are the relationship managers who know their customers better than anyone else.

"I had a very personable rep. She gave me very clear-cut information and it was quite honest. It wasn't one of those things where you had lots of promotions with people dancing through fields, this method was really factual and I immediately could see a role for that medication in my practice. She did a lot of follow up once we had it on our formulary"
– Oncologist, UK

Providing the support HCPs need is where sales reps and MSLs play a key role in relationship management. Whether HCPs want to meet in person or just receive personalized emails, they know how best to engage with customers.

And while the research showed that face-to-face engagement is still seen as critical to physician education and achieving behavior change, time pressures need to be respected. By following up regularly in the first six months of launch, reps can make HCPs feel supported. "Take them with you," said Andrew.

Figure 5
Tailor engagement and support at launch

Ideal process

1. Pre-arrange call to ensure **maximum engagement**
2. **Concise presentation of data** esp. for less anticipated (non blockbuster) launches
3. **Rep follow up** to discuss questions and doubts further
4. **Further rep interactions** every few months in the first 6 months of launch, with updates and emails in between

Post launch

Rule 7: Reputable real-world evidence has impact

HCPs were asked: "If you had to pick one thing for pharma companies to change about product launches what would it be?"

Some immediately replied: "Just having better access to real world evidence. You should try to be objective and work with real-life data."

The research identified a variation in expectations between the US and Europe when it came to using real world evidence (RWE). European HCPs saw RWE as a highly valuable means to providing more realistic data that better reflects real patient scenarios versus carefully selected trial patients. Meanwhile, in the US RWE is often seen in broader terms that also includes clinician experience and insurance registry data.

Rule 8: Advertising is the icing on the cake

Eye-catching/visual materials, especially those based around patient vignettes, increase motivation to prescribe.

"I didn't even know the drug was going to be launched or what its promise was, but the campaign made me immediately sit up and take notice. Their ad designs are very, very unique and attention grabbing. They really brought attention to the fact that it was the 1st in class drug and that the efficacy and safety were really good"
– Hematologist, UK

While advertising did not come up spontaneously during interviews, perhaps because doctors didn't like admitting to being influenced by adverts, Andrew said marketing was critical to generating emotional resonance. Eye-catching visual materials and patient vignettes help cement an idea in doctors' minds about who the drug is suitable for, but they don't want 'loveless marketing', as one put it.

But it's worth heeding a note of caution from the United States, where direct-to-consumer advertising can put doctors on the back foot if their patients suddenly start asking about a new product before doctors are fully comfortable with it. "It's vital to get the timing right and complement consumer campaigns with HCP support," said Andrew.

In a post-COVID world, it's evolution, not revolution

The research demonstrates that pharma needs to take HCPs with them earlier in the process, starting peer and expert insights as the launch approaches to generate that social proof for the product and earn their trust.

In summary, Andrew explained how the research clearly showed that what was important pre-pandemic remains as important today. "It's about building trust through credibility: sharing honest data insights, giving clear, data-backed direction on how and where to use the drug, and following up with tailored, honest rep support," he said.

He was surprised at how aligned HCPs were with pharma professionals. Both see pre-launch as important to generating excitement and stimulating curiosity, but also see it necessary to put in work in the background to get the trial design right.

The launch mindset and organizational muscle memory

With more than 30 years' experience across many therapy areas, Tracey Barnes heads up Launch Excellence at Lumanity, helping the industry evolve in the current landscape to bring medicines to patients in a more effective and efficient way.

Tracey focused on how to foster collaboration, why it is so important and why agile is becoming so critical, looking at the building blocks of successful launches and how to put them together.

"Collaboration, like launch, isn't one thing," said Tracey. "It's a collection, a mindset, an ability within an organization, a mechanism by which we can truly move through this continually evolving changing environment."

Figure 6
What contributes to a successful launch mindset

The 3 pillars of launch excellence – enhancing launch success

In the 1970s, the pharma industry led the way by collaborating with like-minded companies to bring medicines to the market in a faster, more informed way. Fast forward to today, and the industry is now ranked quite poorly for collaboration.

Tracey started by asking what has changed, before explaining that collaboration can be largely incorporated in three key elements.

1. The right teamwork: is there a structure in place that can signpost the need to collaborate, how we need to collaborate and who we need to collaborate with?
2. The right mindset: do we expect to know all the answers, and have we left frustrations at the door?
3. The right mechanism: can we adapt and react at pace to this fast-evolving environment?

"One of the biggest killers of collaboration is defensiveness. When we're in a meeting, can we put this aside?" asked Tracey.

Figure 7
Top tips to drive collaboration

How can we build and foster collaboration?

“The industry is making some common mistakes when it comes to collaboration and ways of working and that comes down to not having the right framework in place,” Tracey

Figure 10
How can we build and foster collaboration

When looking at the right framework to build collaboration, Tracey highlighted seven key factors:

1. Roles: understanding the value of different roles and who is accountable for what.
2. Resourcing: timing of engagement with all stakeholder groups is critical to success.
3. Goals: do these align with incentives and is there clear leadership that opens-up trust, transparency and empowerment?
4. Planning: is there transparency of interdependencies, so everyone understands the cause and effect some decision making may have? What’s the focus?
5. Empowerment: effective launch teams talk about the reds, not just the greens. There needs to be clarity and transparency.
6. Governance: how can organizations make governance less rigid, so it fits the launch not the business?
7. Leadership: affecting internal culture to become a transparent organization requires leadership from the top down.

“Consider any core areas you would like to work with your team on,” advised Tracey, “Having that framework in place can truly unlock innovation.”

Agile methodologies and mindset are key to keeping businesses momentum

An agile approach enables organizations to efficiently adapt to challenges. A strong, agile culture can improve business performance by 235%*

"Consider collaboration as a means by which we can drive innovation and agile as the methodology that takes us on that journey. This way, we end up really collaborating and not negotiating with customers. Adopting a collaborative and agile philosophy is also integral to building trust, which in turn builds stronger teams," said Tracey, driving home how essential it is for every single team member to understand the goal and to value every contribution. However, there needs to be an organizational culture that enables transparency.

And when it comes to failing, Tracey sees an opportunity for greater collaboration: "Embrace failure because we learn from it - but fail fast. See mistakes as a chance to identify solutions collectively."

Prioritization is crucial to an agile philosophy: "In successful launches, 80% is the building blocks, but 20% is a focus on doing things well and doing things right."

Collaboration, transparency, and agility enable teams to learn and adapt fast

It all comes down to looking at launch and collaboration in a different way. It's not about one person having all the answers.

"If you're still on the journey of bringing collaboration and skillsets more to life, then ask yourself three things: Do I need to work on my framework? Do I need to work on my mindset? Do we have an agile enough approach to launch?" – Tracey

Tracey advocates a little introspection when it comes to developing collaborative behaviors and suggested asking yourself: "How do I score on the collaboration scale? Am I a great collaborator? Do I encourage collaboration at every single level?"

Answering a question about strategy and which function should lead strategy planning for launch, Tracey said:

"As an industry, pharma tends to look to commercial to lead because they probably have most of the information. However, it's important to get all the subject matter experts in the room and work together to come up with the answers. That is the way to get buy-in: coming up with different ways of looking at the business and the way to get true collaboration. If as an organization we truly want to change how we work with healthcare so we can bring medicines to the market and to our patients in a faster and more efficient way, we need to think about how we collaborate."

Figure 8
Launch mindset and organizational muscle memory

Strong cross-functional collaborative teams deliver

3x more shareholder value at launch

Transparency fosters trust and teamwork

Being transparent in a team fosters meaningful discussions, helps mitigate risk and course correct

An agile approach enables organizations to efficiently adapt to challenges.

A strong agile culture can improve business performance by 235%*

*JCURV – State of agile culture report

Panel discussion

Mike Kelly moderated the session, introducing a panel of industry experts and a patient voice, and posing a series of questions to deep dive into their own launch rollercoasters. He was joined by:

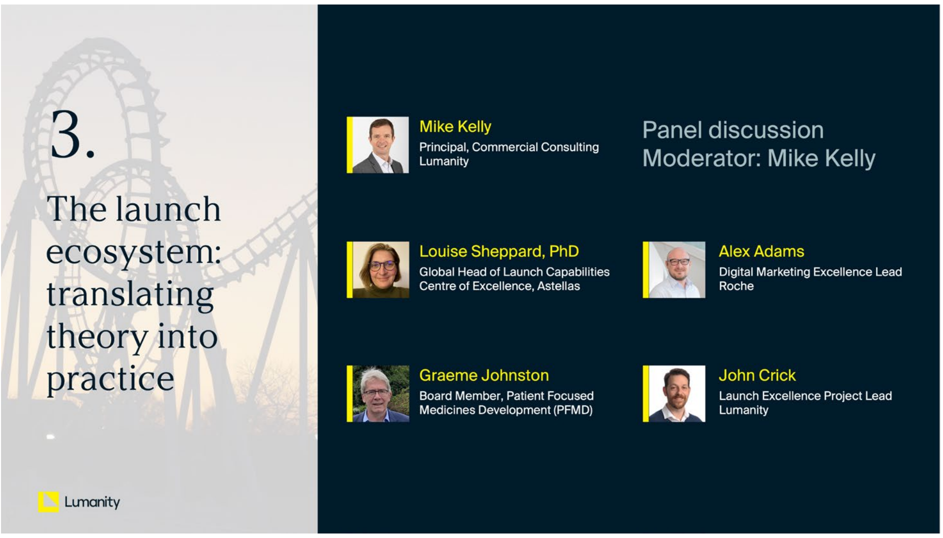
Louise Sheppard, PhD, Global Head of Launch Capabilities Centre of Excellence, Astellas

Alex Adams, Digital Marketing Excellence Lead, Roche

Graeme Johnston, Board Member, Patient Focused Medicines Development (PFMD)

John Crick, Launch Excellence Project Lead, Lumanity

Here are some reflections from the session.



Delivering a truly omni-channel experience

Mike began by expanding on how the insight generated from research indicated that, although face-to-face engagement has certainly changed, it has not completely gone. There remains a strong expectation that face-to-face engagement at launch is key to a multi- channel strategy. He asked panelists for their views on what this meant.

Alex started by outlining the new landscape, saying: "Previously, marketing might have developed some materials for a rep to take to a doctor for a five-minute engagement. Omni-channel really does change everything. Customer expectations of how they engage with companies and organizations have changed and are still changing. HCPs and patients are no different. Engaging seamlessly and consistently across many channels takes a great deal of orchestration."

"We need to make sure that the people who have the patients in front of them have the information that they need to make that right decision for that patient at the right time," said Louise Sheppard. "True omni-channel goes further than a multi-channel approach. Multi-channel is about the same information going through different channels, but when you're talking about omni-channel it's different types of information to different people through different channels."

Mike concluded by saying how organizations need to be set up to build this seamless engagement by breaking down silos. Secondly, the capabilities and skills must be built to create communications channels through which appropriate, seamless content can be shared. The effort and teamwork required is a step-change to where it was ten years ago, but that reflects how the world consumes information.

The power of the patient voice

“Why aren’t we talking more about patient input into the process?”
Graeme Johnston, Board Member, Patient Focused Medicines Development (PFMD)

Graeme Johnston is a rheumatoid arthritis patient, who believes launch success would benefit from greater patient engagement. “The classic thing people try to cure or tackle with rheumatoid arthritis is pain. But to many sufferers, fatigue is as big if not a bigger issue and it is still an unmet need,” he said.

Graeme went on to say that he believes end-to-end involvement of patients in the process could help better identify these unmet needs, chiming with what HCPs are hearing in their clinics. Taking patients on the journey - from trial design and the trial itself to regulatory approvals and finally launch - generates the patient-reported outcomes that HCPs need to give them confidence in new therapies.

“Putting how a new drug will impact the lives of patients into clear scientific and plain language is a real adornment to a launch process because it helps build authenticity, credibility and trust,” he finished, echoing Andrew’s earlier presentation around Cialdini’s Principles of Persuasion.

When it comes to patient engagement to drive revenues, he also said this must be part of the launch strategy, not a ‘bolt-on’ at the end: “Patient engagement shouldn’t be altruistic. To be hard-headed, it can deliver real net-present value to the company.”

This is something that John Crick, Launch Excellence Project Lead at Lumanity, agreed with. He said there’s often a presumption that clinicians are interested in a particular factor that shapes market research but might not actually be the primary driver in the marketplace. This can have an impact on the bottom line. Without early research, an asset that previously had a high revenue forecast when in development might see a softening of expectations as insights become deeper.

“Getting that knowledge earlier, that solid understanding of the landscape and what patients and physicians want, can mean less movement in expected revenue for an asset the closer you get to launch,” agreed Mike.

New vs. extension – what’s the difference?

Mike asked the experts about their views on how to make extension launches a success. The consensus was that the strategy will depend on whether it is a line extension or a completely new product launch.

“If you’ve got an oncology product for one cancer and an extension that goes into another, that’s two very different patient and HCP populations. You’re going into a new area where physicians may not know your company at all, so you’ll need to do work on your company reputation,” said Louise.

Tracey said a line extension comes down to two things: is it within an asset that is already being worked on in an existing therapy area, or is it outside? If it’s within an existing area, leverage the portfolio view and some of the activities that have been conducted already. If it’s a new therapy area, it needs to be looked at as a standalone launch.

Alex agreed and added that it is also important to think about how quickly a second indication might follow the initial launch. If this is on the horizon, consider how to position the product launch slightly differently for the first indication to allow a more natural entry for the second.

Pricing came up as another consideration: the more indications a product has, the more implications there are for pricing that may need to go into different negotiations, especially in different countries.

A shared vision

"Why are we in this business at all and what do we want to do? We want to bring products to the patients at the end of the day, that's certainly where I come from. If we can just make sure everything we do looks at that end goal, we should all be working together,"
Louise Sheppard.

In discussing the importance of collaboration, the panel was unanimous in calling for shared objectives to drive launch success. They discussed how organizational silos can be a barrier to cross-functional collaboration, but how bringing different functions together early in the planning stages can help people understand the interdependencies in the launch process.

Mike asked how organizations can create a culture that demonstrates how those bricks fit together to make the whole thing a success.

"If you've got a shared objective where everybody is being held accountable for their own actions, ultimately everybody is going to be working towards that common vision, whatever it may be," said Louise. "That's quite a mindset change for most organizations where often functions report up globally. But if these objectives can be shared across, it helps to focus the mind. At the end of the year, you can look at how you have delivered as a cross-functional team, not as individual functions."

Whether you are developing your differentiated winning pharma launch strategy or building a global launch roadmap to assure everything is in place at the right time, we can help. At Lumanity, we have the experience, technology solutions, and a proven launch ecosystem to set you confidently on the path to long-term success. Our experience and pragmatic approach to launch excellence will instill the right principles, processes, and competencies to maximize your asset potential and deliver a competitive advantage at launch.

Find out more here:
lumanity.com/launch-excellence

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

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