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Reuters Events Pharma:

Annual Industry Trends Report 2023

Thinking bigger in 2023 to drive better outcomes

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Contents

Introduction

In 2022 we asked pharma leaders to share their thoughts about the key trends going into 2023. An overarching 'meta-theme' is that pharma has been thinking more broadly and holistically, understanding its role, purpose and scope to collaborate within the wider healthcare ecosystem.

The argument for closer collaboration between internal pharma teams was a common theme but so was the need for smarter partnerships with key industry stakeholders such as payers. Pharma is exploring how to be a more active and effective partner able to move the dial for patients.

Many pharma leaders are seeing the need to be a part of much bigger-picture, holistic health approaches that factor in population-level data, such as the social determinants of health, as a means to better reach and serve under-represented populations. The importance of recognising the links between mental and physical health and working to enhance whole-person health is something that many leaders are also waking up to.

Marketing & Commercial

Humans still matter, team working is essential and change needs to be managed carefully to achieve organisational agility

Post pandemic, pharma is pondering how to make the most of the shift towards greater use of data and technology in commercial operations, while factoring in the still crucial role for human interactions.

According to Ricardo Castrillo Pelaz, Chief Commercial Officer of Ferrer: "We are bringing our commercial operations to the next level facilitated by data and tech but defending the crucial and irreplaceable role of humans."

Global customer experience initiatives are seeking to blend the best of digital engagement and the individual efforts of field team members. There is also an increasing move here towards team-based approaches rather than siloed individual efforts, Pelaz adds. "More and more, full integration of the different roles is fundamental for a successful customer experience. We need team players rather than individual stars."

To ensure success in new product launches, pharmaceutical companies are still working to understand changing HCP attitudes and behaviours. Differentiating messaging in a sea of competing content is key and requires smart and sparing leverage of digital and social media that is relevant to personal HCP journeys, experiences, and lifestyles.

Healthcare stakeholders are looking beyond individual therapies and increasingly taking a more holistic approach to wellbeing, focusing, for example increasingly on mental health and the social determinants of health.

Pharma's commercial and marketing functions are waking up to this, since the place of a product or therapy now needs to be considered in this context, says Ashley Ryneska, Executive Director of Digital Communications at Gilead. "The role of a corporate entity is about much more than delivering a product but delivering on a holistic purpose. Consumers – including patients, caregivers, healthcare professionals, and officials – have made their expectations clear. That is just as true in the pharma and biotech space."

Brad Bailey, Senior Vice President and General Manager of Genmab US, states that achieving commercial excellence requires agile operations along with a data-driven and digital approach, as well as access and support programs that ensure optimal access to medicines for all patients.

Paul Upham, Head of Smart Devices at Roche/Genentech, emphasises the growing importance of tailoring products in various formats and settings to meet the needs of patients. He states that this can include "IV infusion for some, subcutaneous injection for others, and self-administration or home delivery for others."

He also highlights the importance of gathering these important contextual data and insights early on, citing an example of ethnographic studies conducted in patients' homes that led to unique digital and device offerings being created.

> "We are bringing our commercial operations to the next level facilitated by data and tech but defending the crucial and irreplaceable role of humans.""
>
> Ricardo Castrillo Pelaz, Chief Commercial Officer of Ferrer

The twin digital and field force revolutions underway in commercial and marketing functions represent a challenge to established ways of working. Adapting to their new requirements won't be easy.

Shannon Hartley, Managing Director, Business Transformation, Health Sciences & Wellness at consultant Ernst & Young, stresses the importance of change management in implementing new technologies and strategies. She notes that "many transformations are failing because companies are not putting enough emphasis on implementing change management" and that "the only way for companies to be successful with these new technologies is to provide robust change management programs to help adjust the ways of working to drive adoption and stickiness of these technologies".

A We need to change the way people think and behave so that we can further build a psychologically safe place to work, where people can show up in full as themselves, are entitled to challenge the status quo and innovate even if that means taking calculated risks.

Florent Edouard, SVP Global Head of Commercial Excellence, Grunenthal

A Significant evolution has happened catalized by the COVID pandemic. We are bringing our commercial Operations to the next level facilitated by data and Tech (but defending the crucial and irreplaceable role of humans).

Beyond that, we have launched a global CX program (we talk about PeopleExperience), impacting more than 30 countries and all our people (1800 Ferrer people around the globe)

All that transformation is happening while our operations stay up and running and while we foster our Specialty Care Business in all Geographies (with the organizational transition it represents)

Ricardo Castrillo Pelaz, Chief Commercial Officer, Ferrer

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- Anchor a clear positive aspirational vision that motivates people to change for the better
- Incentivize top leaders on driving a positive momentum around that new vision
- Invite middle management to map their teams contributions to the newly set vision
- Get teams to actively contribute to implementing change in their functions

Philippe Barillon, Global Head of Integrated Insights (CV TA), Novartis

A In commercial functions, the two outcomes we're looking for are to get the drug available to patient on the market sustainably (Market Access) and 2. get it prescribed by the prescriber (HCP, algorithm being guidelines or AI...)

Way 1: Look at what drives a prescription, not what drives individual careers.

Way 2: Define trend vs mainstream. invest and ring fence the trend (e-teams), while optimizing your mainstream (Sales Force, MSLs)

Way 3: Focus on what's most important - get your ExCo to visit customers, not shareholders

Way 4: Prioritize listening reasonably to customers. They are always right about the present, but they can't tell you what they have not seen yet. You can still surprise them

Quentin Descat, Global Cardiovascular Commercial Launch Brands Lead, Bayer

A

- Keep customers (HCPs and Patients) at the center
- Have a clear set of metrics to measure change progress and celebrate key milestones to maintain organization's motivation (address change fatigue)
- Ensure simple yet effective governance with a clear engagement of top leadership

Chetak Buaria, Vice President - Global Commercial Operations (Oncology), Merck

A Many transformations are failing because companies are not putting enough emphasis on implementing change management. We've seen this acutely in the promotional content management and review space. Life science companies are utilizing new technology to support more personalization and modular content, but not recognizing the transformation and change management needed through the promotion review and approval process. The only way for companies to be successful with these new technologies is to provide robust change management programs to help adjust the ways of working to drive adoption and stickiness of these technologies.

Shannon Hartley, EY Managing Director

A Good preparation
Constant monitoring
Proper adjustment

Ala Fakhfakh, Head of Regional Marketing and Operations Western Europe, Menarini

A At Genmab, we've grown our workforce by 121% in the last two years and in 2022, we are well on our way to grow by an additional 48%, so we are no stranger to change management. We have evolved from an antibody discovery company to an end-to-end biotech with capabilities across discovery, development and commercialization based on a clear 2025 vision and ambition. Recently, and in part due to the progress we've made against this ambition, we introduced an evolved vision for Genmab that by 2030, we aspire that our knock-your-socks off ("KYSO") antibody medicines are fundamentally transforming the lives of people with cancer and other serious diseases.

Introducing and embedding the 2030 vision across our organization from end to end was critical. We were deliberate in articulating what it means for our company, for each employee and for patients. We had a rigorous process to evolve our 2030 vision based on Genmab's business aspirations, global growth and desire to be bold when talking about our future impact. While our Executive Committee provided direction, a cross-functional team provided input throughout the process of workshopping and embedding this evolved vision. It's a nice example of how we approach change management at Genmab.

Anthony Mancini, Executive Vice President & Chief Operating Officer, Genmab

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Forward thinking

Welcoming disruption-Learning agility

Down-to-earth --> make more tangible realities to secure buy-in from all the organization ->Influence/ persuasion without hierarchy

Resilience

Ricardo Castrillo Pelaz, Chief Commercial Officer, Ferrer

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- Ability to leverage digital and data to gain superior insights and translate those insights into omnichannel engagement plans
- Drive engagement through "segment of one" approach
- Ability of the field force to orchestrate omnichannel ecosystem and marketing teams to adapt their content strategy to omnichannel environment.

Chetak Buaria, Vice President - Global Commercial Operations (Oncology), Merck

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- Patient first customer centricity
- Insights-driven decision making
- Predictive healthcare system modelling
- Behavioral science

Philippe Barillon, Global Head of Integrated Insights (CV TA), Novartis

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Business acumen, agility, commercial grit and customer obsession are fundamental capabilities we need to grow in any commercial organisation.

Florent Edouard, SVP Global Head of Commercial Excellence, Grunenthal

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Empathy to start with for patients, HCPs, and our team with the tremendous pressure around us.

People: Fire digital hoppers (selling hopes high, then leaving to the next company). Hire consciously people with super learning agility, regardless of their hard skills in Data, Sales, Medical… unless you don't have a choice.

Field positions: the profile of a rep today should be as qualified as a Product Manager combined with Medical Advisor. Those who are not will not last.

Hard skills; Avoid the shiny object: the fancyness of newness attracts people, but back to basics still works. Metaverse is fancy, 7 HCP interactions to get a new prescription is the reality now.

Leadership to restructure lean structures with a good mix of talent.

One last: set up an AI team now.

Quentin Descat, Global Cardiovascular Commercial Launch Brands Lead, Bayer

A

A deep understanding of the patient's unmet needs, issues, and challenges is a key capability. This, in conjunction with a clear understanding of patient journeys, HCP issues and challenges, and navigating the payer landscapes in each country is critical.

Paul Upham, Head, Smart Devices, Roche/Genentech

A The potential for science to address the most urgent health challenges of our time has never been brighter. It's up to us as an industry to ensure that scientific innovations reach patients, especially those who need them most. Over the past few years, the importance of agile operations and taking a personalized approach to addressing the unique needs of each patient that we serve and the care team members that are responsible for that patient's care, have become even more paramount to our ability to deliver.

This will take seamlessly and genuinely integrating the patient perspective from early discovery through commercialization. It calls for commercial operations built on a foundation of data science and digital technology, enabling an agile and innovative team who leans into our industry's spirit of innovation and is open to doing things differently to best meet patient and care team needs and expectations in real time. Ultimately, this requires access and support programs that truly ensure optimal access to medicines for all appropriate patients.

Brad Bailey, Senior Vice President and General Manager, Genmab US, Inc.

A At Genmab, we have evolved from being a research-focused organization to a fully integrated biotechnology company as we have built strong capabilities across discovery, development and commercialization in order to bring our own innovative medicines to patients.

Effective commercialization requires a clear strategy that is anchored in patient and market insights. This means early and deep insights of the patient journey, and all the key stakeholders that influence it. This can vary across countries based on differences in regulatory requirements, healthcare systems and market access. This ensures a nimble and responsive approach to specific patient and market needs.

It's important to ensure that the early commercial strategy work is done in very close collaboration with R&D so that thoughtful choices can be made in study design, comparators and overall strategy, as well as in which markets to launch, followed by the sequence of countries to optimize value to patients.

Many functions must work together (from insights & analytics, marketing, sales/ account management, market access, medical affairs, but also all the enabling functions: data sciences, IT, finance, HR, legal/compliance, promotion compliance/ country regulatory etc.) to achieve commercialization success. It takes a broad set of functions working together to make a medicine a success in the real world/market.

At Genmab, we are taking a deliberate approach to commercialization, building an innovation model through which we resource appropriately and focus on areas we think will make the biggest impact on patients and HCPs to advance the future of healthcare.

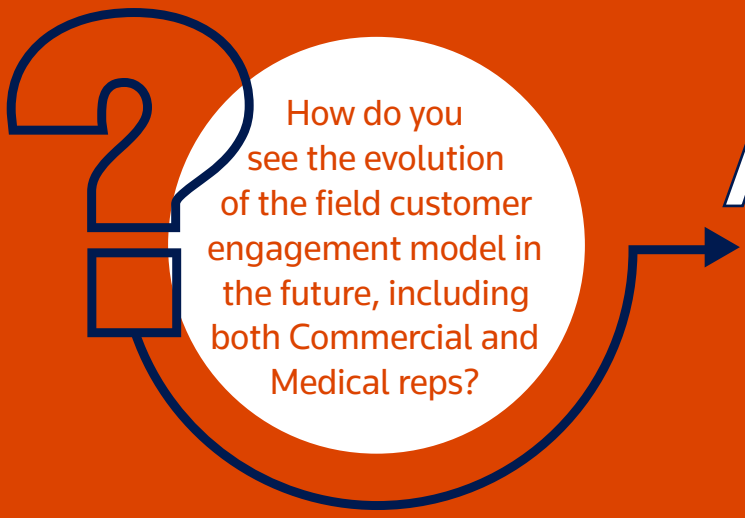
Anthony Mancini, Executive Vice President & Chief Operating Officer, Genmab

A Agility to respond to rapidly evolving science, landscape and customer needs

Ability to prioritize and focus efforts on the highest impact opportunities

Digital as a core component of how we think and act, not a nice to have but central to the strategy

Sonny Shergill, VP Commercial Digital Health, AstraZeneca



A

- Classical "sales rep" model is outdated for innovative pharma companies
- Future engagement model to be increasingly driven by medical - for new launches - and market access
- Key challenge is how to measure effectiveness of medically driven engagement model in absence of sales as a proxy?

Chetak Buaria, Vice President - Global Commercial Operations (Oncology), Merck

A

They were, are and will be critical in our GoToMarket Strategy. However there role is gonna be maximized by tech/digital=data

It will need an evolution in the skills/ capabilities of the teams (not only in field). It will foster productivity at the same time it will improve CX

More and more, full integration of the different roles is fundamental for a successful Customer Experience. We need team players rather than individual stars

Ricardo Castrillo Pelaz, Chief Commercial Officer, Ferrer

A

I see the Field teams becoming the orchestrators of great customer experiences for HCPs, helping them deliver better care to their patients through optimal usage of tools provided by the company.

Florent Edouard, SVP Global Head of Commercial Excellence, Grunenthal

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It will merge in the next few years. Roche Model.

It will decrease in numbers while guidelines drive behaviors.

As long as doctors are human, field customer representation will be human.

Quentin Descat, Global Cardiovascular Commercial Launch Brands Lead, Bayer

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- Our business is about driving positive change at HCS and HCP level to benefit patients and population health.
- Because change is always hard to drive, we will continue to need a high level of human-to-human interactions.
- The role of the commercial and medical reps is more about creating positive ecosystems to drive behavioral change that traditional material-based promotion.

Philippe Barillon, Global Head of Integrated Insights (CV TA), Novartis

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Advances in technology alongside the recent realities of the COVID-19 pandemic have unlocked new ways to deliver medicines and engage with care teams and communities. In a disease space as complex as cancer, where science is rapidly evolving and medicines are becoming more focused on smaller patient populations, how we interact with care teams must also be increasingly personalized. Whether in-person or virtual, at Genmab, we deliver a data-driven, highly customized and coordinated approach across our medical, market access and account management teams. This allows us to better partner with each individual on the care team to help them meet the patient's needs, leading with a patient-first focus, prioritizing scientific engagement and equipping providers with what will have the most impact to deliver optimal care.

Brad Bailey, Senior Vice President and General Manager, Genmab US, Inc.

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Digital engagement will bring Commercial and Field teams closer

Digital content will index to scientific and medical focus vs commercial

Field capabilities will evolve to be more digitally savvy and enabling of digital customer activity

Sonny Shergill, VP Commercial Digital Health, AstraZeneca

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More customer centric (pull more than push)

The customer will choose his partners (opposite of today)

Ala Fakhfakh, Head of Regional Marketing and Operations Western Europe, Menarini

A

I guess it is time to turn around our "usual" approach... we need to build from scratch with and for our customers (considering the whole ecosystem, not only current HCP targeted).

At Ferrer, we have launched an initiative last May22, our Ferrer Living Lab, which is exactly fostering this collaborative innovation with all stakeholders in the health ecosystem.

Ricardo Castrillo Pelaz, Chief Commercial Officer, Ferrer

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Data and Insights are like bricks and mortar. In themselves, they don't do much but they are material to enabling better decisions across an entire organization. People don't want data, they want solutions. All it takes is a shift from "data and systems first" to a "patients first customer centric" mindset. Once you know what you want to build, then you know what data and insights you need. Not the other way round.

Philippe Barillon, Global Head of Integrated Insights (CV TA), Novartis

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Everything that can be counted does not necessarily count; everything that counts cannot necessarily be counted.

Having said that, what matters, ethically, to patients and doctors is a super positive primary endpoint with clinical benefits like mortality.

Quentin Descat, Global Cardiovascular Commercial Launch Brands Lead, Bayer

A Often this can start with ensuring that you are gathering the right data and insights at the beginning. For example, we have conducted ethnographic studies in patients' homes and gathered rich data and insights that we wouldn't have via any other market research methods. We were able to translate these into unique digital and device offerings that solved problems about which we wouldn't have offered solutions without this work.

Paul Upham, Head, Smart Devices, Roche/Genentech

A We are a patient-first organization. We are looking to data and digital solutions to propel us forward. We leverage data insights from end to end, from discovery through development and commercialization. From data science to IT & Digital, our team applies AI and machine learning to integrate and analyze complex data from different stages of the drug development and commercialization process, with a goal to transform our understanding of cancer and other serious diseases and equip us with the key insights to help match the right treatment to the right patient at the right dose. We also do this to help ensure we deploy resources most effectively to the right stakeholder within the healthcare ecosystem at the right time with the right message.

Anthony Mancini, Executive Vice President & Chief Operating Officer, Genmab

A Leveraging available data to define unmet need, developing insights for the reason for gaps in care and then targeting specific actions to address it, and lastly being able to measure our impact and inform forward planning.

Sonny Shergill, VP Commercial Digital Health, AstraZeneca

A From data to impact on quality of life (in stead of 45% of patients improved their blood pressure, we could say: thanks to a better control of their blood pressure, 45% of patients improved their metrics, allowing them a better quality of life

Ala Fakhfakh, Head of Regional Marketing and Operations Western Europe, Menarini

A Life science companies collect so much data and do so much patient research on things like patient journeys; however, I've found that often when defining solutions that will make a positive impact on people's lives, we need to first better understand their lives and not just how they progress through a disease. We do work called 'Day in the Life' where we observe and talk to patients and caregivers as they progress throughout a day. This gives us insights to build solutions as we see the way they adapt or compensate for aspects of their disease. A personal example is I had bone cancer and had to have my left arm reconstructed and no longer have the mobility to reach over my head or around my back. My doctors and therapists were very focused on rebuilding my prior ability as much as possible, that they missed my real need was for independence in everyday tasks, even if that meant doing them differently. I learned on my own that when you can't raise your arm, you need to bend at your waist to do important tasks like dressing and opening a bottle of wine. When I explained my approaches and adaptations to my doctors and therapists, it clicked that they needed to offer different types of support to patients.

Shannon Hartley, EY Managing Director

With regards to new launches, what is the key differentiator in a new launch (Brand? Customers? Patients? Regional Archetypes)? How do we leverage this differentiator to ensure success?

A Real world data based customer insights are paramount to setup and implement the right strategy and complement clinical evidence.

Florent Edouard, SVP Global Head of Commercial Excellence, Grunenthal

A Today's digital environment provides ample opportunity drive business objectives, but it requires working within the current market dynamics and understanding shifting consumer behaviour. More people are turning to digital and social media for answers to real-life questions, including health and medical issues. This has resulted in the decentralization of relevant content and conversations, and segmented audiences on social; briefer content and non-linear storytelling that reflects shorter attention spans and higher-frequency content consumption; secondary sources and commentators gaining further influence; and an increased range of participating voices, including medical professionals, academics and officials.

Consumers – including patients, caregivers, healthcare professionals, and officials – have made their expectations clear: the role of a corporate entity is about much more than delivering a product but delivering on a holistic purpose. That is just as true in the pharma and biotech space. Leading brands must align with stakeholder values by factoring in personal journeys, experiences and lifestyles; bearing relevance to sense of self and identity, including ethnic and cultural connections, gender and sexuality; and demonstrating full health context, including mental health and social determinants of health.

Pharmaceutical companies are viewed differently as a result of COVID-19, and stakeholders are changing their attitude and behaviours. People are becoming more informed and interested in pharmaceutical brands, with growing expectations for brands to connect on a human-to-human level, making tangible impacts on issues - including health equity and legislations to benefit everyone.

Ashley Ryneska, Executive Director Digital Communications, Gilead Sciences

A

- Key differentiator is clinical data against standard of care
- Have a clear segmentation strategy to identify most effective patient population and rights segment of HCPs
- Understand patient journey and ensure mitigation measures to address any access barriers

Chetak Buaria, Vice President - Global Commercial Operations (Oncology), Merck

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- The amount of change that is implied by the introduction of a new medicine in the market
- The overall attractiveness of the market for a given asset
- The strategic importance of a given asset to the company launching it

Philippe Barillon, Global Head of Integrated Insights (CV TA), Novartis

A Clinical design must listen to Market Access. At launch, muscle in the field is still required.

Quentin Descat, Global Cardiovascular Commercial Launch Brands Lead, Bayer

A One of the key differentiators in a new launch is the ability of the Pharma company to offer their products in as many formats and settings as their patients' need it. For example, IV infusion for some, subcutaneous injection for others, and self-administration or home delivery for others. This flexibility of ROAs and settings will improve access and patient satisfaction while enabling tailoring for different markets.

Paul Upham, Head, Smart Devices, Roche/Genentech

A Throughout my career, I've had the distinct opportunity to work on some of the largest launches across oncology and other serious disease areas. The key to the success on all of these projects was the central focus on the patient. Patient insights must be embedded throughout our work, from guiding our research and innovation to how we deliver our medicines and support patients and their care teams. At Genmab, we're applying technology and data science to learn in real time how we can better innovate for patients. The patient is the greatest disrupter in life sciences, so when we can seamlessly and genuinely integrate the patient voice into our launch strategy and operations, we can make decisions that could transform cancer care and fundamentally improve patients' lives.

Brad Bailey, Senior Vice President and General Manager, Genmab US, Inc.

A Identify the relevant targets and answer to the right insights

Ala Fakhfakh, Head of Regional Marketing and Operations Western Europe, Menarini

A Precision engagement based on customer specific insights, with success coming from both personalization and our ability to maintain engagement by reflecting evolving customer needs in real time.

Sonny Shergill, VP Commercial Digital Health, AstraZeneca

What factors do you think are most important for reaching a 'gold standard' of patient engagement?

A Listen to the patient voice

Martha Raymond, Executive Director Digital Communications, Gilead Sciences

What are the biggest challenges to building patient trust, and how do you think we can best overcome these?

A Transparency - straight forward conversation

Martha Raymond, Executive Director Digital Communications, Gilead Sciences

How can pharma work with stakeholders in the wider healthcare system to create better patient experiences end-to-end?

A Include advocacy and patients at every step

Martha Raymond, Executive Director Digital Communications, Gilead Sciences

What is Patient Engagement's role in furthering pharma's mission to address health inequities, and what are the biggest barriers to doing this? What actions are critical for impacting minority outcomes across the value chain?

A Patient Advocacy should reflect and represent all patient demographics

Martha Raymond, Executive Director Digital Communications, Gilead Sciences

Patient engagement

Involve the patient from the start for better, fairer outcomes

Patient engagement leaders cited the growing importance of patient input across every key dimension of the process from drug development to delivery of care in order to ensure healthcare systems, regulators, and payers make decisions that meet their needs.

Michaela Dinboeck, Head of Patient Engagement Global Product Strategy & Lifecycle at Novartis says: "The essence of patient engagement is to get patient input along the value chain to ensure HC systems/medicines/regulator/payor decisions meet the needs of the various stakeholders and foremost those of patients, to generate the best possible value for patients and with that also the HC system."

Patient engagement can play a critical role in addressing health inequities, but will only achieve this in collaboration with other stakeholders. There is a growing awareness of the need to ensure the perspectives, challenges, and health priorities of a broad variety of patients, including underprivileged ones, are reflected in decision making.

Health inequities can also be addressed through a better understanding of the patient journey, including a recognition that there will be regional differences, particularly in underserved areas.

Frank Spinelli, Senior Director of Patient Engagement at Gilead Sciences, states that "pharmaceutical companies have an opportunity to better understand the landscape, particularly in underserved areas and collaborate with community-based organizations to co-create interventions to active patients, link them in care and identify opportunities to maintain persistence in care."

Adam Pryor, Corporate Relations, Neuroscience and Rare Disease at Genentech, believes that reaching a 'gold standard' of patient engagement involves using resources to amplify the voices and experiences of those who have been historically underrepresented and misrepresented.

He cites Genentech's SMA My Way program as an example of this, which supports and raises awareness about the needs of the spinal muscular atrophy community through sharing practical tools and lived experiences of people with SMA, as well as creating empowering connections and building community.

> "Reaching a 'gold standard' of patient engagement involves using resources to amplify the voices and experiences of those who have been historically underrepresented and misrepresented.'"

Adam Pryor, Corporate Relations, Neuroscience and Rare Disease at Genentech

A Trust, including public opinion. Involvement of health authorities and payers in value based healthcare with real world evidence and patient reported outcomes.

Impact measurement.

Daniel De Schryver, Patient Engagement and Advocacy Lead, Janssen, the Pharmaceutical Companies of Johnson and Johnson

A First - Patient Engagement needs to be clearly defined, it is often confused with consumer engagement rather than involving patients in decision making around medicine development and on how we bring them to patients

Second - the gold standard needs to be defined - what does good look like

Third - change management to get to systematic and consistent involvement of patients in health care decision making, in industry and other stakeholders (regulators, payors,...)

Michaela Dinboeck, Head Patient Engagement Global Product Strategy & Lifecycle, Novartis

A A company mindset to always think of bringing in a patient to collaborate with on appropriate projects.

Linda Kollmar, MD, AVP, Patient Innovation and Engagement, Merck

A Understanding the patient perspectives, listening to their needs and integration of the patient voice in medicines development.

Radhika Tunstall, MD, Ph.D., Head, Global Patient Experience and Policy, Santen Inc.

A Making medicines is just one part of our responsibility to the communities we serve. Our commitment goes further. At Genentech, we recognized that we can use our resources to amplify the voices and experiences of those who have been historically underrepresented and misrepresented.

For instance, we built our SMA My Way program to support and raise awareness about the needs of the spinal muscular atrophy (SMA) community. Created together with that community, SMA My Way is a platform to share practical tools and lived experiences of people with SMA. It's also a place to create empowering connections and build community.

Last year, the SMA My Way program supported the creation of SPACES, an award-winning song and music video highlighting the talents and humanity of people with SMA to show that people with disabilities belong in all spaces. This year, we extended that message with Double Take, the first-ever fashion show with start-to-finish SMA community involvement, which aims to break down disability stereotypes and champion adaptive fashion.

Our commitment to the SMA community has also led to a number of other patient-centric projects, such as data registries and newborn screening advocacy.

Adam Pryor, Corporate Relations, Neuroscience and Rare Disease, Genentech

A Cultivating a relationship with those patients you partner with to establish a rapport and a trusting connection is key.

Connie L. Montgomery, Patient Advocate

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First and foremost, they must have the best interests of patients in mind throughout the treatment continuum. I think it is important to consider the patient perspective in aspects of clinical trial design, in marketing strategies, and simply in understanding the ways in which the product they are developing will have an impact on patients' lives and sympathizing with the burden/hardship that health conditions place on patients. Building on this, it also important for pharma to "give back" to patients in more ways than just delivering a drug that improves their health. Supporting patients in their health journeys, through patient access programs, through grants for scholarships, or organizing support groups/chat lines conveys a message that pharma does have patient's best interests in mind.

Ella Balasa, Patient Advocacy and Engagement Consultant

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The confusion of patient involvement and patient engagement as consumers lets patients doubt the intent and may lead to a different intent.

Societal / media perception that the engagement serves industry / not patient purpose.

Michaela Dinboeck, Head Patient Engagement Global Product Strategy & Lifecycle, Novartis

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Increase transparency in how pharmaceutical companies operate and the reasons behind the designs of clinical trials as well as the price of the products. Transparency around cost of conducting clinical research.

Linda Kollmar, MD, AVP, Patient Innovation and Engagement, Merck

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Show impact in public health or in health outcomes by PE.

Daniel De Schryver, Patient Engagement and Advocacy Lead, Janssen, the Pharmaceutical Companies of Johnson and Johnson

A

The biggest challenge to building patient trust is lack of consistent and transparent patient and caregiver engagement.

Radhika Tunstall, MD, Ph.D., Head, Global Patient Experience and Policy, Santen Inc.

A

Science can reveal much about an illness, but it can't tell us how people actually experience their disease.

For every disease community we serve with our medicines, we also listen closely to the needs of that community to learn how we can best support them, beyond treatment alone. We look to our patient communities for valuable insights, to help us deepen our understanding of their day-to-day realities and understand what is important to them.

When we engaged the SMA community, they told us that they wanted to ensure people with disabilities were better — and more accurately — represented in media, social media and the fashion industry, among other places. They wanted to be seen as whole people, not defined by their disabilities. This insight informed the development of two SMA My Way programs, SPACES and Double Take, that have directly delivered on what patients were asking us to do.

Adam Pryor, Corporate Relations, Neuroscience and Rare Disease, Genentech

A Oftentimes a patient's doctor is the main player in building that initial trust between the patient and the overall healthcare system. A person's interactions with their provider/care team whether positive or negative has a direct affect on the capacity to which trust can be built and carried through to other healthcare interactions and relationships that a patient has, from the pharmaceutical industry to insurance, clinical trial research teams and more. Assuring this foundational trust is built between a patient and their physician is crucial since future healthcare relationships are build upon this ground work.

Within the clinical trial space, in order for patients to be comfortable in participation, there must be trust in the company and the actions taken by the research team. In order to build trust, there has to be transparency in what tests will be preformed, what is required of the patient, etc. When the patient feels comfortable in the intentions of the study team and overall study requirements, that's when trust is built.

Some mistrust is tied to a history of exploiting patients in trials and not directly engaging with the patient population to facilitate a relationship which would foster trust. I do think this is changing as patients needs and the idea of disclosure and transparency are becoming important in the consent process and through the trial process.

Ella Balasa, Patient Advocacy and Engagement Consultant

A Challenge yourself to respect all those you serve or partner with by accepting folks where they are in every area of their lives. Then connect with them frequently and authentically to find out what or whom intrinsically motivates your patient and see how the services you provide can support them or lead them to resources that may be able to do so, if you can not.

Connie L. Montgomery, Patient Advocate

A While there are many unique aspects to building patient trust at the individual level, health disparities account for one of the top challenges facing the U.S. healthcare industry today. It's important to approach this challenge from a patient-centric perspective – recognizing that there can't be a one-size-fits-all approach to health equity. We need to address health equity at the local level and engage in meaningful partnerships to address individual community needs to help build trust and respond to areas of greatest need.

Christie Bloomquist, VP, US Corporate Affairs and Government Affairs, AstraZeneca

A Co-develop the new HC environment, need to involve patients, advocates, payers, the industry.

Daniel De Schryver, Patient Engagement and Advocacy Lead, Janssen, the Pharmaceutical Companies of Johnson and Johnson

A Caution with wording on patient experience is very close to consumer experience which is not what we mean by patient engagement. The essence of patient engagement is to get patient input along the value chain to ensure HC systems / medicines / regulator / payor decisions meet the needs of the various stakeholders and foremost those of patients, to generate the best possible value for patients and with that also the HC system.

Pharma can work with stakeholders on alignment of frameworks for patient input, common understanding of design principles for the input and reach of patients that may be under-represented.

Michaela Dinboeck, Head Patient Engagement Global Product Strategy & Lifecycle, Novartis

A Every 4-6 months gather stakeholders to note if there has been a shift in patient engagement areas of need or if some of the services provided by pharma can be altered or changed to better serve clientele.

Connie L. Montgomery, Patient Advocate

A Commitment to gathering feedback from every patient, /caregiver listening to their concerns and creating solutions to overcome challenges identified by the patients.

Radhika Tunstall, MD, Ph.D., Head, Global Patient Experience and Policy, Santen Inc.

A

Continue to talk to different stakeholders to learn what the experience is truly like and learn from these experiences and be willing to make adjustments when able.

Linda Kollmar, MD, AVP, Patient Innovation and Engagement, Merck

A

At its core, health equity means that everyone has a fair and just opportunity to live a healthy life. To realize the full potential of our medicines we need to apply an equity lens at every step — from discovery to delivery. This includes taking steps to remove barriers for minority participation in clinical trials and access to resources. We also need to work with suppliers and others in the ecosystem that share our same commitment to advancing health equity and ensure our medicines are accessible to all individuals once approved.

Christie Bloomquist, VP, US Corporate Affairs and Government Affairs, AstraZeneca

A

Making certain every level of the pharma service industry truly knows what health equity means and how it directly impacts the pharma/patient relationship. The largest barriers are understanding the diverse, underserved and unserved populations and how these individuals or groups collectively survive daily culturally and medically. Making certain pharma is willing to think outside the box or traditional service methods to meet the needs of folks, tailor programs to support community based organization events and listen closely and deeply to what patients and their families are sharing about updates that need to be made to existing pharma surveys, studies and program interventions.

Connie L. Montgomery, Patient Advocate

A

Minorities are subject to treatment biases that are deeply rooted in the beliefs and practices of healthcare systems worldwide. To eliminate these biases there are 3 sets of actions that must be undertaken across the value chain –

A) Drive Awareness: we must become aware of them, understand them. Use patient advocacy groups, medical associations and national / international congresses to ensure minority biases are surfaced and discussed

B) Co-Sponsor Campaigns: Partner with patient groups, PAGs, community health centers and national health agencies to actively communicate the risk of missed participation from minorities leading to sub-optimal outcomes. Minority leaders and patient advocates are needed to identify bias; population health insights are needed to clarify the scope and impact of bias, and collaborative workgroups must be empowered to design and execute solutions

C) Fix minority representation in external communications – Ensure adequate minority representation is built into the design for any market-facing activities – marketing, advertising, clinical trials, medical communications ensuring the published data reaches all communities.

Raymond Short, Life sciences expert at PA Consulting

Medical Affairs

Becoming a more agile, multi-purpose partner for HCPs and patients alike via new skills and capabilities

The responses to our survey reveal that medical affairs leaders are wrestling with a wide range of tasks and working to create new capabilities that have not historically been native to the function.

Many expressed a desire for more agile working, more personalization of communication, better use of data analytics and strategic planning, and the ability to adapt to new developments and stakeholder changing needs within medical affairs.

Medical Affairs leaders see an opportunity, in particular, for the function to be more active and add more value in patient activation and engagement. "Patients may become a key player to decide on medicines choices within the next 10 years," observes Michael Zaiac, Head of Medical Affairs at Novartis Oncology Region Europe, adding that "differentiation may arise through patient reported outcomes which generate information to patients on which they can ultimately make their choice on what matters to them."

This is also a trend identified by Vic Ho, Head of Medical Capabilities and Excellence EUR/INT at Jazz Pharmaceuticals. Patient activation and engagement within the Medical Affairs function must be approached sensitively, he adds.

"It has been a long road to build MSL and Medical Affairs credibility as a scientific partner to healthcare and the same care is needed when working with patients with the added responsibility of protecting the patient / clinician bond. Patients are more expert in their condition now than ever, so Medical Affairs should be their advocate with the clinical community not asking patients to influence clinical choices if this collaboration is to truly help them."

"Patients are more expert in their condition now than ever, so Medical Affairs should be their advocate with the clinical community not asking patients to influence clinical choices if this collaboration is to truly help them."

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT at Jazz Pharmaceuticals

The need for better metrics to demonstrate ROI and impact on patient outcomes is another live issue highlighted by Ho. "We need to move from KPI's to Outcome Indicators, where the company and clinician define the outcome and work towards it together - this not only fosters true collaboration but is less subjectively measured by everyone."

But Ho acknowledges that implementing such novel metrics is not straightforward. "If the outcome is very long term then the milestones towards it need to be agreed. The reason this has taken so long to resolve is the commercial desire to cling to a simple SvT. Despite this being known to be a flawed measure and impossible for MSLs to get behind, it is at least easy to track. We have to put more effort in if we want stronger results for patients."

In terms of metrics and KPIs, says Zaiac, it is important to measure "how many target HCP's do have accurate knowledge of a medicine and the tools to explain this to patients and other stakeholders".

Relevant and engaging online content and interactions with stakeholders is another pressing task that many in Medical Affairs are wrestling with, says John Wahba, Medical Head of the Global Digital Hub at GSK. "Omnichannel is a team sport and medical is a key player. It will be important to leverage the medical insights that are generated to support content creation and address key informational needs.

"It's no longer good enough to think we know what and how information should be communicated, but rather using a data-driven approach to ensure this is done in a focused way. It is increasingly important for medical affairs to personalise the communication of complex information to a variety of audiences, in a bite size, easy to access, on-demand format, aligned to channel preference."

With so much on its plate, the Medical affairs function should take a more dynamic approach to tackling the many tasks before it, he adds. "Key skillsets include agile working and a startup mindset of not being afraid to test, fail and learn. Start small and don't over think it, execute, learn and grow."

There is also a need for broader technical skills such as RWE and advanced analytics within medical affairs. Zaiac, notes that "broader technical skills including RWE, advanced analytics", are necessary to advance workstreams across the business and overcome talent/ knowledge gaps.

Medical Affairs is also going to be playing a key role in addressing health inequities. Insights generation at the HCP/Patient level using RWE and other techniques into uncovering the true disease distribution are the start of this process.

The function is also increasingly going to be a part of the process of bringing trials to a wider array of patients, including those in historically disadvantaged communities, as well as facilitating launches which deliver to all communities.

Dr. Armin Furtwaengler, Global Lead Innovation Scouting - Innovation Hub - Global Medical Affairs & Global Senior Medical Director Healthcare Innovation, Boehringer Ingelheim International, also emphasises the importance of involving more patients and caregivers in the early stages of clinical development programmes, since "patients will gain increasing decision making power, in the context of new and evolving healthcare ecosystems of the future, increasingly becoming the "CEOs" of their own Health."

"It is increasingly important for medical affairs to personalise the communication of complex information to a variety of audiences, in a bite size, easy to access, on-demand format, aligned to channel preference."

John Wahba, Medical Head of the Global Digital Hub at GSK

Understanding the post-Covid challenges with re-engagement in care, the role of telemedicine, and engaging with HCPs and community experts that goes beyond traditional advisory boards.

Frank Spinelli, Senior Director, Patient Engagement, Gilead Sciences

Broader technical skills including RWE, advanced analytics

Improved communication skills exploiting more channels

Rapid content generation based on a rationale risk approach

Strategic mindset and attitude

Michael Zaiac, Head of Medical Affairs, Novartis Oncology Region Europe

- Empathy
- Authentic Leadership
- Credibility - Honesty - Passion
- Human - (Patient - Customer - Consumer - Citizen - Caregiver) - Centered & Holistic Approaches
- Listening to Patients, i.e. the "End-User" ... and - truly - understanding their perceived and real "Unmet Needs"
- Co-Creation with the "End-Users", involving UX-Design, "Real Patients", as well as Patient Advocacy Groups

Dr. Armin Furtwaengler (MD, PhD), Global Lead Innovation Scouting - Innovation Hub - Global Medical Affairs & Global Senior Medical Director Healthcare Innovation, Boehringer Ingelheim International GmbH

Leadership and strategy

Digital & Data Analytics

Elena Rizova, VP, Head of Medical Biogen Intercontinental Region, Biogen

Delivering Medical Value in a composite key account excellence way without compromising the range of activities Medical can be involved with. So linked to this, Influencing without authority and speaking the achievement language that commercial understands without oversimplifying medical value and risking it being misinterpreted.

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT , Jazz Pharmaceutical

Understand overall company strategy and business (Business Acumen), openness and willingness to appropriately communicate (and work) across departments/company, skill and willingness to truly lead the medical aspects of product development and distribution.

Maja Beilmann-Schramm, Global Director Field Excellence and HCP Exchange, Merck KGaA

Knowledge of the patient journey

Understand market access for each therapeutic area

Vitória João Valente Gemas, Field Medical Advisor, LEO Pharman

Being translators, both in terms of language but also translating information for different audiences and via different formats

J.R. Meloro, Group Team Leader, Pfizer

As medical affairs become an important strategic partner in the pharma organization, medical affairs personnel will need to upskill their business acumen to become medical business leaders. Value adding capabilities such as data analytics, business development insights, product strategy as well as early clinical development decision making will enable them to significantly value of their matrix partners beyond just their scientific knowledge.

Temi Folaranmi, VP and TA Head, Vaccines, US Medical and Clinical Affairs, GSK

Key skillsets include agile working and a startup mindset of not being afraid to test, fail and learn. Start small and dont over think it, execute, learn and grow. It is increasingly important for medical affairs to personalise the communication of complex information to a variety of audiences, in a bite size, easy to access, on-demand format, aligned to channel preference. Omnichannel is a team sport and medical is key player.

It will also be important to leverage the medical insights that are generated to support content creation and address key informational needs. It's no longer good enough to think we know what and how information should be communicated, but rather using a data-driven approach to ensure this is done in a focused way.

Additionally, skills in data analytics and strategic planning are key us make data-driven decisions and develop effective strategies across the enterprise. In today's rapidly changing healthcare landscape, the ability to adapt to new developments and stakeholder changing needs, and stay up-to-date on the latest trends (in pharma and outside of pharma) is also critical.

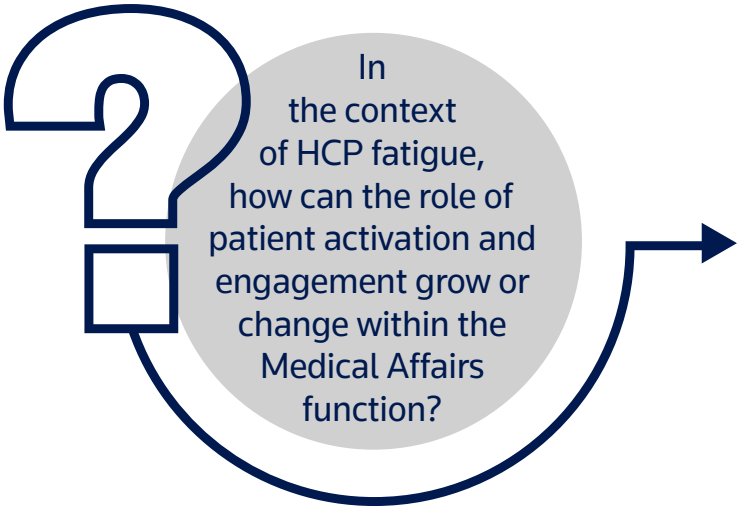
John Wahba, Medical Head of the Global Digital Hub, GSK

- increased business acumen and enterprise thinking
- confidence in challenging current treatment perceptions to advance patient care
- scientific storytelling to bring data to life in a patient-centric manner

Josh Corriveau, Senior Director, Global Field Medical Excellence, LEO Pharma

Launch excellence, Strategic planning, Digital Engagement, Latest disease area expertise

Nindhana Paranthaman, Principal Medical Director, Genentech



A

Pharmaceutical companies have an opportunity to better understand the landscape, particularly in underserved areas and collaborate with community based organizations to co-create interventions to active patients, link them in care and identify opportunities to maintain persistence in care.

Frank Spinelli, Senior Director, Patient Engagement, Gilead Sciences

A

Independently of HCP fatigue, patients may become a key player to decide on medicines choices within the next 10 years. Medicines become more similar in their efficacy/safety balance and differentiation may arise through patient reported outcomes which generate information to patients on which they can ultimately make their choice on what matters to them. That said, for now patient contact goes through HCP's and will probably always need alignment with HCP's . I recall that on some of the US direct to patient campaigns prescribing rates are as low as 3% or worse and these can be improved 10-fold by aligning. Hence Medical Affairs and should be a key contributor to patient engagement

Michael Zaiac, Head of Medical Affairs, Novartis Oncology Region Europe

A

Involve MORE Patients & Caregivers - early on - as early as Phase I of the Clinical Development Programs, as Patients will gain increasing "Decision-Making-Power", in the Context of New and Evolving Healthcare Eco-Systems of the Future, becoming the "CEOs of their Own Health" [Quote of Daniel Kraft, Singularity University & Exponential Medicine]

Finally, Transition Big Pharma Focus from Physicians, Pharmacists, Payors, Insurance Companies, etc. ... to the Patients and their individual Social, Family & Friends Environment, Support Systems and Local Healthcare Eco-Systems / Networks

Dr. Armin Furtwaengler (MD, PhD), Global Lead Innovation Scouting - Innovation Hub - Global Medical Affairs & Global Senior Medical Director Healthcare Innovation, Boehringer Ingelheim International GmbH

A

Patients and patient organization grow as the critical group for Medical to engage with - both in term of scientific exchange and even more by liaising pharma to work WITH patients along lifecycle and value chain.

Digital will also create the opportunity/ even demand for biopharma to respond or help decision making for patients faster than HCP will be able to do.

Elena Rizova, VP, Head of Medical Biogen Intercontinental Region, Biogen

A

It has been a long road to build MSL and Medical Affairs credibility as a scientific partner to healthcare and the same care is needed when working with patients with the added responsibility of protecting the patient / clinician bond. Patients are more expert in their condition now than ever, so Medical Affairs should be their advocate with the clinical community not asking patients to influence clinical choices if this collaboration is to truly help them.

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT , Jazz Pharmaceutical

A

Medical affairs must drive patient disease awareness and empowerment through Patient Association Groups (PAGs) projects and by the inclusion of Patient-reported outcomes (PROs) in clinical studies

Vitória João Valente Gemas, Field Medical Advisor, LEO Pharma

A

Leverage patient preference data to focus clinical conversations on what matters most to patients

Josh Corriveau, Senior Director, Global Field Medical Excellence, LEO Pharma

A

Insights generation at the HCP/Patient level using RWE and other techniques into uncovering the true disease distribution are the start. Be a part or leading to bring trials to patients (site selection, PI training, DCT's) is the middle and then facilitating launches which deliver to all communities

Michael Zaiac, Head of Medical Affairs, Novartis Oncology Region Europe

A

Medical Affairs is in the unique position of addressing inequities through landscape assessment and a better understanding of the patient journey, understanding there are regional differences, particularly in underserved areas. Only when MA uncovers the gaps can we implement strategies to address inequities like digital tools or education resources to help improve health literacy.

Frank Spinelli, Senior Director, Patient Engagement, Gilead Sciences

A

Medical is optimally placed to identify, substantiate with evidence and communicate the social determinants of the health inequities with different stakeholders and potentially steer efforts to address care path obstacles.

In case of the inequities involving access to innovative drugs, alignment with Access/ business functions is key to channel efforts for realistic outcomes.

Elena Rizova, VP, Head of Medical Biogen Intercontinental Region, Biogen

A

Multi-/Omnichannel communication requires close collaboration across departments. The way content is approved needs to be more agile and quicker, compliance teams need to understand the utilization of available channels and "safety" measures which can be put in place while still allowing appropriate communication.

Maja Beilmann-Schramm, Global Director Field Excellence and HCP Exchange, Merck KGaA

A

Addressing health inequities requires taking deliberate steps to ensure that the product we develop meets the need of the diverse population that we serve and help close gaps in health equity. Among others, MA can play significant roles in clinical trial diversity, targeted insight gathering to understand the unmet need of minority populations and working on patient advocacy groups on access to medicine and vaccines for them. The bottom line is we need to think about health inequities from the clinical development stage and not just an afterthought when the product is in the market.

Temi Folaranmi, VP and TA Head, Vaccines, US Medical and Clinical Affairs, GSK

A

Understand overall company strategy and business (Business Acumen), openness and willingness to appropriately communicate (and work) across departments/company, skill and willingness to truly lead the medical aspects of product development and distribution.

Maja Beilmann-Schramm, Global Director Field Excellence and HCP Exchange, Merck KGaA

A

Role - creating evidence about the burden of disease

Barriers - budget

Actions for minority outcomes - generating RW evidence

Vitória João Valente Gemas, Field Medical Advisor, LEO Pharma

A

Medical Affairs can ensure broad engagement and information equity by focusing on a variety of approaches for data dissemination

J.R. Meloro, Group Team Leader, Pfizer

A

For health equity to be achieved in the U.S., our industry must first center on the needs of historically marginalized patients and communities to provide actionable solutions. It is critical to shift power and resources to local communities, while building trust and addressing the root social causes of disease to create the conditions for generational wellness.

At Takeda, our long-term vision engages community-based organizations, actively listens to stakeholders across the health ecosystem for solutions, advocates for policy, improves care delivery, supports patients and caregivers, and accelerates equity in digital health. By sharing the power with the people, we are trying to serve and opening the door to transparent, authentic two-way conversation, we are able to co-design tangible solutions and improve health outcomes.

Lauren R. Powell, PhD, MPA, VP, US Health Equity & Community Wellness at Takeda

A

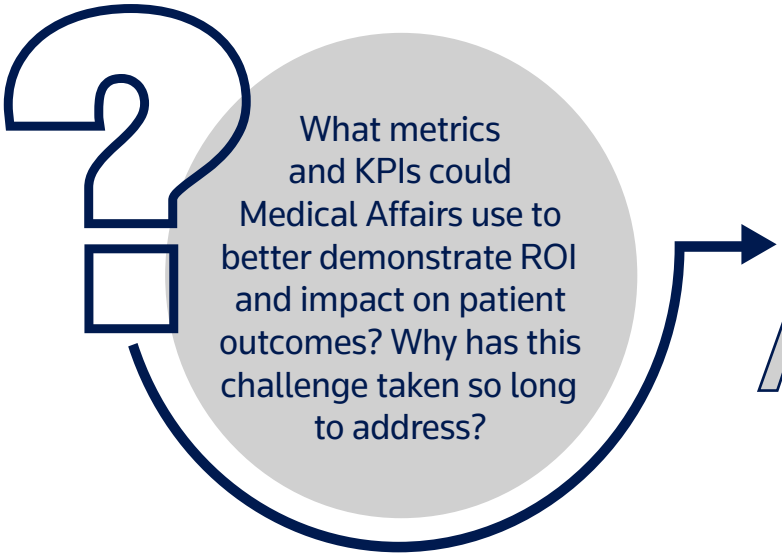
Identifying and nominating clinical research sites with diverse patient populations, which will build upon the evidence available for these patient populations

Josh Corriveau, Senior Director, Global Field Medical Excellence, LEO Pharma

A

Access to diverse patient populations and data through investigator initiated studies & real world data generation; barriers are recruitment, site staffing shortages and often diverse patients don't have access to resources; Actions for impacting minority outcomes include community education, physician engagement and removing logistical barriers.

Nindhana Paranthaman, Principal Medical Director, Genentech



A

#Metrics and #KPIs mean nothing to #Patients and their respective #UnmetNeeds - they will be irrelevant in the #FutureofHealthcare!

Dr. Armin Furtwaengler (MD, PhD), Global Lead Innovation Scouting - Innovation Hub - Global Medical Affairs & Global Senior Medical Director Healthcare Innovation, Boehringer Ingelheim International GmbH

A

The most important part for today is how many target HCP's do have accurate knowledge of a medicine and the tools to explain this to patients and other stakeholders

We often perceive compliance reasons in the way of measuring strong KPI's in medical and there is also a culture of medicine being an art. Which is of course true but great artists also being great because they market themselves and adapt. We may all want to become more like David Hockney who creates art in his late years of life on iPADs.

Michael Zaiac, Head of Medical Affairs, Novartis Oncology Region Europe

A

We need to move from KPI's to K Outcome Indicators, where the company and clinician define the outcome and work towards it together - this not only fosters true collaboration but is less subjectively measured by everyone. If the Outcome is very long term then the milestones towards it need to be agreed. The reason this has taken so long to resolve is the commercial desire to cling to a simple SvT despite this being known to be a flawed measure (and impossible for MSLs to get behind), it is at least easy to track. We have to put more effort in if we want stronger results for patients out.

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT , Jazz Pharmaceutical

A

Performance excellence/ KPIs for Medical should be patient centric, scientific focus and impact driven

Examples can be
- scientific awareness.
- medical alignment on the interpretation of data/science (eg data incorporated in the guidelines)
- appropriate care path (as per guidelines, etc) & clinical use (right therapy for th right patient)
- patient outcomes

Barriers so far
- expectation and difficulty to identify KPIs a straightforward as for other functions (regulatory approval, enrollment & timelines ; targets in trials; number of patients, revenues, prices, level of reimbursement...)
- leadership & accountability show outcomes/ impact ? (in any reasonable form)

Elena Rizova, VP, Head of Medical Biogen Intercontinental Region, Biogen

A

It has been a long road to build MSL and Medical Affairs credibility as a scientific partner to healthcare and the same care is needed when working with patients with the added responsibility of protecting the patient / clinician bond. Patients are more expert in their condition now than ever, so Medical Affairs should be their advocate with the clinical community not asking patients to influence clinical choices if this collaboration is to truly help them.

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT , Jazz Pharmaceutical

A

Publications, HCP advocates, awareness

Immediate results vs sustained results

Vitória João Valente Gemas, Field Medical Advisor, LEO Pharman

A

Changes in scientific awareness over time in the pre, peri, and post-launch periods

Josh Corriveau, Senior Director, Global Field Medical Excellence, LEO Pharma

A

The performance indicators must be closely aligned with the overall strategy of the company/TA/products. The word says it all: "Key Performance Indicator" - if these measures are not achieved as described in the strategy, the task will fail. Therefore, they must be chosen in alignment with the strategy and measure all critical tactics. All other numbers we measure are informative metrics

Maja Beilmann-Schramm, Global Director Field Excellence and HCP Exchange, Merck KGaA

A

One of the main reasons for why ROI in medical affairs in challenging is that the impact of Medical Affairs efforts on patient outcomes is often difficult to measure directly, as it can be influenced by a variety of factors, including the effectiveness of treatments, the quality of care provided by healthcare providers, and the overall health of the patient population. Additionally, the long-term nature of many Medical initiatives can make it difficult to determine the immediate ROI of these efforts. Finally, the complexity of the healthcare system and the various stakeholders involved can make it difficult to accurately attribute the impact of Medical Affairs efforts on patient outcomes. All of these factors can make it challenging to demonstrate the ROI of Medical Affairs activities, but by carefully tracking and analyzing relevant metrics and key performance indicators, it is possible to gain a better understanding of the value of these efforts and their impact on patient outcomes.

There are several metrics and KPIs that we can look at. Quantitative KPIs such as:

- number of medical education programs and activities developed and delivered to healthcare providers, such as symposiums, workshops, and webinars
- number of medical and scientific publications generated, including peer-reviewed journal articles and abstracts
- number of advisory boards and investigator meetings organized and attended
- number of clinical trials and studies supported and the resulting data generated
- number of medical queries and requests for information received and resolved
- number of key opinion leaders and other external experts engaged and the resulting impact on patient care and outcomes

When it comes to content, we can also look at things like NPS score, change in baseline knowledge and potentially impact on clinical practice or perceived behaviour change.

We can also look at qualitative feedback either in the form of surveys or interviews post activity e.g. via an MSL.

By tracking and analyzing these metrics, we can better understand the impact of their efforts on patient outcomes, and use this information to shape and improve out strategies and activities. Additionally, presenting this information in a clear and concise manner can help to demonstrate the value of Medical Affairs to key stakeholders, including senior leadership, healthcare providers, and patients.

John Wahba, Medical Head of the Global Digital Hub, GSK

A

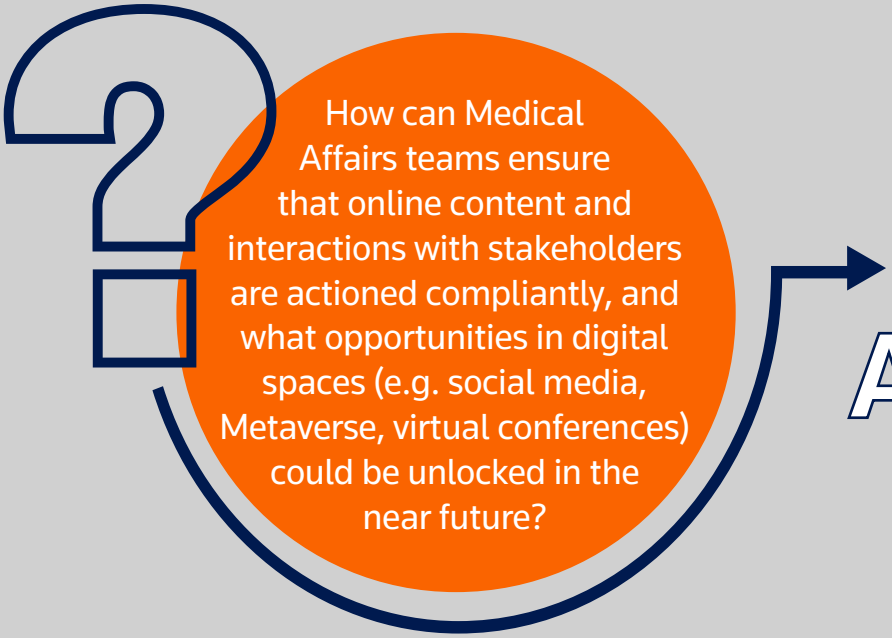
Data, research and measurement processes among historically marginalized communities needs to be improved in order to operate from a source of truth. Better collection, understanding, and interpretation of data, specifically including social determinants of health (SDOH) can help with an accurate baseline that enables us to establish the right resourcing to address issues in communities. SDOH screening tools and innovative technology capture race, ethnicity, sex, primary language, disability status, access to care and insurance, employment and housing status, etc. – all of which are critical layers to a patient's well-being that inform a proper diagnosis and treatment necessary to improve health outcomes. Additionally, diverse, inclusive and equitable research teams are necessary to be able to design and implement successful measurement programs.

Lauren R. Powell, PhD, MPA, VP, US Health Equity & Community Wellness at Takeda

A

Measuring qualitative & quantitative KPIs and defining metrics for impact early on in the drug development & commercialization process for cross-functional teams; Medical affairs impact is more subjective in how it is measured

Nindhana Paranthaman, Principal Medical Director, Genentech



A

Actions should be made through scientific groups, medical associations, or academy

The CME programs must be at the platforms of these stakeholders.

Vitória João Valente Gemas, Field Medical Advisor, LEO Pharma

A

The short-term future will be content hubs offering a broad, highly modular archive which can be composed to HCP needs using AI or simpler technology. In the long run and with truly personalized medicine for diseases such as Oncology and probably immunology on the Horizon we need to find ways to generate bespoke information in the moment and have an AI based checker in the background. In any case, what never changes needs to be the intent to improve care and being able to show a diligent path to that target

Michael Zaiac, Head of Medical Affairs, Novartis Oncology Region Europe

A

The focus of #BigPharma - in general, not only for #MedicalAffairs - needs to be to address the #UnmetNeeds of the ultimate #EndUsers related to ALL #Offerings, #Products, #Pharmaceuticals, #NCEs and #NBEs, and any other type of #Services provided by the #PharmaceuticalIndustry, and - in particular - #BigPharma!

Dr. Armin Furtwaengler (MD, PhD), Global Lead Innovation Scouting - Innovation Hub - Global Medical Affairs & Global Senior Medical Director Healthcare Innovation, Boehringer Ingelheim International GmbH

A

Meta tagging of pieces of data that support a total body of evidence for a product (some will be efficacy claim supporting some will be safety claim supporting etc.) needs to happen to allow individual pieces of data and analysis to be plugged together quickly and in multiple ways (following rules that maintain balance and connection to the populations of patients the data is taken from). Once this database of puzzle pieces (which are each accuracy approved) and rules by country license (which are medically approved) are created, MSL materials for balanced communication can be called into existence without the rate limiting step of endless copy approval of full slide decks. Only then, will the far reaching conversations that MSLs need to have be possible in an omnichannel environment.

Vic Ho, Head of Medical Capabilities and Excellence EUR/INT , Jazz Pharmaceutical

A

"Online" is just another channel hence standards should be the same! (for digital content assembly the technology can support execution of assembly rules - eg "efficacy/ safety balance")

Content/interactions should follow the customer, so leverage those channels, digital spaces where they are.

Elena Rizova, VP, Head of Medical Biogen Intercontinental Region, Biogen

A Teams should focus on bringing the conversation to the platforms where audiences already are, rather than expecting the audience to "come to us." Working with Legal and Regulatory to establish compliant use and engagement with social media is priority.

J.R. Meloro, Group Team Leader, Pfizer

A This is a fast evolving area and our codes of compliance are catching up. To start, it's important to have the right mindset and be an enabler rather than a blocker. If an activity doesn't seem compliant, how can we make it compliant rather than block it. Key things to think about:

1) Risk mitigation steps in place to ensure that there is no inadvertent promotion to the public or access to unsuitable content or content that is aimed at HCPs e.g. verification of users, the use of clear disclaimers
2) Transparency - there are clear disclaimers about the involvement of the pharma company and the relevant hashtags are used when collaborating with Digital Opinion Leaders
3) There is adequate community management and monitoring of posts where commentary is allowed to ensure adverse events are reported and handled expeditiously and any misinformation or disparaging comments are dealt with.
4) Clear response timelines and a traffic light system for escalation and having a timely response
5) Stock or pre-approved responses to allow for efficient and instant responses where possible in line with agreed rules of engagement
6) Being pragmatic about what content needs formal certification e.g. disease awareness content vs what can simply be examined
7) Having clear policies and guidelines about employee social media accountabilities and the Do's and Don'ts
8) Having clear roles and responsibilities when it comes to using online channels for dissemination of content
9) Early involvement of stakeholders from legal, governance, data privacy, pharmacovigilance and regulatory where required to ensure awareness and early actioning of potential issues.
10) Clear roles and responsibilities, expectations and rules of engagement are in place when it comes to working with stakeholders so they are aware of our regulations and the need to mitigate risk. Ultimately, we are accountable for content that is on our channels and also bear accountability for content we ask them to post on their channels.

John Wahba, Medical Head of the Global Digital Hub, GSK

A Social listening, proactive engagement with HCPs & patients on social media, leveraging virtual conferences to disseminate data sooner and reach a broader audience

Nindhana Paranthaman, Principal Medical Director, Genentech

RWE & Market Access

Data from digital diagnostics will increase opportunities for personalised care and proof of superior outcomes but market access remains challenging

Real world evidence is set to start making a difference at scale to patients. Digital diagnostic tools and smarter remote and self-care models will contribute to more efficient care, delivering improved outcomes and a better patient experience, according to responses in our survey.

Patients increasingly want their voice to be heard when it comes to their care and treatment options and this engagement can lead to higher satisfaction and generate real world insights for the company.

Patients will increasingly be identified to receive the proper therapy at the right time in their disease progression. The value added as a result will be "digitally justified" for payers and other decision-makers.

The future is bright, says Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma. "Healthcare will be personalised, and digital health facilitates that on several levels, in addition to providing valuable insights on actual patient populations."

Innovation in market access, meanwhile, remains more elusive. Delay remains rife at all regulatory and payer stages in seeking market access.

To minimise the time from approval to coverage, pharma companies need to efficiently communicate three things:

1. Compelling efficacy and safety data based on evidence
2. Proven service to a patient population with an unmet need and a clinically appropriate position in the treatment pathway
3. Demonstrable product value, based on outcomes

By far the greatest hurdle to clear is being able to adequately demonstrate compelling efficacy safety data to regulators. Pharma companies need to leverage innovative data-generating techniques beyond clinical studies to create a compelling case and minimise the time from approval to coverage.

"The future is bright. Healthcare will be personalised, and digital health facilitates that on several levels, in addition to providing valuable insights on actual patient populations."

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

Amongst payers, HTAs and regulators, which authority creates the greatest delays to market access, and what transformation is needed to overcome these delays and accelerate access?

A

FDA, NICE, and CMS in the US

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

Are patients having a stronger voice amongst market access leaders?

A

No, the patient voice is still not listened to

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

What do you envision pharma's role and reward to be in the future of digital health?

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Healthcare will be personalised, and digital health facilitates that on several levels, in addition to providing valuable insights on actual patient populations

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

How might evidence generation teams need to be upskilled or evolved to meet the growing demands associated with payer value?

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Drugs don't often have to prove cost-effectiveness, but digital health can provide that evidence too.

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

What fundamental guidelines or changes need to be built for higher acceptance of real world evidence?

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Understanding that RCTs provide only one kind of evidence. Perhaps a separate team should evaluate RWE.

Jessica Germaine Shull, Director of Digital Therapeutics at Vicore Pharma

Cell & Gene Therapy

The challenges of scaling up and finding workable payment models, together with tight healthcare budgets need to be resolved for CGT to hit the mainstream

Cell and gene therapy (CGT) stands poised to become an increasingly common treatment in the near future, but commercial challenges remain. Leaders in the field of cell and gene therapy identified the need for innovative payment models, specialized clinical networks, and patient-centred services as key commercial challenges that need to be addressed in order to scale up CGT effectively.

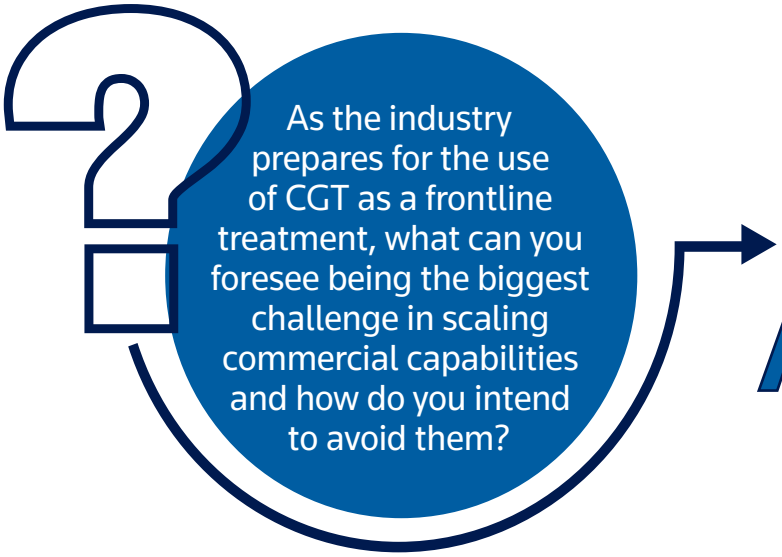
They also note the importance of value-based contracting and the need to link up with policy teams to address the potential reduction of physician/hospital funding streams. Additionally, they highlight the challenges of scaling up processes at a local level and the need for payers to work with small scale programs that are 'approved' or certified as viable providers of the technology.

One of the biggest challenges in scaling commercial capabilities for CGT is addressing the pricing and access challenges that are inherent in the field. Surajit Sen, Partner in the Life Sciences Strategy Practice at EY-Parthenon, notes that successful commercialization will require companies to scale up CGT-specific commercial capabilities that aren't always part of a typical product launch.

This includes creating and operationalizing innovative payment models that address the unique challenges of CGT, activating and certifying a specialized network of CGT-capable clinical sites, and developing next-gen patient services that provide concierge-grade support to help patients navigate the complexities and barriers in the CGT treatment journey.

Mark Trusheim, Strategic Director of NEWDIGS at Tufts Medical Center, believes that commercial teams will have to adapt to bring these unique therapies to market effectively by adopting flexible, value-based contracting approaches. He notes that therapies may reduce physician/hospital funding streams and there may be a need to link up with policy teams to address this issue. Product values may come substantially from patient/caregiver/workplace benefits, which will need to be quantified, perhaps via PROs.

Value-based contracting to help manage CGT costs through warranty type contracting so that payors only pay for products that have sustained durability will be key to commercial expansion of CGT, says David Yoder, SVP of Federal Employees Program at Blue Cross Blue Shield Association.



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Building a center of excellence network that yields convenient patient access and payer acceptance. This will require medical affairs to develop clear, simple materials & streamlined certification processes.

Mark Trusheim, Strategic Director NEWDIGS, Tufts Medical Center

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The use of CGTs in front-line treatment will further exacerbate the pricing and access challenges experienced in this space, and successful commercialization will require companies to scale up CGT-specific commercial capabilities that aren't always part of your typical product launch. Creating and operationalizing innovative payment models that address the unique challenges of CGT (e.g. ultra-high upfront costs, uncertain long-term durability of response), activating and certifying a specialized network of CGT-capable clinical sites, and developing next-gen patient services that provide concierge-grade support to help patients navigate the complexities and barriers in the CGT treatment journey are just a few examples of the additional capabilities required for CGT commercialization. Scaling these capabilities will require a high degree of cross-functional collaboration, potential external partnerships, and early upfront investment to ensure these capabilities are sufficiently developed in time to enable successful product launch.

Surajit Sen, EY-Parthenon Partner

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At the same time manufacturers are building centralized capabilities, there are many others trying to scale the processes at a local level and to reduce cycle times. Payors will be challenged with how to work with small scale programs and how they become 'approved' or certified as viable providers of the technology.

David Yoder, SVP Federal Employees Program, Blue Cross Blue Shield Association

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Ensuring that we have the right technology and systems in place to meet the needs of patients when it comes to the potential and promise of cell therapy in a frontline setting is paramount, and at Janssen, we are preparing by enhancing and expanding our global capabilities across R&D, Commercial and Supply Chain to meet the future needs of patients and physicians.

Biljana Naumovic, Worldwide Vice President, Oncology, Janssen Pharmaceutical Companies of Johnson and Johnson

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An issue I have faced in Cell Therapy is that CMOs are pushing a dedicated suite model and have not embraced processing in closed systems in a ballroom. The dedicated suite model drives up manufacturing costs unless they're enough demand. Closed automated processing systems significantly can drive down cost of goods and new processes are being designed fully closed or close to being fully closed. We are also pushing the ballroom model with CMOs in all new Cell Therapy RFPs.

Antonio Vernacchio, Vice President External MFG, Sangamo Therapeutics

With so many novel indications awaiting approval, how do you think commercial teams will have to adapt to bring these unique therapies to market effectively?

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Adoption of flexible, value-based contracting approaches. Therapies may reduce physician/hospital funding streams so may need to link up with policy teams to address. Product values may come substantially from patient/caregiver/workplace benefits which will need to be quantified, perhaps via PROS.

Mark Trusheim, Strategic Director NEWDIGS, Tufts Medical Center

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The anticipated high costs of these products is front and center on everyone's mind. Value based contracting has the potential to help alleviate these through warranty type contracting so that as payers we only pay for products that have sustained durability. Payers want to pay for products that work and alleviate other treatment costs and the new treatments don't become add on costs with no offsets elsewhere. Million dollar treatments are sustainable in the long or short term and cost structures have to evolve to sustainability for all market participants.

David Yoder, SVP Federal Employees Program, Blue Cross Blue Shield Association

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Delivering cutting-edge, cell-based therapeutics has groundbreaking potential. From an industry perspective, the complexity of delivering these innovations is vastly different from how we have introduced small molecule or biologic therapies in the past, so educating markets and stakeholders is critical. We take this responsibility seriously as patients and families are depending upon us, especially in oncology where many of these therapies are initially approved in the most relapsed/refractory settings, where the outlook for patients is bleak and many times, our efforts are their last hope for more time.

Biljana Naumovic, Worldwide Vice President, Oncology, Janssen Pharmaceutical Companies of Johnson and Johnson

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Cell and Gene Therapy have a significant amount of potential but are still very niche. Until cost and manufacturing variability can be managed I don't believe they will have significant impact on wider Pharma.

Antonio Vernacchio, Vice President External MFG, Sangamo Therapeutics

With the novelty of the space bringing so many unknowns, how can you see CGT impacting the future of wider pharma?

A The payment innovations being created and implemented for cell and gene therapies are already spreading to other conditions.

Mark Trusheim, Strategic Director NEWDIGS, Tufts Medical Center

A This will truly be a 'mass customization' endeavor and not a one-size-fits-all propositions. I see parallels to the large computer companies of the 80's that went from main frame computers to distributed computing and how many of those companies has to morph into leaner and more cost-effective entities or go out of business. The traditional pharma business plans cannot support these new entrants as the scale is small and not able to support the existing business models. Every product can't be a million dollar product or there will be such access restrictions that the techonology gets 'bottled up' and is not used to any extent.

David Yoder, SVP Federal Employees Program, Blue Cross Blue Shield Association

A It's critical that as an industry we come together now with health systems, regulators, payers and policymakers, globally, to prepare for the disruptive potential of cell therapy in oncology, where we have the real possibility to transform outcomes and drive toward cures. At Janssen, we're committed to the future of this immunotherapy paradigm shift as we continue to advance novel therapeutics for hematologic malignancies and solid tumors.

Biljana Naumovic, Worldwide Vice President, Oncology, Janssen Pharmaceutical Companies of Johnson and Johnson

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