



The State of the Biopharmaceutical Industry

2021 Edition

Report Code: GDHCHT247

January, 2021

1	<u>Study Design</u>	7	<u>Watch Outs</u>
2	<u>Key Findings</u>	10	<u>Summary of Key Findings</u>
3	<u>Emerging Industry Trends</u>	11	<u>Appendix</u>
4	<u>Emerging Regulatory and Macroeconomic Trends</u>	12	<u>Contact Us</u>
5	<u>Emerging Technologies</u>		
6	<u>Industry's Growth Prospects</u>		

Abbreviations (1/2)



4EU	France, Germany, Italy, and Spain	CEO	chief executive officer
5G	fifth-generation telecommunication technology	CNS	central nervous system
7MM	US, France, Germany, Italy, Spain, UK, and Japan	COVID-19	coronavirus disease 2019
8MM	US, France, Germany, Italy, Spain, UK, Japan, and China	CRO	clinical research organization
ACA	Affordable Care Act	CVD	cardiovascular disease
ACOT	annual cost of therapy	DCT	decentralized clinical trials
ADA	adenosine deaminase	DPA	Defense Production Act
ADC	antibody drug conjugate	DTP	direct-to-patient
ADME	absorption, distribution, metabolism, excretion, and toxicity	EHR	electronic health record
AI	artificial intelligence	EMA	European Medicines Agency
APAC	Asia Pacific	ESG	environmental, social, and governance
API	active pharmaceutical ingredients	EUA	emergency use authorization
ASCVD	atherosclerotic cardiovascular disease	EVP	executive vice president
ATMP	advanced therapy medicinal product	FH	familial hypercholesterolemia
BLA	biologics license application	GDPR	General Data Protection Regulation
BMS	Bristol-Myers Squibb	GI	gastrointestinal
CAGR	compound annual growth rate	GTN	gross-to-net
CAR-T	chimeric antigen receptor T cell	HCP	Healthcare professional
CBD	cannabidiol	HEOR	health economics and outcomes research
CDMO	contract development and manufacturing organization	HITECH	Health Information Technology for Economic and Clinical Health

Abbreviations (2/2)



ICI	immune checkpoint inhibitor	PSP	patient support program
ICU	intensive care unit	RA	rheumatoid arthritis
IDN	integrated delivery network	RNA	ribonucleic acid
IO	immuno-oncology	ROW	rest of the world
IP	intellectual property	RPM	remote patient monitoring
IRB	Institutional Review Board	RWD	real-world data
IT	information technology	RWE	real-world evidence
KOL	key opinion leader	SAMHSA	Substance Abuse and Mental Health Services Administration
LGBTQ	lesbian, gay, bisexual, transgender, and queer/questioning	SEC	Securities and Exchange Commission
LNP	lipid nanoparticles	SVP	senior vice president
MAA	marketing authorization application	VBP	value-based pricing
mAbs	monoclonal antibodies	VP	vice president
mRNA	messenger RNA	YE	year end
MS	multiple sclerosis		
M&A	mergers and acquisitions		
NICE	National Institute for Health and Care Excellence		
NSCLC	non-small cell lung cancer		
PDUFA	Prescription Drug User Fee Act		
POMC	pro-opiomelanocortin		
PPE	personal protective equipment		

Published Related Reports

- GlobalData (2020). Thematic Research: Regenerative Medicine in Pharma, November 2020, GDHCHT211.
- GlobalData (2020). Digital Transformation and Emerging Technology in the Healthcare Industry – 2020, October 2020, GDHCHT206.
- GlobalData (2020). Thematic Research: Cybersecurity in Healthcare 2020, October 2020, GDHCHT185.
- GlobalData (2020). Coronavirus (COVID-19) Sector Impact: Pharmaceutical Trade and Supply Chain Survey – Q3 2020, September 2020, GDHCHT184.
- GlobalData (2020). Coronavirus Disease 2019 (COVID-19) Sector Impact: The COVID-19 Pandemic Impact on Clinical Trials, August 2020, GDHCHT167.
- GlobalData (2020). Coronavirus Disease 2019 (COVID-19) – Sector Impact: Use of Telemedicine in the US During the COVID-19 Pandemic, August 2020, GDHCHT169.
- GlobalData (2020). The State of the Biopharmaceutical Industry – 2020, January 2020, GDHCHT047.
- GlobalData (2020). Thematic Research: The Future of Work, July 2020, GDTMT-TR-S277.

Upcoming Related Reports

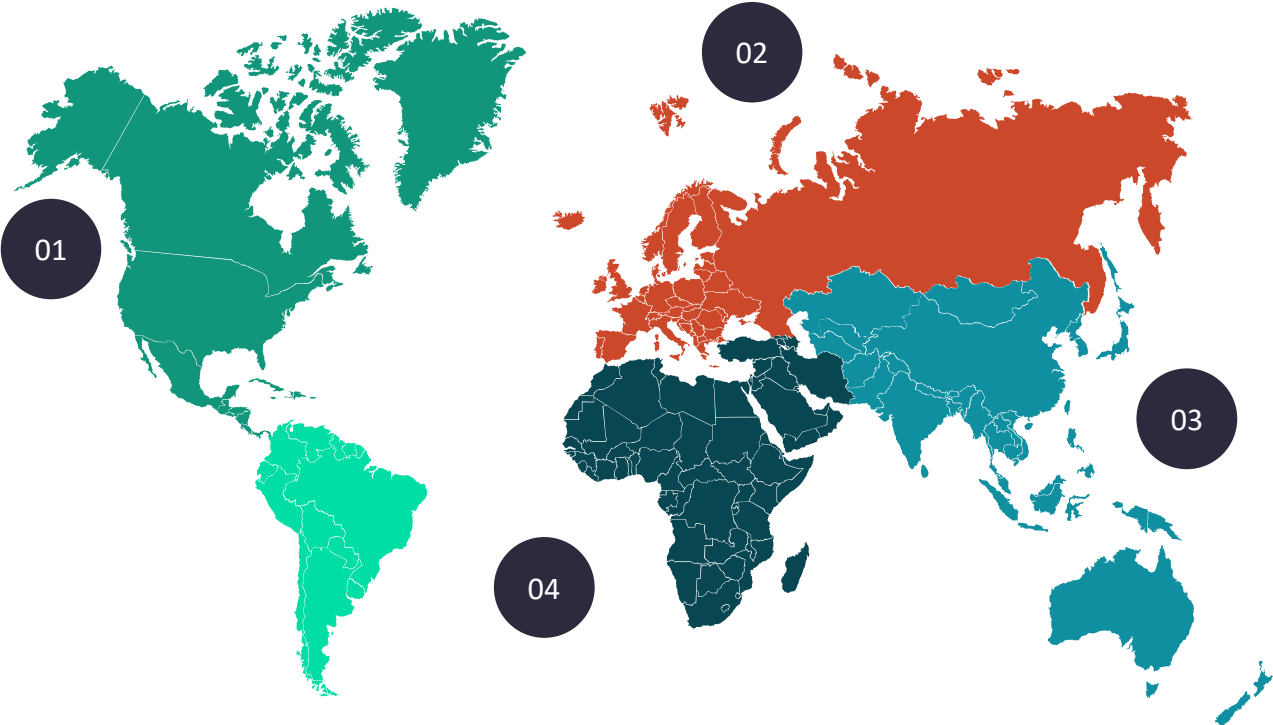
- GlobalData (2021). Artificial Intelligence in Healthcare, to be published.
- GlobalData (2021). Remote Patient Monitoring, to be published.
- GlobalData (2021). Social Media in Healthcare, to be published.
- GlobalData (2021). Brexit – Impact on Pharma, to be published.
- GlobalData (2021). Clinical Trials: A Look at Virtual Trials – update, to be published.



Study Design



Geography



01	●	North America N = 89
02	●	Europe N = 64
03	●	Asia Pacific N = 25
04	●	Rest of the world (ROW) N = 20

Study Design

“

Despite the challenges of COVID-19, 2021 has the potential to be highly significant for our industry. The rapid development of successful vaccines has provided an opportunity to restate the value of the industry to wider public, and some of the shifts brought about by COVID-19-related restrictions (e.g., to clinical trials or HCP interactions) may accelerate much-needed change.

”

- Europe VP/SVP/EVP

Objectives and Design



2021 Global Biopharmaceutical Industry Outlook

2021 promises to be a year of continued innovation and change in the biopharmaceutical industry. As the COVID-19 pandemic continues to take its toll on businesses worldwide, pharmaceutical companies will be looking for new ways to create value, prepare for the future, and remain competitive in the ever-changing business landscape.

In this report, GlobalData examines the business environment and trends that are going to shape the biopharmaceutical industry in 2021. The report also highlights the most impactful emerging technologies, industry, regulatory, and microeconomic factors that are going to impact industry's growth prospects.

Study Objectives

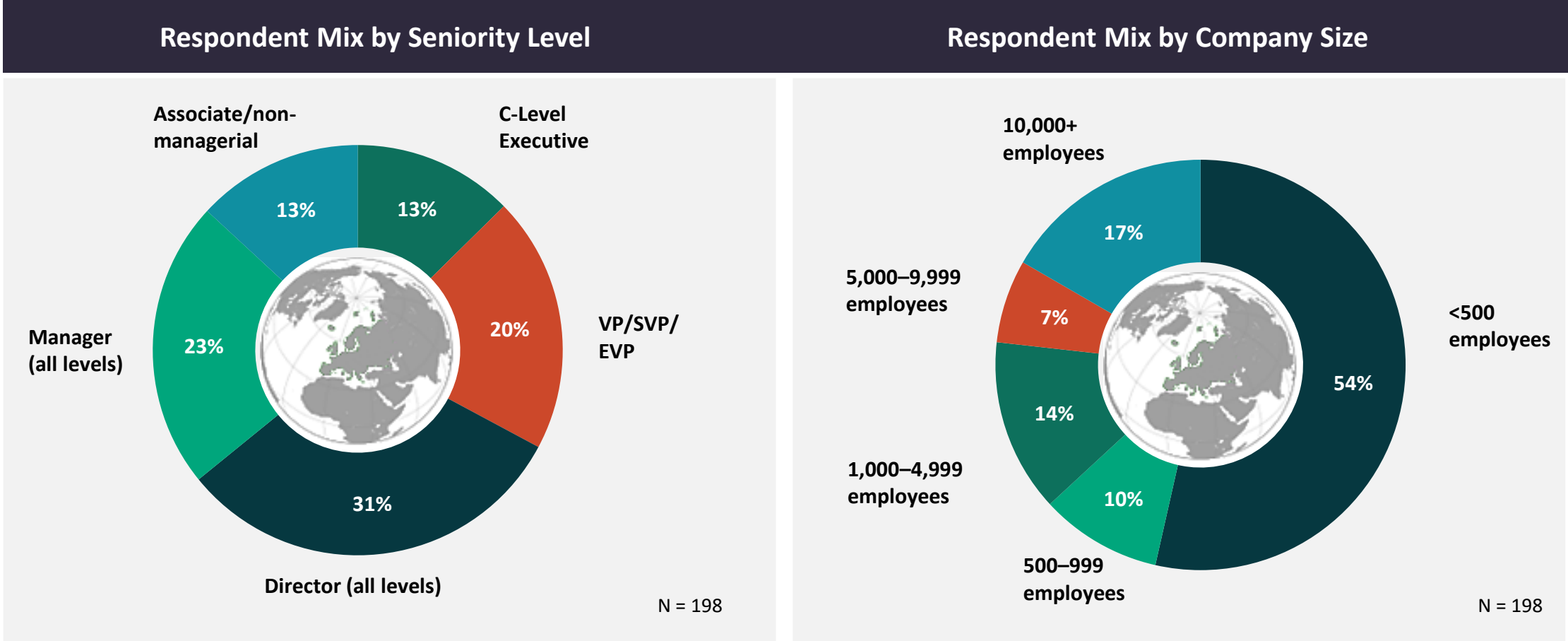
- Benchmark the impact of major themes on the biopharmaceutical industry in 2021, including:
 - Emerging technologies
 - Regulatory trends
 - Macroeconomic trends
 - Industry trends
- Identify themes that will have the greatest positive or negative impact in 2021.
- Capture opinions on these themes from industry respondents.
- Assess the impact of COVID-19 on the biopharmaceutical sector.

Study Design

- A total of 198 GlobalData Pharma clients and prospects participated in the 10-minute survey, which was fielded from **November 17, 2020, to December 11, 2020.**

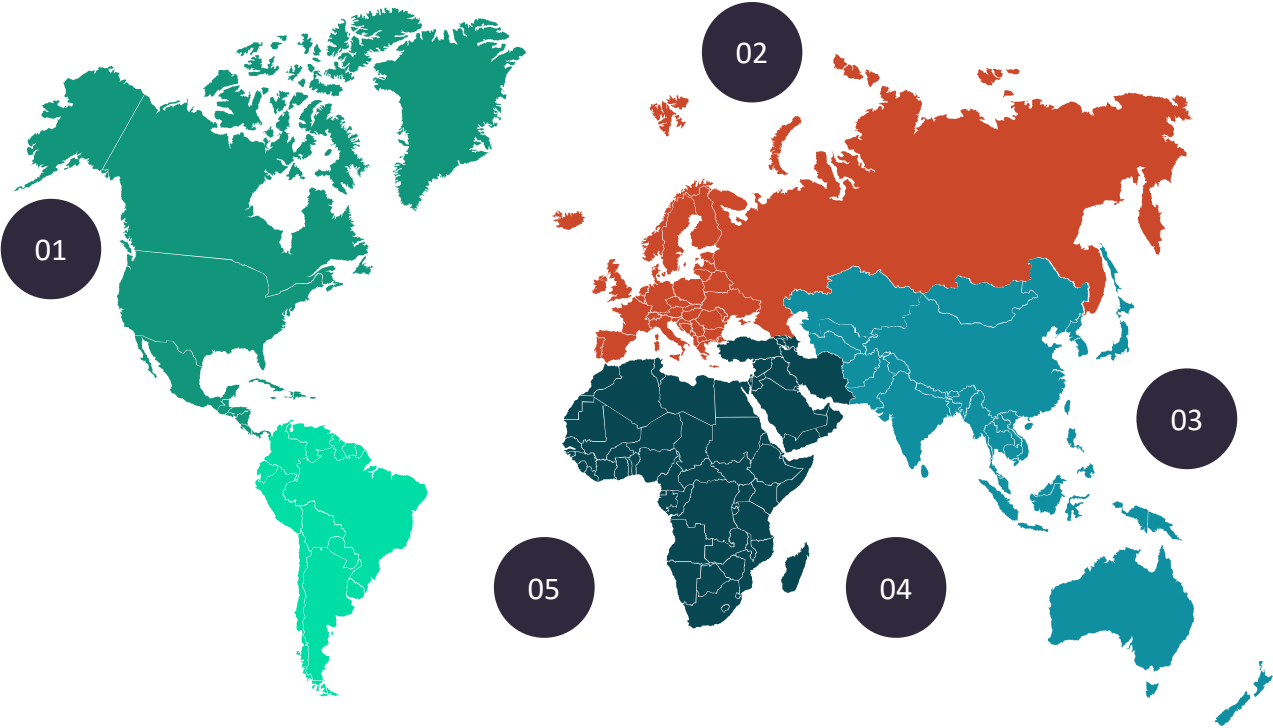


Seniority Level and Company Size



Q: What best describes your position in your organization?
Q: What is the size of your organization?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

Headquarters Location



01	●	North America N = 82
02	●	Europe N = 63
03	●	Asia Pacific N = 24
04	●	Middle East & Africa N = 14
05	●	Rest of the world N = 15

Study Design

Q: Please select the country your headquarters is located in?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition



Key Findings

1

COVID-19-driven changes will continue to transform and reshape the biopharmaceutical industry in 2021

- COVID-19 has been a wake-up call for pharma to innovate, rethink their operations, and adopt new ways of working in order to harness relationships with customers, regulators, and investors.
- With the new policies, regulations, and technologies constantly emerging, the pharmaceutical industry will be looking to offset the challenges arising from COVID-19 and seize opportunities to modernize the processes in its core value chain.

2

Immuno-oncology (IO) and personalized medicine are expected to continue to lead as the most impactful trends in the biopharmaceutical industry

- IO and personalized/precision medicine received the highest scores among emerging industry trends likely to have an impact on the pharmaceutical industry in 2021. Both of these areas were trending in 2019 and 2020 and will continue to dominate as essential components in developing more effective and innovative treatment approaches.

3

Remote patient monitoring (RPM) is set to reach the greatest impact on the pharmaceutical industry in 2021

- Despite much lower uptake in previous years, RPM got off to a very strong start and witnessed a massive uptake in the life-sciences sector in 2020. With more patients, payers, and physicians getting accustomed to virtual interactions, RPM will continue to lead to a fundamental change in healthcare delivery and clinical trials.
- Adoption of RPM tools will also continue to increase due to advances in technologies such as wearables, artificial intelligence (AI), cloud computing, and deployment of 5G.

4

Drug pricing pressures will continue to hinder growth, forcing pharmaceutical companies to reassess their strategies and market focus

- About half of survey respondents believed that drug pricing and reimbursement constraints will have the greatest negative impact on the pharmaceutical industry in 2021, which constitutes the highest percentage compared to the past two years.
- Decreased tax revenues will pressure governments to manage healthcare budgets and drug costs due to the need to contain public spending and balance borrowing caused by COVID-19.

5

Pharma is divided on the most positive industry trends, with patent expiry of biologics, vertical integration, and clinical and manufacturing outsourcing being highlighted

- Survey respondents were mixed on the factors that will have the greatest positive impact on the industry. Patent expiry of biologics, vertical integration, and clinical and manufacturing outsourcing are expected to have relatively equal positive impact, at 13–20% each. Supported by governments' policies, the combination of these trends may be associated with lowering drug prices and overall healthcare spending.

6

Big Data and AI will continue to dominate as transformational forces in healthcare

- AI, followed by Big Data, will continue to trend as integral parts of the future of pharmaceutical research and healthcare service delivery. AI powered by Big Data will be used across a spectrum of processes ranging from target identification to commercialization activities and will eventually reduce R&D cycle time and costs, paving the way to a stronger and more sustainable drug pipeline.

7

Across the entire value chain, drug development will be impacted the most by the COVID-19 pandemic in 2021

- Over 30% of the respondents believed that the drug development process will face the biggest impact from COVID-19 in 2021. Despite COVID-19 disrupting clinical trials worldwide, the pandemic can also act as a catalyst for a change in the current paradigm of traditional drug discovery and development, ushering in a new era for decentralized/virtual clinical trials (DCTs).

8

The biopharmaceutical industry feels optimistic about industry growth during the next 12 months

- More than 70% of the respondents felt optimistic or very optimistic about industry growth in 2021, most likely due to the pharmaceutical sector remaining relatively resilient during the pandemic.
- Even though the pharmaceutical industry has long struggled to showcase its value and change negative public perception, COVID-19 has given a unique opportunity for pharma to redeem its reputation by collaborating on COVID-19 therapeutics and vaccines.

9

The pharmaceutical industry will be under increasing pressure to become more sustainable, with more companies committing to environmental, social, and governance (ESG) strategies

- For a long time the impact of the pharmaceutical industry on sustainability was rather overlooked, but as the pressures to manage sustainability risks are intensifying on a global scale, the pharmaceutical industry will need to act on this trend.
- Over the coming years, the incorporation of greener processes in R&D, supply chain, waste, and resource management will transform the way that business is conducted, as customers and regulators will demand greater actions to address ESG issues.

10

2021 will see a resurgence in clinical trials, with oncology, central nervous system (CNS), and infectious diseases standing out as the main therapy areas

- Clinical trial investigations for COVID-19 and oncology indications will take up the largest portion of planned clinical trials in 2021, further highlighting the high demand for new therapeutic approaches to address unmet medical needs in these areas.
- More than 60% of 2021 planned trials are industry-sponsored, with big pharma dominating the research space.

11

COVID-19 vaccines' development and rollout will lead the agenda in 2021

- 2020 has proven to be a remarkable year for development of agents to respond to COVID-19, particularly for vaccines, which have been developed in record time and will see significant uptake.
- The focus on COVID-19 vaccines' development and rollout is likely to continue throughout 2021. The increasing availability of vaccines will add to a growing confidence to return to the times resembling pre-COVID-19 normality.

12

2020 witnessed a burst in health- and science-related misinformation that will continue into 2021

- Online platforms possessing sophisticated algorithms and troves of data that allow them to tailor and personalize content to reach those most likely to be influenced are often blamed for the misinformation spread.
- The US elections and COVID-19 have given this issue more urgency and although the governments are turning their attention to regulatory measures, the legislative field is still in infancy stage. While the election turmoil recedes, COVID-19 remains, leaving room for health-related misinformation to continue to spread.



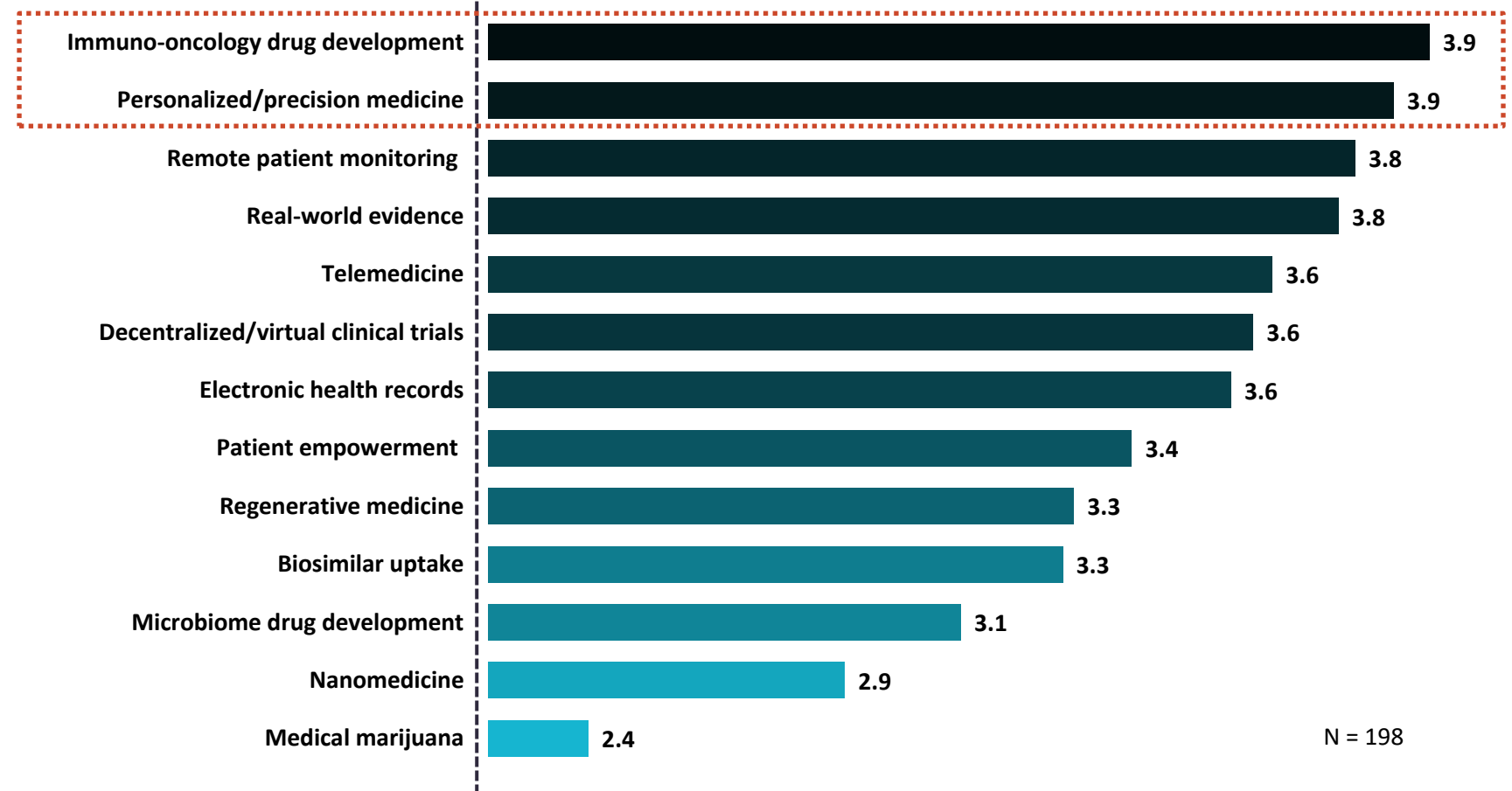
Emerging Industry Trends

- Similarly to previous years, **IO drug development** and **personalized/precision medicine** received some of the highest scores among emerging industry trends likely to have an impact in 2021. These closely related trends have already begun to reshape disease treatment paradigms and the provision of healthcare. Their influence will continue to grow as additional IO drugs reach the market and the emphasis on value-based healthcare models and personalized, patient-centric strategies continues.
- **Telemedicine** has emerged as an important tool to support healthcare systems during the ongoing COVID-19 pandemic to limit the risk of person-to-person transmission, triggering policymakers in many countries to relax regulations in order to facilitate widespread usage and adoption of telehealth.
- With more patients, payers, and physicians getting accustomed to virtual interactions, **RPM** will bring a fundamental change in the delivery of healthcare and clinical trials.

Emerging Industry Trends

Immuno-oncology and Personalized/Precision Medicine Identified as the Top Emerging Pharmaceutical Industry Trends for 2021

Survey fielded November 17, 2020, to December 9, 2020

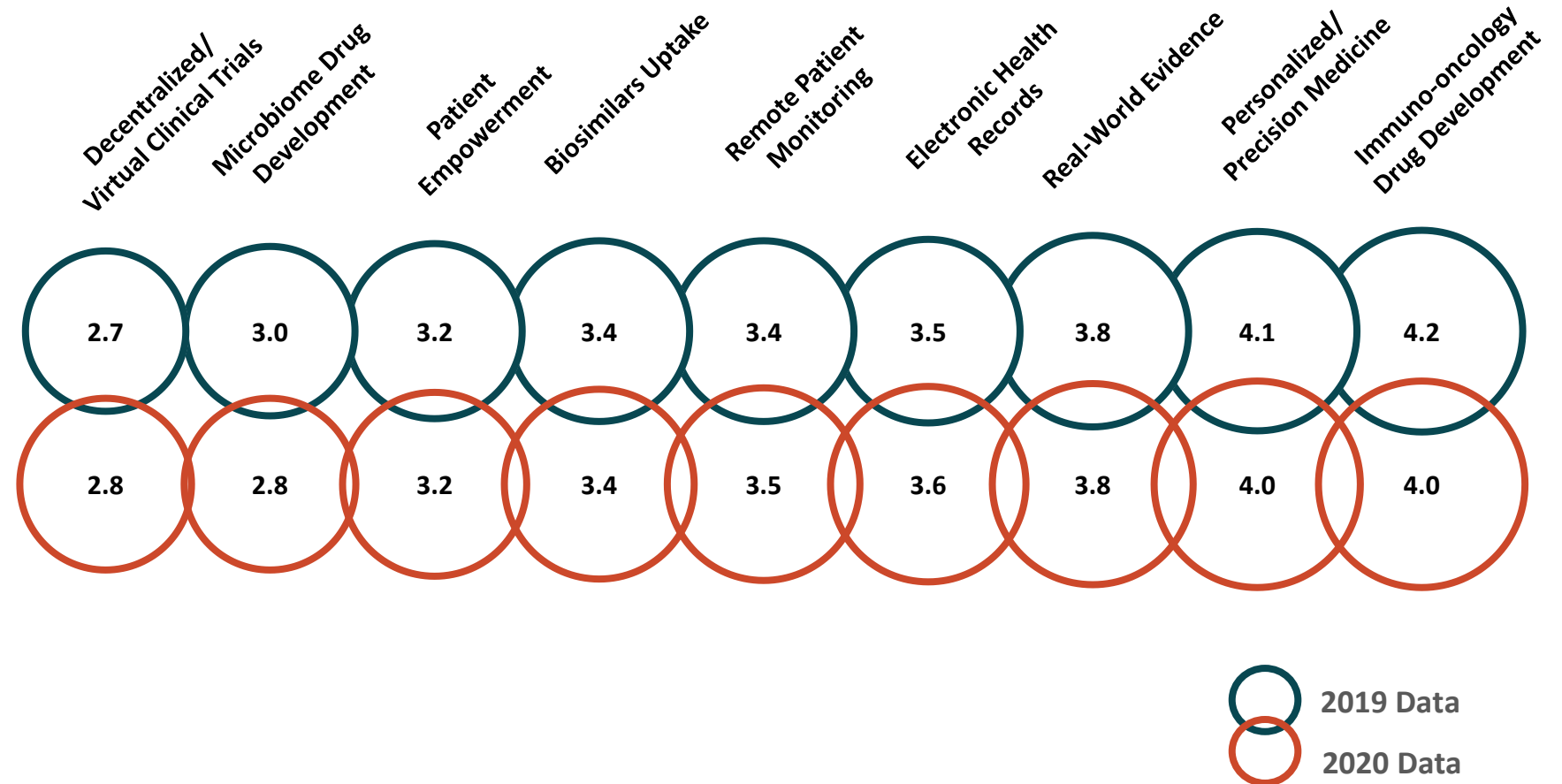


Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging industry trends on the pharmaceutical industry in 2021.
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

- **Real-world evidence (RWE)**, which was rated as the third most impactful trend during previous years, is becoming a tool in the industry to help pharma companies discover new drug targets and enable more efficient clinical trials. Stakeholders across the spectrum—including regulatory decision-makers, healthcare payers, clinicians, and patients—are increasingly demanding evidence of the benefits of treatment interventions. GlobalData expects to see the further utilization and growing role of RWE across disease areas in 2021.
- Continuing a trend that was seen in 2019 and 2020, increased adoption of new **electronic health record (EHR)** platforms is likely to remain a mainstream in 2021 as more of the customized, integrated, technologically advanced, and secure information storage solutions come into the market. The implementation of EHR will be also boosted by continuous adoption of **telemedicine**, **RPM** tools, and a shift towards **DCTs**.

Emerging Industry Trends

RWE and EHR Rounded Out the Top 4 Trends in 2019 and 2020, But Were Surpassed by RPM in 2021



Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging industry trends on the pharmaceutical industry in 2019/2020.

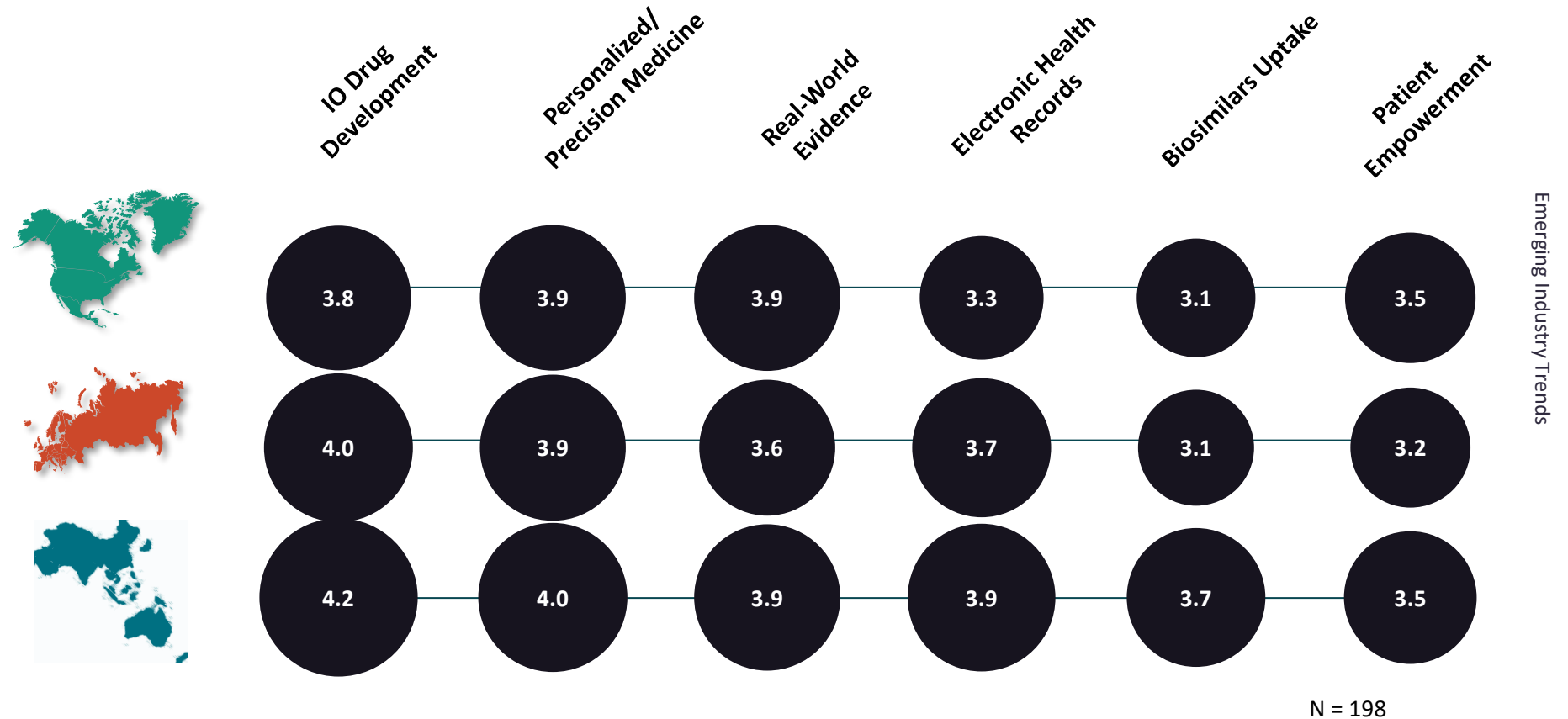
Source: The State of the Biopharmaceutical Industry Survey, 2020 Edition; The State of the Biopharmaceutical Industry Survey, 2019 Edition

- The IO space is becoming increasingly recognized as a pillar of cancer care. Most of the **IO drug development** concentrates in 10 countries, with the US being well-established and China an emerging leader in the development of IO therapies.
- **Personalized/precision medicine** has flourished in oncology thanks to a developed deeper understanding of cancer, discovery of predictive biomarkers, and growing successes in immuno-oncology therapies. Further development in the personalized/precision medicine field will extend its lead beyond cancer, helping to deliver more targeted treatments and better outcomes across other therapy areas.
- The favorable regulatory framework, manufacturing capacity growth, government support, and increasing prominence to reduce the healthcare costs will further drive **biosimilars** importance and uptake in Asian markets.

Emerging Industry Trends

Immuno-oncology and Personalized/Precision Medicine Identified as the Top Emerging Industry Trends Across all Regions

Survey fielded November 17, 2020, to December 9, 2020



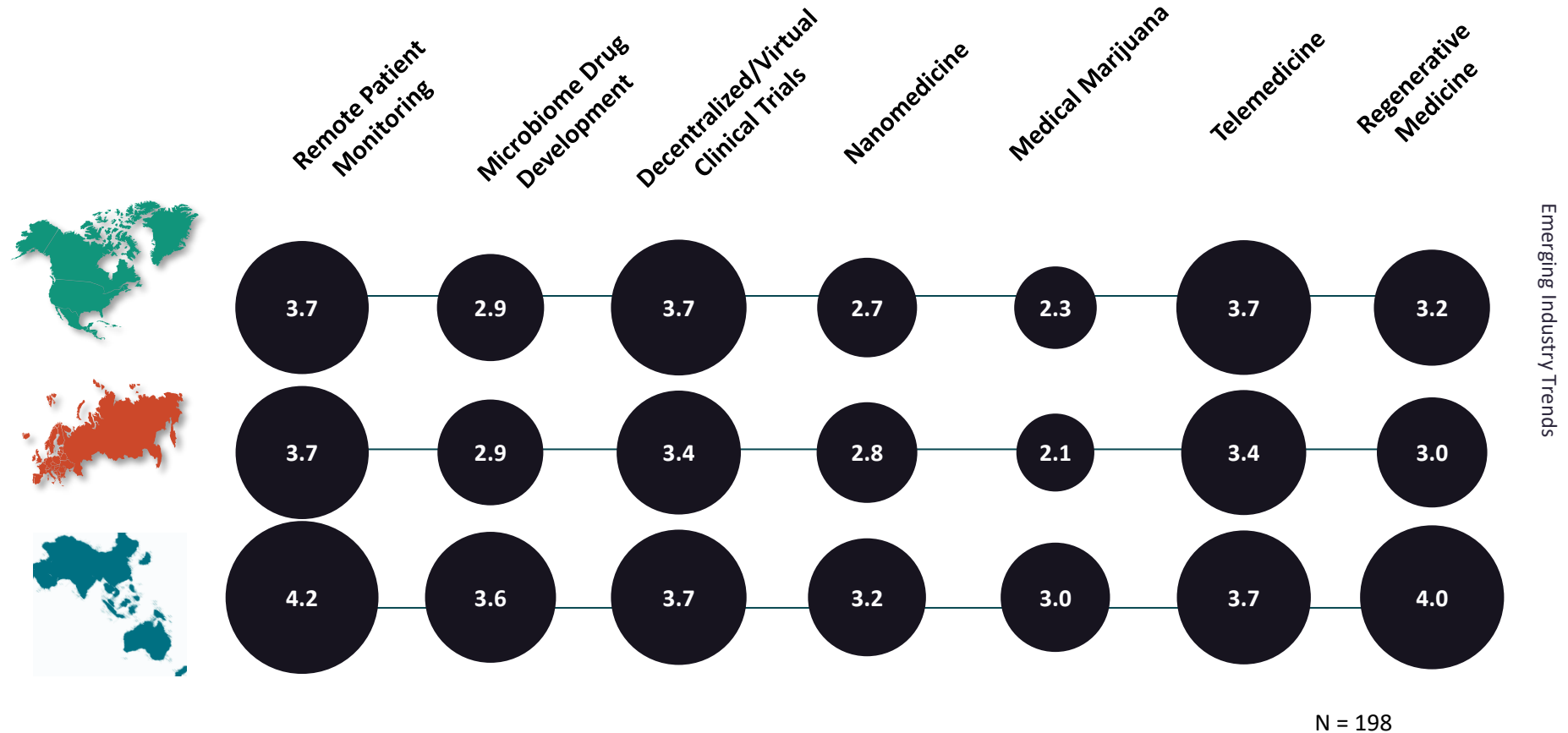
Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging industry trends on the pharmaceutical industry in 2021.
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

- In the past decade, **regenerative medicine** received much attention from regulatory bodies and research organizations, with Japan becoming the biggest player in adopting regenerative medicine advancements worldwide. However, with its recent enactment of the Act on the Safety and Support of Advanced Regenerative Medical Treatment and Medicine, aimed at strengthening regulatory support for the development of advanced regenerative medical treatments, South Korea is expected to spark more innovations in the field.
- Even though **medical marijuana** has been gaining acceptance in Europe and North America, it still remains highly stigmatized in Asian countries. Nevertheless, with increasing numbers of APAC countries softening their attitudes towards medical marijuana use, the region presents huge opportunities for investments and business growth.

Emerging Industry Trends

Medical Marijuana and Regenerative Medicine Are Gaining Momentum in APAC Region

Survey fielded November 17, 2020, to December 9, 2020



Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging industry trends on the pharmaceutical industry in 2021.
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

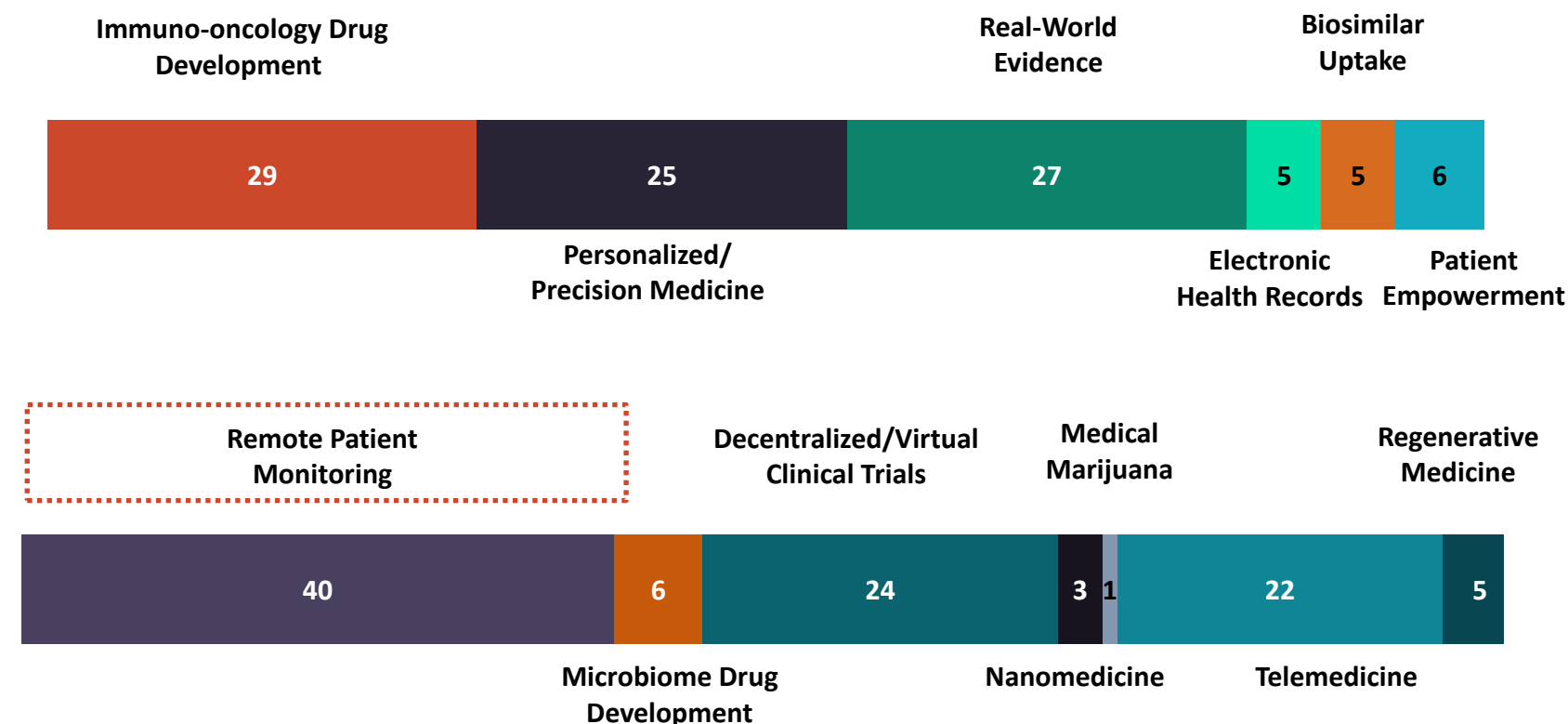
- Despite much lower uptake in previous years, **RPM** got off to a very strong start and has witnessed a massive uptake in the life-sciences sector in 2020.
- COVID-19 added a sense of urgency to remote monitoring deployments, in turn propelling emerging industry trends such as **patient empowerment, telemedicine, EHR, RWE, and DCTs**. The accelerated expansion of these pharmaceutical industry trends will be further sustained by increasing technological advancements, need to improve healthcare access in rural areas, increasing aging populations, and the growing burden of chronic diseases.
- With increasing numbers of patients, clinical practices, and pharmaceutical companies getting hands-on experience with RPM, GlobalData expects the adoption of remote monitoring tools to remain solid even after the COVID-19 pandemic recedes.

Emerging Industry Trends



Remote Patient Monitoring Is Expected to Have the Greatest Impact on the Pharmaceutical Industry in 2021

Survey fielded November 17, 2020, to December 9, 2020



N = 198

Q: Of the industry trends listed in the previous question, which one do you expect to have the greatest impact on the pharmaceutical industry in 2021?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

Spotlight on Remote Patient Monitoring

20%

A total of 20% of survey respondents (N = 40) identified remote patient monitoring as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



Ongoing lockdowns and requirements of social distancing have swiftly pushed healthcare provision and patient monitoring towards remote options. Virtual care solutions coupled with RPM have emerged as a viable solution to continue clinical support while protecting vulnerable populations from COVID-19 infections.

Even though RPM was already used before the start of the COVID-19 pandemic, the uptake of technology was relatively low, primarily used to ensure better post-acute care and manage chronic conditions such as diabetes. The COVID-19 outbreak provided a unique opportunity for RPM to demonstrate value and subsequently become a “new normal” in healthcare provision and clinical trials.

Due to the changes in access, reimbursement, and regulations related to implementation of DCTs and virtual care, GlobalData predicts that RPM technologies will continue to enhance the delivery of telemedicine and ensure more sustainable move towards DCTs. The uptake of RPM tools will also continue to grow due to increased deployment of technologies such as EHRs, wearables, AI, cloud computing, and implementation of 5G.

Respondents' Perspective

“The major obstacle for this field, the resistance of the medical community and hospitals to embrace digital technologies, was dropped down due to the COVID-19 new situation.” – Middle East and Africa C-Level Executive

“COVID-19 shutdowns made these a more reliable go-to, and they are gaining wide adoption. They enable higher patient retention, as participants can report without taking time off from work; removing yet another barrier in trials, so we can get closer to a cure faster.” – North America Associate/non-managerial

“The pandemic has accelerated the need to remotely collect data and remote monitoring with wearables, provides rich data on the real impact of medicines and disease in patients.” – North America Manager

“In 2021 it will still be hard to treat patients in hospitals/clinics due to the corona pandemic. Companies will capitalize on this need to treat/follow-up on patients remotely.” – Middle East and Africa VP/SVP/EVP

“Technology is rapidly evolving in healthcare [AI, continuous monitoring, etcetera], and proper implementation can have a huge impact on current healthcare.” – Europe Manager

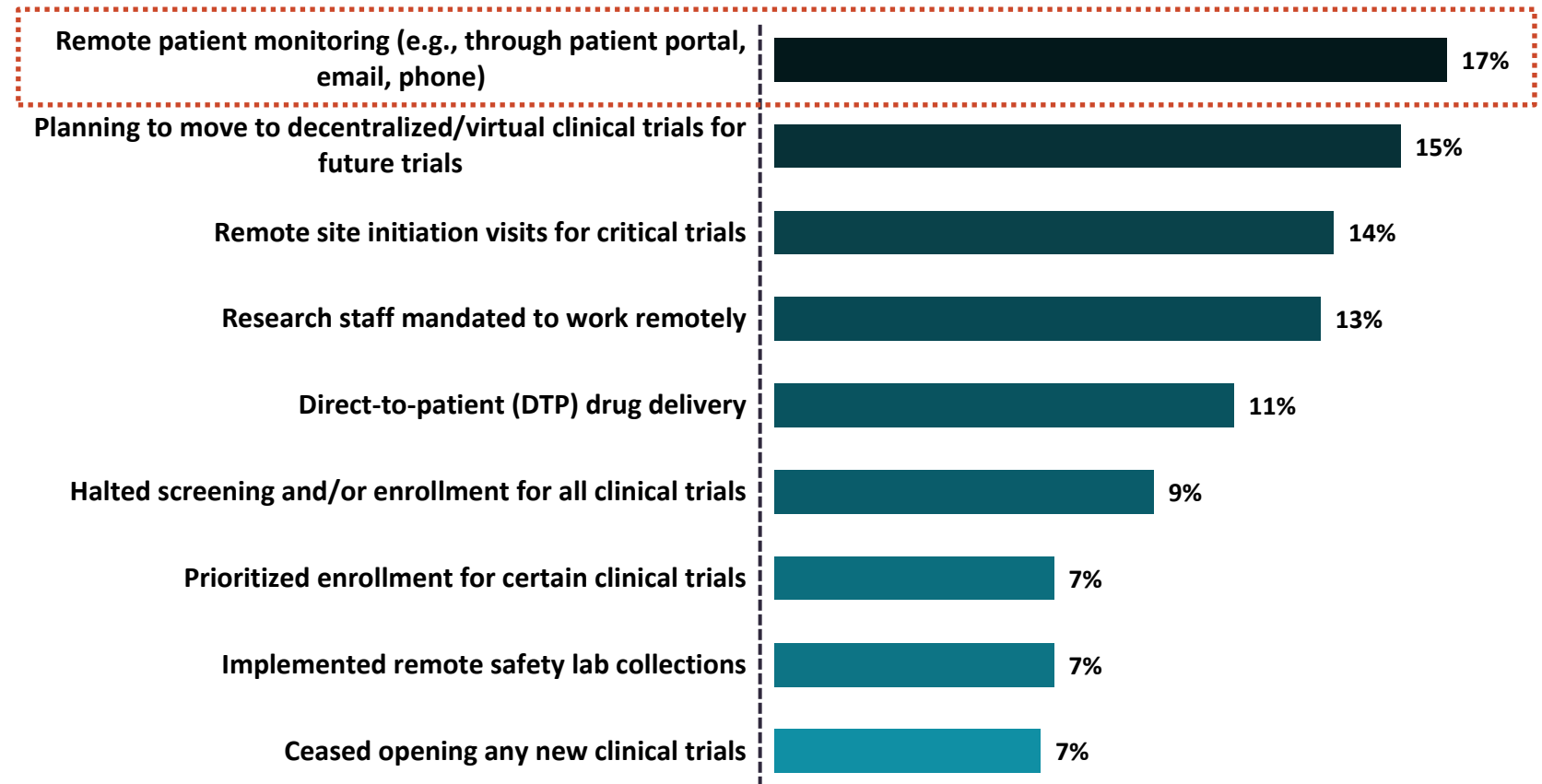
- According to “The COVID-19 Pandemic Impact on Clinical Trials” survey conducted by GlobalData in June 2020, RPM was indicated as one of the most common methods that companies used to address clinical trial disruptions.
- Although leveraging RPM in clinical trials was widely discussed as a means to ensure better patient retention even before the COVID-19 outbreak, RPM became mainstream due to the need to limit onsite interactions to ensure the safety of participants and prevent the transmission of COVID-19.
- Respondents overwhelmingly commented that the shift toward DCTs—which allow the collection of safety and efficacy data from study participants by using a range of digital technologies requiring minimum number of site visits—was already planned, but the COVID-19 pandemic increased the interest from sponsors and propelled the adoption forward.

Remote Patient Monitoring and Clinical Trial Disruptions



Addressing Clinical Trial Disruptions Related to the COVID-19 Outbreak

Survey fielded June 4, 2020, to June 22, 2020



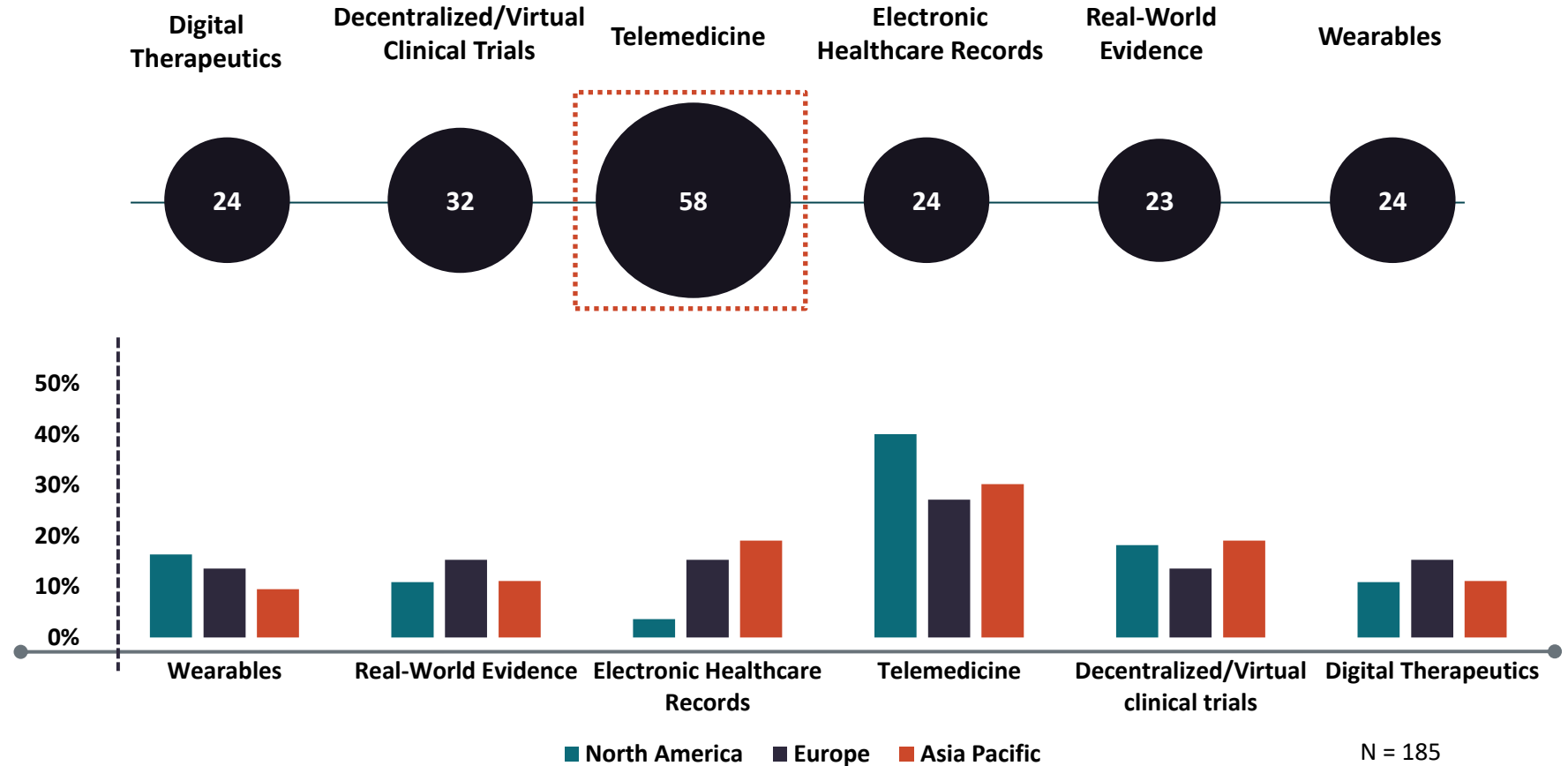
- COVID-19-disrupted provision of healthcare is becoming increasingly dependent on technologies. As the future of healthcare requires a shift from treatments to prevention, **RPM** technologies are uniquely positioned to become the flag-bearer of this trend.
- In GlobalData's poll, which was completed by pharmaceutical industry professionals during December 6, 2020–January 12, 2021, respondents believed that **telemedicine** will be the main industry trend benefiting from remote patient monitoring tools, as indicated by 37% of 185 respondents.
- Telemedicine** has been pushed into the spotlight by COVID-19. When paired together with RPM, telemedicine can enable healthcare providers to get data-driven insights into patient conditions and eventually to deliver patient-centric treatments and disease management approaches.

Industry Trends Benefiting from Remote Patient Monitoring



Remote Patient Monitoring Is the Future of Standard Patient Care

Poll fielded December 6, 2020, to January 12, 2021



Q: Which lifescience industry trend will benefit the most from remote patient monitoring tools?

Source: GlobalData's Poll, Conducted December 6, 2020, to January 12, 2021

Spotlight on Immuno-Oncology

15%

A total of 15% of survey respondents (N = 29) identified immuno-oncology as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



Immuno-oncology drug development continues to mature, demonstrating good efficacy and safety profiles in late-stage trials as well as in the clinic, resulting in additional approvals as both monotherapy and combination regimens.

In addition to the continued development of checkpoint inhibitors in 2021, with new targets and combinations currently in late-stage testing, GlobalData anticipates further clinical development in other major IO classes, including oncolytic viruses, off-the-shelf chimeric antigen receptor T cell (CAR-T) therapies, and bi- and tri-specific monoclonal antibodies.

Clinical studies investigating combination partners for IO therapies for use in treating resistant tumors, the optimal sequencing of IO regimens, and re-treatment studies are also gaining momentum and should start yielding data in the coming year.

Respondents' Perspective

"If immunotherapy continues to show that promise that it does, it will have a dramatic positive impact across all of these areas." – North America C-Level Executive

"Due to climate change, living habits, and stress there will be more emphasis on immunology as due to the carcinogenic [junk] foods, and lifestyle, people are more prone to carcinogenic infections." – Asia Pacific Director

"The effectiveness is just so overwhelming, and it is not a lab-bench concept—it is in the patients now and only need clinical testing and scaling. For example, bispecific CD3/CD20-antibody treatment linking cancer cell and killer cell." – Europe Director

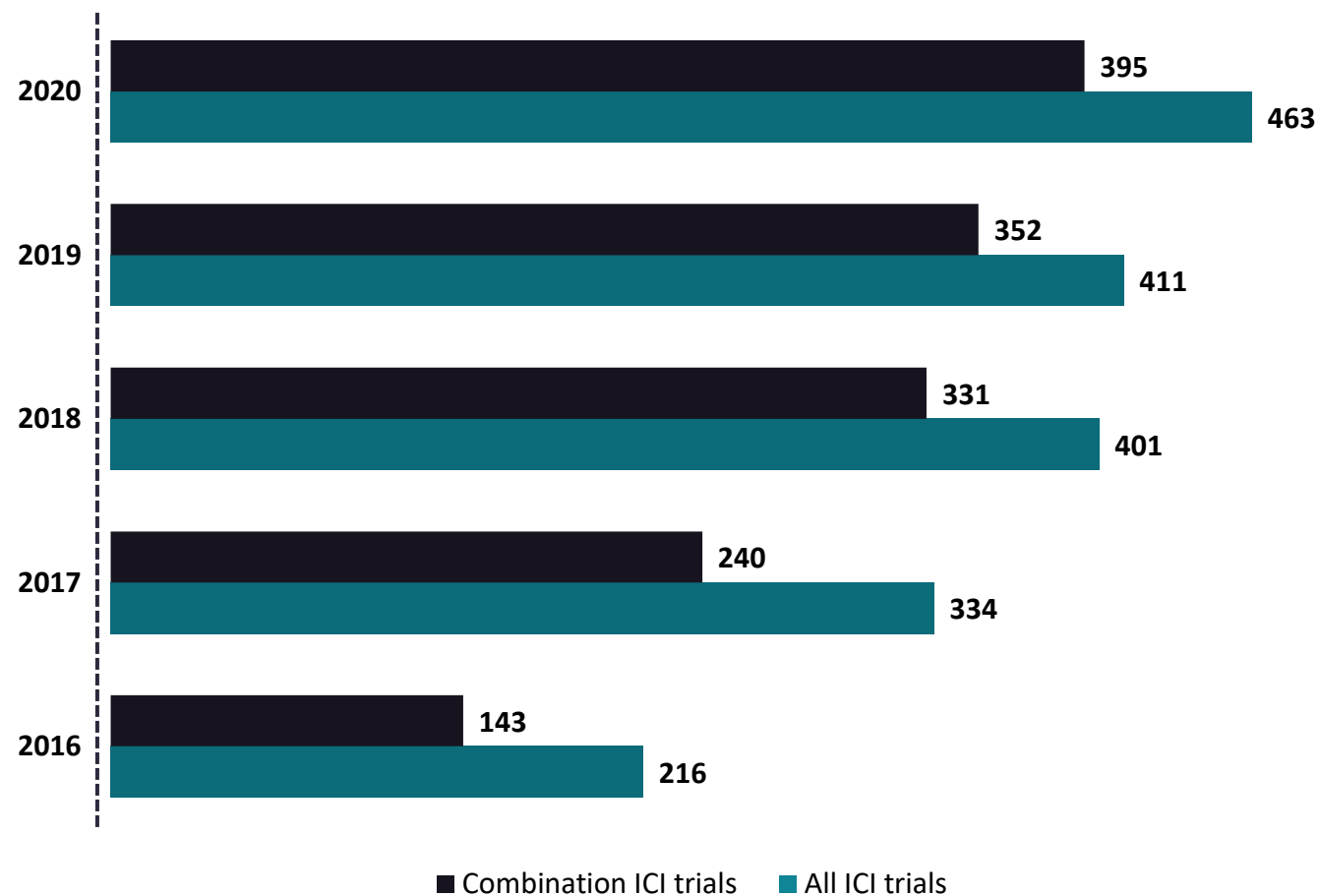
"Because looking at all-cause mortality, cancer shows the 2nd highest total death rate per year globally [behind cardiovascular disease]. A greater proportion of cardiovascular diseases [CVD] can be reduced by lifestyle changes so oncology would benefit from greater medical intervention. Also, immuno-oncology is the bullet which will target drugs, improving efficacy of treatment and reducing side effects." – Europe Manager

- Over the past five years, the numbers of industry-sponsored global Phase II and III trials testing ICI has increased just over two-fold, with 216 starting in 2016 and 463 starting in 2020.
- In the same time period, the numbers of trials testing ICIs in combination with other therapies increased 2.75-fold, from 66% of all ICI trials in 2016 to 85% in 2020.
- There are currently 11 approved ICIs, with an additional 4 in pre-registration in the 8MM (US, France, Germany, Italy, Spain, UK, Japan, and China). However, the increasing numbers of combination trials over the past five years indicates a growing trend for including this drug class in label expansions in various combination regimens.
- The larger proportionate increase in ICI combination trials also aligns with the movement of ICI combinations into the treatment paradigms of a number of different cancers.

Emerging Industry Trends

Spotlight on Immuno-oncology

Late-stage clinical trial testing of IO combination therapies including immune checkpoint inhibitors (ICIs) is increasing.



Source: GlobalData, Pharma Intelligence Center (Accessed December 15, 2020)

Emerging Industry Trends



Spotlight on Immuno-oncology

In 2021, multiple IO drugs across the US, Europe, and Japan will be approved and launched. Highlights include:



- Approval and launch of **cusatuzumab** in acute myelocytic leukemia
- Approval and launch of **Tecartus (KTE-X19)** in acute lymphocytic leukemia
- Approval and launch of **Opdivo** in the adjuvant setting in gastric cancer
- Approval and launch of **Opdivo + chemotherapy** in HER-2-negative gastric cancer
- Approval and launch of **Keytruda** monotherapy in 1L HER-2-negative gastric cancer
- Approval and launch of **cemiplimab** in non-small cell lung cancer (NSCLC)
- Approval and launch of **Yervoy** in bladder cancer



- Approval and launch of **Keytruda** monotherapy in 1L HER-2-negative gastric cancer
- Approval and launch of **Yervoy** in bladder cancer
- Approval and launch of **ERC-1671** in glioblastoma



- Approval and launch of **Blinicyto (blinatumomab)** in acute lymphocytic leukemia
- Approval and launch of **CS-1001** in NSCLC
- Approval and launch of **sintilimab** in NSCLC
- Approval and launch of **tislelizumab** in NSCLC



- Approval and launch of **Keytruda** monotherapy in 1L HER-2-negative gastric cancer
- Approval and launch of **Bavencio** in bladder cancer
- Approval and launch of **Tecentriq** in bladder cancer
- Approval and launch of **Yescarta** in non-Hodgkin's lymphoma

Spotlight on Personalized/Precision Medicine

13%

A total of 13% of survey respondents (N = 25) identified personalized/precision medicine as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



The field of personalized/precision medicine is moving forward very quickly, due to technological advances in high-throughput sequencing methods translating to quicker turnaround times and lower assay costs, with the FDA approving nearly twice as many of these therapies in the first half of 2020 as in all of 2019.

While 2021 will continue to see approvals and label expansions for personalized drugs, such as CAR-T therapies, the 'precision' medicine component will move to the forefront with biomarker-driven approvals expected in NSCLC and hematological cancers in 2021, and approvals targeted in a variety of additional cancers in future years.

GlobalData anticipates that current unmet needs for precision medicine therapies will start to be met as new efficacy biomarkers are identified and validated over the coming year.

With greater access to genomic sequencing technologies, clinical trials will incorporate more exploratory biomarker analyses, yielding valuable data for biomarker validation.

Respondents' Perspective

"More and more therapies are becoming personalized and with the increased focus on gene therapies we will see more [personalized therapies] to come to market in 2021." – North America Director

"More targeted therapies will be sold in small volumes, but at higher prices, and be more effective. Pharma has been built on mass producing and selling large-volume medicines, so will need to change their business model and how they justify prices to patients." – North America Manager

"People are different one from the other and different can be the aspects of the 'top level' of same disease. Personalized medicine can be considered the next level, achievable thanks to technological advancements." – Europe Manager

"It offers the greatest prospect of most favorable outcomes for all patients." – North America VP/SVP/EVP

"This imply a complete revision of the standard approach to develop, evaluate, and use a drug." – Europe Director

Emerging Industry Trends



Spotlight on Personalized/Precision Medicine

A range of personalized medicine drugs across therapy areas are expected to launch in 2021.

Drug	Disease(s)	Region(s)
AstraZeneca and Daiichi Sankyo's Enhertu	HER-2-positive gastric cancer	Global
Forma Therapeutics' olutasidenib	IDH-1 mutant acute myelocytic leukemia	US
Daiichi Sankyo's Vanflyta (quizartinib)	FLT-3 mutant acute myelocytic leukemia	US
Astellas' Xospata (gilteritinib)	FLT-3 mutant acute myelocytic leukemia	China
Roche and Blueprint Medicine's pralsetinib	RET mutant NSCLC	EU, Japan
Loxo Oncology's Retevmo (selpercatinib)	RET mutant NSCLC	EU, Japan
Novartis' Tabrecta (capmatinib)	MET mutant NSCLC	EU, Japan
Helixmith's VM-202	Diabetic neuropathic pain	US
Sylentis' tivanisiran	Ocular pain	EU
Rhythm Pharmaceuticals' setmelanotide	Pro-opiomelanocortin (POMC) deficiency obesity, leptin receptor deficiency obesity	US

Spotlight on Telemedicine

11%

A total of 11% of survey respondents (N = 22) identified telemedicine as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



Prior to COVID-19, telemedicine had never reached its full potential, with barriers such as reimbursement, accessibility, lack of awareness, resistance to change, and connectivity issues preventing its widespread uptake. Telemedicine emerged as a critical strategy during the pandemic to limit the risk of transmission and allow patients to receive care during lockdown measures, which led to policymakers in many countries relaxing regulations to facilitate its widespread usage and adoption.

GlobalData predicts COVID-19 to be the tipping point for telemedicine as its benefits are increasingly realized. Telemedicine could address some of the ongoing issues faced by healthcare systems worldwide, such as workforce shortages, an aging society, accessing affordable care, and increased healthcare spending. However, implementation of telemedicine will only be successful if governments, healthcare institutions, and technology companies work together. This includes ensuring that adoption of telemedicine is not obstructed by restrictive regulatory guidelines and reimbursement schemes.

While telemedicine is a promising technology, it is not a flawless solution. In-person consultations, patient assessments, and certain diagnostic tests cannot be fully replaced by virtual care. Finding a balance between traditional and innovative methods can maximize the benefits of telemedicine.

Respondents' Perspective

"With the new reality of COVID-19, it has become more important than ever to ensure patient access to medical access and monitoring via telehealth. Patients are delaying in-office visits due to high-risk of possible exposure to COVID-19. But patient health is extremely important, and the role of healthcare providers and pharma companies will have to step up to facilitate patient trust in the transition process." – North America Director

"COVID-19 pandemic has accelerated the development of innovative telemedicine solutions and greatly enhanced their adaptation in the healthcare systems." – Europe C-Level Executive

"2020 has shown the promise of telemedicine and, even after the pandemic recedes, many patients and HCPs will find it more convenient and impactful to shift some interactions to the telemedicine space, freeing up resources and increasing efficiency. In rural areas in particular, access to specialists through telemedicine will become a basic human right." – Europe VP/SVP/EVP

"[Telemedicine provides] opportunity to reframe how care is delivered and change the cost structure." – North America VP/SVP/EVP

Emerging Industry Trends

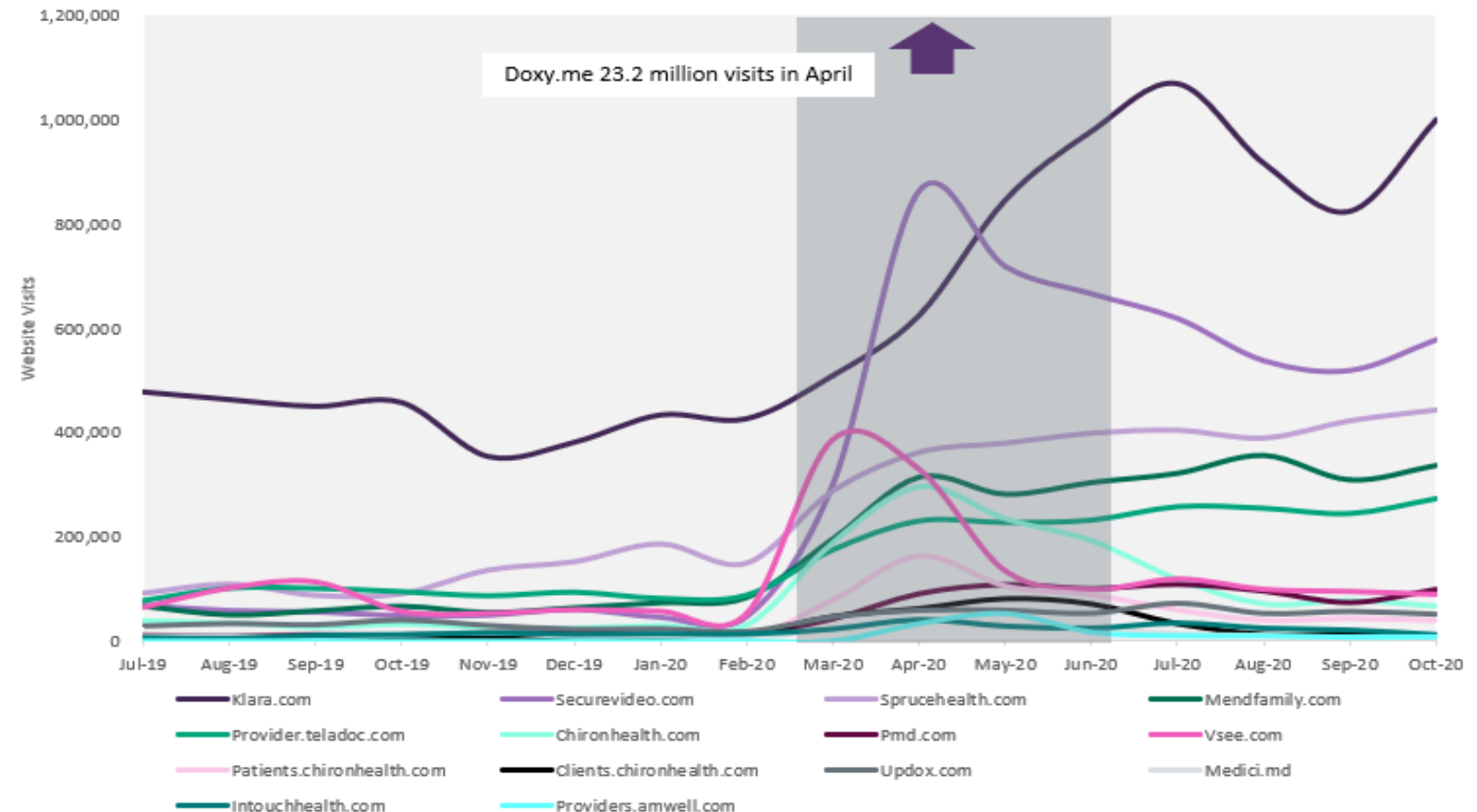


Spotlight on Telemedicine

Increased Demand for Leading Patient and Provider Telemedicine Platforms During the Pandemic

- Telemedicine companies have reported an increase in demand for their services since the COVID-19 pandemic began.
- For example, Teladoc Health announced it conducted 2 million virtual visits in Q1 2020, almost double that achieved for all of 2019.
- MDLIVE reported a 72% increase in visit volume in April 2020 compared to March 2020, while Updox reported that it onboarded over 10,000 new customers over two weeks in March, allowing it to facilitate more than 45,000 telemedicine visits per day.
- A leading telemedicine platform for healthcare providers, Doxy.me, saw a significant increase in monthly visits, rising from over 250,000 visits in February to a peak of 23.2 million visits in April. Monthly visits have remained at 11–12 million since June.

Website Traffic for Leading Healthcare Provider Telemedicine Platforms in Q2 2020



Source: GlobalData; SimilarWeb (Accessed November 2020)

Spotlight on Real-World Evidence

13%

A total of 13% of survey respondents (N = 26) identified RWE as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



RWE is a rich source of data collected from real-world settings (e.g., EHRs, claims data, connected devices, registries, social data, etc.) that provides healthcare professionals and pharma with a view of how drugs are used outside of clinical settings, treatment patterns, and patient outcomes.

GlobalData expects RWE to continue to play a pivotal role in drug approval submissions as well as market access. Regulatory bodies are now more willing than ever to use these data sets in regulatory submissions, with the FDA set to published official guidance in 2021. RWE is particularly important for the approval of drugs in diseases where clinical data may be lacking, such as rare diseases or oncology. In addition, payers can use RWE to inform decisions about the cost-effectiveness and overall value of a drug.

Increased use of connected digital devices will lead to the generation of large amounts of real-world patient data, often referred to as digital biomarkers. These data are expected to enable better insights into patient health, disease tracking, and preventive medicine, while reducing the cost associated with care delivery.

RWE has also been touted as key to managing the COVID-19 outbreak, by providing insights to better understand, monitor, and prepare for the challenges caused by the pandemic.

Respondents' Perspective

"RWE and health economics and outcomes research [HEOR] studies will be increasingly critical to demonstrate therapy value, justification for pricing/value, and ensure access to innovative therapies." – North America VP/SVP/EVP

"Real-time feedback from different geographies and populations can allow for more targeted distribution of products and resources, as well as more specific efficacy data." – North America Manager

"AI and Big Data from the real-world will drive not only clinical trial designs and patient stratification, but also drive drug and target discovery." – Europe VP/SVP/EVP

"[The trend will be important] to establish confidence in vaccines and therapeutics that will effectively end the COVID-19 pandemic." – North America Director

"Connecting the dots between clinical/statistical significance and level outcomes." – North America VP/SVP/EVP

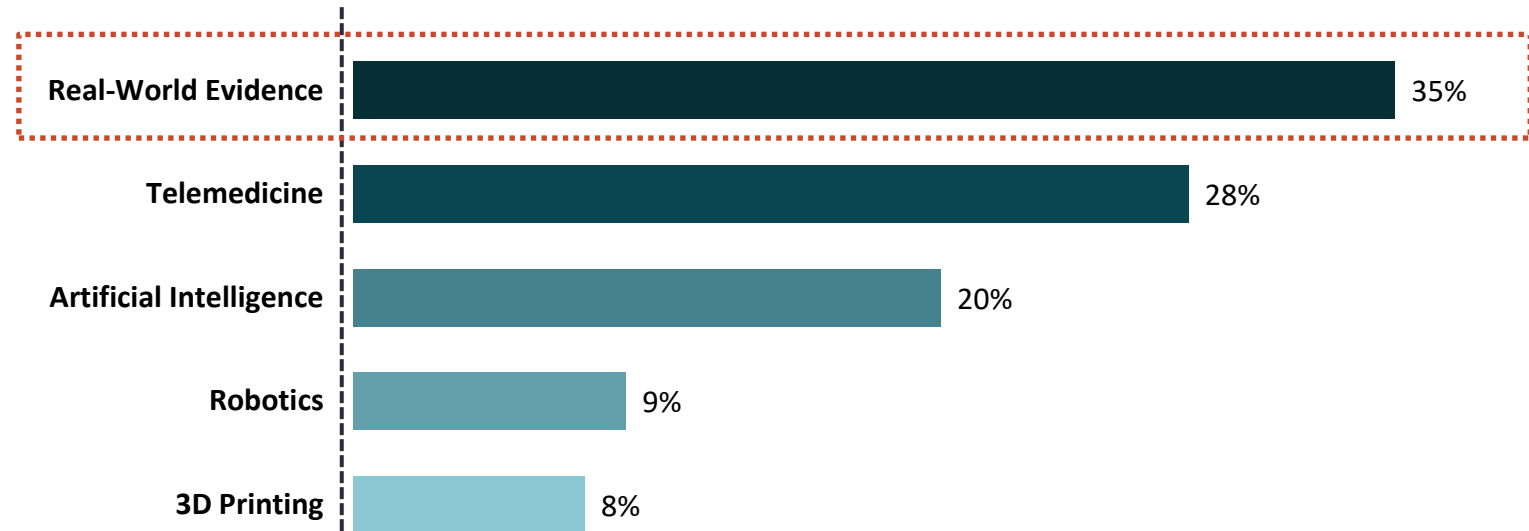


Emerging Industry Trends

Spotlight on Real-World Evidence

The Value of Real-World Evidence during the COVID-19 Outbreak

The utilization of RWE in infectious disease control is not a new concept. During the Ebola crisis in 2014, forecasters quite successfully used GLEaM simulations that combined RWE on populations and its mobility together with rigorous stochastic models of disease transmission to predict the global spread of the disease. By understanding where and how quickly an outbreak is likely to appear, the same tracking models could be adapted to fight any upcoming COVID-19 outbreaks.



N = 935

Q: Which of the below emerging technologies will have the greatest impact on managing COVID-19 outbreak?

Source: GlobalData's Poll Conducted April 6, 2020, to April 20, 2020

- According to the “Impact of Technologies on Managing COVID-19” poll conducted by GlobalData in April 2020, more than 1/3 of respondents indicated that RWE will have the greatest impact in managing the COVID-19 crisis.
- With the COVID-19 pandemic unfolding, the data collected from sources such as contact tracing apps, wearable devices, medical practice, testing centers, and clinical trials can play an important role in suppressing the spread of COVID-19.
- RWE has the potential to facilitate resource and capacity planning for intensive care, identify at-risk patient groups and geographic locations, assess the impact of potential treatments, and accelerate the development of new medicines.

Spotlight on Decentralized/Virtual Clinical Trials

12%

A total of 12% of survey respondents (N = 24) identified decentralized/virtual clinical trials as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



Pharmaceutical companies operate in highly regulated environments. The industry constantly faces multiple pressures coming from competitors, legislative bodies, healthcare systems, and consumers who want to impose greater transparency, accountability, and price control. All these factors contribute to a risk-averse culture, which slows down innovations and emerging technologies uptake in pharma, including adoption of DCTs.

Patient recruitment and retention is often seen as one of the most challenging aspects in conducting clinical trials. Decentralization's primary goal is to make the participation in clinical trial as seamless as possible, enabling participants to continue with their daily routines and consequently decreasing any possible drop-outs. Even though an increasing number of companies were already turning to more patient-centric clinical trial designs, COVID-19 prompted significant regulatory relaxations that are commonly seen as a trigger for the faster shift towards DCTs.

GlobalData believes that improved patient recruitment and engagement, technological advancement, and the possibility to improve data collection and reduce clinical trials costs will be the main factors contributing to increased adoption of decentralized/virtual clinical trials in 2021.

Respondents' Perspective

"[The trend is gaining importance] in response to ongoing COVID-19 pandemic and finding ways to enable the implementation of trials utilizing virtual means as well as wearable technology for data collection." – Europe VP/SVP/EVP

"It changes the paradigm for the conduct, participation, and speed/cost for the trial. It completely disrupts the interactions between the sponsor, CRO, and research site." – North America C-Level Executive

"Because participants will be wary of committing to spend time in transit and then within sites. Exposure, and the anxiety around it, will push sponsors to consider alternate pathways to collect data." – North America VP/SVP/EVP

"2020 has opened the door for more rapid change processes. It seems that long-existing barriers [hesitation to change] within the pharmaceutical industry have been exposed by the pandemic situation. Remote activities and higher flexibility are rapidly becoming more common." – North America C-Level Executive

"This shift changes the game for patient access—it means the net is cast much wider, leading to greater enrollment potential and better retention due to reduced patient burden." – Europe Manager

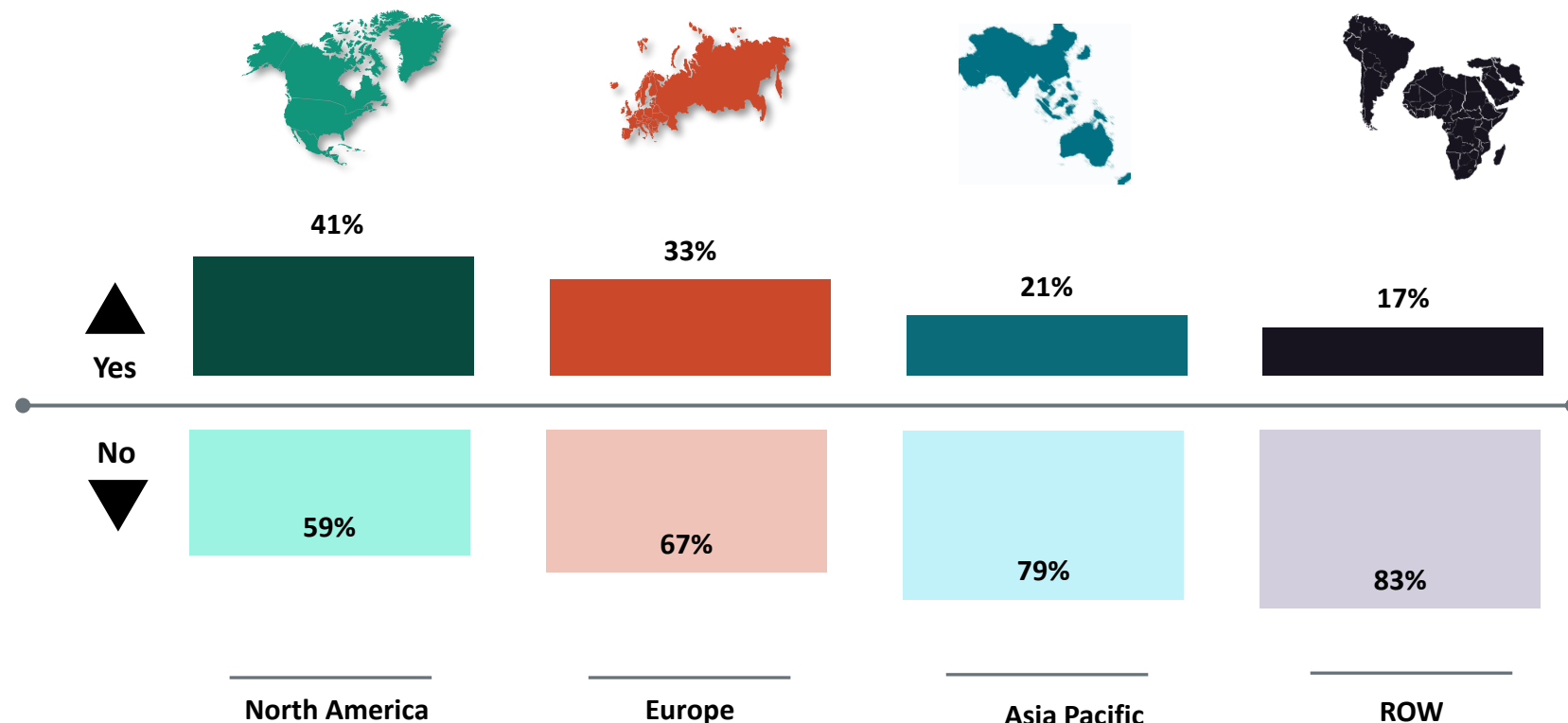
- According to GlobalData's "COVID-19 and Decentralized Clinical Trials" survey conducted with pharmaceutical industry professionals in June, 1/3 of the respondents already used DCTs before the COVID-19 pandemic.
- North American respondents were pioneering in using DCTs at 41%, which can be associated with the region also having the largest share of CROs. These organizations, according to the same survey results, were the biggest adopters of DCTs pre-COVID-19.
- DCTs that had initiated before the COVID-19 pandemic generally faced more regulatory hurdles, especially outside North America and Europe.
- Pre-COVID-19 DCTs were most commonly used for rare diseases to meet subject accrual, in pediatric clinical trials, and for indications such as lower-level chronic diseases (including asthma and dermatology).

Emerging Industry Trends

Spotlight on Decentralized/Virtual Clinical Trials

Pre-pandemic Decentralized Trials Use by Region

Survey fielded June 4, 2020, to June 22, 2020



N = 150

Q: Was your company previously using decentralized/virtual clinical trials before COVID-19?

Source: GlobalData, Coronavirus Survey – COVID-19 and Decentralized Clinical Trials

Spotlight on Microbiome Drug Development

3%

A total of 3% of survey respondents (N = 6) identified microbiome drug development as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective

Microbiome therapeutics are agents designed to treat a disease by targeting microbial dysbiosis in an affected organ or organ system. These therapies typically consist of living bacteria or non-living products that promote the growth of beneficial microbial species. Although no marketed microbiome therapeutics are yet available, there are currently 63 agents being evaluated in clinical trials, nine of which are in Phase III studies.

The most active areas of microbiome therapy development are gastrointestinal (GI) diseases, like inflammatory bowel disease, and infectious diseases, particularly those that affect the GI tract, like *Clostridium difficile*. However, interest in targeting the microbiome continues to expand to other therapy areas. For example, in the dermatology and oncology fields, numerous new agents have entered early-stage clinical development in the past few years.

Although there is great opportunity in the microbiome space, there are also numerous challenges to address. Some of the most important of these include identifying a microbiome therapeutic's mechanism of action, identifying regulatory standards, and determining clinically relevant endpoints. These challenges highlight the inherent complexity of targeting the microbiome and the need for further standardization in this nascent field.

Respondents' Perspective

"Huge potential across many areas and ability to disrupt the current paradigm and therapies." – North America C-level Europe Director

"I think it's a very interesting class of medications. I think there's a lot of activity in the private and biotech sector. I think that there's a lot of promise, yes, as a dermatologist we're always looking for new therapies, so I would be excited to see how these progress." – North America KOL

"There are a lot of smaller companies that are working with, definition of the microbiome and manipulation of the microbiome. It does sound like a very promising area, just very, very complex." – North America KOL

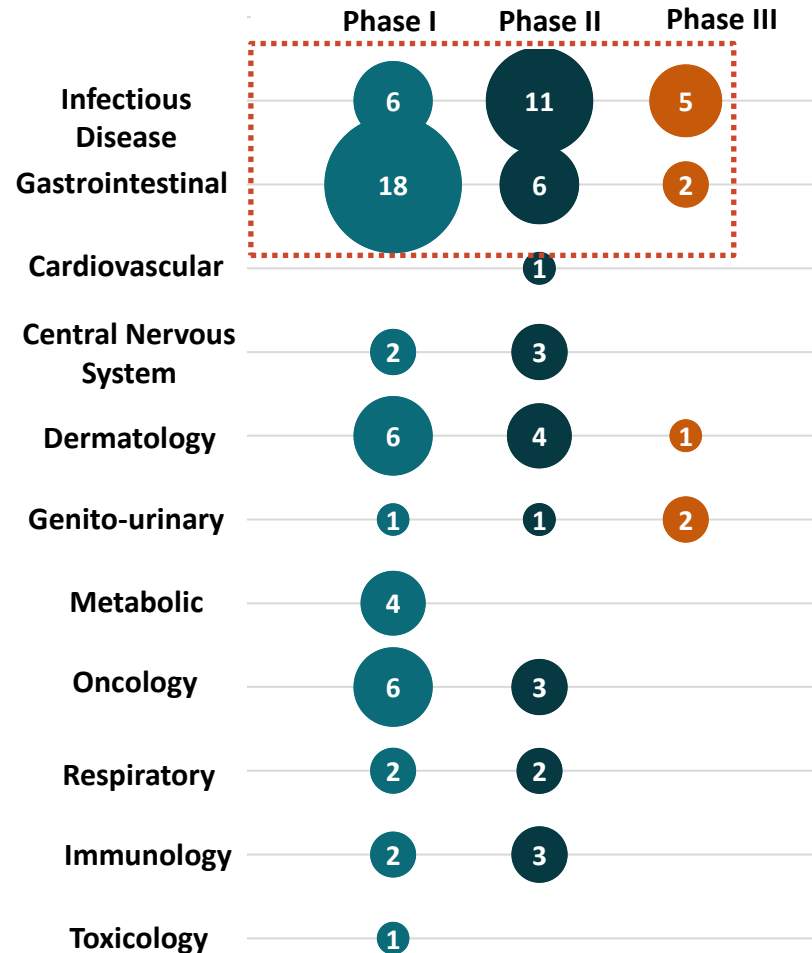
"Because we have knowledge and experience in pharma and food grade manufacturing, and this [microbiome] is on the borderline between." – Europe Director

Emerging Industry Trends

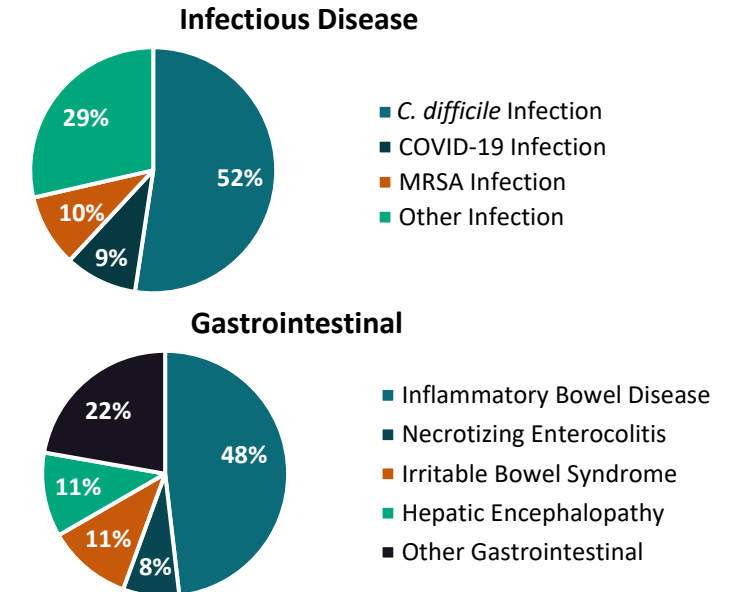
Spotlight on Microbiome

The Microbiome Pipeline Will Continue to Grow and Expand in 2021

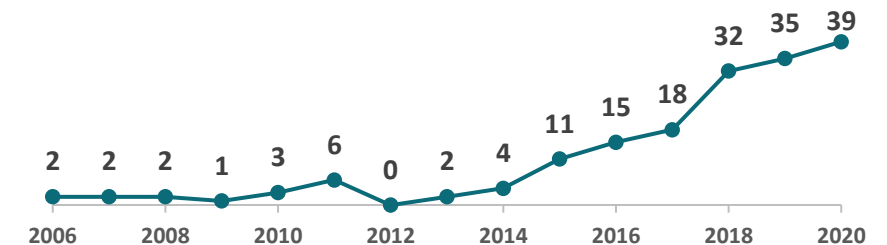
Microbiome Agents in Development in Each Therapy Area



Percent Microbiome Agents in Development for Each Indication



Number of Clinical Trials Initiated per Year with Microbiome Therapeutics



Spotlight on Biosimilars Uptake

3%

A total of 3% of survey respondents (N = 5) identified biosimilars uptake as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective

The expense of sponsoring Phase III trials for biosimilar products keeps the number of competitors lower and pricing higher than generic counterparts. However, the higher sales are for a brand, the more interest generated from biosimilar developers.

The **European** biosimilars market is currently highly competitive, with an established market for infliximab. Further erosion of Enbrel and Humira is expected in 2021, following the introduction of biosimilars in 2018 and 2019, respectively. Substitution is facilitated by price negotiations between the biosimilar manufacturers and local and regional regulatory bodies. There are restrictions and quotas in place mandating that all new patients be placed directly on the biosimilar, while physicians are also required to switch most of their treatment-experienced patients onto biosimilars eventually.

In the **US**, biosimilar substitution has been weaker. Experts believe that interchangeability status, allowing for automatic substitution, would drive use; however, no agent to date has received this. Infliximab biosimilar uptake will continue to be low in 2021 and with only two products on the market, competition is lacking. Payers are hopeful that the situation will be different for Humira, the top-selling pharmaceutical product for over 5 years. Adalimumab biosimilars already have six approvals, the most recent being Mylan's Hulio in July 2020. Even with multiple approvals and more in the pipeline, adalimumab biosimilars are restricted from entering the market until 2023.

Respondents' Perspective

"Authorities will search for quick wins to control budget impact after COVID-19." – Europe Director

"This trend is already underway, eroding market share for branded products. It will continue to do so with increasing impact over the next few years." – North America Director

"Increased therapy access will drive competition in major segments of revenue stream." – Europe VP/SVP/EVP

"If there were an incentive where you get more money if you have more patients on a biosimilar, you can be sure that very rapidly, most patients would be on biosimilars." – Europe KOL

"We're all eager to see more biosimilars come to market. We're trying to create more alignment with physicians to be cost-conscious with patients in terms of cost-share. I think we need them [biosimilars] desperately. However, think we're looking for more than a 10% cost difference because within 10%, we usually think of it as price parity." – North America Payer

Emerging Industry Trends



Spotlight on Biosimilars Uptake

In 2021 multiple biosimilars across the US, Europe, and globally will be approved and launched. Highlights include:



- PDUFA for **Alvotech's** adalimumab biosimilar
- Approval of **Alvotech's** adalimumab biosimilar
- PDUFA for **Samsung Bioepis'** ranibizumab biosimilar
- Launch of **Bioeq's** ranibizumab biosimilar
- Biologics license application (BLA) filing of **Bio-Thera Solutions'** tocilizumab biosimilar
- BLA filing of **Lupin's** ranibizumab biosimilar
- BLA filing of **Coherus BioSciences'** bevacizumab biosimilar
- BLA filing of **Momenta Pharmaceuticals'** aflibercept biosimilar
- Approval of **Nichi-Iko Pharmaceutical's** infliximab biosimilar



- Approval of **Bio-Thera Solutions'** bevacizumab biosimilar
- Marketing authorization application (MAA) filing of **Lupin's** ranibizumab biosimilar
- MAA filing of **Bio-Thera Solutions'** tocilizumab biosimilar
- Approval of **Alvotech's** adalimumab biosimilar

Global

- Launch of **Shanghai Henlius Biotech's** bevacizumab biosimilar
- Launch of **Mylan's** rituximab biosimilar
- Launch of **Bioeq's** natalizumab biosimilar

Japan



- Approval of **Gene Techno Science's** ranibizumab biosimilar
- Launch of **Gene Techno Science's** ranibizumab biosimilar

Source: GlobalData, Pharma Intelligence Center (Accessed November 28, 2020)



Spotlight on Electronic Healthcare Records

3%

A total of 3% of survey respondents (N = 5) identified EHRs as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



EHRs are used by hospitals, pharmacies, and other healthcare providers to keep track of patient data, enhance data integration, and allow for the transfer of patient data between healthcare professionals. EHRs are therefore a source of rich RWE that can be tapped by the pharma and research industries to yield insights to improve patient outcomes and inform regulatory and payer decision-making. It can include demographic information, patient and family history, physical reports and consultation notes, and any hospitalization information.

Limitations to using RWE from EHRs include ensuring data validity and accuracy, as much of it can be unstructured, such as physician notes. However, advances in data analytics and AI are now allowing researchers to gain more reliable insights from EHRs.

The secure transfer and storage of patient information also remains a significant concern. The healthcare industry is vulnerable to cybersecurity attacks due to the sensitivity of this data. The industry has witnessed a significant increase in attacks from cybercriminals exploiting the COVID-19 pandemic, with remote working as well as a sharp increase in the use of telemedicine platforms providing additional avenues of attack.

Respondents' Perspective

"Ease of accessing data provides significant opportunities to [leverage] patient information." – Europe C-level Executive

"National governments will have a better access to health-related statistics and pharmaco-economic considerations specific to their region of intervention." – Europe Director

"Data [efficacy, safety both in clinical research and market] could be available quicker and more validated." – Europe Director

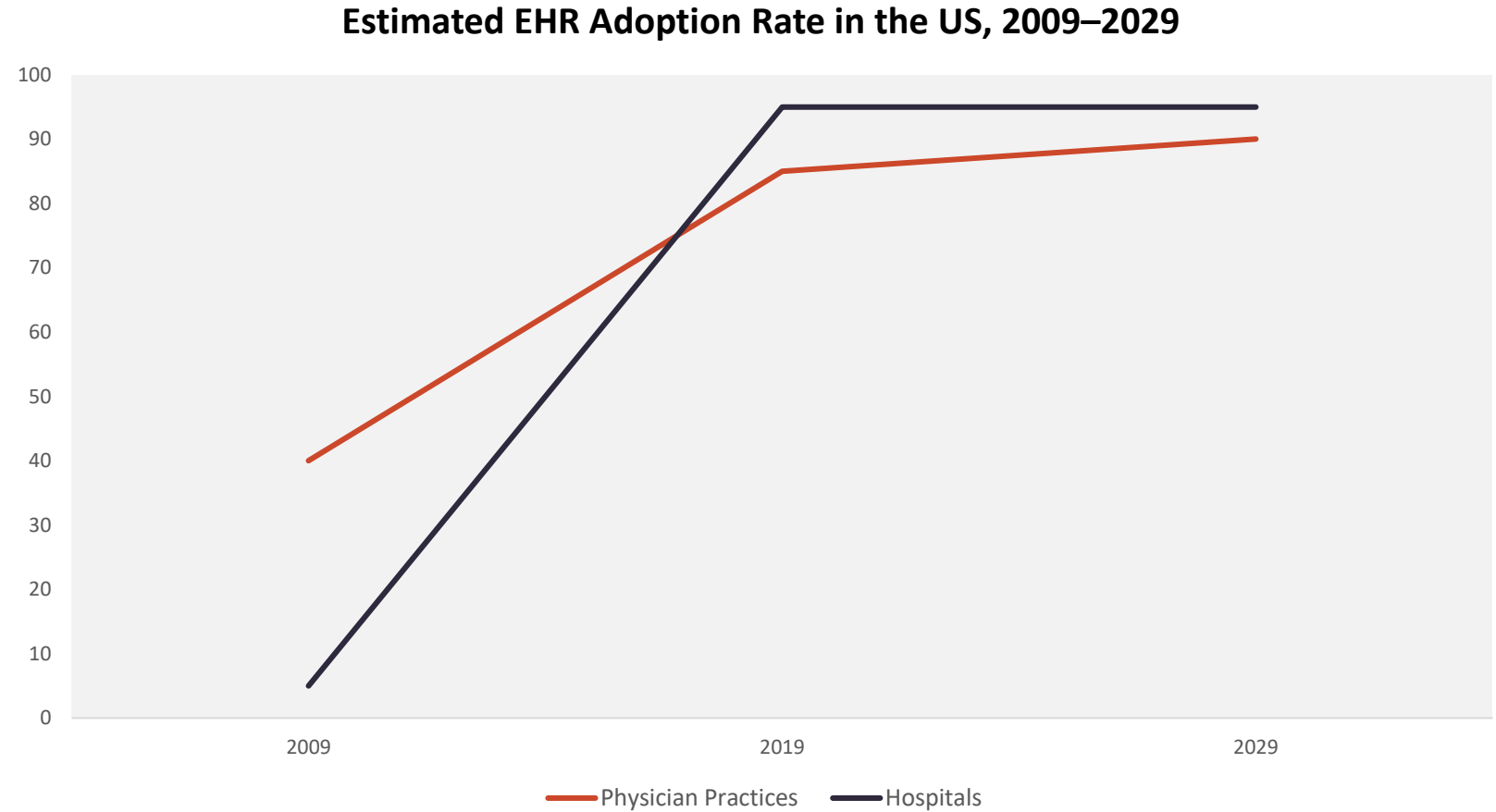
"I don't think you can separate RWE from wearables and EHR as they are somewhat interlinked—the point being it is all about increased [amount of] data [derived] from more data sources, which enables better trials." – Europe Director

- Globally, the EHR market is estimated at \$30B and is expected to rise to \$40B within the next five years.
- In the US, the Obama administration earmarked over \$30B to incentivize adoption of EHRs by healthcare professionals and hospitals, while penalizing those that did not. This initiative is known as Health Information Technology for Economic and Clinical Health (HITECH) and resulted in 96% of US hospitals implementing EHRs, compared to less than 10% that were using EHRs before 2008.
- In the UK, most physicians are now using EHRs, and in Denmark, Finland, and Sweden, national programs have promoted EHR strategies since the 1990s.
- An important factor that has contributed to the growing implementation of EHRs is the decreasing cost associated with storing large amounts of data. Since 1970, the cost of data storage has fallen from \$1,500/MB to just \$0.0001/MB today.

Emerging Industry Trends

Spotlight on Electronic Healthcare Records

EHR Adoption Rates Have Increased Significantly in the Past 10 Years



Source: GlobalData, Thematic Research: Protection of Electronic Health Records (2019)

Spotlight on Patient Empowerment

3%

A total of 3% of survey respondents (N = 6) identified patient empowerment as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



In the past, the focus of the pharma industry was mainly around drug pricing and access, with little attention paid to patient voice. However, there has been a recent shift in how the industry is interacting with patients, with many striving to become “patient-centric” organizations.

Pharma companies can implement several strategies to become more patient-centric, and getting patient input into the design of these initiatives will ensure they are truly valuable to the end-user.

These include branded patient support programs (PSPs) that offer real value to patients, their families, and care teams. Typical PSPs include product information, disease education, lifestyle support, and financial information. One area that PSPs often lack, however, is emotional support.

Companies can also provide unbranded educational resources to support disease management such as websites, portals, social media, and mobile apps. These are especially important during the ongoing COVID-19 pandemic, where lockdown measures and social distancing are preventing many patients from seeing healthcare professionals and getting in-person support.

Pharma can also involve patients in clinical trial design, in order to improve the clinical trial experience, recruitment, and adherence, as well as in health technology assessments with payers.

Respondents' Perspective

“In light of the pandemic, patients have limited access to their providers. They will feel more empowered with their healthcare and ensure their time with their provider is efficient as possible.” – North America VP/SVP/EVP

“Patients want to be empowered to help drive their own health goals, and physicians often don't have enough time to spend with each patient to fully understand their complex medical history. Pharma has increasingly prioritized patient-centric strategic imperatives in their business plans year over year.” – North America Manager

“Patients having to make more decisions for themselves given lower access to HCPs.” – North America VP/SVP/EVP

“Patients have learned in the pandemic that they have options. I work in clinical trial arena and it is going virtual, with wearables becoming more important.” – North America Director

“The decision has a huge impact now from the patient.” – South America Manager

Emerging Industry Trends



Spotlight on Regenerative Medicine

3%

A total of 3% of survey respondents (N = 5) identified regenerative medicine as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData's Perspective



Regenerative medicine is a multidisciplinary field that seeks to repair, augment, replace, or regenerate damaged or diseased human cells, tissues, genes, organs, or metabolic processes to restore normal function. It may involve the transplantation of stem cells, progenitor cells, or tissue, or the use of cells as delivery vehicles for therapeutic agents such as genes and cytokines.

The field is rapidly expanding, with over 50 products now marketed in the 7MM (US, France, Germany, Italy, Spain, UK, and Japan) and South Korea, and 175 drugs in development, including gene and cell therapies and tissue-engineered products. The gene and cell therapy market was valued at \$2.4B in 2020 and is forecast to reach over \$65.5B by 2026, according to GlobalData's Drug Sales and Consensus Forecast Database, driven by gene therapy (\$46B).

Special designations and programs exist across the 7MM and South Korea that expedite the development and approval of regenerative medicines. However, the high cost of certain products, such as gene therapies, could hinder their adoption and accessibility for patients.

Payers consider the emerging value-based pricing (VBP) concept to be the best method for pricing new regenerative medicines, as it allow them to manage the impact on budgets and mitigate any financial risk if these treatments do not perform as expected.

Respondents' Perspective

"Many of these [regenerative medicine] products are going to be successful. And once they are, they open the door for many other versions of the same product. The classic example would be CAR T-cells. So, CAR T-cells started about five, six years ago with a small academic trial in Pennsylvania. And now we have lots of products already in the market, and we have hundreds of potential products will be in the market in the next three, four years. And they all started from a very small company. So potentially, there's a lot of opportunities there from a small biotech to become a big fish. Very, very big opportunity. If you've got the right products, yes." – North America KOL

"I think gene therapy is definitely going to succeed in certain areas. There is going to be a day when certain genetic diseases like thalassemia, adenosine deaminase [ADA] deficiency, sickle cell, cystic fibrosis, these may all be cured with gene therapy." – North America KOL

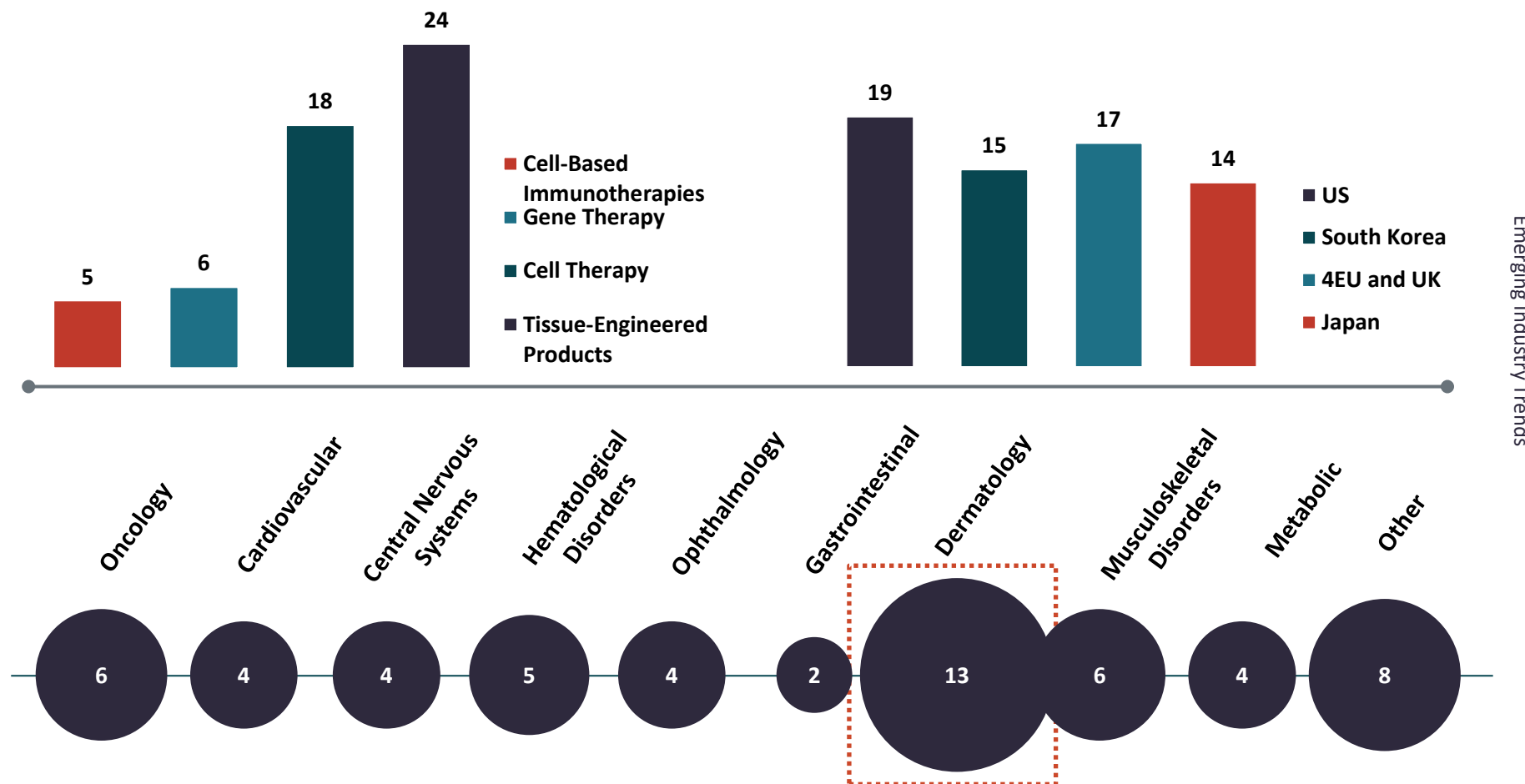
"Many clinical data updates and investment deals are anticipated [in the field of regenerative medicine]." – Asia Pacific Manger

- There are currently **53** marketed regenerative medicines in the **7MM and South Korea**. Tissue-engineered products lead the category with **24** products followed by cell therapy with **18** approved drugs.
- The majority of approved regenerative medicines are available in the US, with **19** products available, followed by the 4EU (France, Germany, Italy, and Spain) and the UK with **17** products and South Korea and Japan with **15** and **14** approved products, respectively.
- The therapy area with the most marketed regenerative medicines is dermatology with **13** approved products. This is followed by oncology and musculoskeletal disorders with 6 marketed products each.

Emerging Industry Trends

Spotlight on Regenerative Medicine

Dermatology Is a Leading Therapy Area for Regenerative Medicine



Source: GlobalData, Thematic Research: Regenerative Medicine (November 2020)

Spotlight on Nanomedicine

2%

A total of 2% of survey respondents (N = 3) identified nanomedicine as the emerging industry trend likely to have the greatest impact on the industry in 2021.

GlobalData’s Perspective

One approach being investigated by the pharmaceutical industry is the use of nanotechnology in drug development. Nanopharmaceuticals have many physical and biological advantages over conventional medicines, such as enhanced efficacy, reduced toxicity, improved solubility and stability, targeted tissue selectivity, and extended release.

Nanopharmaceuticals allow the implementation of personalized medicine, particularly in cancer. Immunoconjugates, including antibody drug conjugates (ADCs), are an important new class of nanopharmaceuticals that deliver a toxic payload to tumor cells via a linker attached to a monoclonal antibody (mAb) that binds to a specific antigen expressed on cancer cells. This targeted strategy has enormous potential in oncology as it reduces toxicities and side effects of highly potent chemotherapy and radiotherapy.

GlobalData forecasts that sales for ADCs alone will reach \$27.7B in 2026, led by Daiichi Sankyo’s Enhertu, Roche’s Kadcyla, and Seagen’s Padcev.

Several biopharmaceutical companies, including Pfizer/BioNTech and Moderna, have developed ribonucleic acid (RNA)-based COVID-19 vaccines that utilize lipid-based nanotechnology. Enzymes in the body rapidly degrade any extracellular messenger RNA (mRNA) and prevent broader distribution. Lipid nanoparticles (LNPs) protect mRNA against degradation and result in effective drug delivery to target sites.

Respondents’ Perspective

“Nanomedicine will have greater impact as the size is small, with greater absorption, distribution, metabolism, excretion, and toxicity [ADME] properties and will be targeted easily. These drugs [nanomedicines] can also be transferred to area with tight junctions.” – Asia Pacific Director

“It [nanomedicine] has a wide range of medical applications.” – Asia Pacific Manager

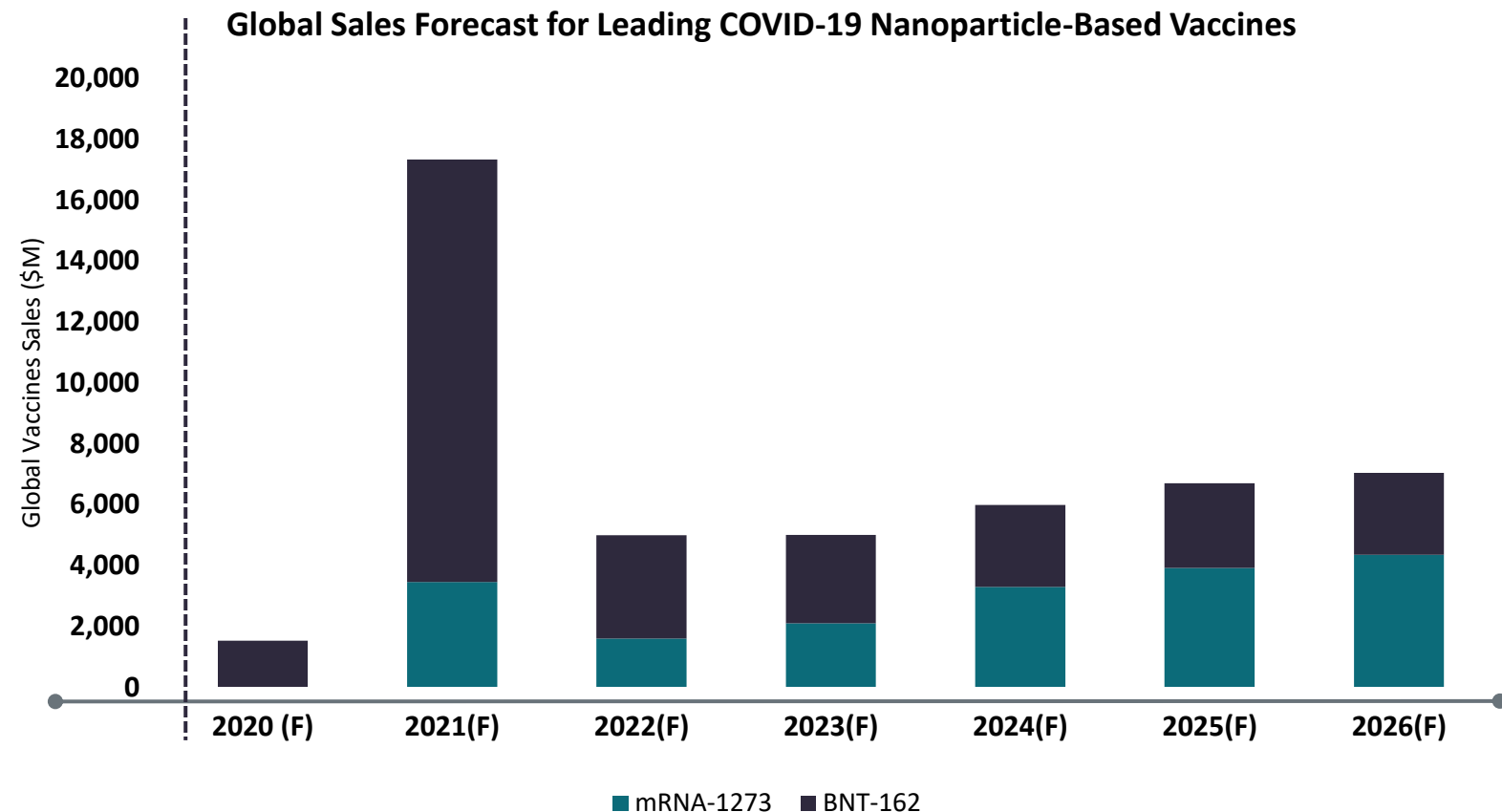
“It [nanomedicine] is new and will be the future.” – Middle East and Africa Associate/non-managerial

- Several biopharmaceutical companies have developed RNA-based COVID-19 vaccines that utilize lipid-based nanotechnology.
- Examples of COVID-19 vaccines that use nanotechnology include Moderna's mRNA-1273 and Pfizer/BioNTech's BNT-162.
- BNT-162 is expected to generate \$30B in sales from 2020 to 2026, according to GlobalData's Pharma Intelligence Center Drug Sales and Consensus Forecast Database. BNT-162 was the first COVID-19 vaccine to gain Emergency Use Authorization (EUA) from the FDA and conditional approval by the EMA, in December 2020, and has also received emergency use approval in the UK, Canada, and other countries.
- mRNA-1273 is expected to generate sales of \$19B between 2021 and 2026. The vaccine received EUA from the FDA and conditional approval in Canada in late December. It also received conditional approval in Europe in early January 2021.

Emerging Industry Trends

Spotlight on Nanomedicine

Leading COVID-19 Vaccine Candidates Have Incorporated Nanotechnology



Source: GlobalData, Pharma Intelligence Center (Accessed December 11, 2020)

Spotlight on Medical Marijuana

N =
30

30 survey respondents identified medical marijuana as the emerging industry trend likely to have a great impact on the industry in 2021.

GlobalData's Perspective



Growth in the medical marijuana market continued during 2020, despite the uncertainty brought about by the onset of the COVID-19 pandemic. Clinical trials are being used to examine the efficacy and safety profiles of medical marijuana products to treat indications such as autism, tuberous sclerosis, neuropathic pain, and scleroderma. Increased prevalence of psychiatric illnesses such as depression and anxiety has led to a growing number of patients who use CBD oil to alleviate symptoms of panic disorders that include hyperhidrosis, shortness of breath, and insomnia. This trend is expected to continue throughout 2021, despite the emergence of vaccines for COVID-19, which may reduce feelings of stress and anxiety. Nonetheless, financial instability and lack of human contact due to quarantine measures employed by governmental bodies around the world are likely to continue in 2021. These factors among others are projected to drive growth in the medical marijuana market.

GlobalData expects that patients with a history of psychiatric disorders will become increasingly reliant on pharmacotherapy, due to greater use of telemedicine and measures that prevent mental health specialists from physically seeing patients in clinical practice. Compared to traditional antidepressants such as paroxetine and sertraline, and anxiolytic drugs such as alprazolam, there is an impression among users that medical marijuana products have more favorable side-effect profiles. This is expected to increase uptake throughout 2021 among treatment-experienced and treatment-naïve patients alike.

Respondents' Perspective

"It [would be] great to have data [to prove marijuana works] for more diseases. Neurological and other conditions could really benefit from medical cannabis. I think [that] the market will grow once we have clearer evidence. [The market is] actually growing even though we don't have enough evidence now!" – North America Key Opinion Leader

"[Medical marijuana is] touted as the new holy grail that everybody wants to use. People are using it to treat their own epilepsy, treat their anxiety, their sleep, [and sometimes] they give up their prescribed medication to smoke [marijuana]. That gives me an internal conflict, so I think that education needs to improve. Marijuana is the juicing of the 2020s. There's a huge market and it's untapped. People aren't looking into it [as much as they should be] but [it's] a growing market. It's an evidence-based medicine now." – North America Key Opinion Leader

"Early trials suggest strong efficacy and the product can be readily available." – Asia Pacific VP/SVP/EVP

- The medical marijuana industry has adapted to meet the needs of patients, despite the presence of an ongoing pandemic.
- In the US, some medical marijuana dispensaries are serving consumers with designated appointment times. In certain establishments, only people with an identification card that authorizes them to access treatment are allowed to purchase medical marijuana.
- Production facilities for medical marijuana products in countries such as Germany and Italy are limited. For these reasons, therapies are often imported from other European countries such as the Netherlands and the UK. Logistical challenges along with the need to confirm that drugs have been developed in accordance with legal guidelines make this process challenging.
- Interest in medical marijuana is expected to increase alongside growing media coverage and passage of laws that permit its use in more countries around the world.

Emerging Industry Trends



Spotlight on Medical Marijuana

Unmet Needs in the Medical Marijuana Market in 2021

Unmet Need	More clinical research to characterize the effects of medical marijuana products	Clear labeling and treatment guidelines on products, including information on dosing and contraindications	Increasing the affordability of products to reduce the need for frequent out-of-pocket payments	Promotion of advances in medical marijuana research
Type of Need	Clinical	Clinical and Environmental	Environmental	Environmental
Gap Analysis	Lack of research is a major barrier in this market.	Clear labelling and treatment guidelines are needed to encourage more physicians to prescribe medical marijuana to patients in need.	Seeking market authorization from regulatory bodies such as the FDA and EMA will improve patients' access to treatment.	Encouraging updates about breakthroughs in the medical marijuana space may raise awareness of therapies that could benefit patients living with diverse medical conditions.
Initiatives	There are several planned clinical trials involving products targeting cannabinoid receptors that will examine the efficacy of medical marijuana in treating an array of underserved indications, such as dementia and substance abuse.	With the emergence of FDA-approved therapies such as GW Pharma's anti-epileptic drug, package inserts containing important information relating to marketed drugs are helping doctors and patients effectively manage treatment regimens.	Approval of GW Pharma's Epidiolex (cannabidiol) in the US and EU has significantly reduced therapy costs for patients with refractory childhood epilepsies.	Increased media coverage and publication of the results of scientific research will boost public awareness of medical marijuana.

Source: GlobalData, Pharma Intelligence Center (Accessed November 28, 2020)



Emerging Regulatory and Macroeconomic Trends

Emerging Regulatory and Macroeconomic Trends

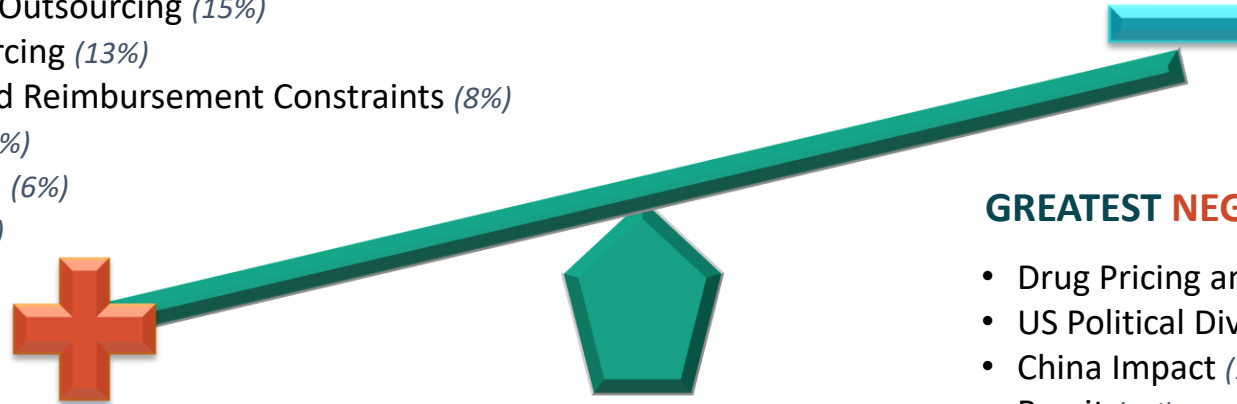


The positives outweigh the negatives: on average, most emerging regulatory and macroeconomic trends are expected to have a positive impact on the pharmaceutical industry in 2021.

Survey fielded November 17, 2020, to December 9, 2020

GREATEST POSITIVE IMPACT (N = 185)

- Patent Expiry of Biologics (20%)
- Vertical Integration (15%)
- Manufacturing Outsourcing (15%)
- Clinical Outsourcing (13%)
- Drug Pricing and Reimbursement Constraints (8%)
- China Impact (7%)
- Data Protection (6%)
- Mega M&A (6%)



GREATEST NEGATIVE IMPACT (N = 167)

- Drug Pricing and Reimbursement Constraints (49%)
- US Political Divide (19%)
- China Impact (10%)
- Brexit (5%)
- Vertical Integration (5%)
- Mega M&A (3%)
- Data Protection (3%)

Figures represent the percent of survey respondents who chose factors having **greatest positive** or **greatest negative** impact.

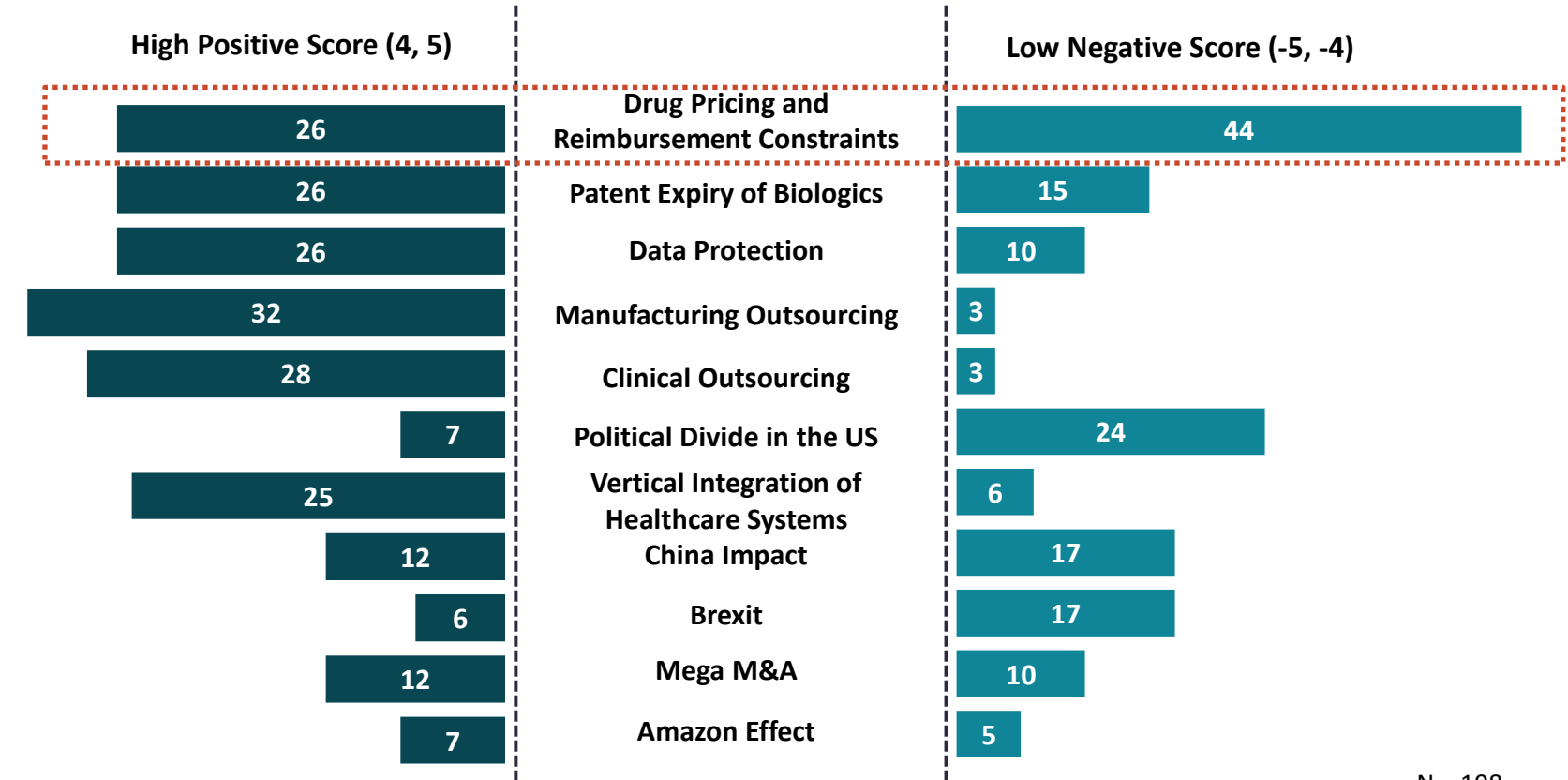
Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest positive impact on the pharmaceutical industry in 2021?

Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest negative impact on the pharmaceutical industry in 2021?

Emerging Regulatory and Macroeconomic Trends

Drug Pricing and Reimbursement Constraints Was the Most Scored Industry Trend

Survey fielded November 17, 2020, to December 9, 2020



N = 198

Figures represent the number of respondents who selected a high negative or positive score.

Q: On a scale of -5 to +5, please rate the anticipated impact of each of the following emerging regulatory and macroeconomic trends on the pharmaceutical industry in 2021.
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

• **Drug pricing and reimbursement constraints** elicited the strongest responses from survey respondents, with 35% of respondents (N = 70) rating it a 5, 4, -4, or -5. The majority of these respondents viewed the trend as having a negative impact in 2021, most likely since drug pricing and reimbursement questions are expected to be scrutinized by the governments due to the need to contain healthcare spending and to offset borrowing booms caused by COVID-19. Despite these concerns, 2021 kicked off with pharma companies raising US list prices for over 500 drugs. Similar annual increases have been seen for the past several years.

• *“Pricing pressures have been amplified by US financial situation driven by COVID-19. Patient migration from commercial health plan coverage to Medicaid and health exchange plans is real. State Medicaid programs are already strapped and, in some cases, seeking federal funding to address needs. Ongoing consolidation and vertical integration will greatly increase IDN, health system, and health insurer leverage. Pharma will need to consider potential GTN impact based on the high likelihood of increased discounts required to ‘play.’”* – North America VP/SVP/EVP

Emerging Regulatory and Macroeconomic Trends



A Closer Look at Drug Pricing and Reimbursement Constraints

GlobalData's Perspective on Immunology Drug Pricing

The immunology space is filled with expensive branded biologic therapies, with US annual costs of therapy (ACOTs) reaching over \$160,000. Often, US patients have restricted access to specialty products, such as biologics, due to very high cost and payer management tactics that include prior authorization and step therapy. Contracting is the norm, and payers expect deep discounts on the list price of products, creating a very competitive environment for immunology products. Due to significant discounting seen in the TNF α class of therapies, access to drugs with novel modes of administration (MOAs) are typically restricted to patients who cannot receive a TNF α or who had a treatment failure on one. Although the price of branded biologics is not as steep in the EU, national health systems like the National Institute for Health and Care Excellence (NICE) are stringent with cost-benefit criteria. In 2021, players launching biologics will have to take into account the ACOT of established biologics in the disease space and the ACOT of biosimilar products, especially in Europe where they are forecast to steal as much as 60% of the originator product sales because of the biosimilars' cheaper cost.

GlobalData's Perspective on Neurology Drug Pricing

The multiple sclerosis (MS) market has some of the most expensive drugs in neurology, with the ACOT of these brands generally increasing year-on-year. Currently, the ACOT of MS brands in the US is approximately \$80,000. As such, increased pricing pressures will make it difficult to command premium pricing for new drugs entering this market. Watchdog agencies such as NICE have consistently rejected products for recommendation in the UK that fail to meet specific cost-benefit criteria. Austerity measures in Europe have also prevented pharmaceutical companies from pricing drugs at a premium unless they are proven to be substantially better than the medications currently available to patients. Additionally, increasing cost competition and reduced disparity in the prices of MS drugs will discourage current players from raising their prices significantly above benchmark levels. Companies seeking to compete in the crowded future MS market may benefit from pricing their products competitively to existing novel therapies or undercutting competitors in terms of price, in a bid to navigate the pricing and reimbursement pathways faster and gain increased patient adoption.

GlobalData's Perspective on Immuno-oncology Drug Pricing

The global IO market was valued at \$66B in 2020 and is projected to increase to \$180B in 2026, according to GlobalData's Drug Sales and Consensus Forecast Database, indicating that IO remains one of the most rapidly growing segments of the oncology market. Pricing and reimbursement were important issues for IO therapies across the major markets in 2020 and are expected to continue to be predominant themes in 2021. As such, major global IO drug developers are facing challenges in obtaining label expansions and reimbursement for their therapies in certain disease settings in the more cost-conscious European markets. In addition, increased domestic development of IO drugs in China is expected to compete with geographic expansion of global IO developers to China over the next few years. While R&D strategies are moving towards greater testing of IO combinations and the use of IO drugs in earlier lines of therapy, US and EU payers interviewed by GlobalData have expressed concern over the cost for combination therapies, stating that the benefit-to-cost ratios could decrease over time and with use of combinations of more than two drugs. Perceptions by payers of decreased return on investment in 2021 may lead developers to assess their R&D strategies and could spur more creative reimbursement schemes, which would also be a win for patients.

Emerging Regulatory and Macroeconomic Trends



A Closer Look at Drug Pricing and Reimbursement Constraints – Respondents’ Perspective

Respondents’ Perspective on Pricing and Reimbursement Constraints	Respondents’ Perspective on Political Divide in the US	Respondents’ Perspective on China’s Impact
<p><i>“If there is a substantial drop in drug pricing, then it could dissuade companies from pursuing new developments.” – North America Director</i></p> <p><i>“Drug pricing transparency, the global nature of pharmaceuticals, and the necessity of collaboration across sectors in the recent pandemic has shone a potentially new light on drug pricing. Integration of insurers and providers will create the advent of utilization of new data streams to influence drug discounts with manufacturers if they want a place on plan schemes.” – Europe VP/SVP/EVP</i></p> <p><i>“After COVID-19 pandemic many countries might need to take away resources from the healthcare to re-balance their economy.” – Europe Director</i></p> <p><i>“This has the potential to negatively impact drug discovery, drug development, drug access, and drug manufacturing. We see what blindly driving to lowest costs results in and this could lead to poor-quality products being produced.” – North America C-Level Executive</i></p>	<p><i>“Political divide in the US could lead to future unrest and less economic stimulation. Reduction in healthcare spending and slowdown in economy could result in less funding by major manufacturers on research.” – North America Director</i></p> <p><i>“The most critical one is that the lack of support of FDA from the administration during this difficult time makes FDA’s responses too slow for most companies. In the meantime, the general public is losing their confidence in FDA for guarding the safety of the products [drugs, diagnostics, and devices].” – North America VP/SVP/EVP</i></p> <p><i>“The US is currently divided in two completely different tracks. This will take quite a while before everybody is facing the same side again and therefore make constructive decisions.” – Europe Manager</i></p> <p><i>“[Political divide in the US] will impede implementation and adoption of new therapies, research, and business models.” – North America VP/SVP/EVP</i></p>	<p><i>“Uncertainty and lack of trust with China will likely have a negative effect for years to come and cause companies to exit China in terms of physical presence.” – North America VP/SVP/EVP</i></p> <p><i>“Value-based purchasing coupled with a reduced scrutiny on intellectual property [IP] protections could slow overall global innovation.” – North America VP/SVP/EVP</i></p> <p><i>“Uncertainty of stable supply of drug formulations currently produced in China as US and other countries attempt to onshore manufacture of critical drug products.” – North America Director</i></p> <p><i>“China today dominates the manufacturing of intermediates, any change in that region impact us all.” – South and Central America Manager</i></p> <p><i>“Introduces concerns regarding quality, honesty, and accuracy.” – North America VP/SVP/EVP</i></p>

Emerging Regulatory and Macroeconomic Trends



A Closer Look at Patent Expiry of Biologics and Vertical Integration

GlobalData's Perspective on Patent Expiry of Biologics

Numerous blockbuster biologics are beginning to confront patent expiry and associated competition from biosimilar products.

GlobalData believes that biosimilar competition will serve to limit market size across multiple indications, particularly in the oncology and immunology therapy areas. For example, in rheumatoid arthritis, global biosimilar market share is expected to increase from 4.5% (\$1.2B) in 2019 to 27.5% (\$7.2B) in 2029.

Biologics developers have adopted numerous strategies to try and curb their losses from biologic patent expiry. The most common strategy is to extend product lifecycles, which includes defending patent exclusivity, creating opportunities for patent extensions, and adding novel indications and formulations.

GlobalData believes that although biologic patent expiry will limit pharmaceutical market growth in the coming years, lowered prices will help to increase patient access to life-saving drugs. It is also likely to drive innovation, as companies seek to develop drugs that eclipse the performance of their older therapies.

Respondents' Perspective on Patent Expiry of Biologics

"Biosimilar companies will have greater opportunity in healthcare systems that are particularly pressured financially." – Europe Manager

"As unfortunate as it is for research companies, it will keep a lid on pricing and ensure a push for new medications that will be patented." – Asia Pacific VP/SVP/EVP

"Patent expiry for biologics will open doors for other manufacturers to deliver medicines at lower cost—something that most payers are looking at as the reality of the impact of the pandemic bites on budgets. Anything that will reduce costs and decrease hospital or outpatient capacity will be seen as a positive by the healthcare sector." – Europe VP/SVP/EVP

"Biosimilars will drive down treatment costs, reducing the economic burden on healthcare systems and allowing space for new therapeutic options." – Europe VP/SVP/EVP

GlobalData's Perspective on Vertical Integration

Vertical integration in healthcare is touted as a substantial opportunity to improve efficiency, lower cost, and synchronize data flows between all components of value chain: from manufacturing and logistics to marketing and sales.

Vertical integration in healthcare industry has already gained a place in recent years, with Cigna–Express Scripts, Optum–UnitedHealth, and Aetna–CVS Health being among the noted examples.

GlobalData predicts that the healthcare industry will witness more vertical integration and joint ventures in upcoming years. One of the main drivers for the vertical integration in pharma will be the need to have more visibility and control over supply chains to create more resilience.

The appetite for a reliable supply chain will continue to grow as the companies will try to mitigate disruptions related to COVID-19, policy-driven events such as Brexit, protectionism of economies, and trade wars.

- The rheumatoid arthritis (RA) disease market will experience significantly slowed growth over the next decade due to biologic patent expiry and biosimilar erosion.

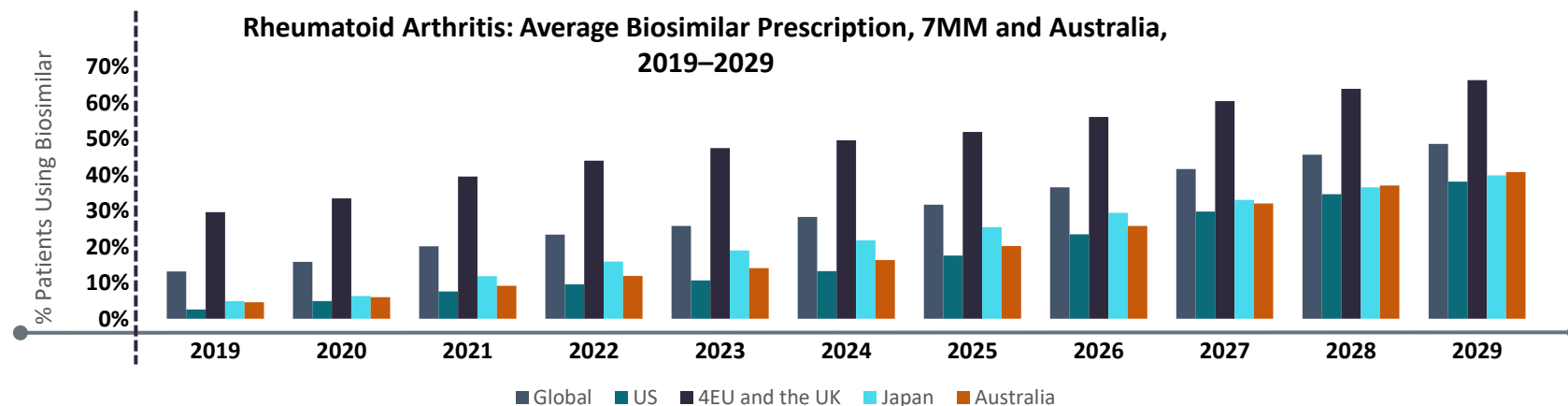
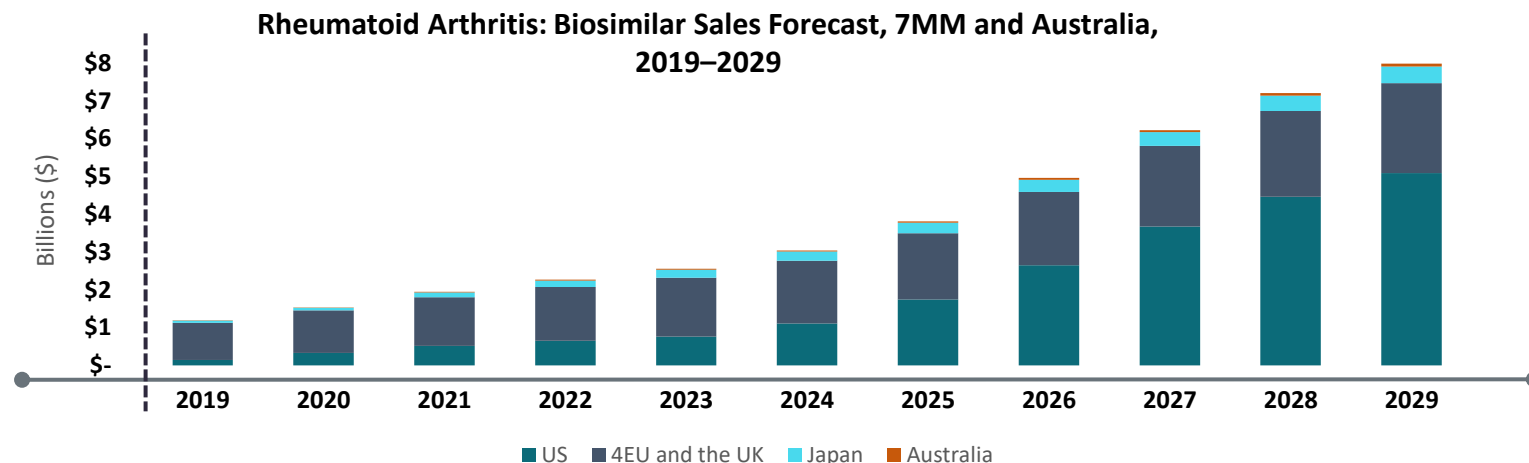
- Between 2019 and 2029, GlobalData forecasts biosimilar sales will increase from 5% to 28% of total sales throughout eight major pharmaceutical markets: US, France, Germany, Italy, Spain, UK, Japan, and Australia. This equates to a jump from \$1.2B to \$8.0B in biosimilar sales.

- For biologics with expired or expiring patents during the forecast period, GlobalData anticipates that by 2029, about 50% of prescriptions will be for biosimilar versions. Biosimilar uptake is expected to be the strongest in the 4EU and the UK due to stronger regulations and incentives promoting their use.

Emerging Regulatory and Macroeconomic Trends



Example: Impact of Biologic Patent Expiry and Biosimilars on the Rheumatoid Arthritis Market *Patent Expiries on 10 Key Biologic Products Will Significantly Limit Sales Growth*



Emerging Regulatory and Macroeconomic Trends



A Closer Look at Clinical Outsourcing

COVID-19 has disrupted clinical trials operations and continues to affect patient enrollment in non-COVID-19 trials.

Opportunities and Obstacles for Clinical Research Organizations

- CROs and other services that help with patient recruitment and implementing alternate strategies such as remote patient monitoring will be in high demand.
- CROs that offer specialized mobile health platforms that allow improved participant access through the use of decentralized/virtual clinical trials will flourish.
- Detailed risk and mitigation strategies are important; CROs will need plans to support trial continuity and patient safety.
- Regulatory guidance and navigation are critical and currently somewhat fluid; CROs that offer expertise in protocol modifications, amendments for home visits, and Institutional Review Board (IRB) submissions will be in demand.
- Also in demand will be CROs with strong partner networks that can provide drug delivery or at-home support by trained nurses and phlebotomists to decrease the risk of infection at sites/hospitals.

COVID-19 Clinical Trials

- CROs that specialize in infectious disease will be in increased demand for COVID-19 trials, which continue to grow in number, with the US leading the way.
- After COVID-19 vaccines and therapeutics are widely available, CROs that specialize in respiratory indications will still be in high demand due to “long-haul” patients.

Non-COVID-19 Clinical Trials

- CROs will resume trials for life-threatening indications as COVID-19 levels decrease, helping CROs that specialize in oncology and other such indications.
- CROs that specialize in non-life-threatening indications will take longer to resume as COVID-19 levels decrease, hurting CROs that specialize in cosmetic indications.
- CROs that specialize in ATMPs (cell and gene therapies) for non-COVID-19 indications will be hampered by the manufacture of COVID-19 vaccines.

Emerging Regulatory and Macroeconomic Trends



A Closer Look at Manufacturing Outsourcing

Top Trends for Manufacturing Outsourcing

COVID-19

- COVID-19 has brought an unprecedented boon for the contract development and manufacturing organization (CDMO) industry:
 - Increased drugs and vaccines in the pipeline.
 - Simultaneous production of commercial supplies at the same time as clinical development.
 - High-volume demand for production.
 - Direct funding of CDMOs by government and nonprofit sources.
 - Investment in injectable-dose manufacturing capacity for vaccines.
 - Capital expenditure on new vaccine technology that will make advanced technologies such as mRNA API manufacture more affordable in the future.

Advanced Therapy Medicinal Products (ATMPs)

- Increases in ATMP (cell and gene) pipeline drugs will continue to increase the demand for ATMP API production, as shown by GlobalData's Contract Service Agreement report.
- In the short term, ATMP pipeline drugs will compete with COVID-19 viral vector vaccines and other injectables for manufacturing and packaging space.
- In the long term, there will be more facilities and more trained personnel for ATMP manufacturing.

Developed Markets

- Continuing spin-offs of marketed pharmaceutical facilities to become or be sold to CDMOs.
- Culminating in the anticipated creation by Sanofi of a giant API CDMO.
- Increases in demand and facilities for injectable dosage due to COVID-19.
- Continued competition between second-tier publicly traded dose CDMOs.
- These spin-offs and ATMP demand will continue to interest private equity in CDMOs.

Emerging Markets

- Continued growth based on demographic issues.
- Increase in generic drugs manufacturing in part driven by COVID-19.
- An increase in sophistication driven by partnerships to manufacture COVID-19.

Emerging Regulatory and Macroeconomic Trends



A Closer Look at Vertical Integration, Clinical Outsourcing, and Manufacturing Outsourcing – Respondents' Perspective

Respondents' Perspective on Vertical Integration	Respondents' Perspective on Clinical Outsourcing	Respondents' Perspective on Manufacturing Outsourcing
<p><i>"COVID-19 pandemic has forced a rapid acceleration in vertical integration."</i> – Europe C-Level Executive</p> <p><i>"Finally, might get some joined-up thinking in the delivery of healthcare and the use of medicines, rather than a siloed, short-term budget mentality which has no regard for the long-term potential positive impact of a new intervention for the relevant patient population."</i> – Europe C-Level Executive</p> <p><i>"More consolidation, while it is still allowed, will push systems towards greater and greater efficiency."</i> – Europe VP/SVP/EVP</p> <p><i>"This [vertical integration] is the only thing that will help to put pharma companies as a positive area in healthcare."</i> – North America Director</p> <p><i>"This [vertical integration] is very much overdue. I believe vertical integration will increase efficiencies in healthcare if it is done with the right focus on patient."</i> – Europe Director</p>	<p><i>"Increased outsourcing is more efficient and leads to quicker, cheaper trials."</i> – Europe Director</p> <p><i>"The number of companies developing new therapies, devices, and diagnostics is increasing; however, this is being driven by emerging/virtual companies that don't have the in-house capability to manufacture nor manage clinical trials."</i> – Asia Pacific Director</p> <p><i>"Stands to unlock process efficiency gains with potential to significantly accelerate path to drug approvals."</i> – North America VP/SVP/EVP</p> <p><i>"Post-COVID-19, I expect to see significant changes in thinking in relation to clinical trial programs, from companies and from regulators. In order to quickly shift to a new paradigm, and to reduce risk/costs, there will be real opportunity for further outsourcing and/or partnerships."</i> – Europe VP/SVP/EVP</p> <p><i>"By outsourcing more of the clinical process, we will be able to accommodate more decentralized trials."</i> – North America Director</p>	<p><i>"The ability to manage investment in adjacent capacity can be advantageous for the industry, while also providing supply redundancy [enhancing overall supply chain reliability]."</i> – North America VP/SVP/EVP</p> <p><i>"We see with the COVID-19 crisis how rapid scale up of manufacturing has become—almost as big issue as treatment efficacy."</i> – Middle East and Africa C-Level Executive</p> <p><i>"Because there is an ease in manufacturing outsourcing than in-house manufacturing due to capital investment and labor. Moreover, more investment can be directed towards marketing and R&D."</i> – Asia Pacific Director</p> <p><i>"Political issues especially in the US that could disrupt supply chains and put patients at-risk."</i> – North America VP/SVP/EVP</p> <p><i>"Allows specialization of companies based on expertise between drug development and manufacturing."</i> – North America Director</p>

- COVID-19 has disrupted nearly every part of the pharmaceutical supply chain, exposing the vulnerabilities of many organizations, especially those that have a high dependence on markets such as India and China to meet their raw materials or finished products' needs. Even though this has driven government officials, particularly in the US, to attempt to encourage domestic production of drugs, the global demand for pharma products will continue to power **clinical and manufacturing outsourcing** trends.

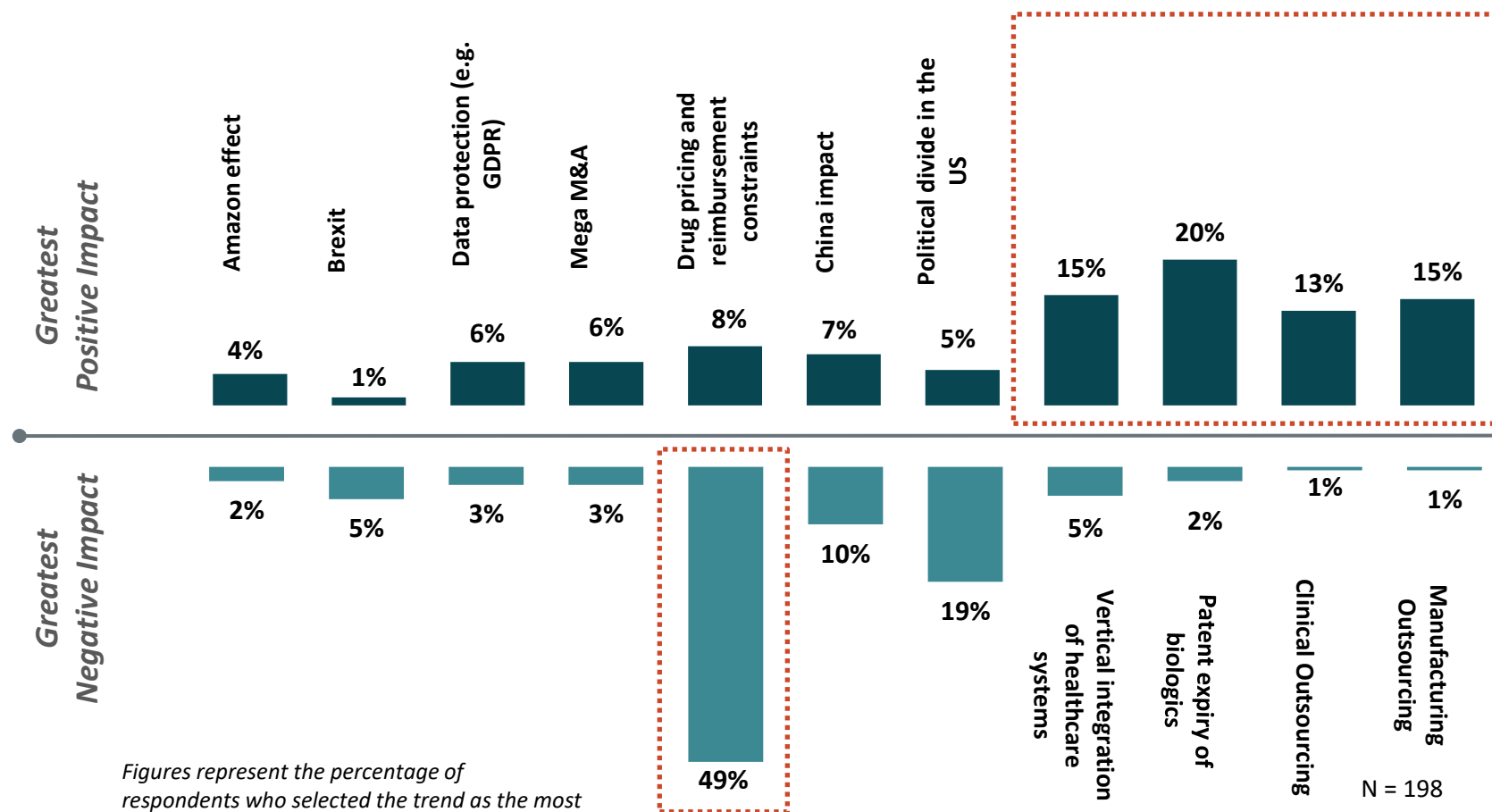
- Vertical integration** will continue to gain ground in 2021 due to its potential to improve agility, enhance productivity, facilitate the decision-making process, increase competitiveness, and cut associated costs.

- "[Vertical integration] has the potential to change the overall economic model of drug discovery, drug development, and drug manufacturing globally and reduce costs."* – North America C-Level Executive

Emerging Regulatory and Macroeconomic Trends



The most frequently selected trends with a positive impact on the pharmaceutical industry were patent expiry of biologics, vertical integration, and clinical and manufacturing outsourcing, while drug pricing and reimbursement constraints are set to have the most negative impact.



Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest positive impact on the pharmaceutical industry in 2021?

Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest negative impact on the pharmaceutical industry in 2021?

Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

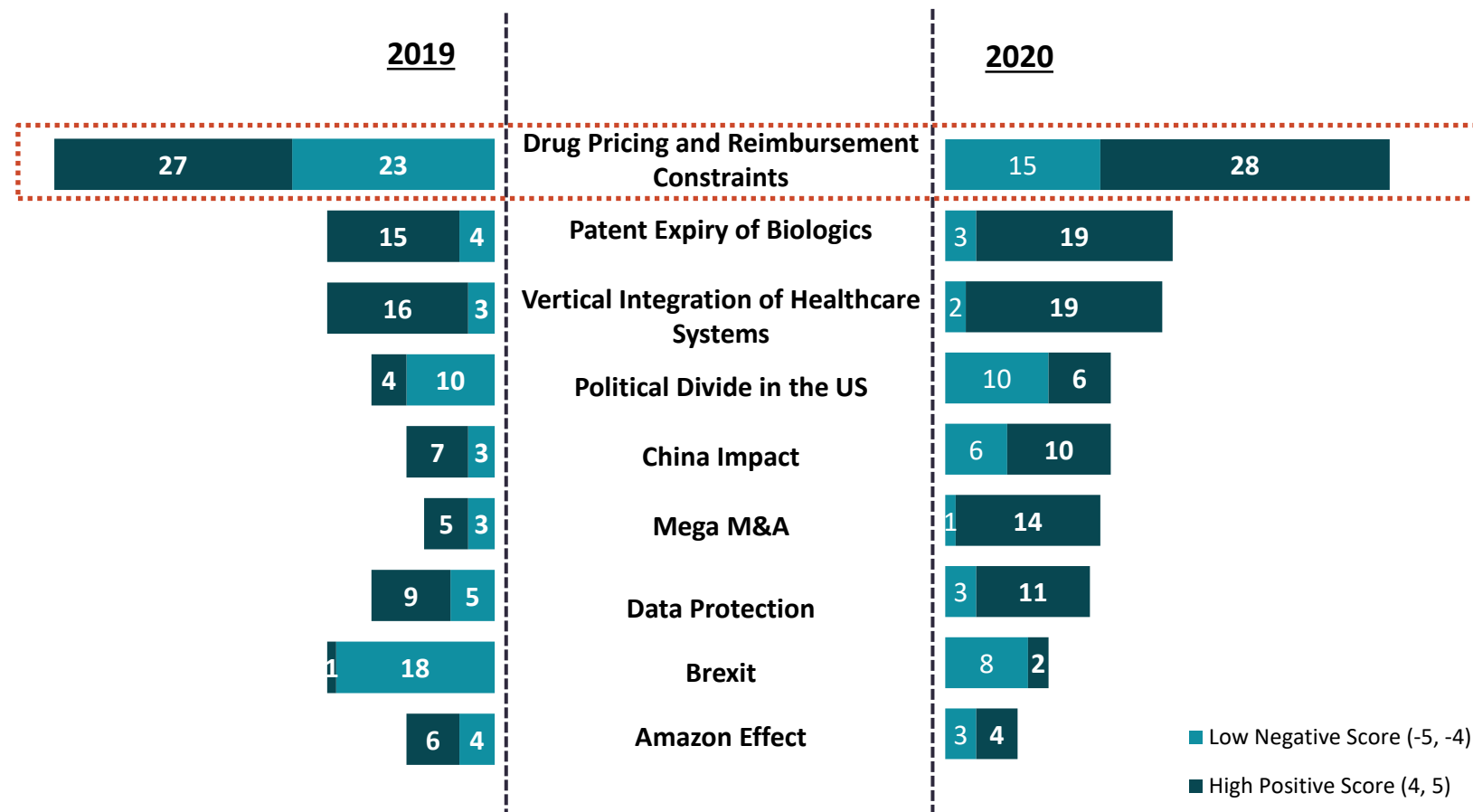
- While **drug pricing and reimbursement**-related concerns remained the leading impediment to industry growth in 2021, the industry trends such as **patent expiry of biologics** and **vertical integration** may eventually help to control the price hikes or even lower costs.
- Even though **patent expiry of biologics** maintained its position as one of the most positive trends, it received more negative sentiment as compared to the previous years. While production of biosimilars remains at a fast-increasing demand, it bites into the profits of big pharma that have already suffered financially from COVID-19-prompted supply chain disruption, regulatory pressures, and delays in clinical trials.
- “Post-COVID-19 healthcare systems and governments will need to reduce expenditure; pricing and budgets would seem to be an obvious target. Biosimilar adoption will play a role in this, and there may be shifts in the perceived value of rare/very rare disease treatments.” – Europe VP/SVP/EVP

Emerging Regulatory and Macroeconomic Trends



Pricing and Reimbursement Constraints Has Been the Major Negative Trend Since 2019, While Patent Expiry of Biologics Has Been One of the Most Positive Trends Since 2019

Survey fielded November 17, 2020, to December 9, 2020



Emerging Regulatory and Macroeconomic Trends

Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest positive impact on the pharmaceutical industry in 2019/2020?

Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest negative impact on the pharmaceutical industry in 2019/2020?

Source: The State of the Biopharmaceutical Industry Survey, 2019 Edition; The State of the Biopharmaceutical Industry Survey, 2020 Edition

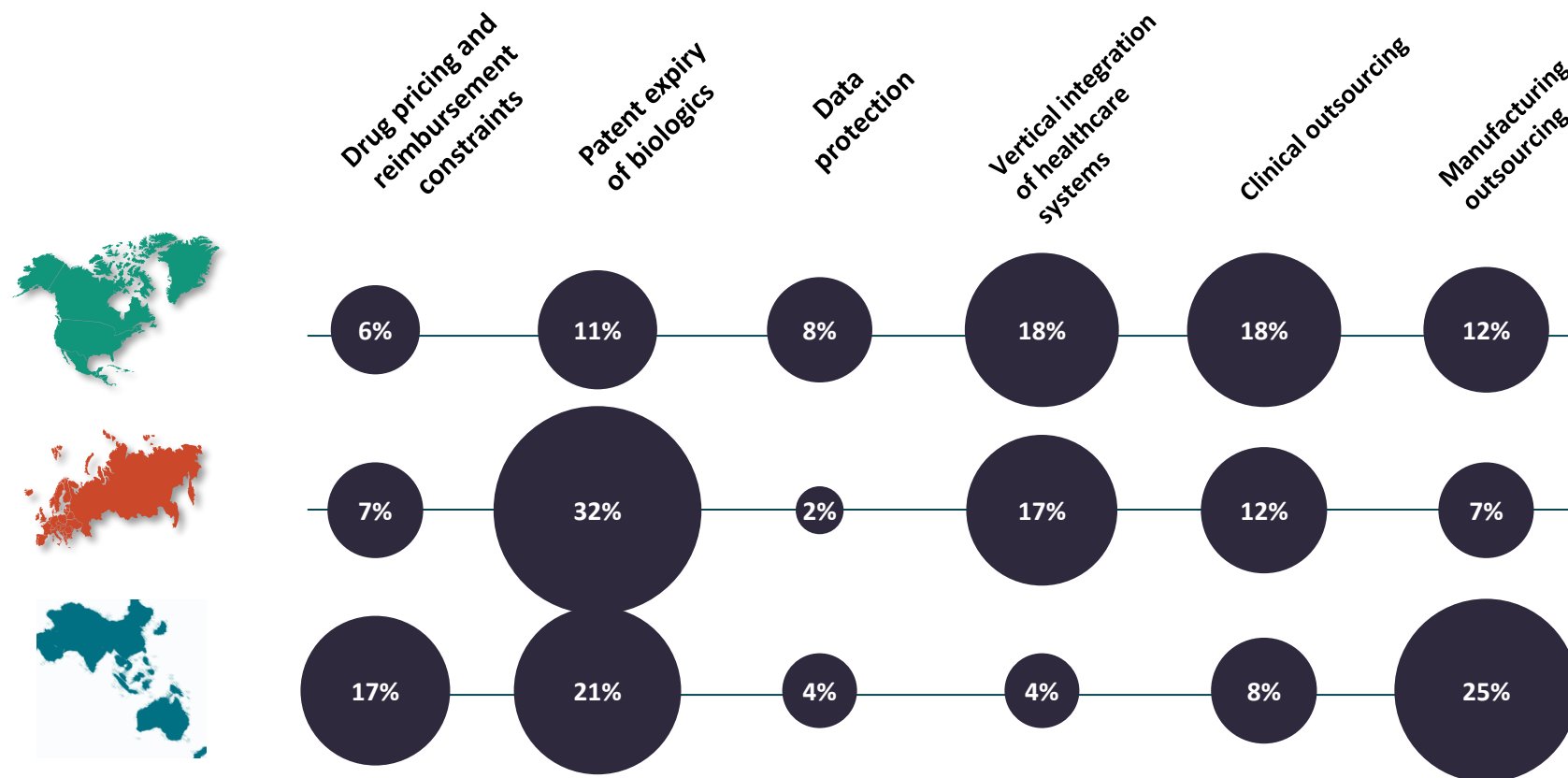
- With **drug pricing and reimbursement pressures** becoming a major concern worldwide, biosimilars are expected to gain a stronger foothold and drive significant cost savings for healthcare.
- Over the past 10 years, the EU has approved the highest number of biosimilars worldwide, accumulating extensive experience with their use and safety. With the legal framework for biosimilars having been established relatively early, the EU developed a solid background for the future **biosimilar product development and uptake**.
- **Vertical integration** was ranked as one of the biggest trends in North America and Europe. By vertically integrating all the aspects of the pharmaceutical value chain, companies in these regions have a hope to restore competitiveness by delivering high quality of products to patients, while at the same time improving product delivery timelines and costs.

Emerging Regulatory and Macroeconomic Trends



Top Positive Emerging Regulatory and Macroeconomic Trends—Strongest Positive Scores by Geography

Survey fielded November 17, 2020, to December 9, 2020



Emerging Regulatory and Macroeconomic Trends

Figures represent the percentage of respondents who selected the trend as the most impactful positive trend, segmented by geography.

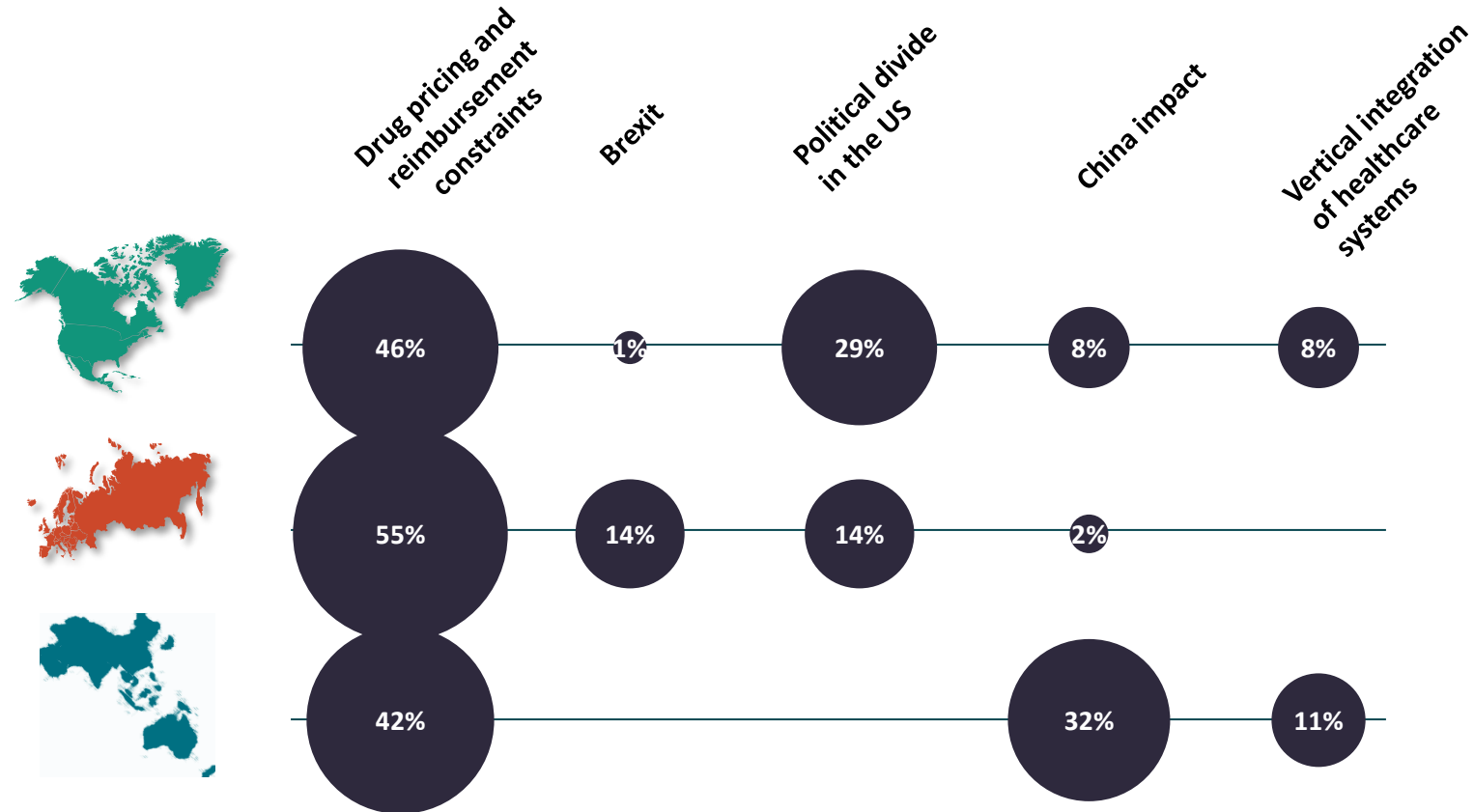
Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest negative impact on the pharmaceutical industry in 2021?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

Emerging Regulatory and Macroeconomic Trends



Top Negative Emerging Regulatory and Macroeconomic Trends—Strongest Negative Scores by Geography

Survey fielded November 17, 2020, to December 9, 2020



Figures represent the percentage of respondents who selected the trend as the most impactful negative trend, segmented by geography.

Q: Of the regulatory and macroeconomic trends listed in the previous question, which one do you expect to have the greatest negative impact on the pharmaceutical industry in 2021?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

- **China impact** emerged as a particularly strong negative trend in APAC. Even though the emerging Asian markets have been capturing an interest from pharmaceutical industry, COVID-19 showcased that relying on China, and other Asian countries—the largest outsourcing hubs for pharmaceutical ingredients’ production and supply—may be a risky road to take.
- Despite having effects on a number of economies worldwide, the **political divide in the US** and **Brexit** scored the highest negativity points in the regions that will be impacted the most from these events. North America and Europe are expected to deal with ongoing uncertainty and standstill, while at the same time still grappling with the COVID-19-induced economic recession.
- Despite the benefits that **vertical integration** can bring, it poses a risk to some industry players. Vertical integration may lead to reduced competition, drive out smaller vendors, and eventually increase prices of products.



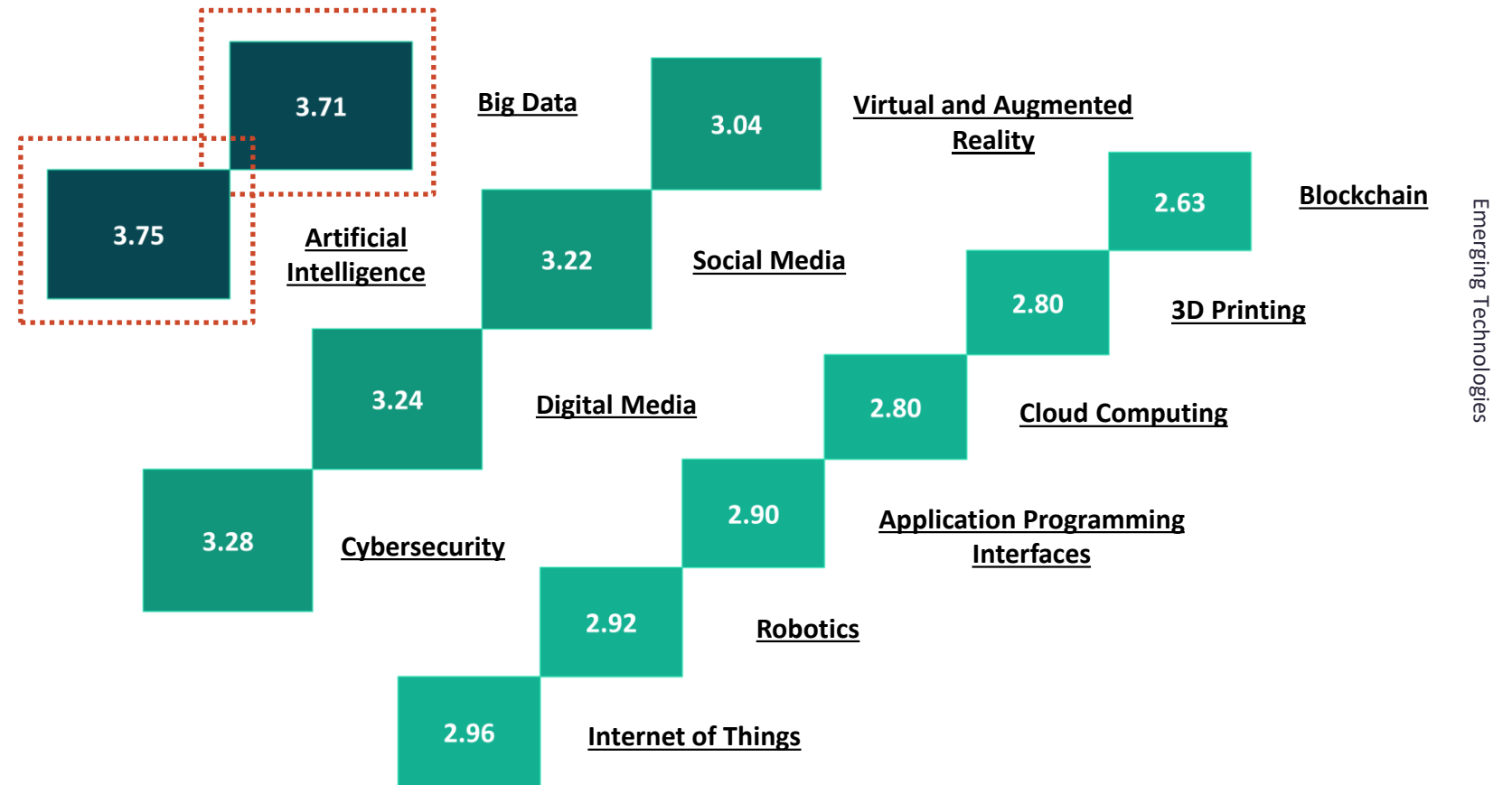
Emerging Technologies

- Even though digitalization in the biopharmaceutical sector has already been an essential strategic initiative, digital transformation has taken on heightened importance due to the COVID-19 pandemic.
- Similar to previous years, **AI**, followed by **Big Data**, scored the highest among emerging technologies likely to have an impact on the industry. These two trends go hand in hand, as the analysis of **Big Data** is best powered by **AI**. Competence in these areas is vital for healthcare companies, as it provides improved patient care at a micro level and, more broadly, drives a higher level of insights and trends that benefit operational and clinical efficiency.
- **Social and digital media tools** together with **virtual and augmented reality** technologies will continue to gain a strong foothold in the biopharmaceutical sector due to the ongoing COVID-19 crisis, enabling pharma to engage with patients and stakeholders, improve training initiatives, and strengthen corporate reputations.

Emerging Technologies

Across all Geographies, AI and Big Data Are Expected to Have the Biggest Impact on the Pharmaceutical Industry in 2021

Survey fielded November 17, 2020, to December 9, 2020



Q: On a scale of 1 - 5, please rate the anticipated impact of each of the following emerging technologies on the pharmaceutical industry in 2021. (5 indicates the greatest impact, 1 indicates minimal impact.)

Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

Emerging Technologies – Closer Look at AI and Big Data



AI and Big Data in healthcare are linked. Use of the former will continue to grow rapidly, especially when considering the amount of data that can now be mined from patient records and used to design treatment plans, develop drugs, or improve clinical trial outcomes.

Healthcare Data Management

Medical data collection, storage retrieval, and analytics



Manage and Engage Patients

Enhance physician experience with intelligent patient follow-up



Diagnosis and Patient Care

Identify high-risk patients and provide at-home care



Sales and Marketing

Call tracking and personalized advertisements



Privacy and Security Concerns

Ensure that healthcare data are secure without any breach of information



Control and Manage Costs

Allow health plans to collect and analyze volumes of data that could lead to customized care programs



Medical Treatments

Select the optimal treatment plan for a patient



Target Identification

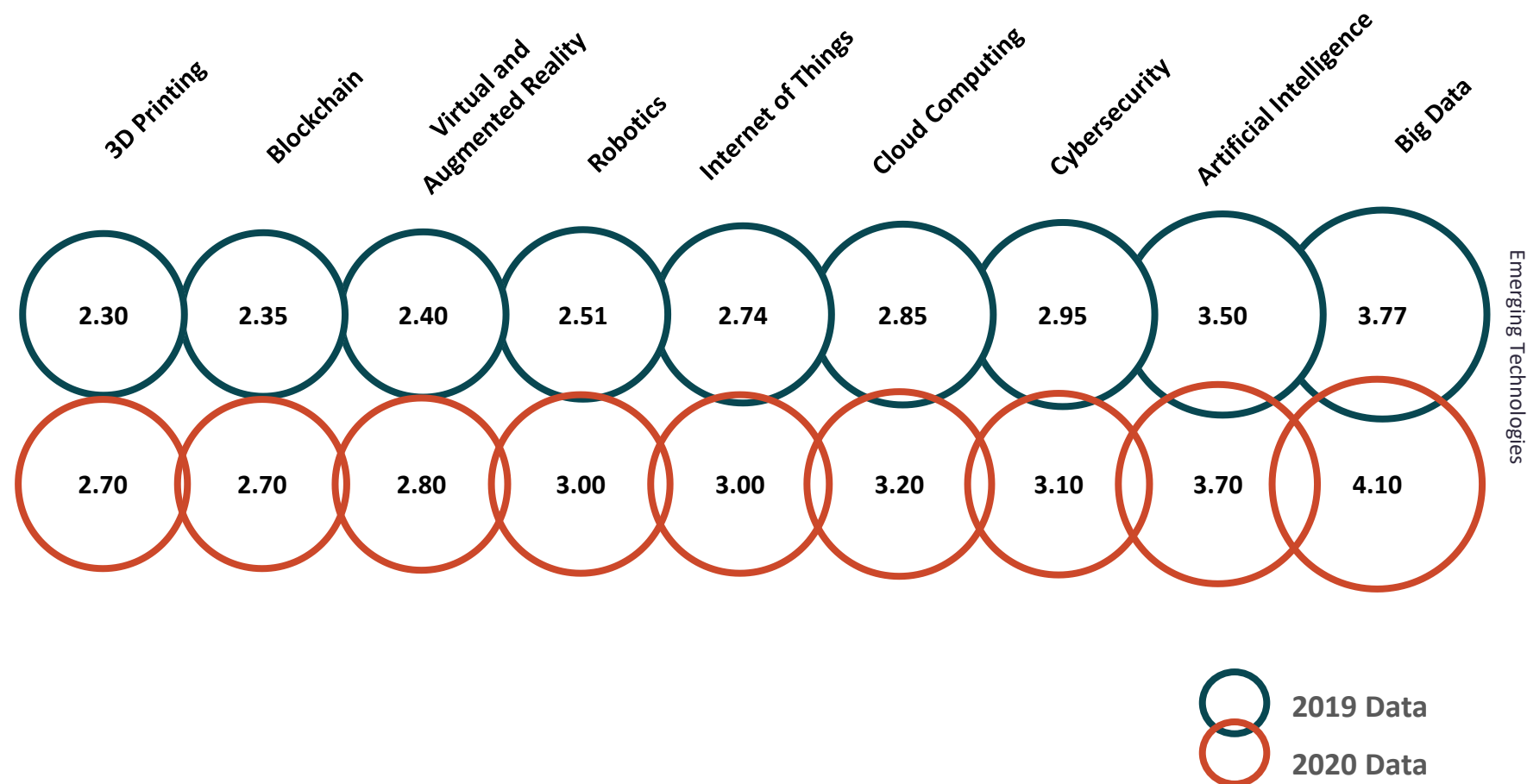
Expedite target identification and easily identify targets by analyzing data from multiple sources



- Companies need to understand their vulnerabilities in order to capitalize on the digital transformation and uplift emerging technologies uptake. Innovative technologies are providing pharma businesses with new methods to improve operational efficiency, explore new business opportunities, and build better rapport with regulators, patients, and prescribers.
- However, the more the industry embraces digital technology, the more it exposes itself to emerging cyber risks. No wonder that **cybersecurity** continues to gain increasing importance to pharma.
- Despite witnessing high levels of interest during the past two years, **cloud computing** is expected to reduce its relevance to pharma, most likely due to accelerated current uptake. Cloud computing served as a crucial technology in enabling organizations to quickly apply digital solutions such as virtual meetings and remote work to maintain business continuity and support COVID-19 response.

Emerging Technologies

AI and Big Data Were Rated as the Most Impactful Technologies in the Pharma Industry in 2019 and 2020



Q: On a scale of 1 - 5, please rate the anticipated impact of each of the following emerging technologies on the pharmaceutical industry in 2019/2020. (5 indicates the greatest impact, 1 indicates minimal impact.)

Source: The State of the Biopharmaceutical Industry Survey, 2019 Edition; The State of the Biopharmaceutical Industry, 2020 Edition

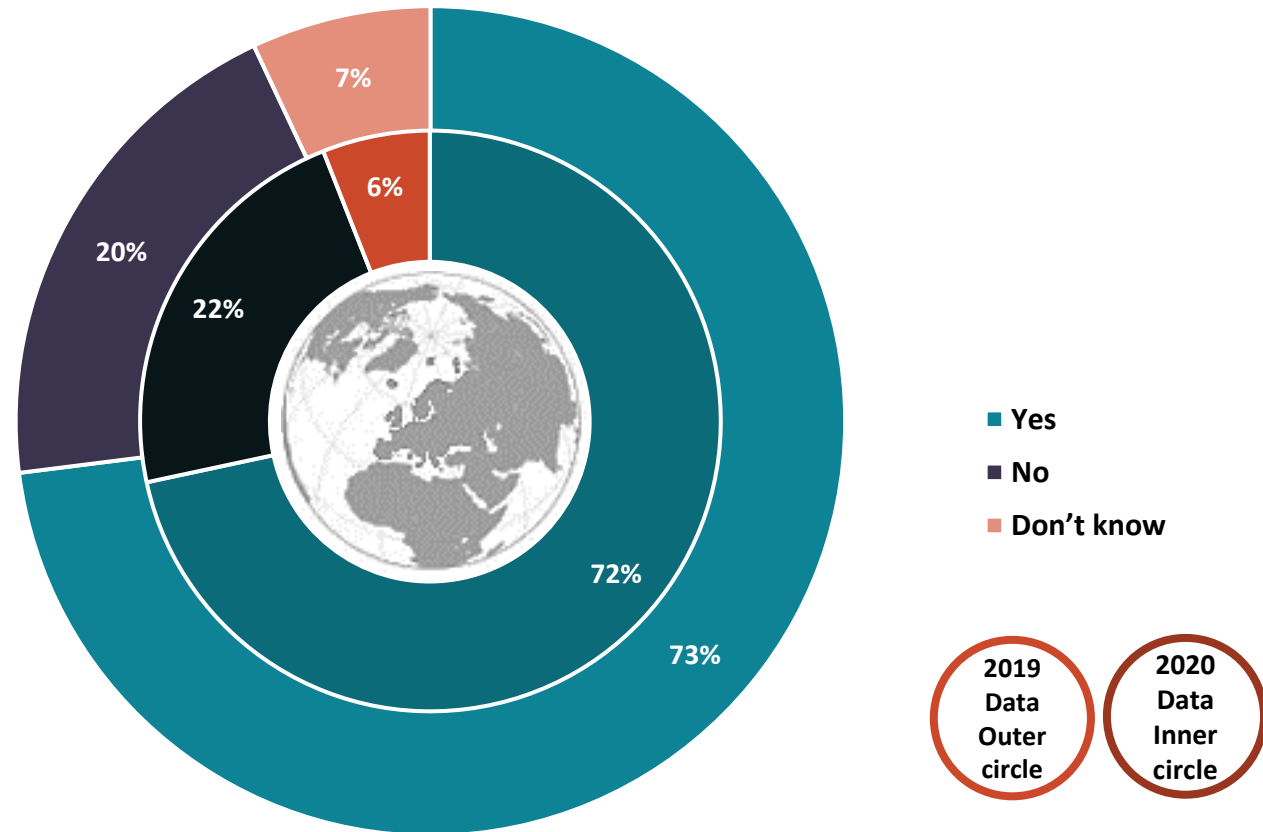
- Cyber threats are an ever-growing problem and as digitalization evolves, the nature of cyber risks is also changing. According to GlobalData's Emerging Technology survey conducted with pharmaceutical industry IT professionals, investment in **cybersecurity** has remained relatively stable since 2019, with more than 70% of companies investing in internal network protection.
- The pharmaceutical industry is extremely vulnerable to cyber threats due to the amount of valuable and sensitive data it processes. Breaking into pharmaceutical companies' systems can expose information related to clinical trials, trade secrets, and IPs associated with drug formulation processes and technologies. The losses that companies can suffer extend far beyond revenue. Any cyberattack that leaks confidential information can damage brand reputation, cause delays in the supply chain, or result in litigating actions.

Emerging Technologies – Closer Look at Cybersecurity



Investment in Cybersecurity – 2019 vs. 2020 Data

Survey fielded May 29, 2020, to July 9, 2020



Q: Is your business currently investing in the following technologies? (Cybersecurity)

Source: GlobalData, Emerging Technologies Survey 2020; GlobalData, Emerging Technologies Survey 2019

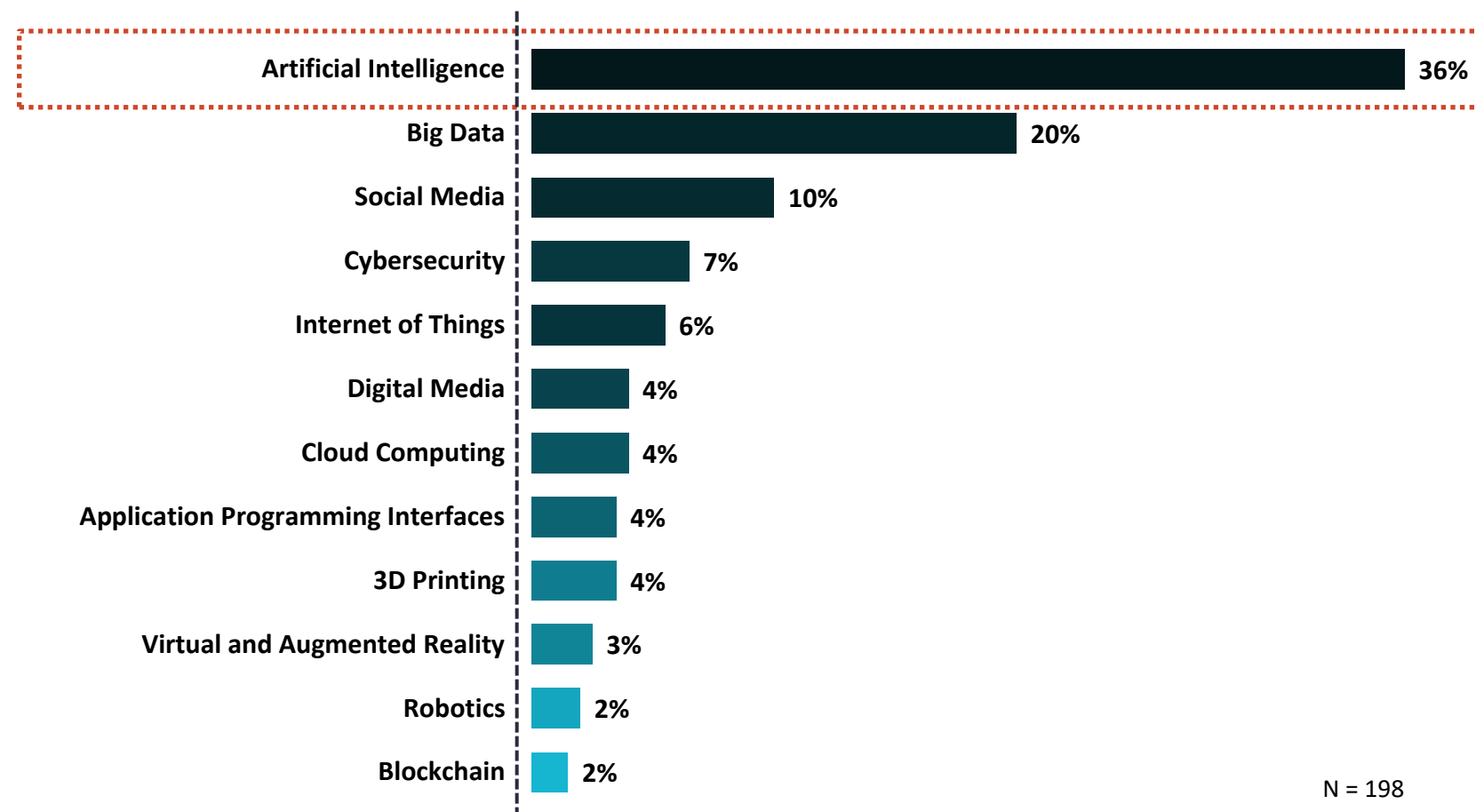
- AI holds the capability to deliver productivity improvements and efficiencies across the entire pharmaceutical industry's value chain—from drug discovery process to the way companies are engaging with stakeholders and communicating product value.
- AI has already hit some significant milestones—2020 started with Sumitomo Dainippon Pharma and Exscientia's announcement that an AI-created compound will be used in human clinical trials for the first time. The same year, BenevolentAI identified Eli Lilly's drug baricitinib as a potential COVID-19 treatment, which is now in Phase III clinical trials.
- *"AI is a driver of predictive modelling with huge application for predicting disease outcome, identifying patients at-risk before diagnosis [Dx], projecting off of RWE, building prospective cost models, etc."* – North America VP/SVP/EVP

Emerging Technologies



AI Will Continue to Trend as the Most Disruptive Emerging Technology in the Pharmaceutical Sector in 2021

Survey fielded November 17, 2020, to December 9, 2020



Emerging Technologies

Q: Of the technologies listed in the previous question, which one do you expect to have the greatest impact on the pharmaceutical industry in 2021?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

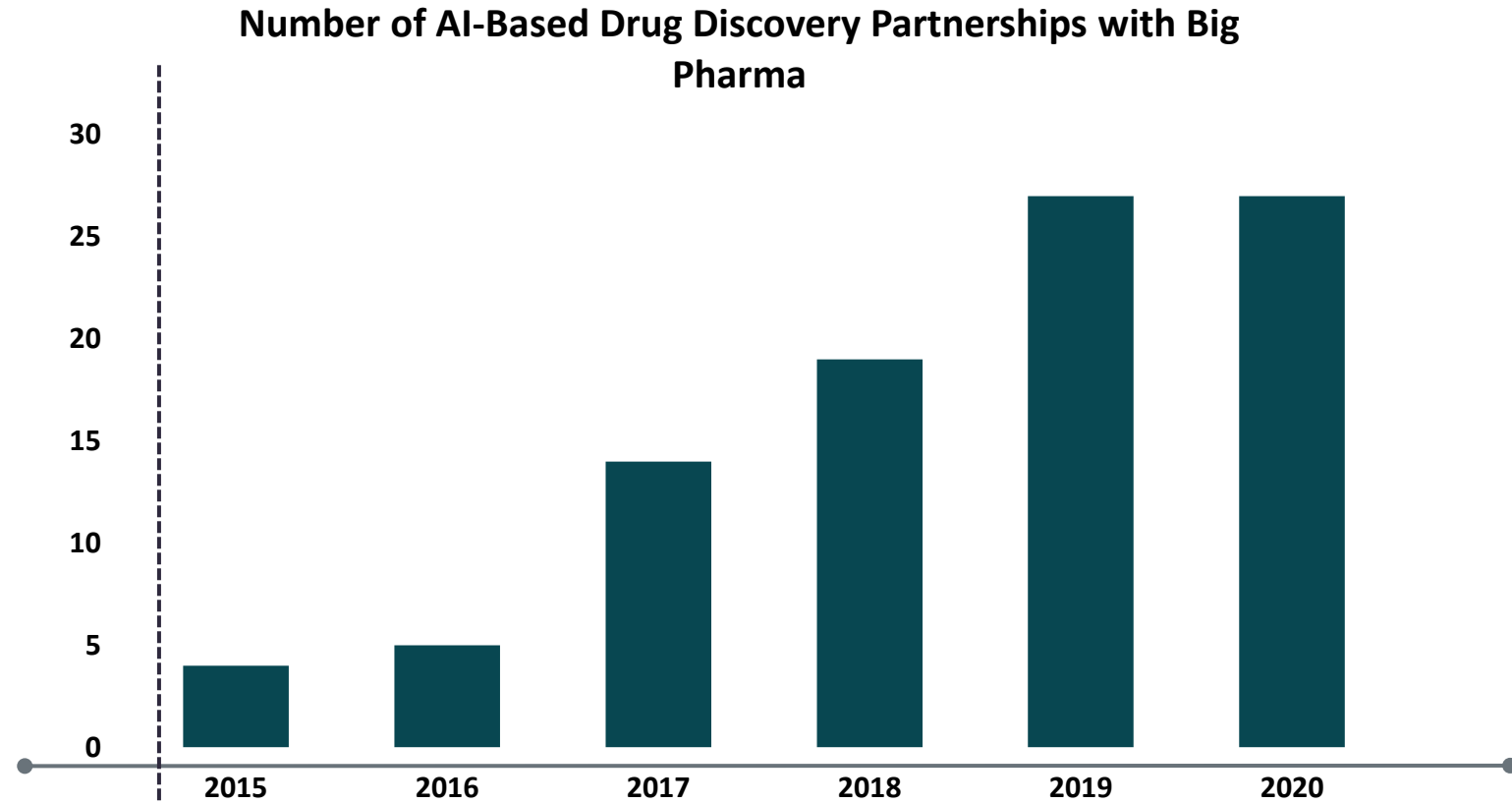
- AI has the potential to dramatically reduce the time and expense of taking a drug to market and can also improve the probability of a drug's approval.
- The pharma industry has been slow to adopt AI technology but an increasing number of companies are now partnering with smaller AI start-ups for their expertise in drug discovery.
- GlobalData analysis shows that there were just four partnerships for AI-based drug discovery forged by big pharma in 2015. By 2017, this had increased to 14.
- For both 2019 and 2020, 27 deals have been identified, with most involving key players such as Iktos, Recursion, Insilico, Exscientia, Atomwise, and BenevolentAI.
- Pharma companies with high numbers of deals include Takeda, Pfizer, AstraZeneca, Gilead, Roche, Novartis, Janssen, and Boehringer Ingelheim.

Drug Discovery AI Partnerships with Big Pharma Increasing



AI Drug Discovery Partnerships with Big Pharma Have Increased Significantly Over the Past Five Years

As of December 16, 2020



Emerging Technologies

Emerging Technologies



A Closer Look at the Most Impactful Technological Trends

Respondents' Perspective on Artificial Intelligence	Respondents' Perspective on Big Data	Respondents' Perspective on Cybersecurity
<p><i>"[Artificial intelligence] can have big positive impact on speeding up and improving everything from disease diagnosis, screening, novel drug development, public health monitoring and responsiveness, etc." – Asia Pacific VP/SVP/EVP</i></p> <p><i>"From drug discovery through finding the right endpoints and patient populations, AI can provide insights that older methods cannot." – North America Manager</i></p> <p><i>"AI combined with big data will enable faster drug development and repurposes of prior investments with sunk cost that find utility in unmet needs." – North America C-Level Executive</i></p> <p><i>"As trials become decentralized, we will need to find ways to leverage technology—specifically AI—to uncover data patterns that would reveal fraud, safety, and efficacy." – North America Director</i></p> <p><i>"AI is becoming key in exploring early drug development through clinical trials." – North America VP/SVP/EVP</i></p>	<p><i>"More information used correctly can allow for more targeted therapies, and less risk on go-forward decisions for therapies." – North America Manager</i></p> <p><i>"Our ability to generate large volumes of data has increased over the years and our ability to analyze, understand, and find utilizations for that data will determine its value." – North America VP/SVP/EVP</i></p> <p><i>"Big Data will continue to support many of the changes in the pharmaceutical industry, from AI in clinical trials to better commercial resource allocation. All of these rely on Big Data." – Europe VP/SVP/EVP</i></p> <p><i>"More data leads to better understanding. As technology in healthcare is used ever more, more data can be collected analyzed, more patterns, trends, hypotheses can be identified and tested." – Europe Manager</i></p> <p><i>"The ability to evaluate data on a large scale will lead to new discoveries." – North America VP/SVP/EVP</i></p>	<p><i>"Cybersecurity is a problem that cannot be completely managed with the current rules for encryption and has already demonstrated how seriously hacking can damage a pharmaceutical." – Middle East and Africa C-Level Executive</i></p> <p><i>"General Data Protection Regulation [GDPR] and data security are high on the issues and concerns for 2021 especially for COVID-19 treatments and vaccines." – North America Director</i></p> <p><i>"More threats to patient, manufacturing, and clinical data may delay drug advancement and increase patient distrust." – North America VP/SVP/EVP</i></p> <p><i>"Need to stay on top of cybersecurity so as to protect intellectual property of clinical research and prevent it from falling into hands of adversaries." – North America VP/SVP/EVP</i></p> <p><i>"Safety and data protection will be ever more an issue." – Europe Director</i></p>

Source: GlobalData

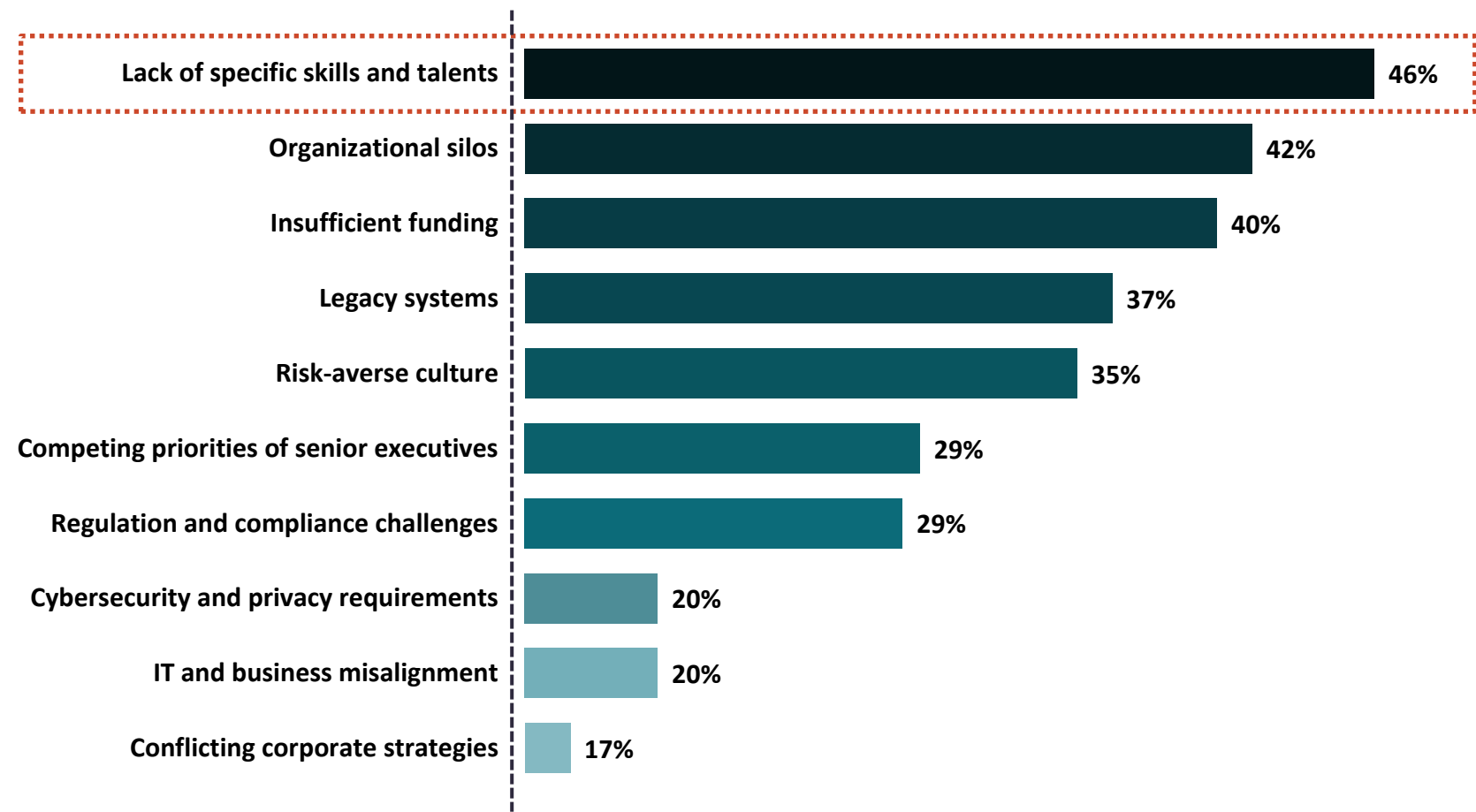
- COVID-19 silenced any lingering doubts about the need for the pharmaceutical sector to digitally transform. Pressed by the pandemic, in a short space of time many companies have witnessed years-long digital transformation roadmaps squeezed into weeks in order to adapt to reduced in-person interactions, mobility restrictions, a shift towards remote working, and application of digital communication and collaboration tools.
- Nevertheless, technologies will fail to add value if people do not know how to work with them. In the “Digital Transformation and Emerging Technology in the Healthcare Industry” survey conducted by GlobalData in Q3 2020, the pharmaceutical industry professionals highlighted lack of specific skills and talents as a top factor slowing down digital transformation in the sector. While COVID-19 response scaled up digital transformation, it left many companies’ employees unprepared. The existing workforce may not have sufficient skills or time to keep up with the pace of digital transformation.

Emerging Technologies



Lack of Specific Skills and Talents Hinders the Digital Transformation and Technologies Uptake in Pharma

Survey fielded September 17, 2020, to October 6, 2020



Emerging Technologies

Q: Which of the following factors hinder digital transformation at your organization?
 Source: GlobalData, Digital Transformation and Emerging Technology in the Healthcare Industry, 2020 survey



Industry's Growth Prospects

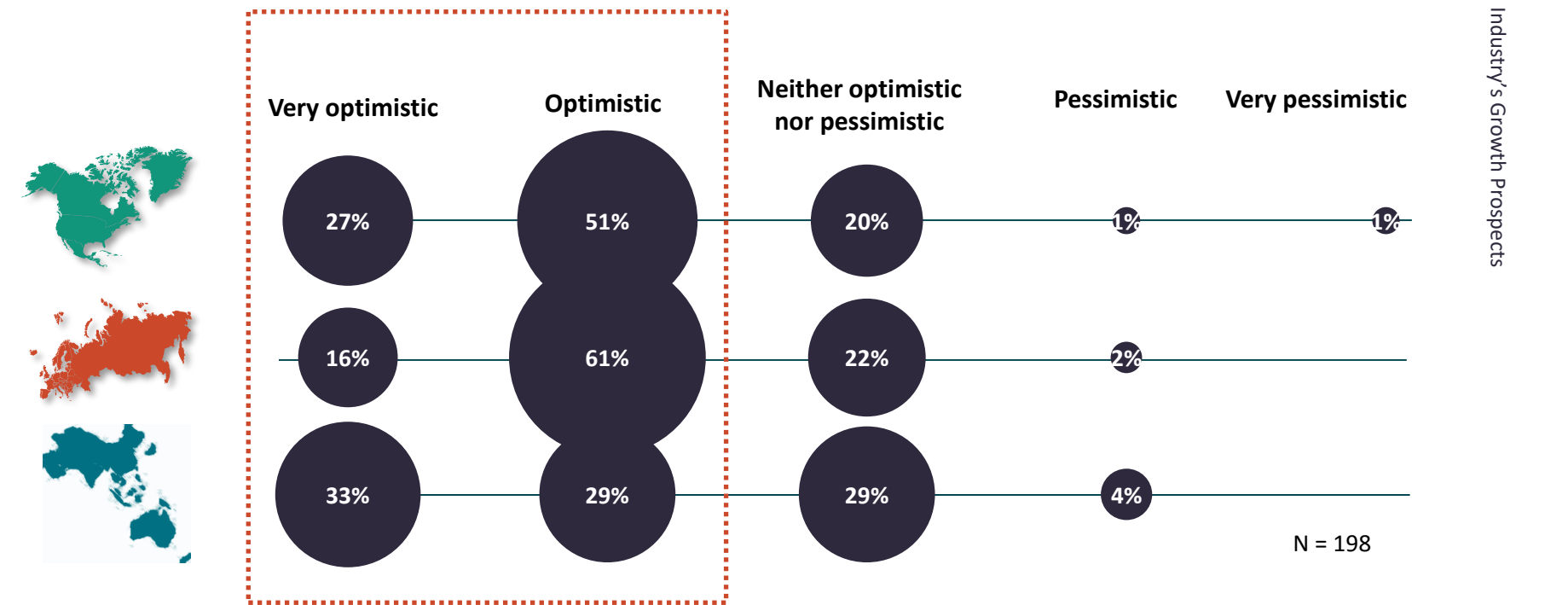
- The public perception of pharma is often shaped by issues like the opioid crisis, increasing drug costs, lack of transparency in clinical trials, or corporate greed. Even though the pharmaceutical industry has long struggled to showcase its value, COVID-19 has provided a unique opportunity for pharma to redeem its reputation by collaborating on COVID-19 therapeutics and vaccines.

- While demand changes, supply chain disruptions, suspended clinical trials, and regulation alterations may be seen as short-term negative impacts of COVID-19, the pandemic also presents huge growth opportunities for the pharmaceutical industry, especially for the companies taking center stage in the COVID-19 fight.

- *“Pharma has a big opportunity to show that we can be tremendous contributors to society and it’s not all the inflated drug price and negativity of capitalism; however, we need to be cautious that we are doing our parts responsibly.”* – North America Director

Industry’s Growth During the Next 12 Months

More than 70% of Respondents Felt Optimistic or Very Optimistic about Industry’s Growth During the Next 12 Months
Survey fielded November 17, 2020, to December 9, 2020



Q: How optimistic are you about the industry’s growth during the next 12 months?
 Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

COVID-19 and the Pharma Value Chain



No part of the pharmaceutical value chain is unaffected by COVID-19, with a wide range of activities from drug development to sales and marketing having to adapt.

	Drug Development	Supply Chain & Manufacturing	Sales & Marketing	End Users (Patients, HCPs, Hospitals)
Short-term impact	Developers of COVID-19 interventions could thrive; the bulk of the industry is facing challenges with running trials and dealing with supply chain disruptions.	Logistic and supplies of APIs and intermediates is the major issue for all players involved in the manufacture and marketing of finished dose forms.	With disruptions in face-to-face meetings, sales forces are switching to using virtual engagement and electronic marketing tools.	Hospitals struggling with supplies and resources needed to handle large influxes of patients with severe disease.
Mid-term impact	Developers will have to cut losses and terminate COVID-19 programs if they do not appear promising.	As concerns over availability of APIs subside, manufacturing processes will begin to resume, though they will initially lag relative to regular operations.	Sales will begin to recover once supply chains and sales forces are less disrupted by COVID-19 and associated safety measures.	Healthcare providers will continue to struggle to provide adequate patient care as long as COVID-19-associated hospitalization rates are high.
Long-term impact	Experience with developing COVID-19 agents could be leveraged for other investigational programs.	Growth will be derived from opportunities to manufacture and support distribution of COVID-19 interventions.	The approval of an effective therapeutic or vaccine for COVID-19 could drive blockbuster revenues for a developer.	The availability of a vaccine or therapeutic will significantly improve public health, reducing stress on the healthcare system.

Industry's Growth Prospects

Source: GlobalData

■ Significant negative impact
 ■ Moderate negative impact
 ■ No impact
 ■ Moderate positive impact
 ■ Significant positive impact

- Despite COVID-19 vaccines beginning to roll out, there is a significant level of uncertainty over pharmaceutical manufacturing continuity in Asian markets, especially those historically dependent on outsourcing. COVID-19 caused disruptions in supply chains, recalls of products, deepened geopolitical tensions, and renewed discussion in countries like the US to move drug production back to their own shores.

- While COVID-19 is not expected to end the globalization in pharmaceutical sectors, it may cause a gradual diversification of supply sources, resulting in substantial problems for current contract manufacturing leaders in the APAC region.

- “Access to raw materials, components, equipment, and PPE have been severely impacted and will remain so for an extended period of time. This impacts development and clinical/commercial manufacturing negatively.” – North America C-Level Executive*

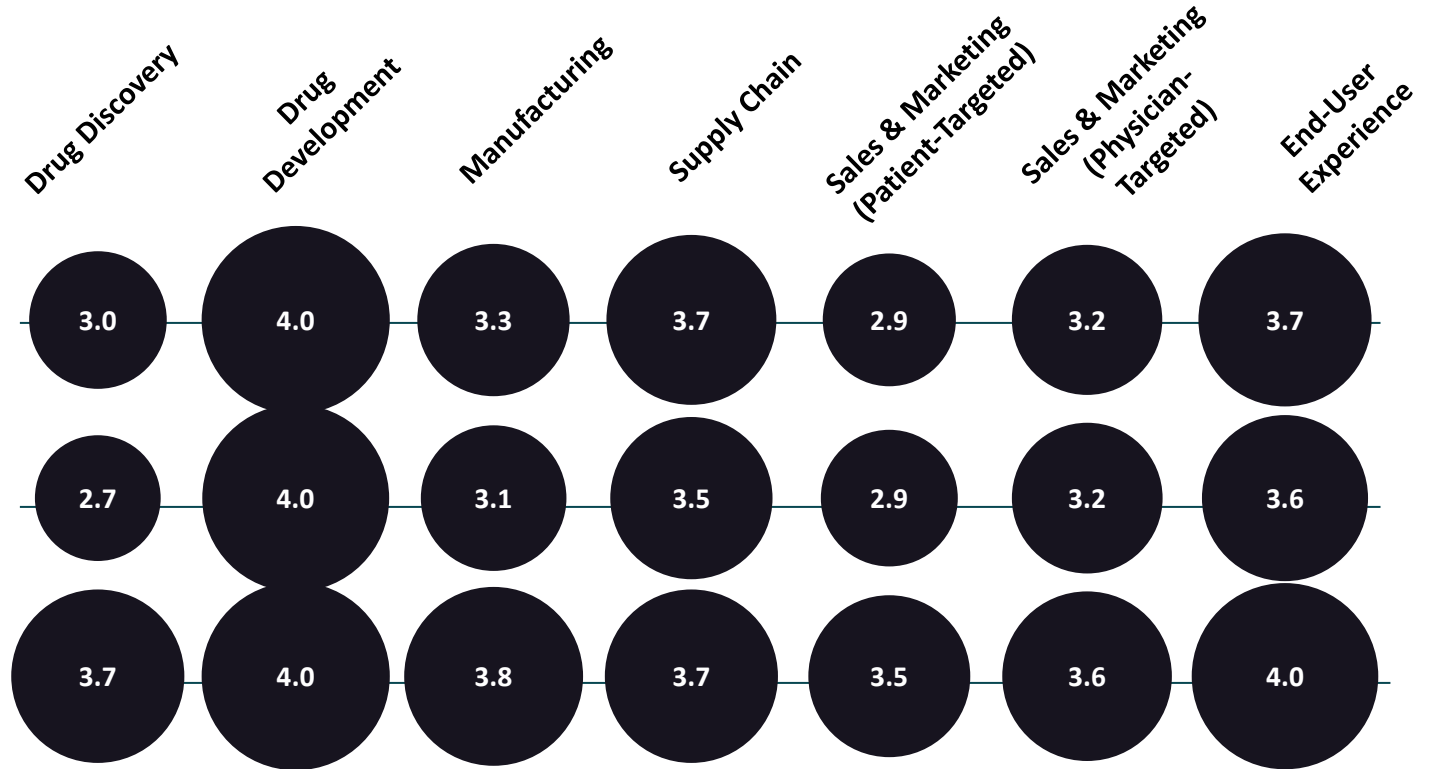


COVID-19 Impact on Pharmaceutical Value Chain – By Region



Respondents from Asia Pacific Were More Concerned about Anticipated COVID-19 Impact on Pharmaceutical Value Chain as Compared to Other Regions

Survey fielded November 17, 2020, to December 9, 2020



Industry's Growth Prospects

N = 198

Q: On a scale of 1-5, please rate the anticipated impact of COVID-19 on each of the pharmaceutical value chain components in 2021.
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

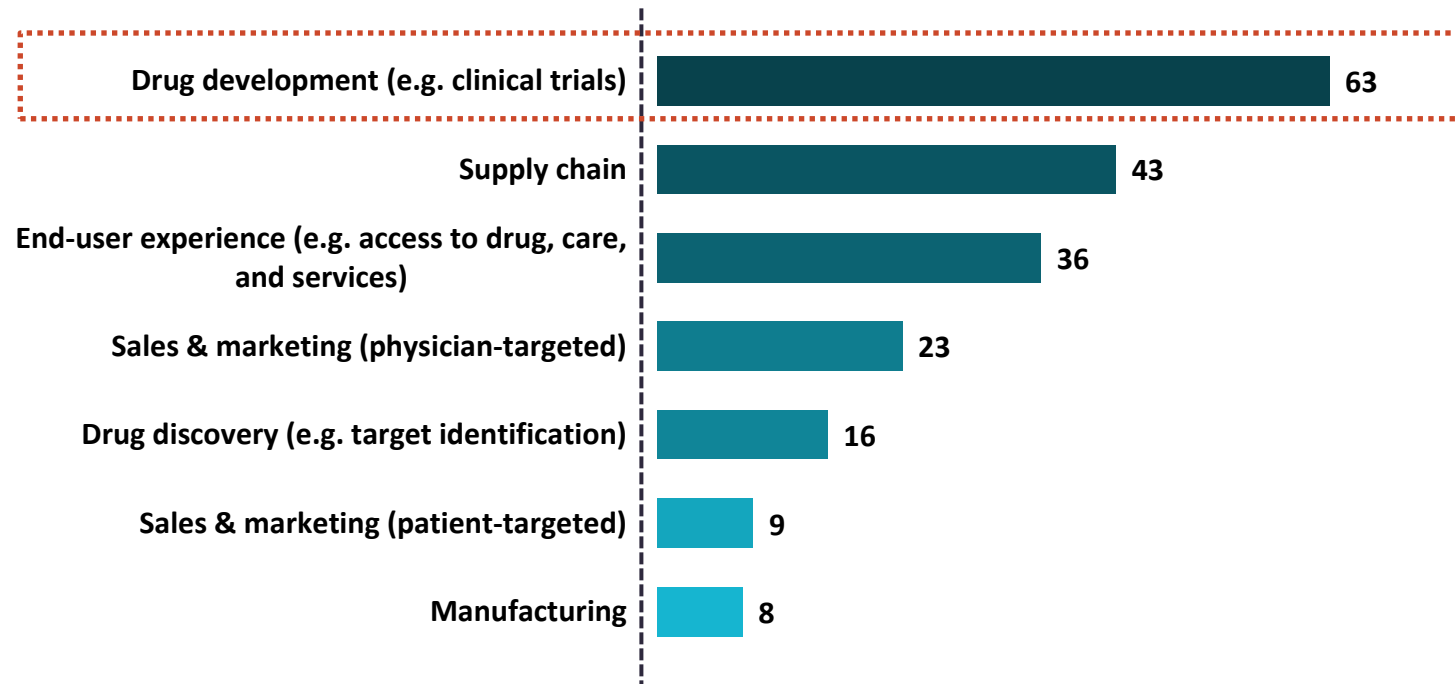
- The COVID-19 pandemic has created a massive global effort centered around finding effective therapeutics and vaccines. While development and commercialization of a safe vaccine typically takes at least several years to materialize, Pfizer/BioNTech has beaten that timeline by a considerable margin, with the UK becoming the first market to approve the shot.
- Nevertheless, with pharmaceutical companies shifting their strategies to focus on the development of COVID-19-related assets, the other **drug development** programs have been brought to a temporary standstill. Non-COVID-19 drug developments were extensively affected by the cancellation, suspension, or delays in clinical trials.
- *“Limited ability for sites and participants due to COVID-19 restrictions or travel bans could significantly delay new drugs and devices.”* – North America C-Level Executive

COVID-19 Impact on Pharmaceutical Value Chain



Drug Development Activities Will Be Impacted the Most by COVID-19 in 2021

Survey fielded November 17, 2020, to December 9, 2020



Industry's Growth Prospects

N = 198

Q: Of the value chain components listed in the previous question, which one do you expect to be impacted the most by COVID-19 in 2021?
Source: The State of the Biopharmaceutical Industry Survey, 2021 Edition

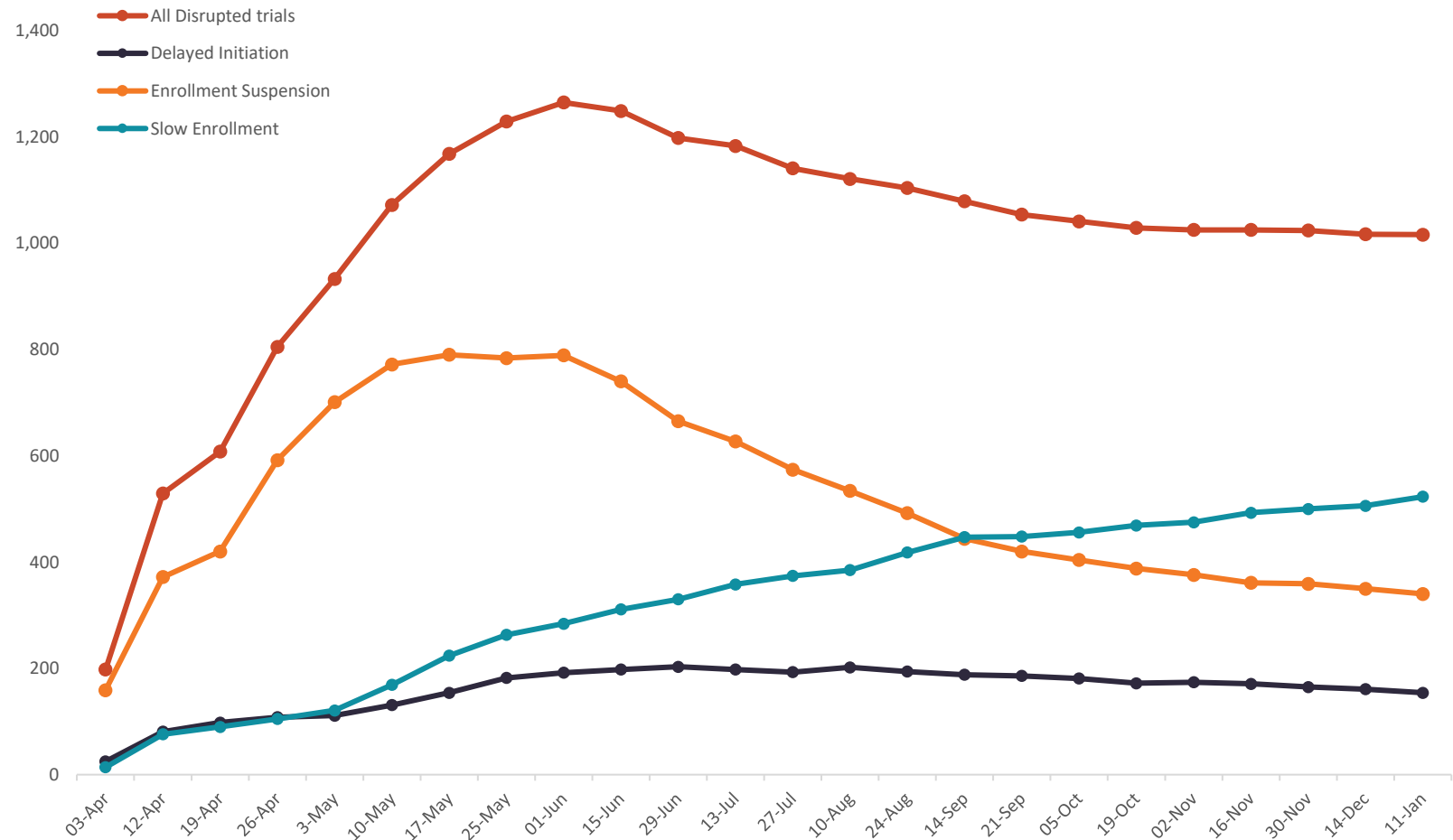
- Since early March, around 1,000 organizations supporting clinical trials as a sponsor, collaborator, or contract research organization have publicly announced disruptions to planned and ongoing clinical trials in their press releases, Securities and Exchange Commission (SEC) filings, and clinical trial registries, as well as on social media. Companies have delayed the initiation of planned trials or withdrawn them completely, have suspended enrollment in ongoing trials, or have terminated these trials.
- Regulatory bodies such as the FDA have issued guidance for industry, investigators, and institutional review boards on conducting clinical trials during the COVID-19 pandemic. Methods that could help keep the research going or get started include virtual visits, phone interviews, self-administration, and remote monitoring.

COVID-19 Impact on Pharmaceutical Value Chain – Clinical Trials



A Closer Look at COVID-19 Impact on Clinical Trials – Disrupted Clinical Trials

April–January 2021



Source: GlobalData, Pharma Intelligence Center, Clinical Trials Database (Accessed January 11, 2021)

COVID-19 Impact on Pharmaceutical Value Chain – Respondents' Perspective



A Closer Look at the Most Impacted Pharmaceutical Value Chain Components

Respondents' Perspective on Drug Development	Respondents' Perspective on Supply Chain	Respondents' Perspective on End-User Experience
<p><i>"[Drug development will be affected the most due to] delays to accessing patients to be involved in non-COVID-19 trials and the acceleration needed towards digital/remote trials." – Europe VP/SVP/EVP</i></p> <p><i>"Companies, regulators, clinicians will need to rapidly adjust expectations of clinical trials to overcome the delays and subsequent ripple effects from 2020." – Europe VP/SVP/EVP</i></p> <p><i>"COVID-19 has demonstrated that new paths can be explored when it comes to drug development and time to market. The industry will be impacted in general based on these possibilities [not new but now more evident and proven]." – North America C-Level Executive</i></p> <p><i>"[Drug development] process has gone unchanged for far too long. There has been resistance to modernization and adoption due to all the approvals and the extremely high costs. COVID-19 nearly brought clinical trials to a standstill. It exposed weaknesses in the current process. There should be substantial changes in the next 12 months." – North America VP/SVP/EVP</i></p>	<p><i>"The launch of numerous COVID-19 vaccines is going to 'flood the zone' and dominate supply chains in 2021. This will squeeze out capacity for non-COVID-19 medications." – North America Manager</i></p> <p><i>"Companies and governments may re-evaluate the balance of geography & dependence in manufacturing location and outsourcing." – Europe Director</i></p> <p><i>"Diversion of resources for pandemic response has likely resulted in deep negative impact on sustainability and business survival of companies involved in non-pandemic-related businesses from transport, materials production, manufacture, etc." – Asia Pacific VP/SVP/EVP</i></p> <p><i>"COVID-19 showed us the supply chain is fragile. I'm not convinced we are fully recovered from the shock." – North America C-Level Executive</i></p> <p><i>"Supply chain will become a more critical issue as restrictions due to political issues may disrupt supply of key raw materials, APIs, and finished dosage forms." – North America VP/SVP/EVP</i></p>	<p><i>"The inability of patients to have easy direct access to healthcare is seriously affecting the diagnosis and treatment of anything that is not COVID-19." – Middle East and Africa C-Level Executive</i></p> <p><i>"The biggest disruption is distraction: So much of the healthcare landscape across all of the value chain has been focused on COVID-19 that will still crowd out other meaningful developments. In 2021, much of this will be supply chains for the distribution of vaccines taking up headspace." – Europe VP/SVP/EVP</i></p> <p><i>"Due to loss of employment and then loss of coverage, access and affordability will be critical for even more people." – North America VP/SVP/EVP</i></p> <p><i>"Access to services continues to be restricted in Q1 2021." – Europe VP/SVP/EVP</i></p> <p><i>"Experience will be the reality—whether negative or positive. Patients will react on this experience." – Middle East and Africa Director</i></p>



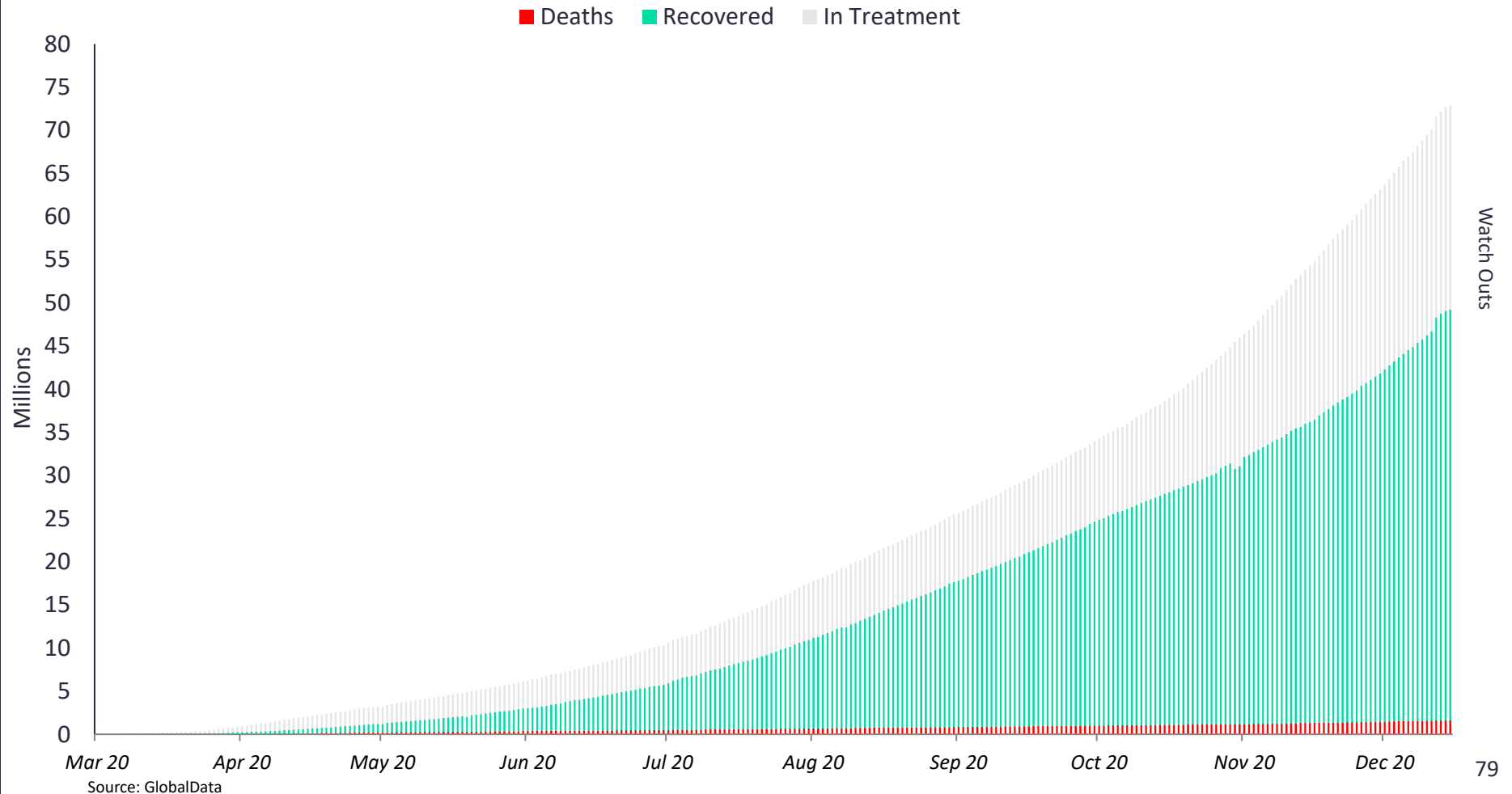
Watch Outs

- The COVID-19 pandemic has now killed over 1.98 million people worldwide. This sobering milestone comes nearly 12 months after the first death was reported on January 11 in Wuhan, China.
- The virus has spread to 194 countries, with more than 92.9 million confirmed cases, and the highest official case counts are in the US, India, Brazil, Russia, France, the UK, Turkey, Italy, Spain, and Germany.
- The number of confirmed cases in the US exceeds 21 million. The US reported over one million new confirmed cases each week in late 2020.
- The US has recorded the highest number of fatalities, with more than 364,000.
- With multiple vaccines having demonstrated efficacy in disease prevention now being rolled out, hope has been restored for regions that have failed to control the outbreak.

COVID-19 Outbreak – A Slow Return to Normal by YE 2021



The COVID-19 outbreak has proven both devastating and nearly impossible to control for many regions; however, hope for control is on the horizon due to vaccine approvals and implementation.





COVID-19 Interventions – Vaccines Rollout on a Global Stage

2020 has proven to be a remarkable year for development of agents to address COVID-19, particularly for vaccines, which have been developed in record time and will see significant uptake.

Therapies	Vaccines
<ul style="list-style-type: none">Continued use and uptake of Veklury in combination with immunomodulators such as OlumiantAs understanding of COVID-19 is still nascent, patient management is still evolving, and will continue to incrementally improve over timeAntibody-based therapies such as bamlanivimab and REGN-COV-2 will see strong use in the near-term, especially in regions such as the US where the outbreak has devastated hospitalsMultiple immunomodulators with novel mechanisms of action will readout, possibly transforming the COVID-19 treatment paradigmAs highly efficacious vaccines are already being employed in high-risk groups in regions such as the US and UK, the window of opportunity for treatments is rapidly contracting, especially for those in early-phase development	<ul style="list-style-type: none">Pfizer/BioNTech's BNT-162 and Moderna's mRNA-1273 will drive rapid declines in morbidity and mortality in select regions in early 2021Vaccines such as Russia's Sputnik V and Sinopharm's BBIBP-CorV will see significant use in developing and emerging marketsVaccines from Johnson & Johnson, AstraZeneca, Novavax, and others will subsequently play a role in controlling the outbreak throughout 2021 and into 2022Groups considered high-risk, such as those with comorbidities or working in healthcare, will be targeted first, with wider, larger groups being subsequently targeted in order to develop herd immunityThe timing for establishing control of the outbreak will firmly depend on the efficacy and availability of vaccines in combination with effective rollout strategies

Watch Outs

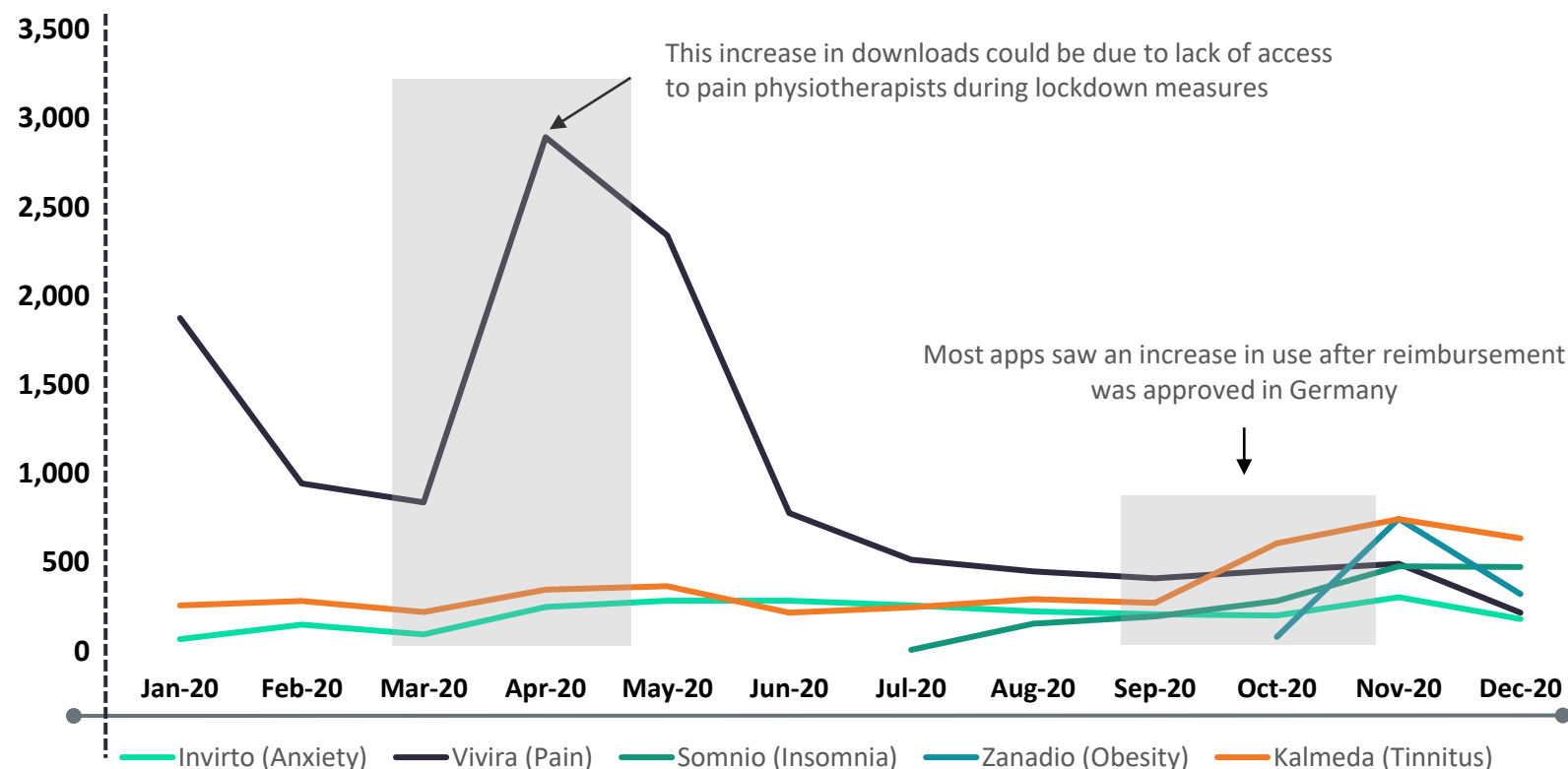
- There were several significant events in the digital therapeutics space in 2020, which are likely to lead to increased use of these products in 2021 and beyond.
- For example, in Germany, the first prescription digital health applications (Digitale Gesundheitsanwendungen – DiGA) have been approved for reimbursement since September. These span a range of conditions including tinnitus, insomnia, anxiety, pain, and obesity. Now, approximately 73 million people can get these applications prescribed and reimbursed.
- In the US, the FDA released new guidance in April that provides an expedited pathway to market for digital health therapeutic devices for the treatment of psychiatric disorders for the duration of the COVID-19 pandemic. One company, Orexo, reported that it accelerated the launch of two of its products in July as a result of this guidance, and also hopes to launch another product in Q2 2021, a year ahead of schedule.

Digital Therapeutics

Trend to Watch – Digital Therapeutics

Germany is the first country to provide national reimbursement of digital health applications

Mobile App Downloads of Digital Therapeutics Reimbursed in Germany



Source: GlobalData

- Medical misinformation can include pseudoscience (or unscientific claims) and junk science, which involves claims based on fraudulent or disproven data.

- The spread of misinformation, especially on social media, is an increasing public health concern, particularly in the midst of the ongoing COVID-19 crisis.

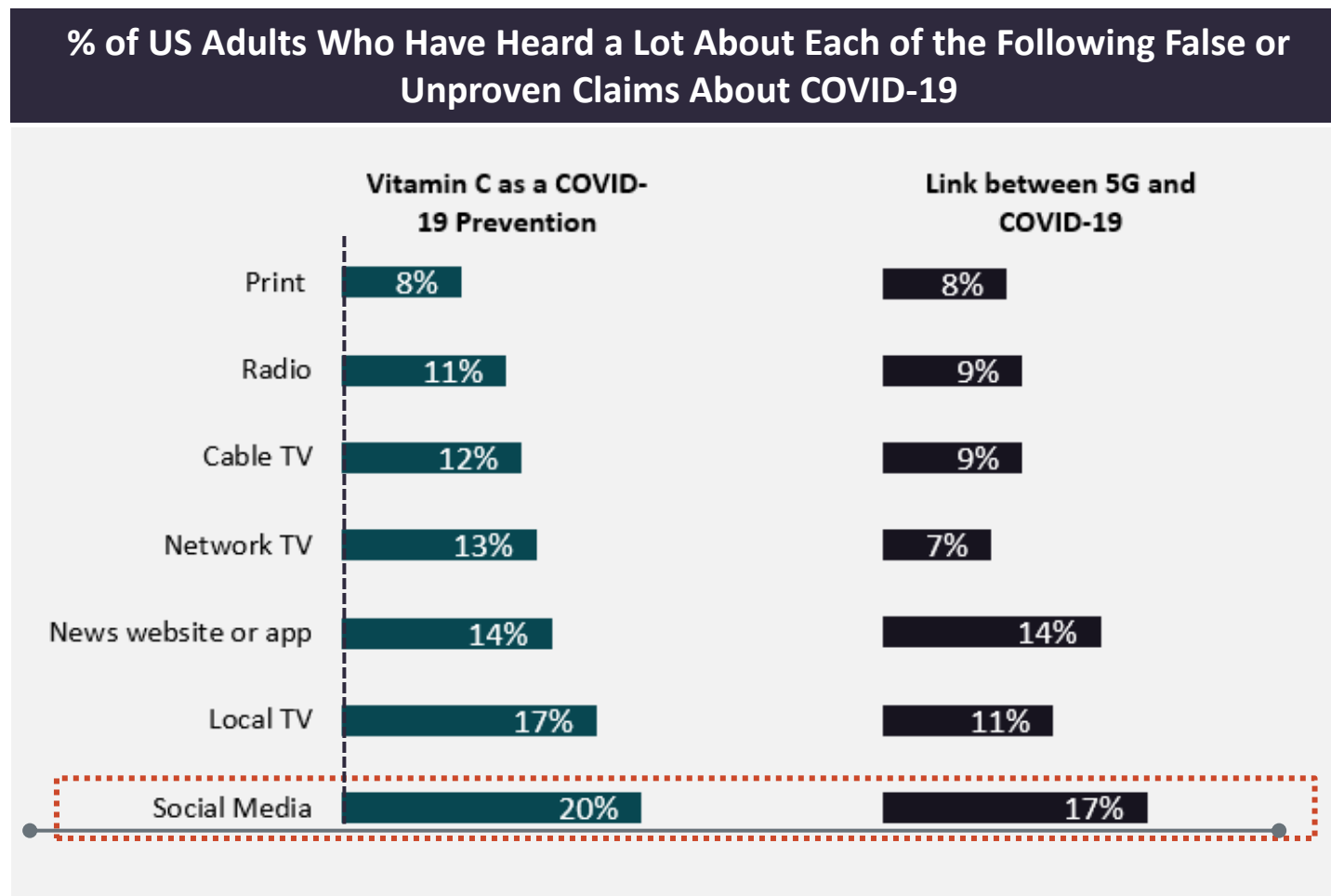
- For example, a recent survey by the Pew Research Center found that people who received most of their news through social media heard more about unproven COVID-19 theories than those who received their news from other sources.

- A study by the London School of Hygiene & Tropical Medicine surveyed 8,000 people about COVID-19 vaccines. Results found that 54% of those in the UK and 41.2% in the US said they would “definitely” take a vaccine. After being shown online misinformation, this dropped by 6.4% in the UK and by 2.4% in the US.

Misinformation



On the cusp of one of the largest immunization programs in history, widespread online misinformation about COVID-19 vaccines has the potential to severely undermine these efforts.



Watch Outs

- For pharma, COVID-19 will lead to permanent changes in work across many functions including sales and marketing, manufacturing, and clinical trials.
- COVID-19 rapidly undermined traditional sales and marketing methods, leading to increased demand for online marketing platforms that allow remote engagement with physicians. This is likely to continue for some time until hospitals and other healthcare settings are no longer overwhelmed and also are safe for in-person visits.
- Clinical trial investigators have also increased use of RPM, connected devices, and telemedicine to monitor participants during the pandemic. This trend is likely to continue post-COVID-19 in line with a shift towards virtual trials.
- Manufacturers are likely to accelerate the adoption of new technologies in order to mitigate any potential risk to supply chain disruptions due to reduced workforce situations in the future. These include AI, virtual reality, and digital twins.

Future of Work



COVID-19 has allowed businesses to implement profound changes to the way we work. From digitizing processes to reshaping supply chains, the pandemic will leave a lasting legacy.



Watch Outs

Sustainability is not viewed as an important priority for the pharmaceutical industry, but it needs to be.

- Sustainability has morphed into an umbrella term for environmental, social, and governance issues, and the spotlight is now on corporations to address these concerns.
- Over the coming decade, sustainability will transform the way that business is conducted.
- Pharma companies that take sustainability seriously now will be better placed to succeed in the future.

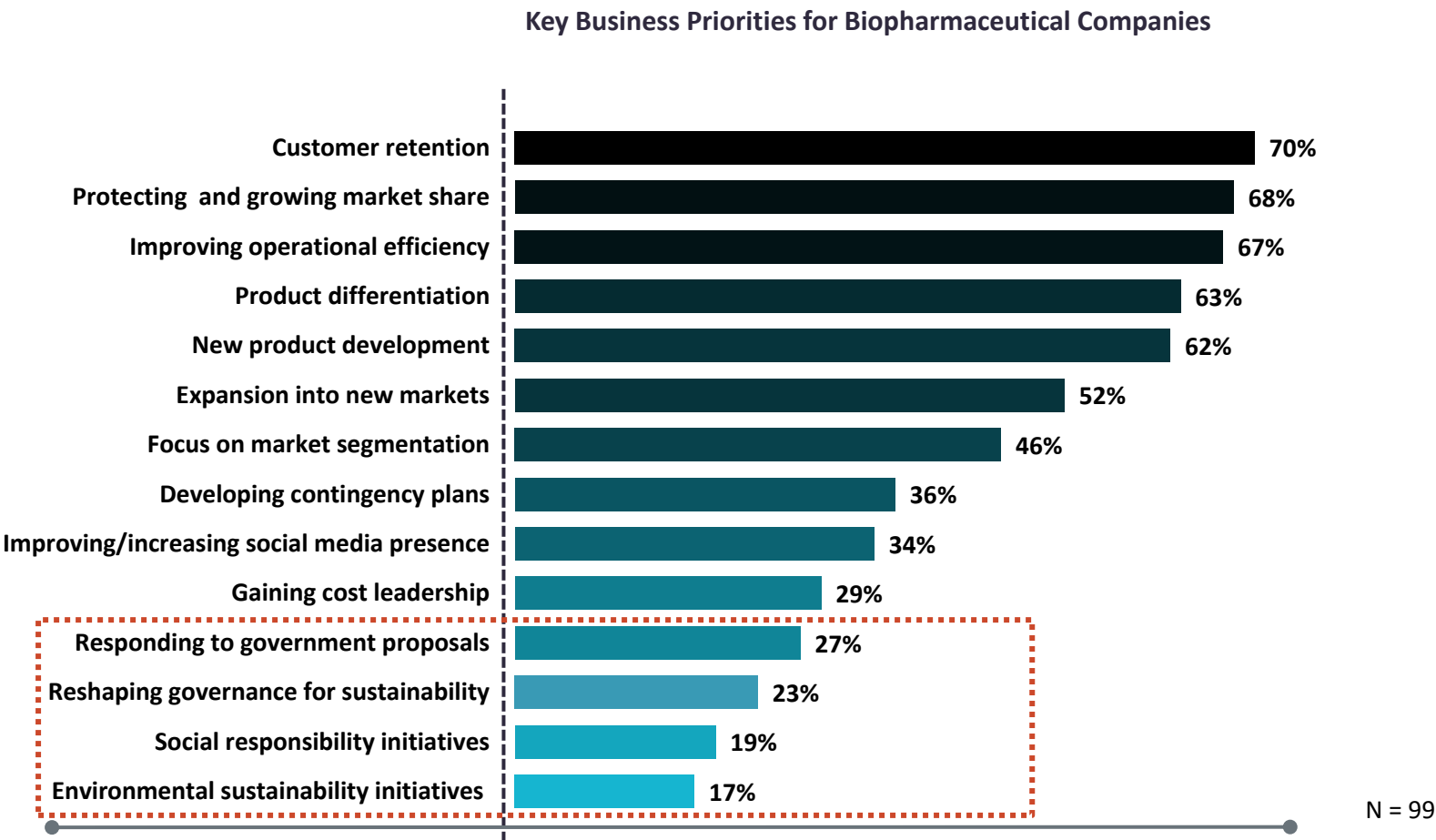
ESG Ratings for Select Biopharmaceutical Companies

Company	Market value \$bn	Country	CSHub	MSCI	Arabesque S-	Sustainalytics Ray
Johnson & Johnson	394.6	USA	98	BBB	64	33
Roche	295.6	Switzerland	96	A	63	25
Pfizer	214.7	USA	84	B	51	30
Novartis	211.4	Switzerland	93	A	57	21
Merck & Co	205.2	USA	96	A	57	23
AbbVie	174.9	USA	96	A	60	31
AstraZeneca	148.6	UK	97	AA	64	27
Bristol-Myers Squibb	143.8	USA	91	A	51	28
Amgen	138.2	USA	91	AA	49	21
Eli Lilly	136.2	USA	85	A	62	34
Sandoz	127.5	France	93	A	52	28
Novo Nordisk	123.3	Denmark	98	AAA	65	22
CSL	101.8	Australia	94	A	51	25
GlaxoSmithKline	94.6	UK	93	AA	41	23
Gilead	76.0	USA	93	AA	55	23
Bayer	55.3	Germany	74	BB	48	34
Takeda Pharmaceutical	54.0	Japan	97	A	43	30
Biogen	38.3	USA	90	A	59	24
Astellas Pharma	28.7	Japan	97	AA	65	20
Alexion Pharmaceuticals	28.0	USA	49	BB	47	19
Otsuka Holdings	22.7	Japan	67	BBB	54	40
Eisai Co	22.5	Japan	86	AA	50	31
UCB	21.4	Belgium	92	A	60	26
Teva	16.9	Israel	77	B	52	38
Vifor Pharma	8.8	Switzerland	79	A	61	29
Mylan	8.4	UK	79	BB	48	37

Sustainability



Sustainability is an important theme for 2021 and beyond as the pharmaceutical industry grapples with a number of ESG issues including the opioid crisis, lack of transparency on pricing, price gouging, and kickbacks.



Q: How much of a priority are the following over the next 12 months for your organization? (N = 99)
 Source: GlobalData, Healthcare Industry Business Confidence Report 2020


Watch Outs

US Election Fallout



The Joe Biden presidency, along with Democrat control of House and the Senate, has major implications for the pharmaceutical industry over the next four years, but controlling the pandemic will be the priority in the near term.

A Biden government will push for broader healthcare coverage, lower drug prices, and a federal-led strategy to tackle the pandemic.

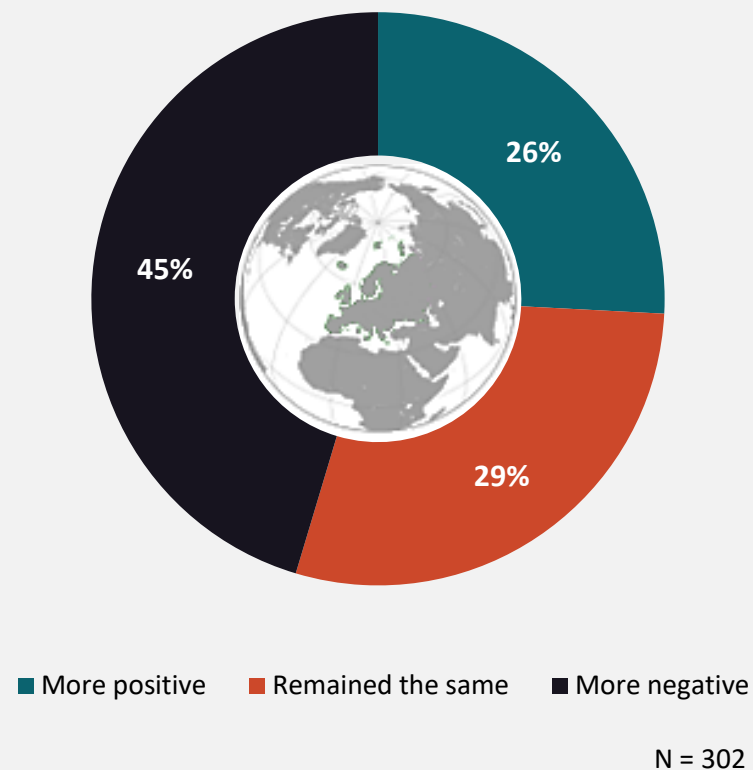
Issue	What Will Likely Happen in a Biden Presidency 	Implications for Pharma
Prescription Drug Pricing	<ul style="list-style-type: none"> Federal government drug price negotiations for Medicare and other payers Drug pricing bills involving taxation schemes and targeting launch pricing 	<ul style="list-style-type: none"> Reforms aimed at lowering drug prices will cut into profits and have an impact on payer negotiations, prompting the need for revisiting reimbursement strategies
Affordable Care Act (ACA) & Medicaid	<ul style="list-style-type: none"> Build on the ACA by increasing premium assistance and creating a Medicare-like public option plan that would be available to anyone Federal government could negotiate drug prices for Medicare and other public and private purchasers 	<ul style="list-style-type: none"> More US patients could seek medical care due to having more comprehensive insurance coverage, driving up diagnosis rates, the size of the drug-treated resulting in increased revenue for pharma Unclear if a conservative Supreme Court will overturn certain parts of the ACA
COVID-19 response	<ul style="list-style-type: none"> Focus on free testing and increased access to treatment and vaccines Providing aid to state and local governments Less political pressure on the FDA to expedite EUAs and vaccine Management of the pandemic at a national level including invoking DPA with various industries, including pharma 	<ul style="list-style-type: none"> Possibly longer approval times for vaccines and therapeutics New DPA contracts for PPE, diagnostic tests, etc., could impact companies' production capacity on certain R&D activities not deemed critical at this time.
Mental Health and Addiction	<ul style="list-style-type: none"> ACA will be expanded, assuming it is not repealed by a conservative-leaning Supreme Court. Suicide prevention programs for LGBTQ teens and veterans will likely be strengthened and funding for SAMHSA could increase. 	<ul style="list-style-type: none"> Continued bipartisan push for pharma companies to bear some responsibility for the opioid crisis with potential fines, criminal charges, etc.
Telemedicine	<ul style="list-style-type: none"> Expanded access to medical care through telemedicine Federal grant funding to assist broadband expansion in rural areas 	<ul style="list-style-type: none"> Opportunity for pharma to form strategic alliances with virtual care providers as part of branded patient support offerings. Opportunity for pharma/contract service providers to use telemedicine as part of virtual clinical trial processes.

- With the world still grappling with the COVID-19-induced economic recession, the UK and the EU have another challenge to face—Brexit. While economists are debating whether 47 years in the EU has helped or hurt the UK's economy, there is no doubt that the UK's decision to leave the EU will make both sides lose out economically.
- Even though the trade agreement between the EU and the UK was achieved just before Christmas, eliminating the tariffs and restrictive quotas on goods, there will be new customs and regulatory requirements to comply with that will add additional burden on supply chains and trading.
- Concerns related to funding for research and manufacturing, reduction in number of clinical trials conducted in the UK, increased drug pricing, and talent attraction across the life-sciences sectors will also continue to play a prominent role in the life-sciences industry post-Brexit.

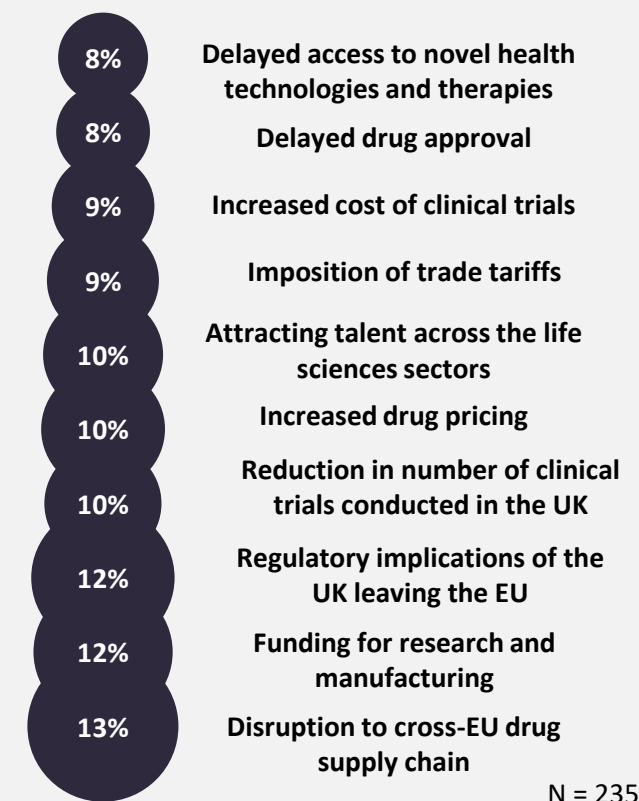
Brexit

Brexit will continue to generate uncertainty about the prospects of research, manufacturing, funding, regulatory affairs, and trade in pharmaceutical industry.

How has your sentiment on the impact of Brexit on the UK healthcare sector post-Brexit changed since the COVID-19 crisis started?



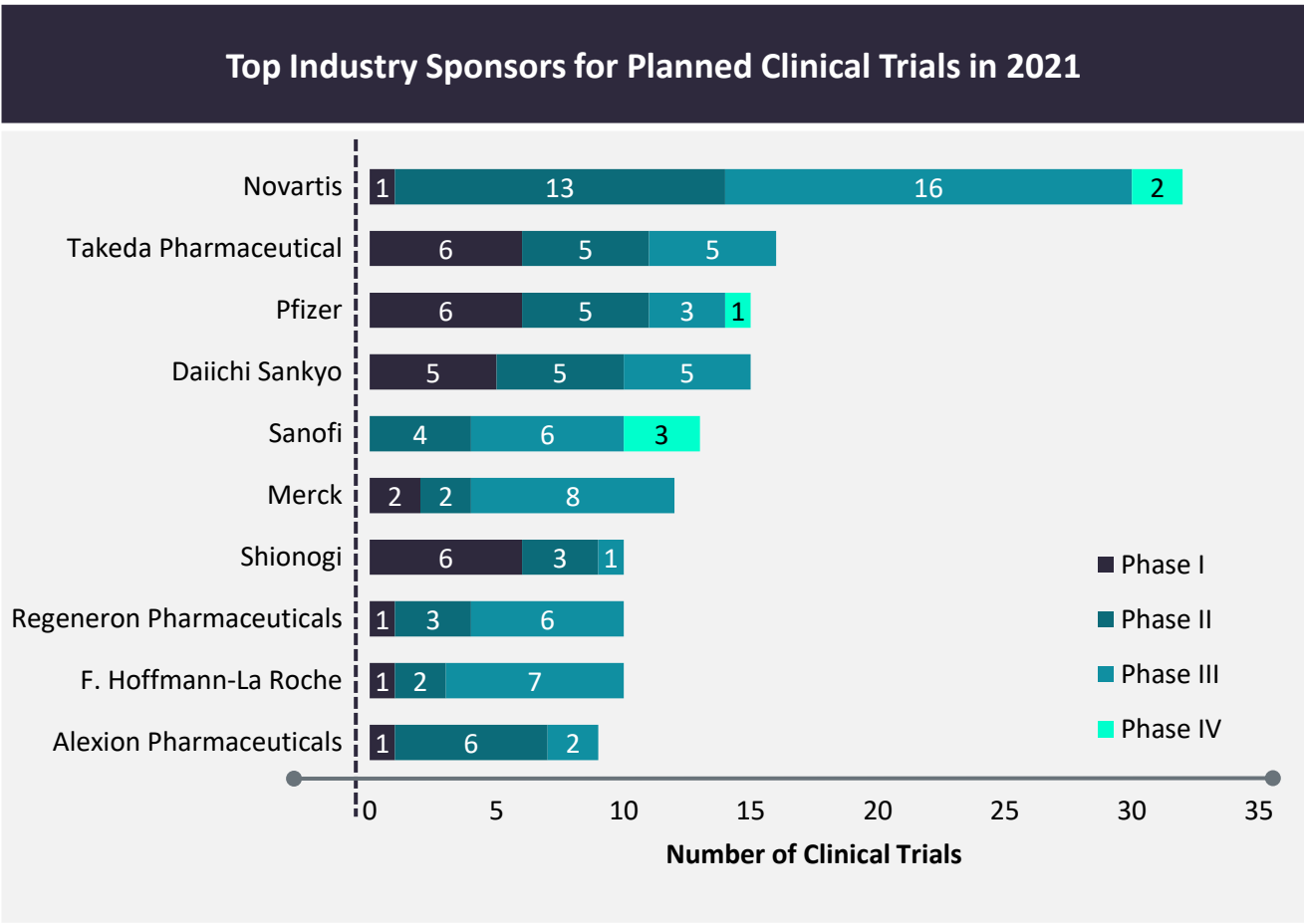
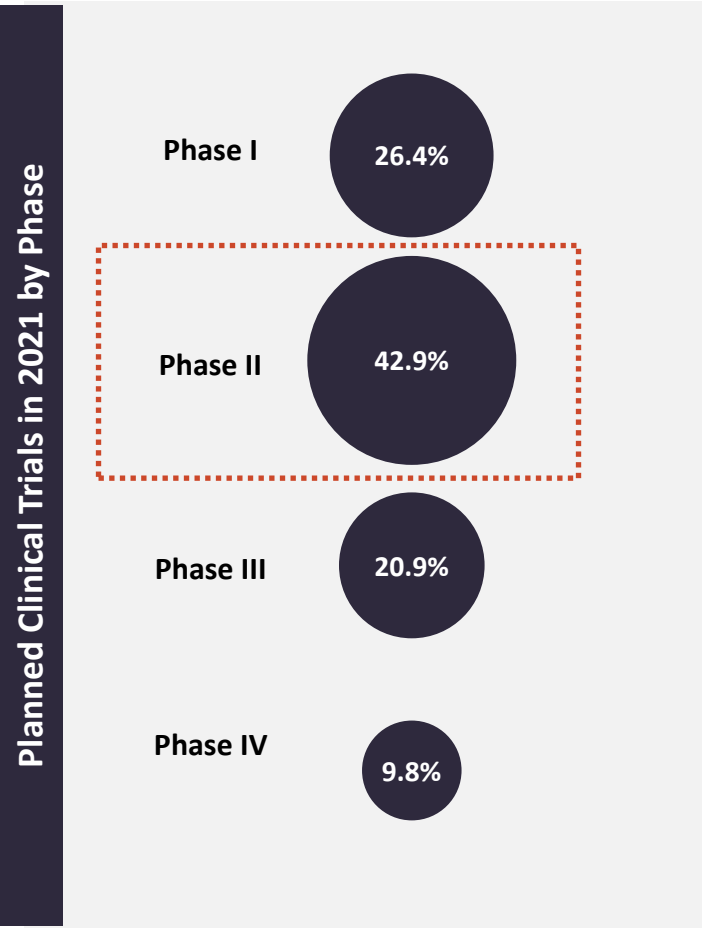
In your opinion, which of the following will impact the UK healthcare industry post-Brexit?



Planned Trials – 2021



GlobalData anticipates that **2,525 clinical trials have a planned initiation date in 2021**, the majority of which are in Phase II. About 62% of 2021 planned trials are industry-sponsored, and big pharma dominates the research space with Novartis as the top industry sponsor.

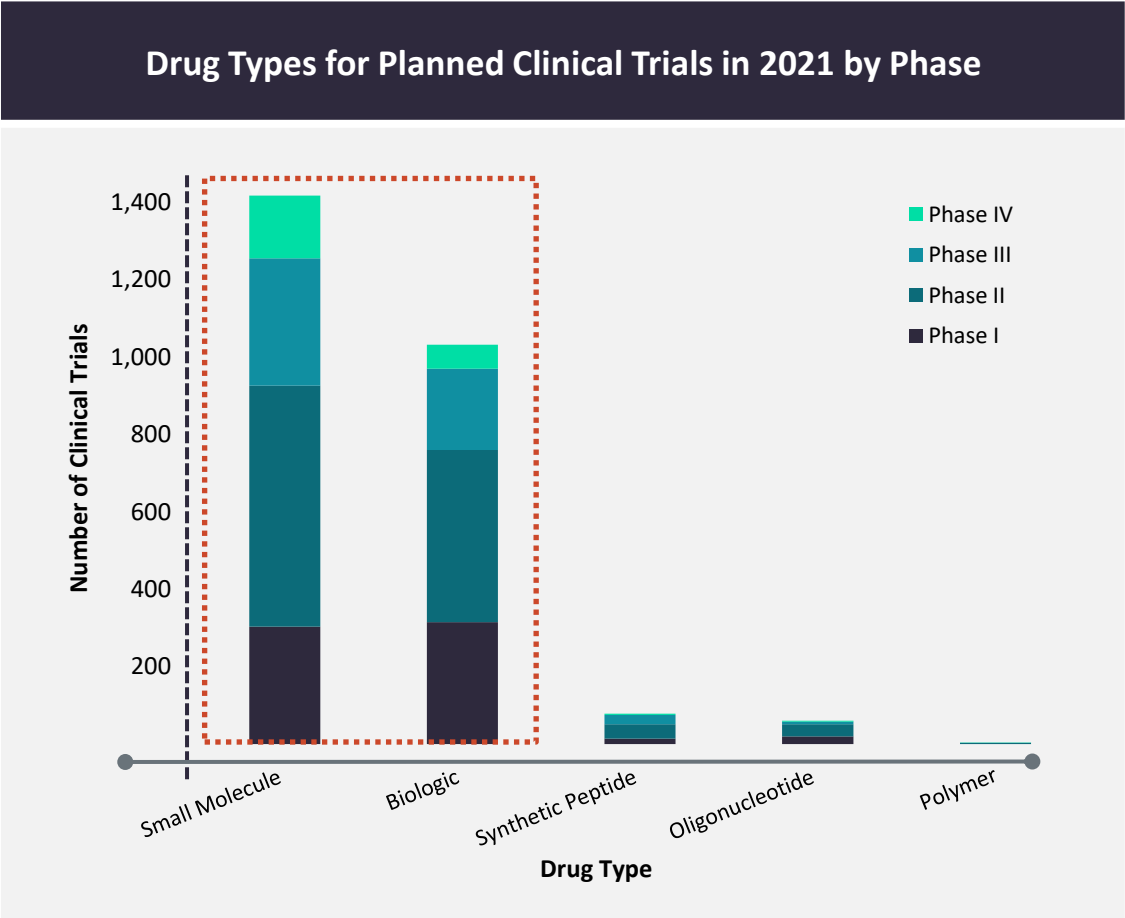
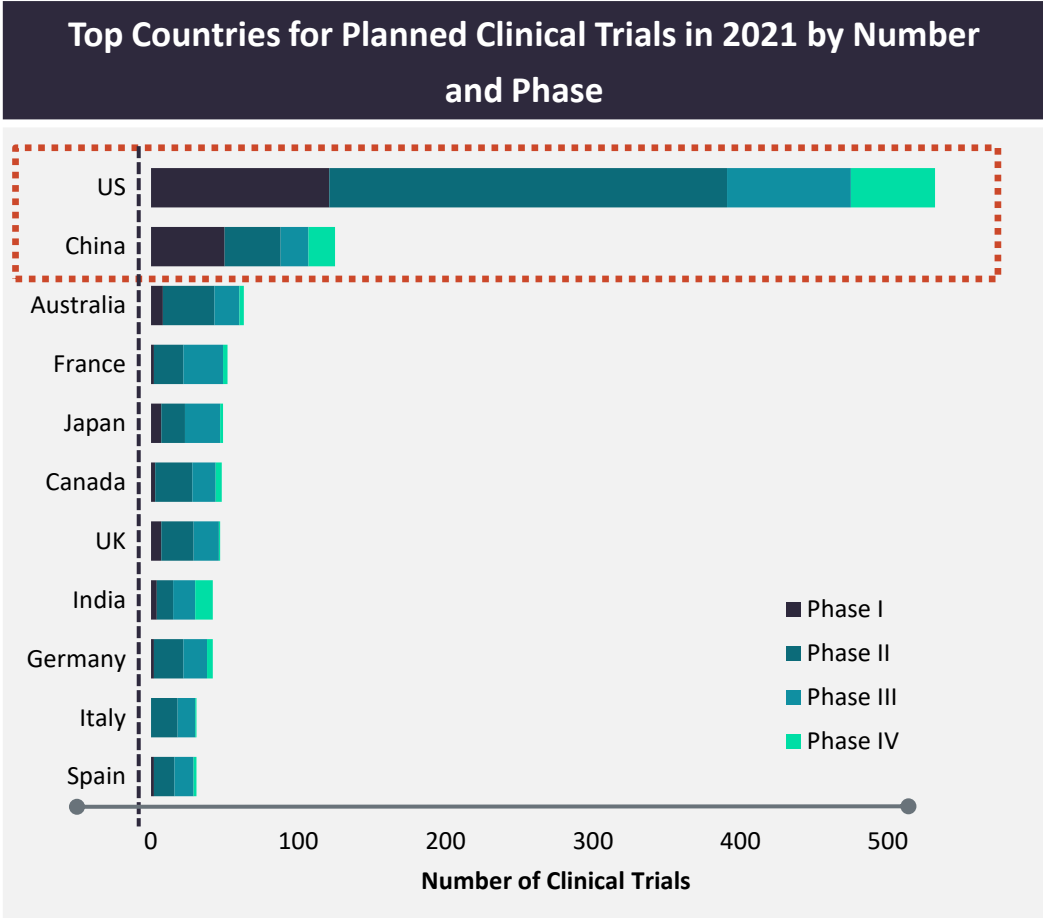


Watch Outs

Planned Trials – 2021



About **35% of planned trials (532)** with a location reported will be in the **US**, with China being a distant second. Small molecules will account for 55.9% of trials, representing more than all other molecule types combined. While **biologics will account for approximately 40.7% of trials**, this drug type will have an almost equal percent of Phase I studies compared to small molecules.

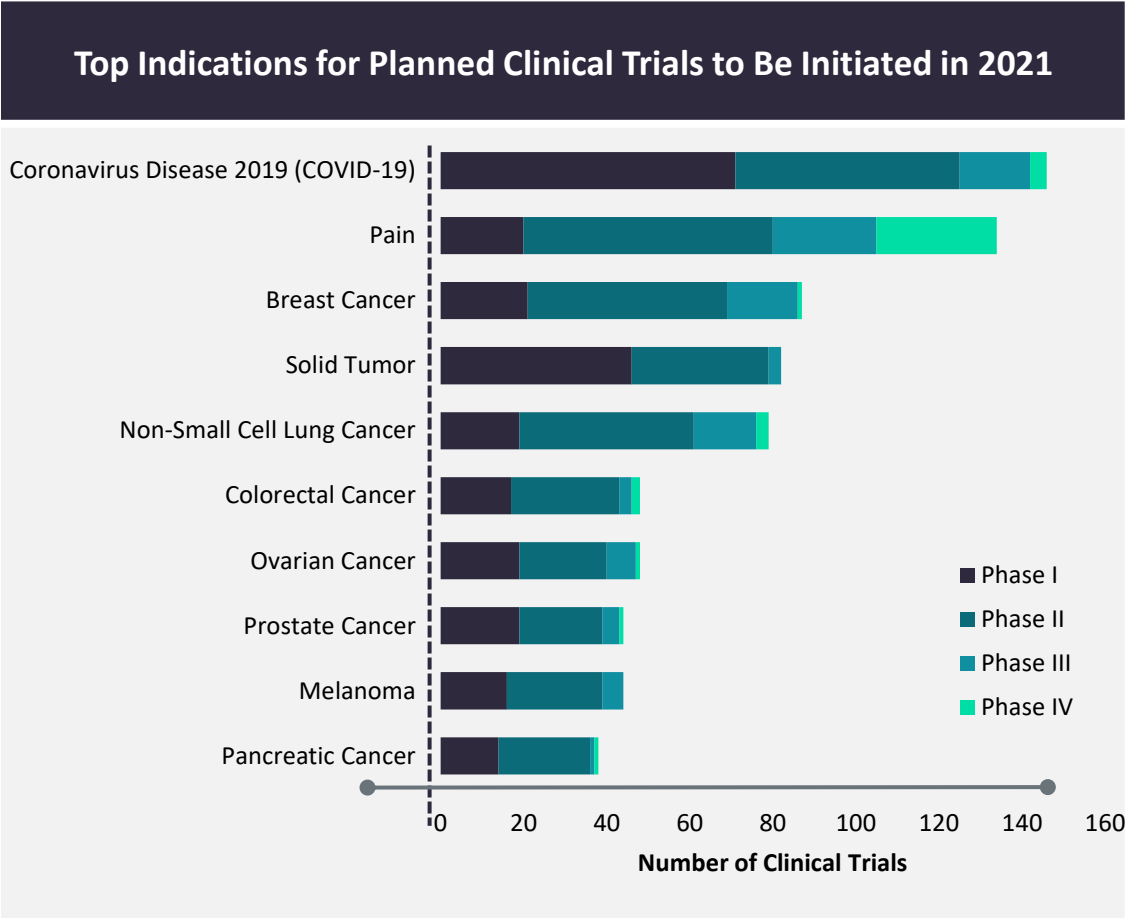
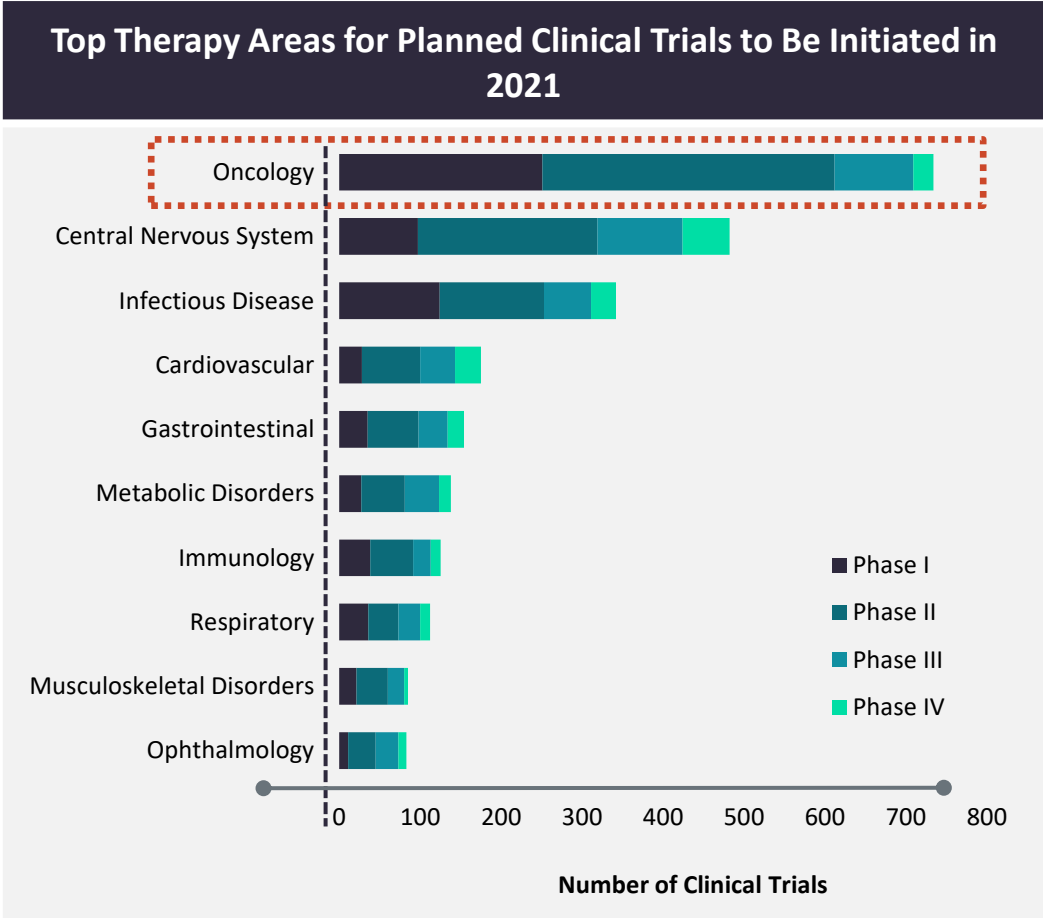


Watch Outs

Planned Trials – 2021



Oncology trials (734) will outnumber CNS (482) and infectious disease (342) trials. Notably, clinical trial investigations for COVID-19 take up the largest portion of planned trials in 2021.

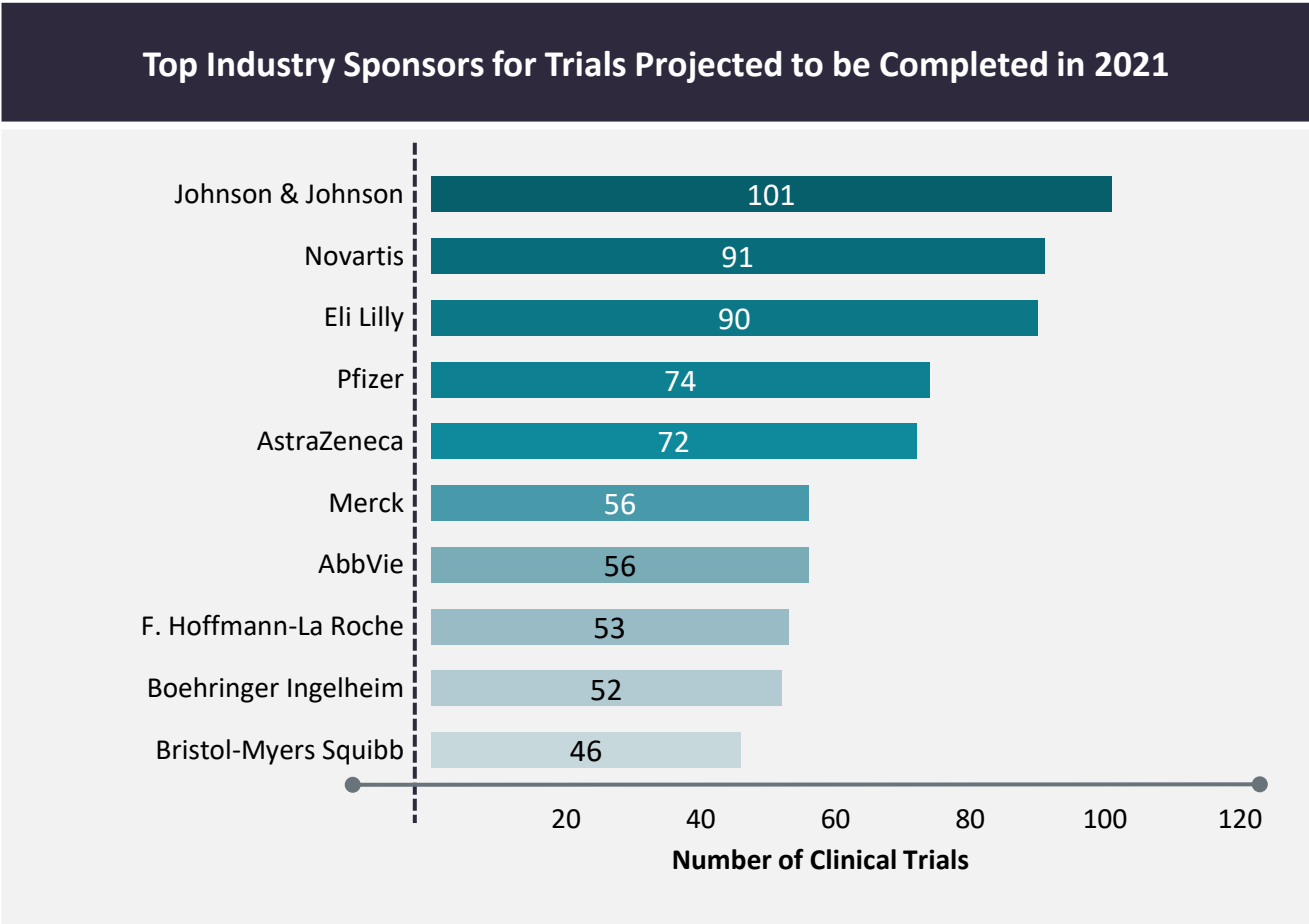
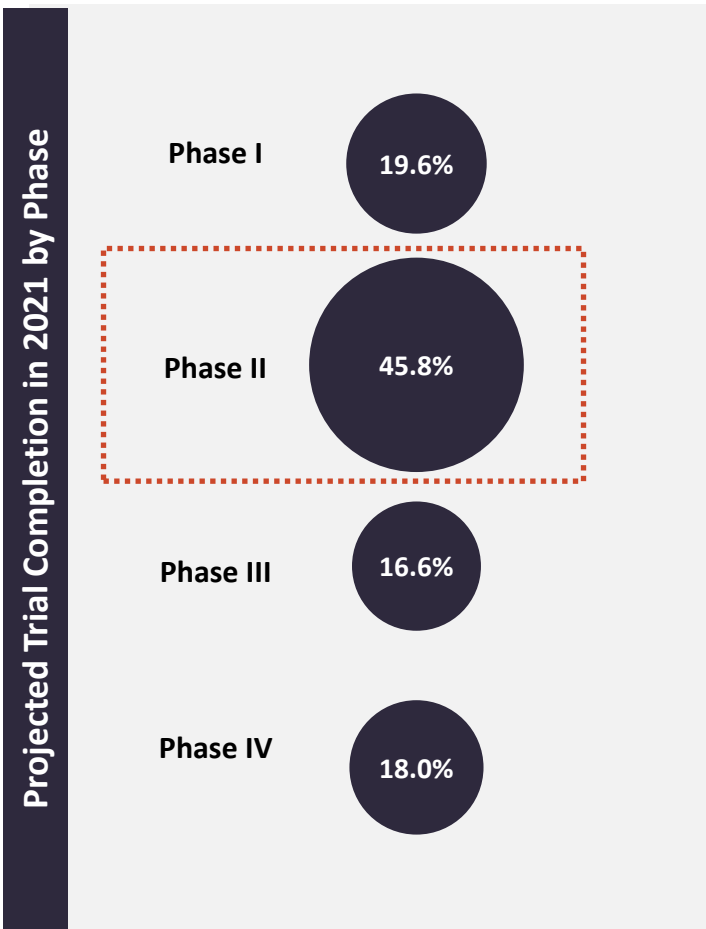


Watch Outs

Projected Trial Completions – 2021



The majority of trials projected to be completed in 2021 are in Phase II. Out of these, the **greatest proportion are ongoing, recruiting trials (60.9%)** followed by **planned trials (25.5%)**. Many of these planned trials will likely update or change their projected start and end date before they initiate. Johnson & Johnson, Novartis, and Eli Lilly will likely complete the most industry trials this year.



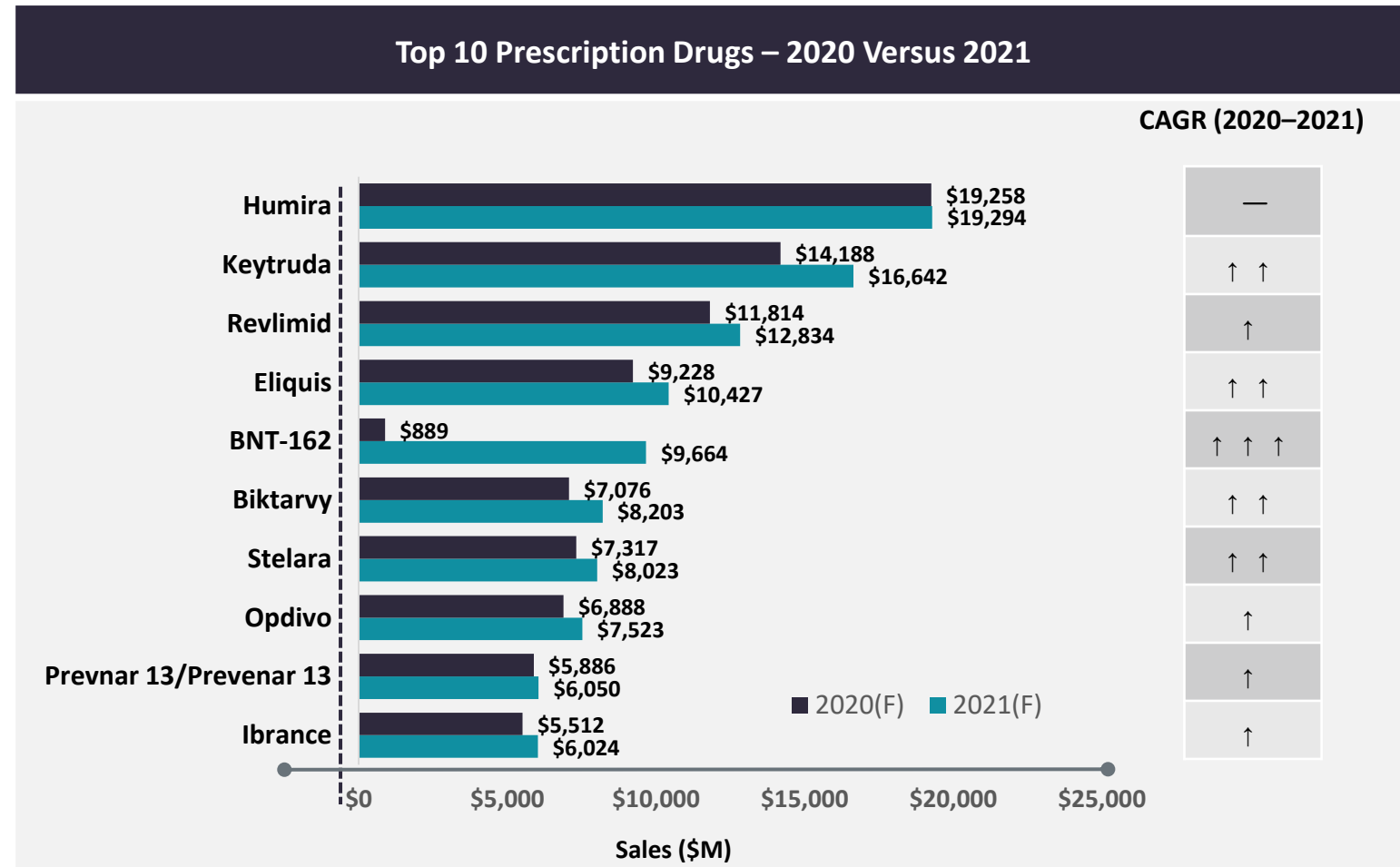
Watch Outs

- **AbbVie's Humira** was the best selling drug in 2020 and is **predicted to maintain its leadership role** into 2021.
 - Humira will experience the smallest growth (<1%). The growth of Humira in the US is offset by negative growth in other markets such as Europe and Japan, which have more readily adopted biosimilars.
- Keytruda sales display the second largest growth in 2021 (17%) due to its approval for additional oncology indications including triple-negative breast cancer and squamous cell carcinoma.
- BNT-162 is a new addition to the top 10 and enters into 5th place for 2021, due to the ongoing COVID-19 pandemic.
 - Pfizer/BioNTech SE's BNT-162 vaccine will experience the largest predicted year-on-year growth (987%)
 - BNT-162's success is predicted due to it being the first COVID-19 vaccine to receive emergency approval in a major market.
 - It is possible that the BNT-162 forecast will change dramatically as other COVID-19 vaccines near approval.

Top 10 Selling Drugs – 2020 Versus 2021



AbbVie's Humira will continue to lead prescription drug sales.



Source: GlobalData, Pharma Intelligence Center (Accessed December 9, 2020)
 Note: ordered by Analyst Consensus Forecast 2021 revenue

Watch Outs

Oncology

- Remains the single largest therapy area going into 2021, driven by high-growth drugs such as Keytruda and Revlimid.

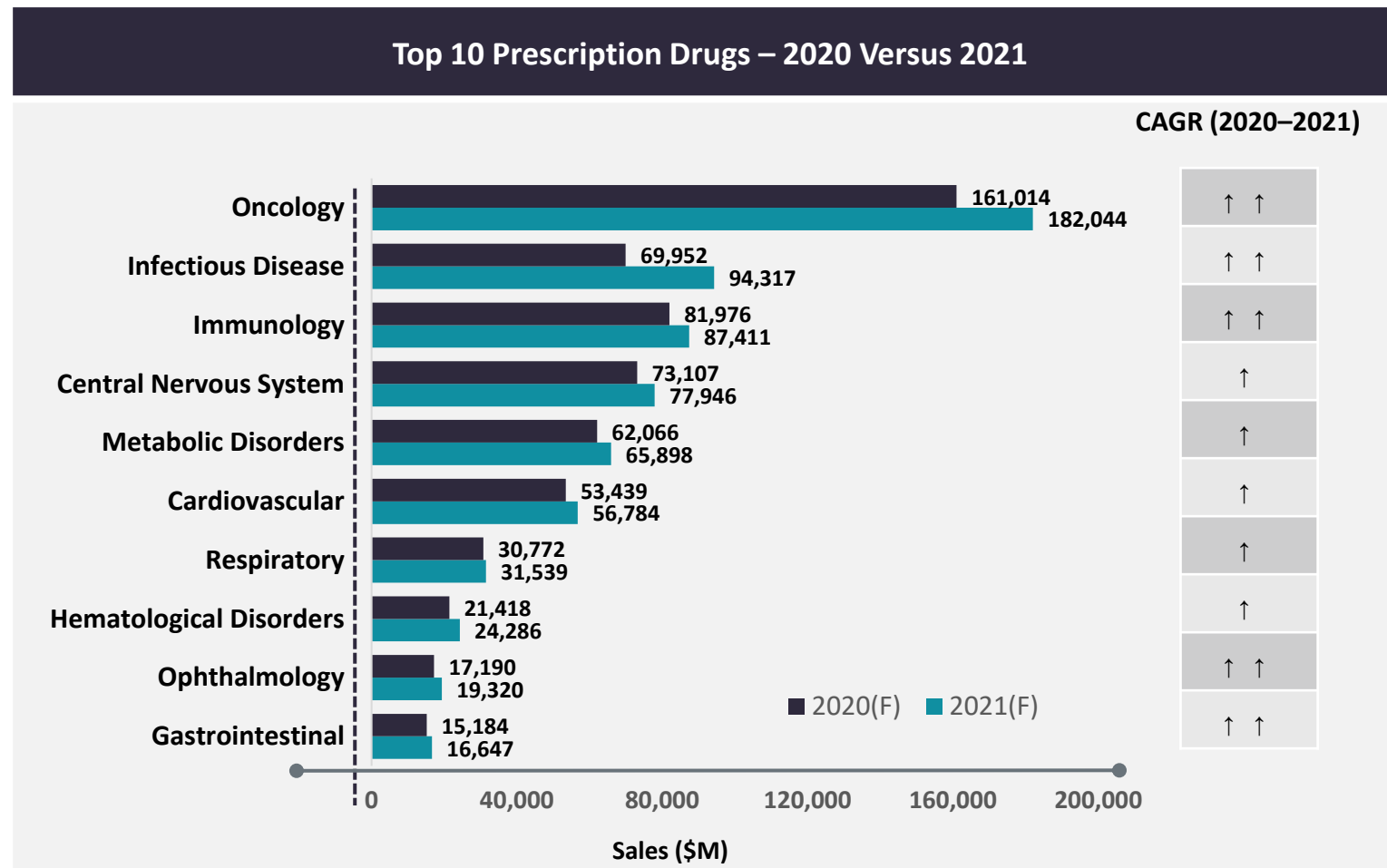
Infectious Diseases

- The appearance of COVID-19 and the subsequent pandemic has dramatically increased infectious disease projected sales.
- Infectious disease is predicted to grow 35%, outstripping oncology growth by a significant amount.
- This growth can be attributed to the large forecast for the new COVID-19 market, which is expected to be worth over \$26B in 2021.
- This increase is principally driven by the first wave of COVID-19 vaccines, such as Pfizer/BioNTech's BNT-162 and Moderna's mRNA-1273, which will account for 91% of infectious disease growth in 2021.
- It is possible that the infectious disease forecast will change dramatically as other COVID-19 vaccines near approval.

Top 10 Therapy Areas – 2020 Versus 2021



Oncology remains the top therapy area, but **Infectious Disease gained ground** due to the COVID-19 pandemic.



Watch Outs

Source: GlobalData, Pharma Intelligence Center (Accessed December 9, 2020)

Note: ordered by Analyst Consensus Forecast 2021 revenue

Drug Launches – 2021



At least **9** drugs currently in pre-registration stage are expected to launch in 2021 and are predicted by analyst consensus forecast to achieve blockbuster status by 2026, with **aducanumab** expected to have the biggest commercial launch. Drugs targeting the **CNS** and **oncology** dominate the list of future blockbusters. Drugs and vaccines for COVID-19 have been excluded, as those are expected to go through emergency approval pathways.

		Q1	Q2	Q3	Q4	2026 Sales
1.	Biogen Inc/Eisai Co's aducanumab for Alzheimer's disease	US Approval			Japan Approval US Launch	\$11.28B
2.	Bristol-Myers Squibb/bluebird bio's idecabtagene vicleucel for Burkitt lymphoma, and multiple myeloma	US Approval			US Launch	\$1.78B
3.	Ascendis Pharma's lonapegsomatropin for growth hormone deficiency		EU Approval US Approval		Global Launch	\$1.42B
4.	Apellis Pharmaceuticals' pegcetacoplan for paroxysmal nocturnal hemoglobinuria		US Approval EU Approval		Global Launch	\$1.41B
5.	BridgeBio Pharma's infigratinib phosphate for metastatic bile duct cancer		US Approval		Global Launch	\$1.28B
6.	Novo Nordisk's NN-9536 for obesity			EU Approval	EU Launch US Launch	\$1.16B
7.	Bristol-Myers Squibb's lisocabtagene maraleucel for follicular lymphoma, diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma and non-Hodgkin's lymphoma		Japan Approval			\$1.13B
8.	Takeda Pharmaceutical/Mirum Pharmaceuticals maralixibat chloride for Alagille syndrome and progressive familial intrahepatic cholestasis			US Approval	Global Launch US Launch EU Launch	\$1.06B
9.	TG Therapeutics ublituximab + umbralisib tosylate for follicular lymphoma and marginal zone B-cell lymphoma				US Launch	\$1.06B

Source: GlobalData Pharma Intelligence Center (Accessed January 8, 2021)

Watch Outs



Summary of Key Findings

Key Finding

What to Watch For

1

2021 will present a new and uncertain environment for the pharmaceutical sector to navigate

- The biopharmaceutical sector has traditionally been labelled as highly resistant to economic recessions and financial crisis, and while COVID-19 has presented and will continue to present some daunting challenges, ranging from supply chain disruption to suspension of clinical trials, the industry still retains its resilience despite the grim economic outlook.



- The COVID-19 crisis has forced the pharmaceutical industry to embrace a reactive, rather than proactive risk management approach, mainly focusing on short-term strategies and tactics. Unfortunately, the ongoing pandemic coupled with geopolitical events such as Brexit and the US political divide make long-term planning unfeasible due to continued uncertainty involved.

2

COVID-19 will continue to challenge the drug development process

- Bringing a drug to market is a risky and time-consuming process. However, despite seriously affecting the ability to carry out clinical research, COVID-19 is also proving to be a catalyst that may transform the drug development process, with technological innovations taking center stage in driving this change.



- Regulatory agencies play an important role in the pharmaceutical industry, ensuring that requirements and procedures related to drug development are duly met. While some of these regulations were relaxed due to COVID-19, it is important to maintain some of the regulatory reliefs post-pandemic, as more regulation often translates into more time to bring new drugs into the markets.

3

Technology-driven advancements will become pharma's integral part

- COVID-19 uncovered a strong need for remote work and monitoring deployments, in turn leading to increased technological uptake across the entire value chain. The accelerated expansion of innovations in the sector will be further sustained by increasing technological advancements and need to improve internal processes, healthcare access, and spending.



- Even though pharma used to display a conservative stance towards adoption of new technologies, COVID-19 triggered acceleration in its digital transformation efforts. Still, apart from agility and competitiveness that transformation provides, it increases industry's dependency on technologies and tech-savvy people who can help companies to capitalize on the opportunities that innovations bring.

Key Finding

What to Watch For

4

Drug pricing and reimbursement-related concerns will remain the leading impediment to industry growth

- In 2020, the COVID-19 crisis massively pushed up governments' borrowing in order to drag economies out of COVID-19-induced slumps. Given that healthcare spending represents a considerable proportion of budgets, the need to cut spending will likely put pressure on drug pricing and reimbursement schemes.



- While COVID-19 provoked significant financial disruption, it is too early to assess the full impact of the pandemic and what lengths the governments will take to reduce budget deficits. Aside from unprecedented spending, COVID-19 caused delays and cancellations of treatments for chronic conditions, which may lead to yet another crisis in healthcare.

5

Patent expiry of biologics, vertical integration, and clinical and manufacturing outsourcing are set to have a positive impact on industry

- Pressured by governments and regulators, pharmaceutical companies are looking into vertical integration and outsourcing as the ways to enhance profitability by decreasing internal operating costs. Although biosimilars growth has been rather slow, more governments are starting to recognize the cost-savings potential and create favorable regulatory environments to encourage biosimilar development and uptake.



- Vertical integration in the pharmaceutical industry has gained attention as companies, through ownership of main suppliers, are looking to decrease costs along the supply chain. But at the same time, vertical integration may lead to reduced competition, drive out smaller vendors, and eventually increase prices of products—which is something that governments are trying to prevent.

6

COVID-19 can help pharma to rebuild its crumbled public image

- The pharmaceutical industry has been battling a negative reputation that was shaped by the opioid crisis, high drug costs, questionable ethical practices, and corporate greed. COVID-19 has given a unique opportunity for pharma to redeem its reputation and heighten its value by delivering COVID-19 therapeutics and vaccines.



- COVID-19 highlights the rapid pace at which the global pharmaceutical industry can react to healthcare emergencies and find effective treatments solutions even if pressure is extremely high. Nonetheless, if the pharma industry fails to demonstrate that it put patients' needs before profits, its reputation may be further jeopardized.



Appendix

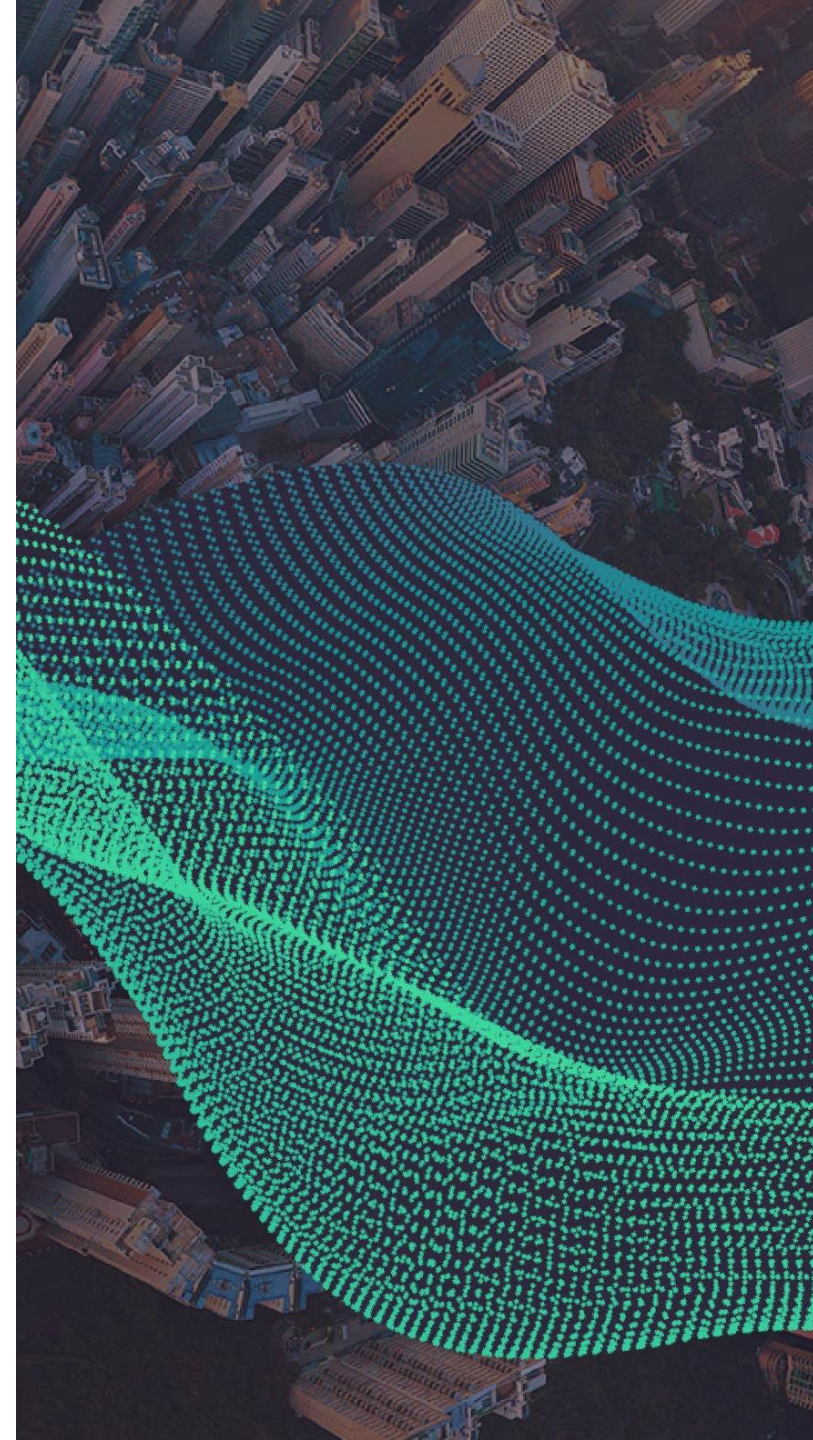
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Urte Jakimaviciute, MSc, is Senior Director of Market Research in the healthcare division at GlobalData, London. Her primary responsibility includes managing the market research process for the syndicated portfolio, thematic reports, and custom consulting projects. Urte has more than 10 years of experience in the market research industry; her experience is evenly split between qualitative and quantitative methodologies. Prior to GlobalData, she held management roles at market research agencies providing consulting and market research services to the healthcare/technology industries. Urte holds a MS in Economics from the LUISS Guido Carli University, Italy and BA in Information Management Systems from Vilnius University, Lithuania.

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Kathryn (Kitty) Whitney, MSc, is Director of Thematic Analysis in the healthcare division of GlobalData, London, where she is responsible for delivering all research projects within the space. Previously, she was the Principal Analyst for Digital Marketing Intelligence and Infectious Disease & Metabolic teams at Sociable Pharma. Kathryn's pharmaceutical industry knowledge is comprehensive, gained from her time working within Healthcare at Home's business strategic group, as well as her time in analysis positions at Intelligentsia Worldwide and IMS Health. Prior to this, Kathryn worked within biotechnology commercialization at both UCB and Wyeth. Kathryn has an MSc in Biotechnology from University College Galway (Ireland), and a BSc in Plant & Microbial Biotechnology from University College Cork (Ireland).



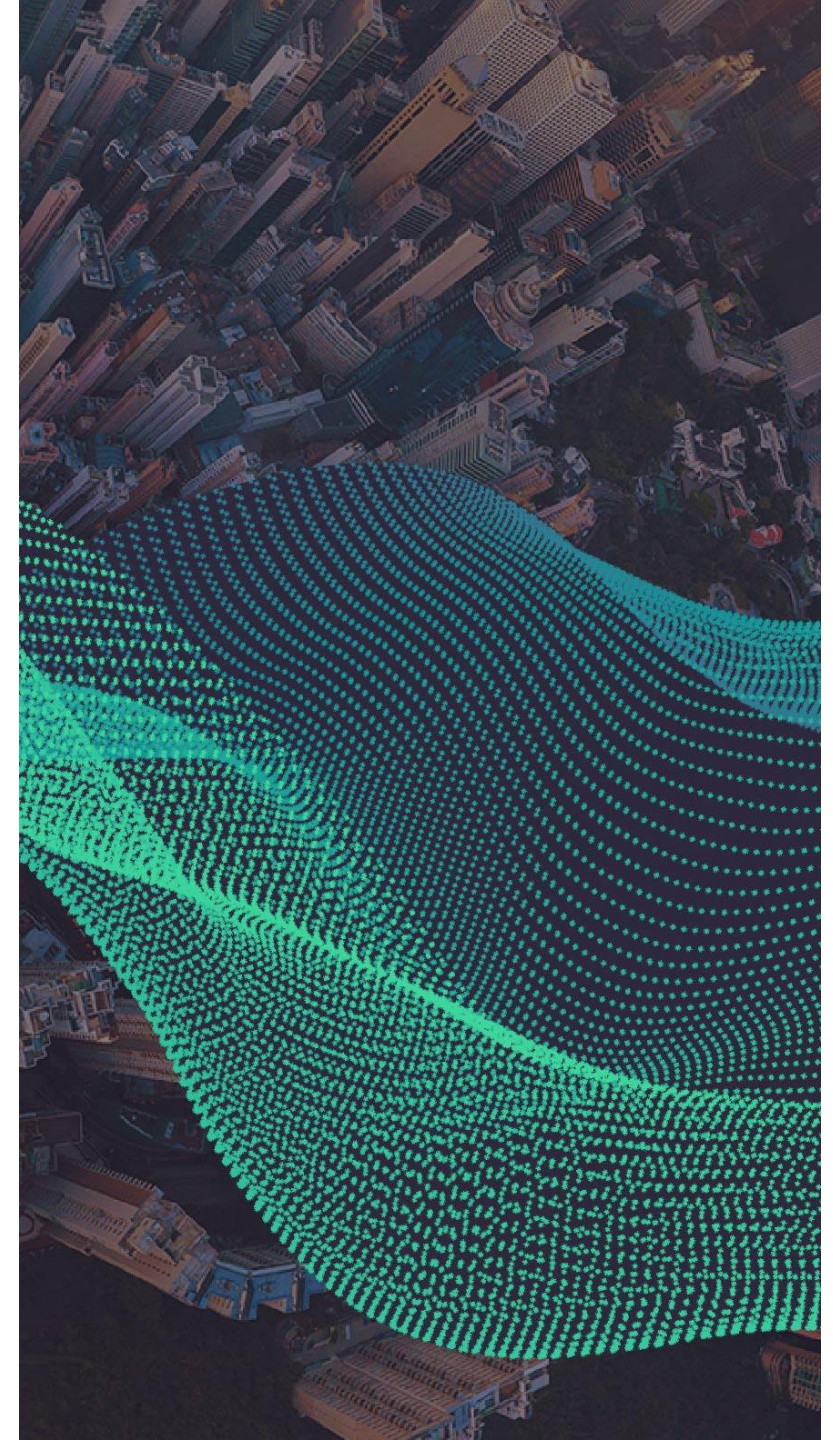
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Claire Herman, MPH is Global Director of Therapy Analysis and Epidemiology at GlobalData. She has more than 15 years of experience in the healthcare industry, during which she has led teams in the development and delivery of industry-leading competitive intelligence product offerings. Prior to her current role, Claire was the Director of Autoimmune/Inflammation, CNS, and Ophthalmology for Citeline/Informa's Trialtrove database, where she managed her team's daily operations and was involved in various product enhancement initiatives. Previously, she worked in consulting at Citeline, and as an analyst and epidemiologist at Decision Resources. Claire holds a Bachelor's degree from Wellesley College and a Master of Public Health degree in epidemiology from Boston University.

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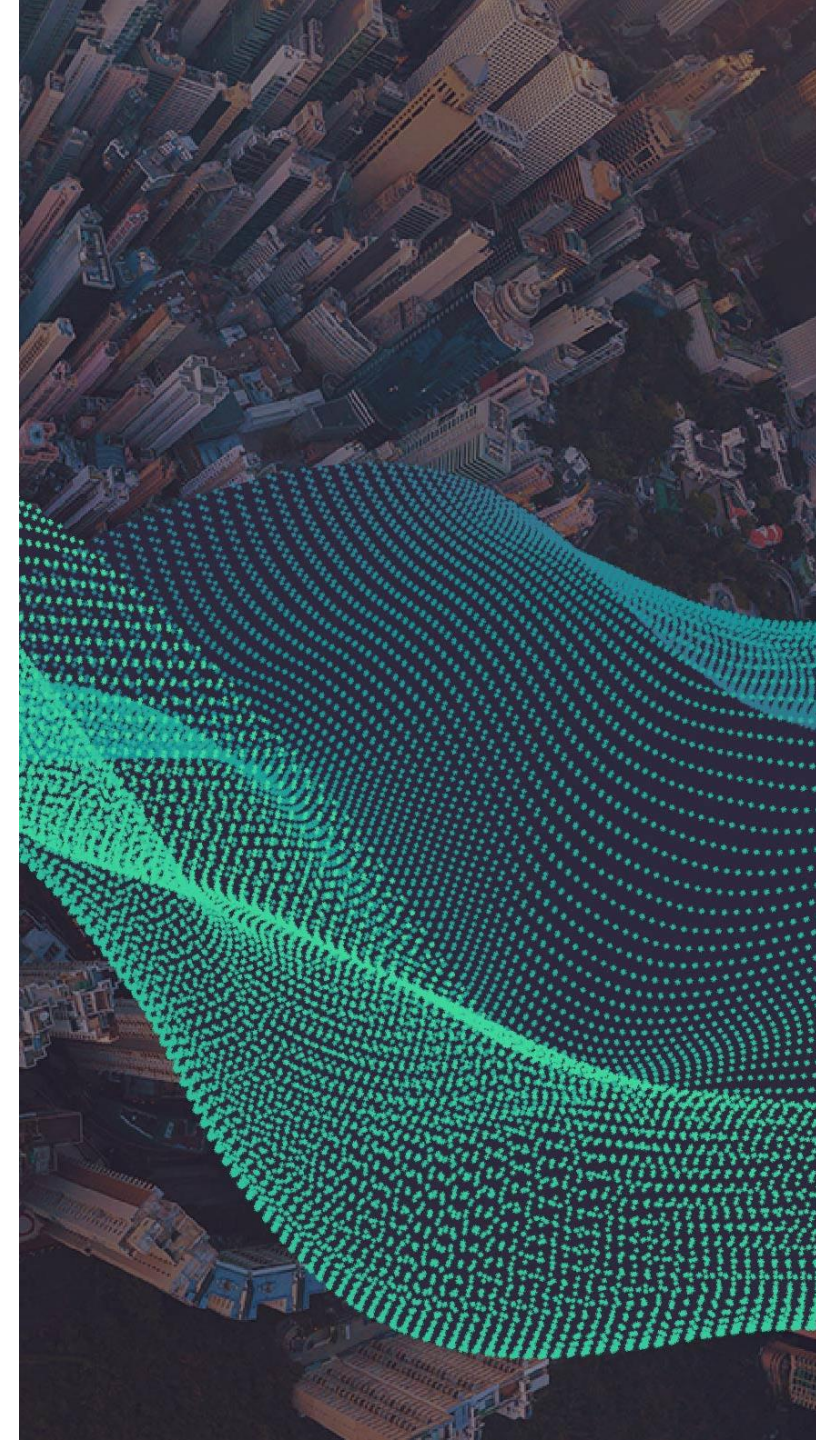
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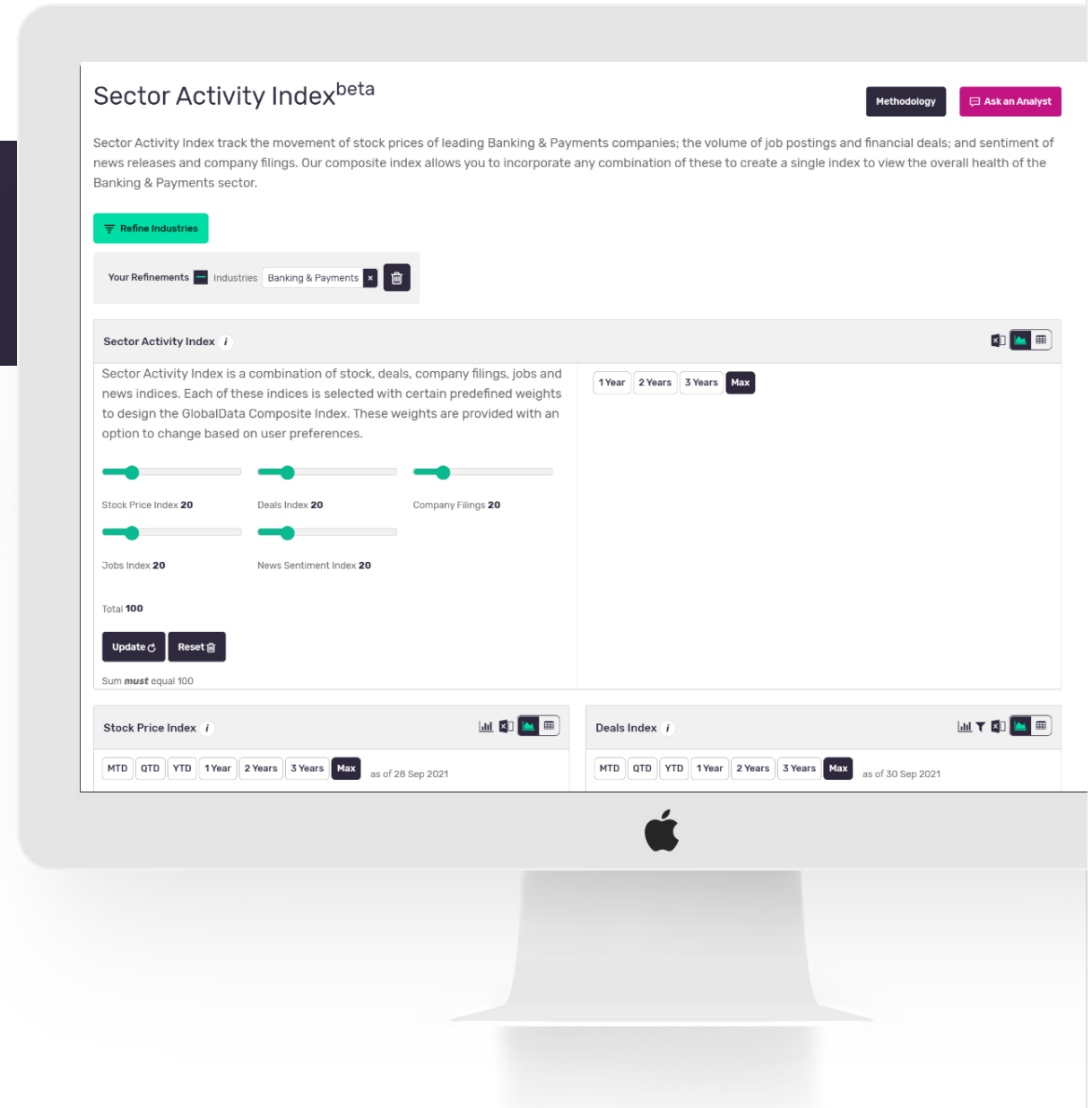
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