#68 Marketing Club 10th Riyadh

Global Pharmaceutical Market Trends

Tuesday 6-12-2022

8 PM EGY 9 PM KSA 10 PM UAE

FOUNDER & HOST

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GCC Regional Brand Manager

Global Pharmaceutical Market Trends

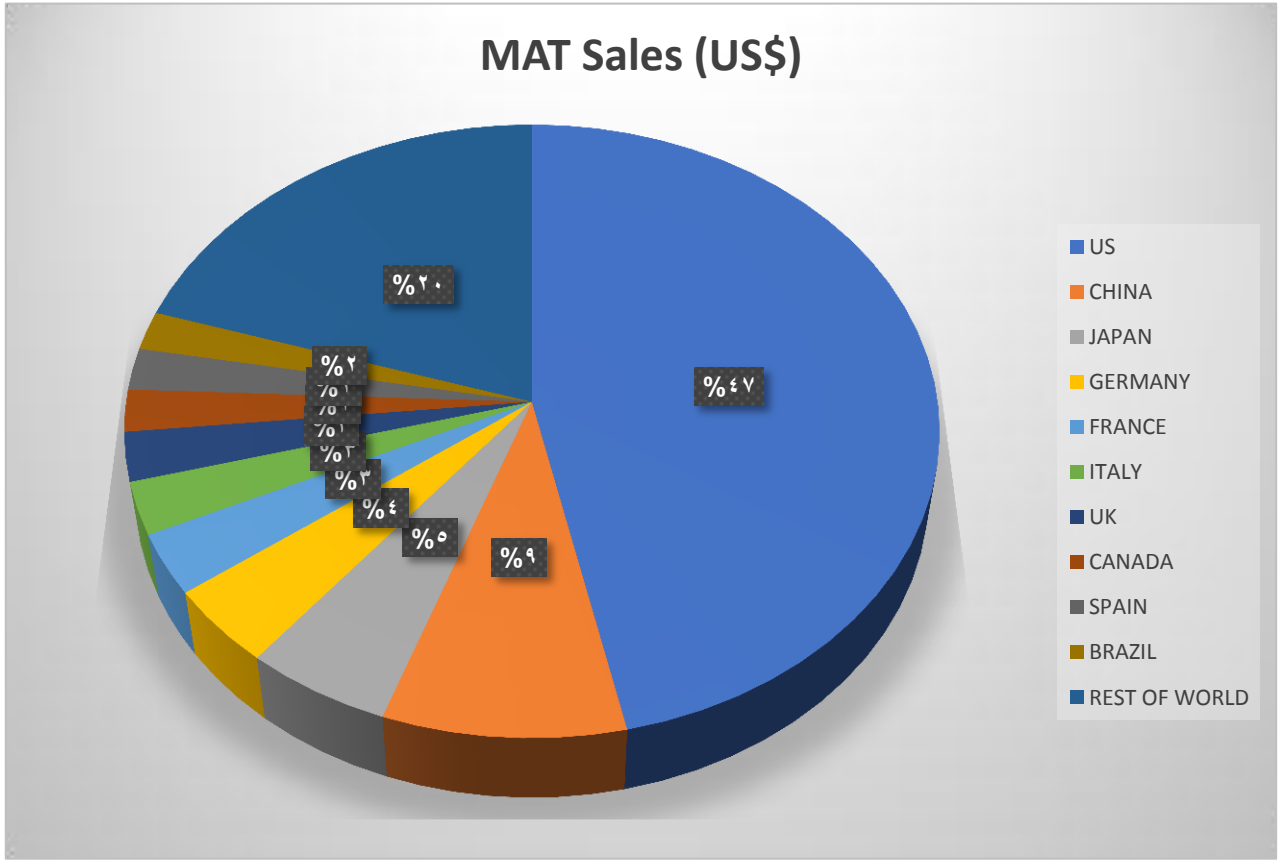
MOHAMED ROHAYEM

Mohamed Rohayem

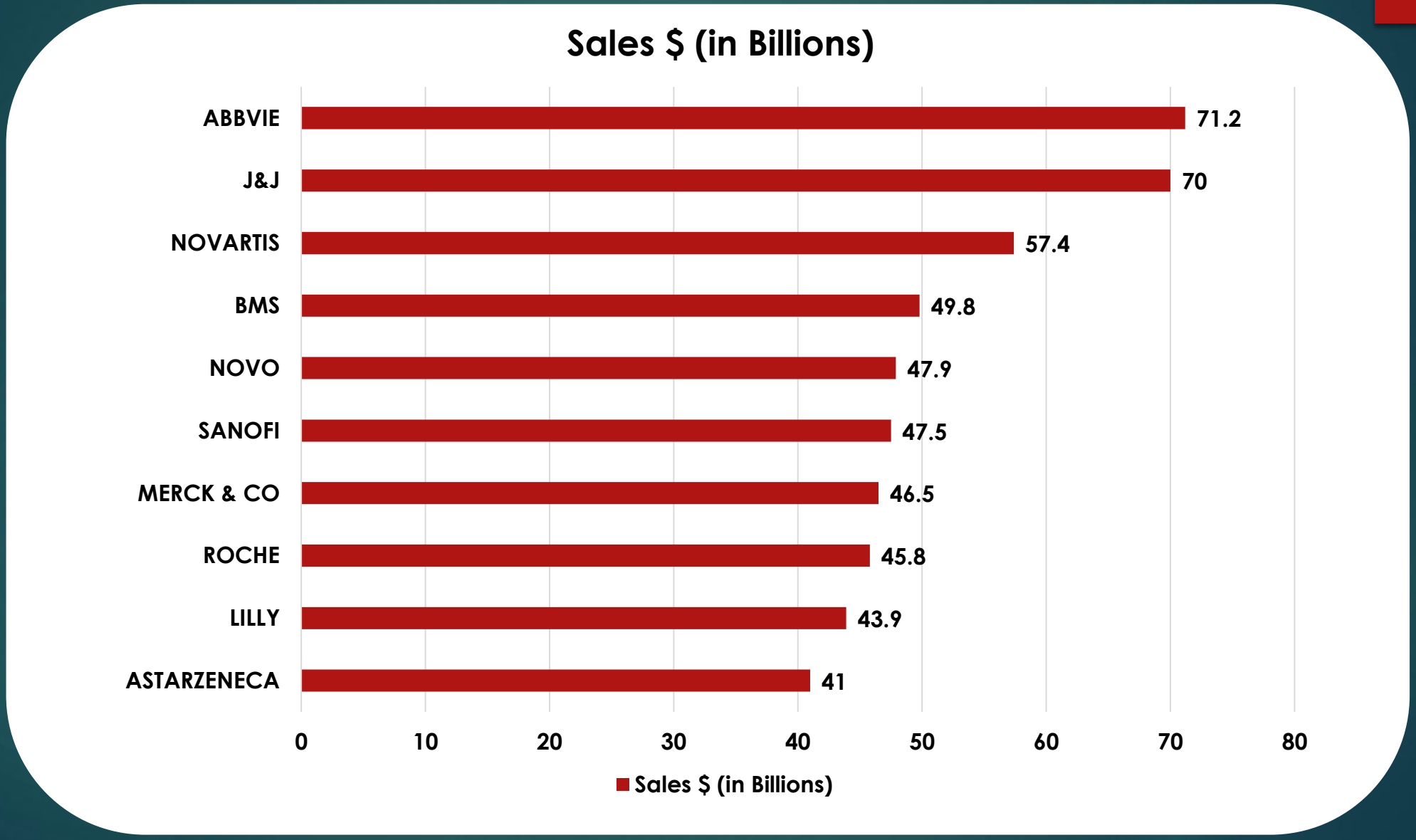
- GCC Brand Manager, Biotechnology Unite, Hikma Pharmaceutical.
- Pharmacist.
- Around 20 years of sales & marketing experience.
- Based in Riyadh, KSA.
- Married & have 3 kids.

Top 10 Countries: MAT Q3/2022

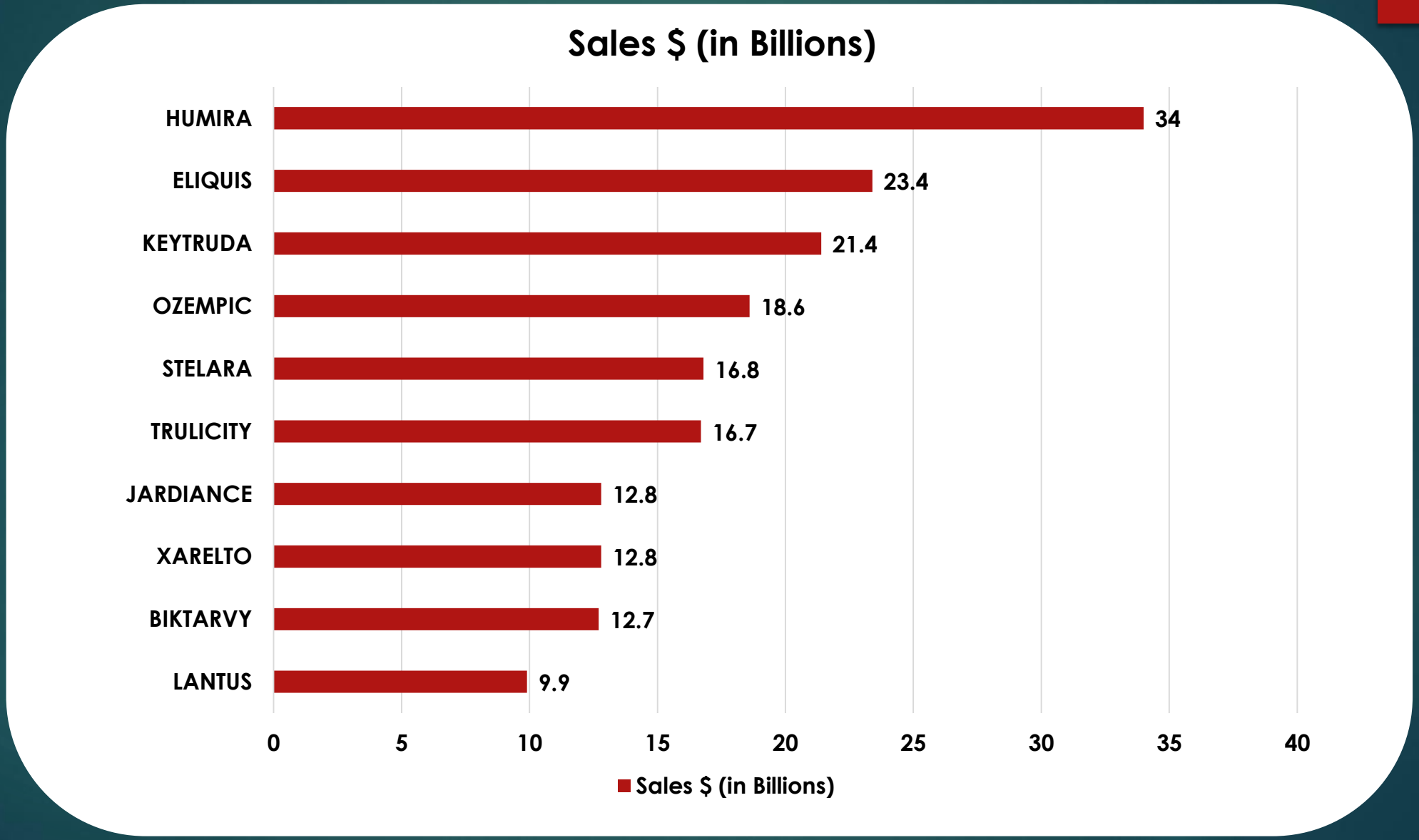
	Country	MAT Sales (US$)	Share	Growth
1	US	$615,430,342,675	47%	9%
2	CHINA	$116,966,626,584	9%	-1%
3	JAPAN	$70,662,983,346	5%	-11%
4	GERMANY	$54,513,294,049	4%	-2%
5	FRANCE	$42,147,505,854	3%	1%
6	ITALY	$36,510,082,902	3%	0%
7	UK	$34,066,537,036	3%	0%
8	CANADA	$29,226,922,797	2%	9%
9	SPAIN	$28,945,544,633	2%	-1%
10	BRAZIL	$26,869,792,711	2%	21%
11	REST OF WORLD	$265,868,192,578	20%	4%



Top 10 Corporations: MAT Q3/2022



Top 10 International-Products: MAT Q3/2022



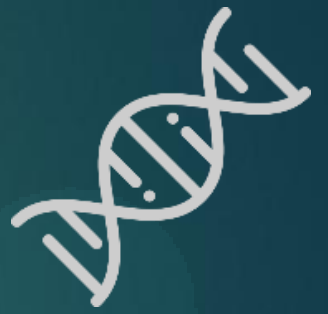
Top 10 International-Products: MAT Q3/2022

Product	Company	Indications
HUMIRA	AbbVie	RA , JIA , PSA , Axial-SPA , AS , PS, pPS , CD , pCD , UC , pUC , HS & UVT
ELIQUIS	BMS/Pfizer	Anticoagulant
KEYTRUDA	MSD	Melanoma, Non-Small Cell Lung Cancer, Head and Neck Squamous Cell Cancer, ….....
OZEMPIC	Novo Nordisk	(GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.
STELARA	Janssen	PSA, CD,UC & PS
TRULICITY	Eli Lilly	(GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.
XARELTO	Janssen	Anticoagulant
JARDIANCE	Boehringer Ingelheim	An adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.
BIKTARVY	Gilead	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and paediatric patients
LANTUS	SANOFI	patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus

Trends Driving the Pharma Industry

Biosimilars

Value-based Care & Access



Cell & Gene Therapy

Patient Centricity & Engagement

Real World Evidence

Diagnostics

Digital & AI

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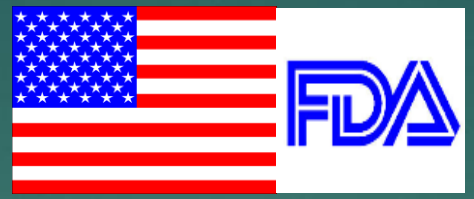
Biosimilarity: Regulatory Definitions



- **The American Food & Drug Administration (FDA)**: A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.(1)

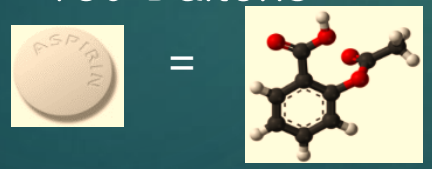
- **European Medicines Agency (EMA)**: A biosimilar medicine (‘biosimilar’) is a medicine highly similar to another biological medicine already marketed in the EU ‘reference medicine’. Due to the natural variability of the biological source, strict controls are always in place during manufacturing to ensure that minor differences do not affect the way the medicine works or its safety. (2)

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar
imilars in the EU, Information guide for healthcare professionals

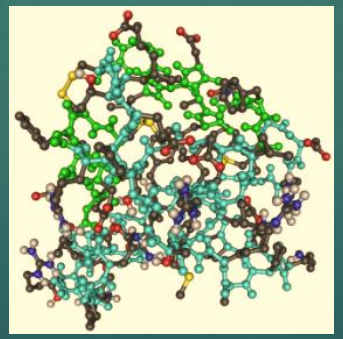
How Biologics Are Different In Comparison To Chemical Medicines?

In comparison to small chemical molecules, biologics are large, and they are often 200 – 1000 times larger than the chemical molecules. Moreover, biologics are significantly more complex with 3D protein structured.(1)

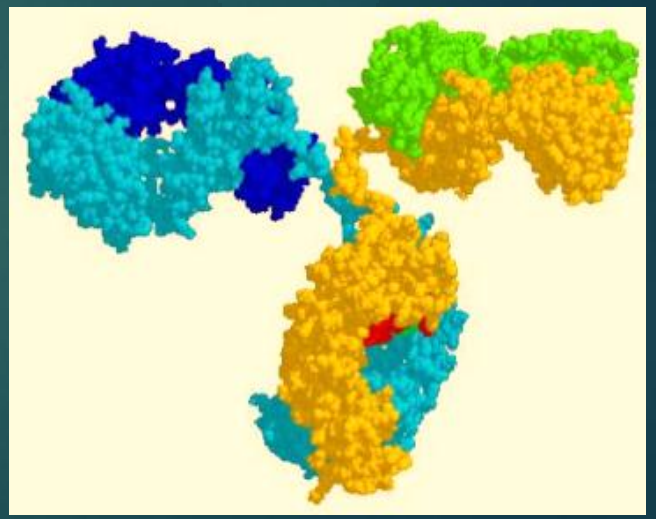
Aspirin
(Acetylsalicylic acid)
180 Daltons



Insulin
5,700 Daltons



mAb
150,000 Daltons



. What are “Biologics” Questions and Answers. [Accessed September 2014]. http://www.fda.gov/AboutFDA/default.htm

Why ‘Biosimilars’ Are Not ‘Generic Drugs’?

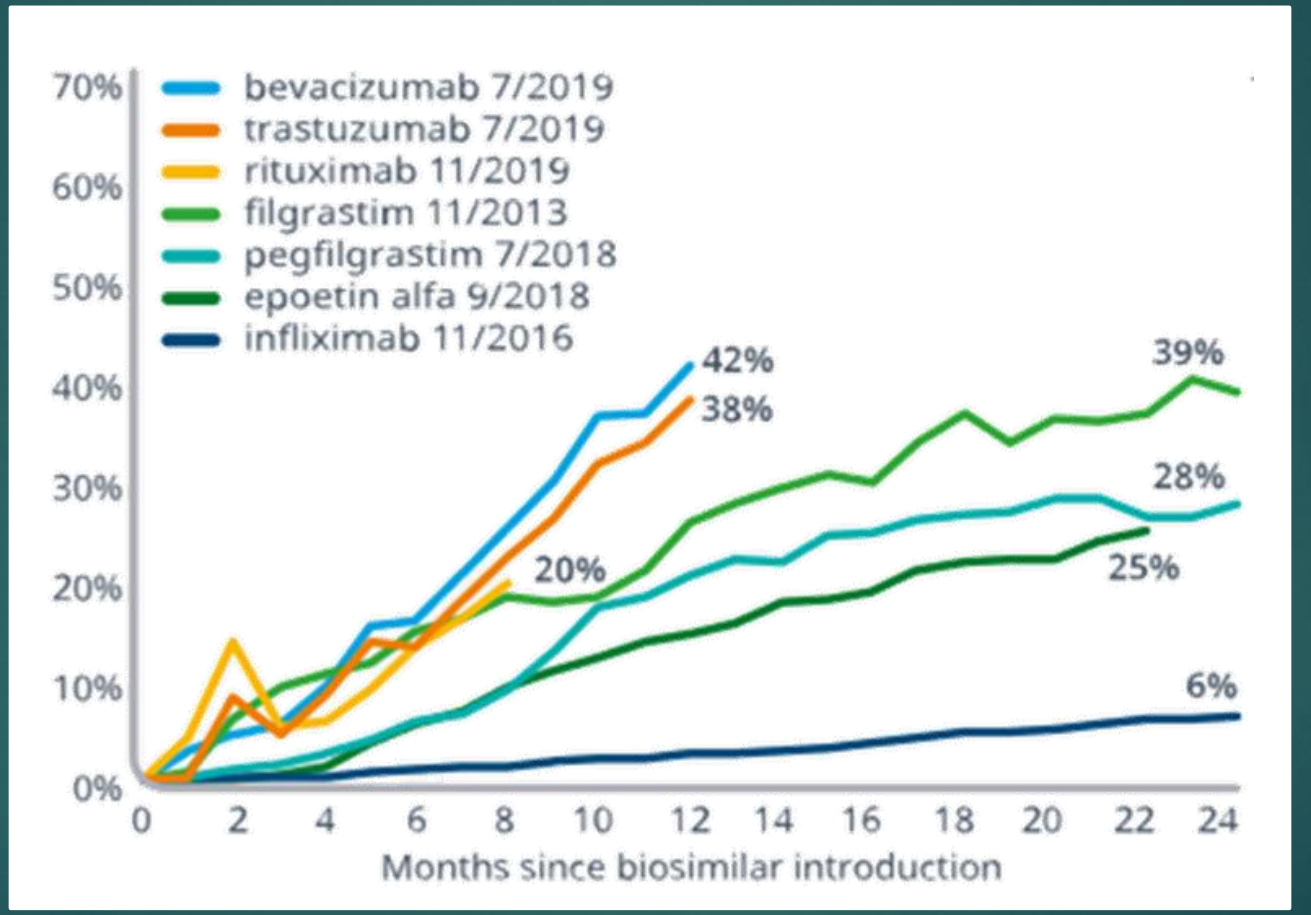
Biosimilars

Biosimilars differ from generics in complexity, manufacturing processes, and in the data needed to demonstrate similarity for approval1,2-3

Properties	Generics	Biosimilars
Size	Small	Large
Molecular Weight	~150 Daltons	~150,000 Daltons
Structure	Simple and well-defined	Complex with potential structural variations
Manufacturing	Predictable chemical process to make identical copy	Specialized biological process to make similar copy
Complexity	Easy to fully characterize	Difficult to characterize
Stability	Relatively stable	Sensitive to storage and handling conditions
Adverse Immune Reaction	Lower potential	Higher potential
Manufacturing Quality Tests	≤ 50	≥ 250
Approval Requirements	Small clinical trials in healthy volunteers	Large clinical trials in patients

amacho LH, Frost CP, Abella E, Morrow PK, Whittaker S. Biosimilars 101: considerations for U.S. oncologists in clinical practice. Cancer Medicine. 2014;3:889-899. 2. Niederwieser D, mitz S. Biosimilar agents in oncology/haematology: from approval to practice. Eur J Haematol. 2011;86:277-288. 3. Alten R, Cronstein BN. Clinical trial development for biosimilars. Semin ritis Rheum. 2015;44:S2-S8.

Recently Launched Biosimilars Have Significantly Higher & Faster Market Share than Prior Biosimilars[1]

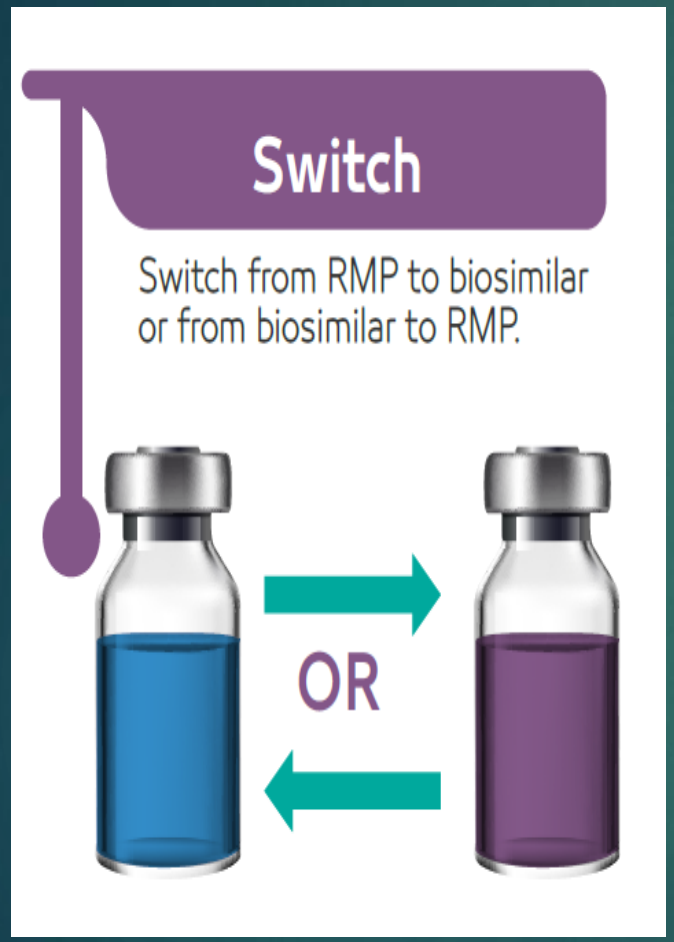


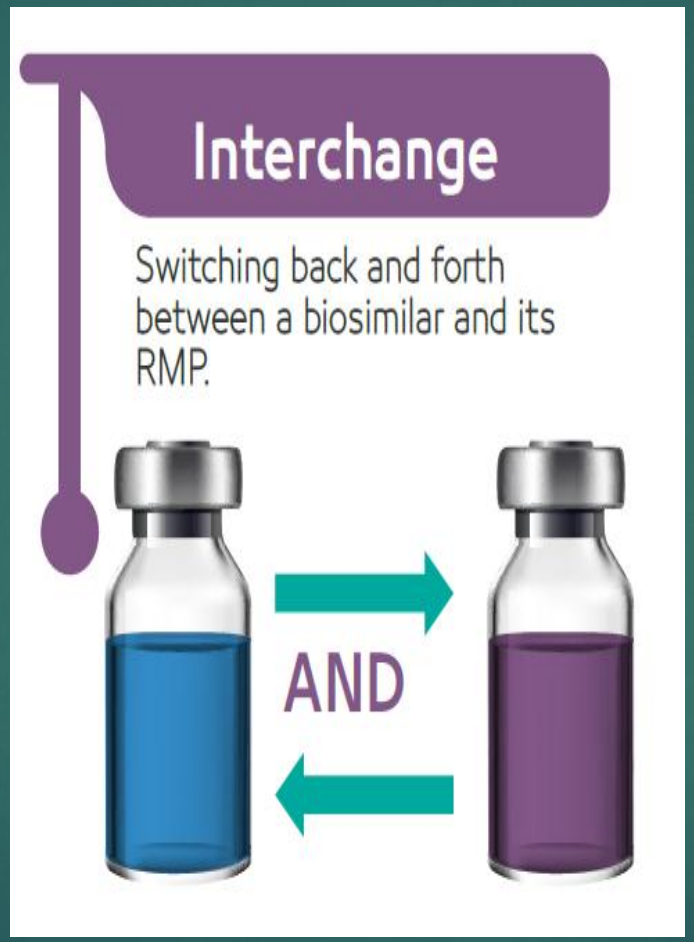
[1] ...similars in the United States 2020–2024 Competition, Savings, and Sustainability. IQVIA, Sept 2020 (https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024),

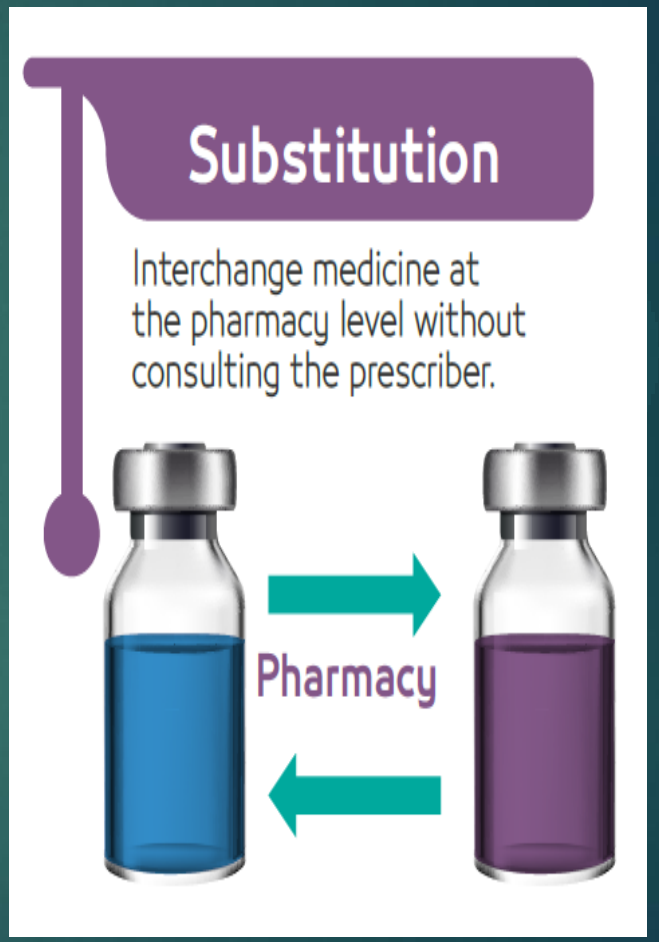
Biosimilars Main Players :

https://www.pharmashots.com/24011/top-biosimilar-companies-with-approved-and-pipeline-products-in-the-us-and-eu

Definitions of Switch, Interchange and Substitution:



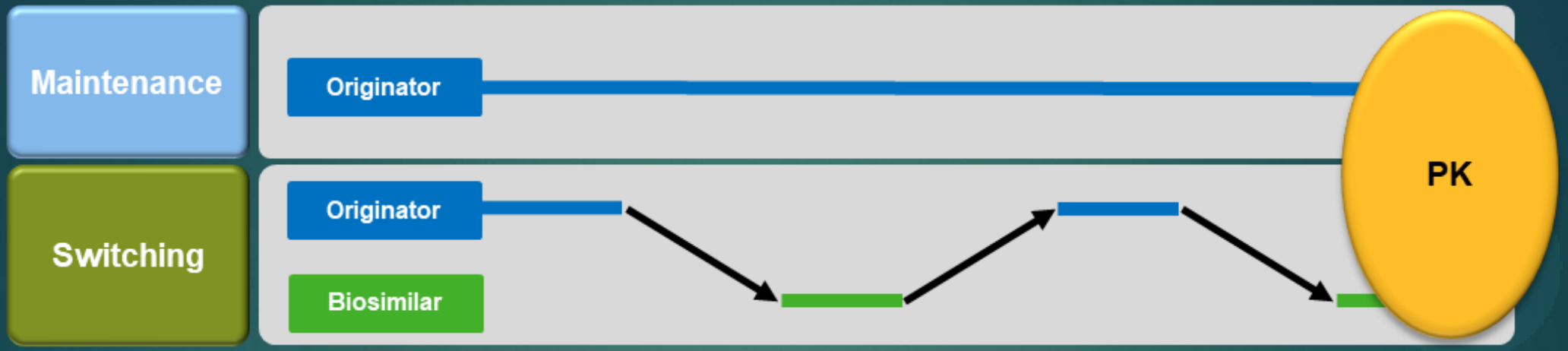




https://www.pharmashots.com/24011/top-biosimilar-companies-with-approved-and-pipeline-products-in-the-us-and-eu

Interchangeability (US FDA Guideline) :

- Switch study design

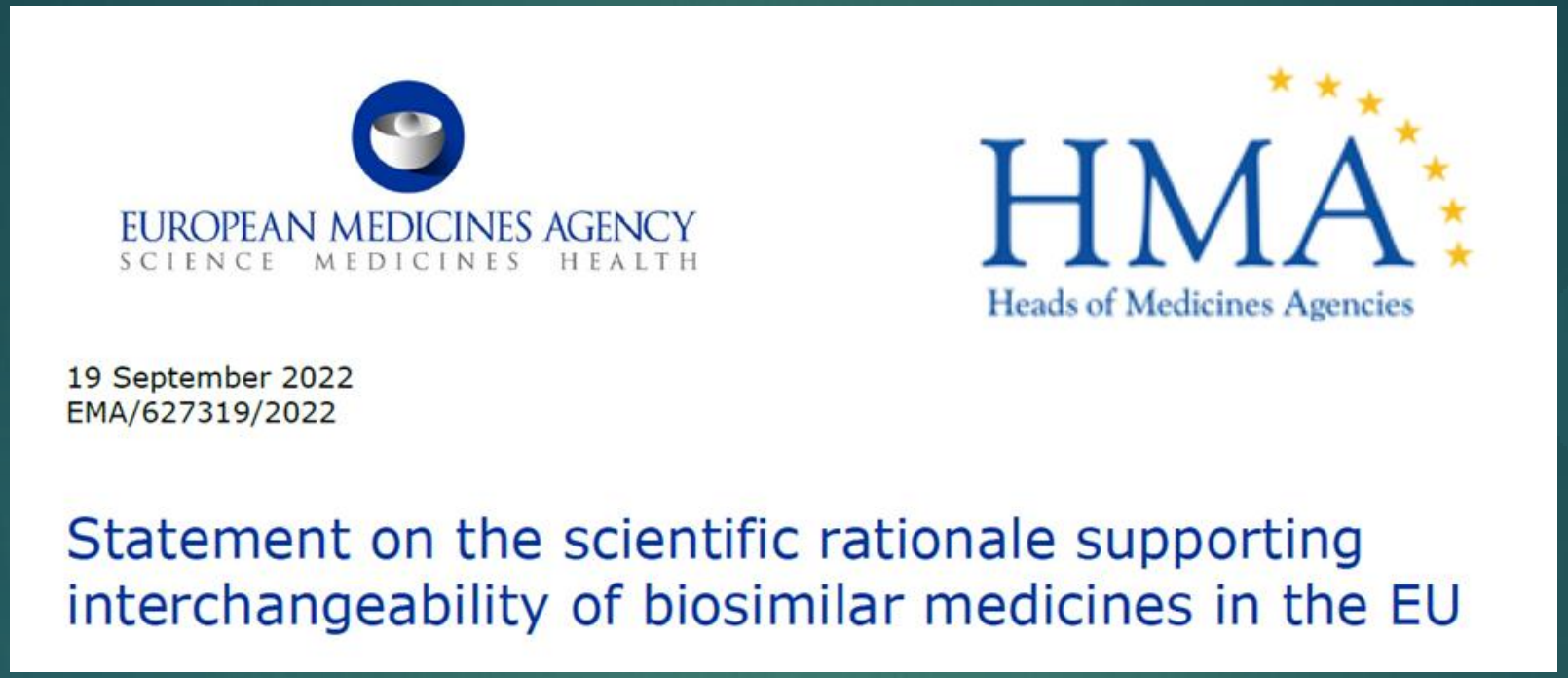


- Clinical Data Needed

Study Endpoints	Study Design	Study Population	Extrapolation	Route of Administration
- PK - PD - Immunogenicity - Safety	- Sample size based on PK - At least 2 doses both for reference and test drugs	Adequately sensitive population	Support extrapolation of data to other conditions of use	Assessment of clinical changes in safety risk & efficacy

FDA. Guidance for Industry. 2017

Interchangeability (EMA) :



HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.

1Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU EMA/627319/2022

Trends Driving the Pharma Industry

Value-based Care & Access

Biosimilars

Cell & Gene Therapy

Patient Centricity & Engagement

Real World Evidence

Diagnostics

Digital & AI

Old vs New Pharma Business Models

Value-based Care & Access

Old business model		New business model
Pill/vial	End product	Health outcome
Physicians	Customer	Patients, providers, payers
Chemical, biological	R&D tools	Chemical, biological, digital
Pharma and biotech	Competitors	Pharma, biotech, technology players (including consumer-focused online businesses, digital health and digital therapeutics firms)

Source: Datamonitor Healthcare

Value-based Care & Access - What is it?

Value-based Care & Access

Value-based care is a function of access, outcomes and costs. To achieve higher value, we must deliver the best possible population and patient outcomes in the most efficient way

Patient engagement is also seen as a central tenet of value-based care. To the degree that providers and insurers can get people activated and engaged in their own care, using enabling technologies and robust data likely offers better potential to achieve improved health outcomes at a lower cost.[1]

[1]Allen, S. **2020 Global Health Care Outlook:** Laying a foundation for the future. Deloitte Insights. 2019. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/global-health-care-sector-outlook.html.

What is Value in Healthcare?[1]

Value-based Care & Access

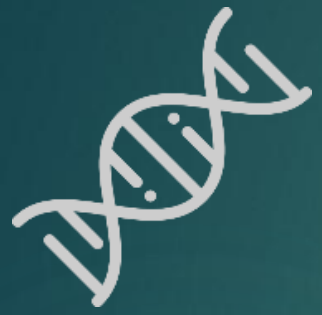
Quality

$$\text{Value} = \frac{\text{Set of health results that matter for the condition}}{\text{Total cost of all necessary services over the care cycle}}$$

Cost **Time**

[1]The Case for Bundled Payments in Healthcare, a Harvard Business Review Webinar Featuring, Robert S Kaplan and Michael E. Porter.

Trends Driving the Pharma Industry



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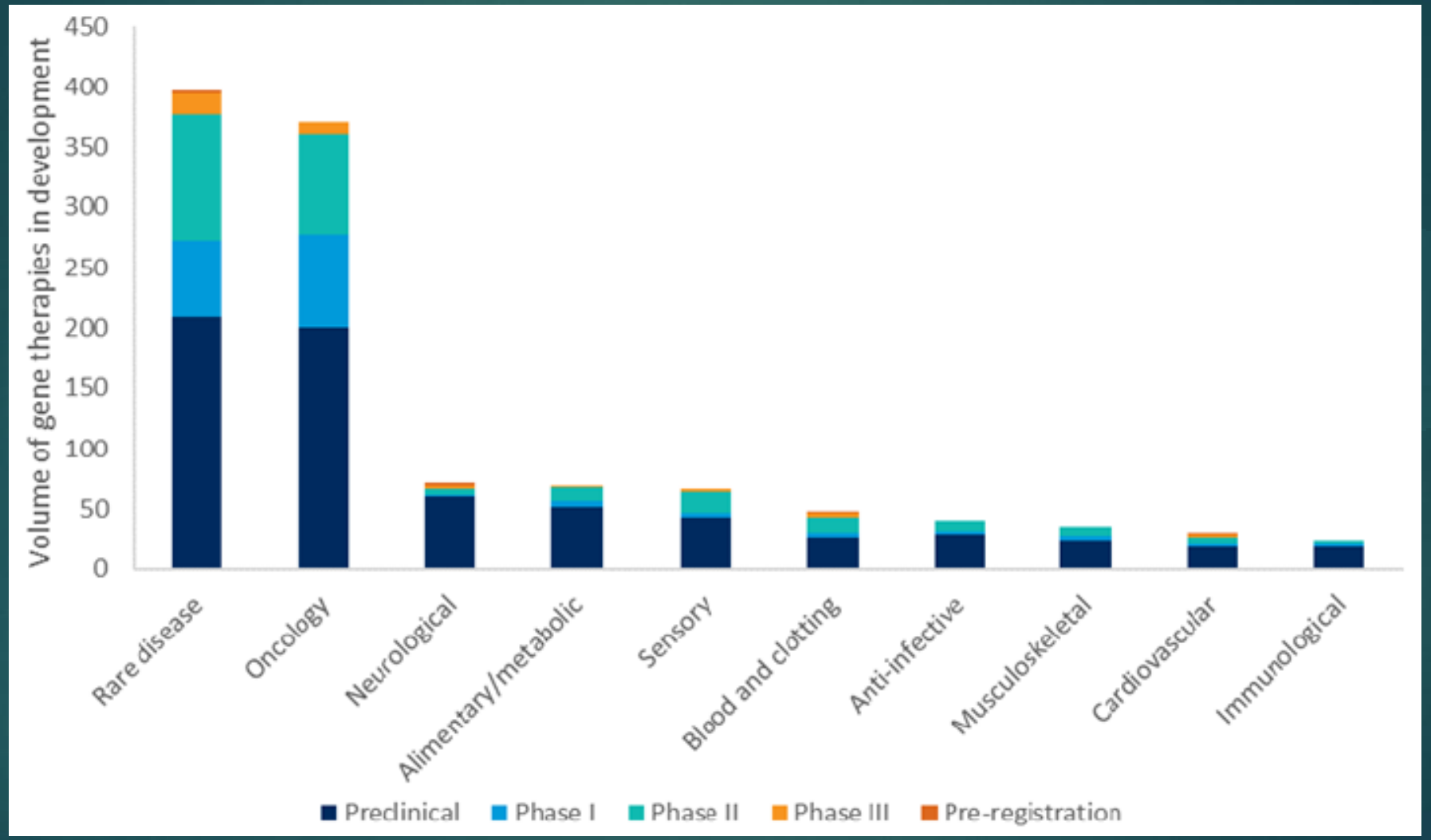
Gene therapy : EMA & FDA Definitions

Cell & Gene Therapy

EMA definition	FDA definition
• Contains or consists of recombinant nucleic acid, inserted into the body, to regulate, repair, replace, add, or delete a genetic sequence	• Genetic material administered to modify or manipulate gene expression, or to alter the biological properties of living cells for therapeutic use

Gene Therapy Pipeline, by Therapy Area & Phase

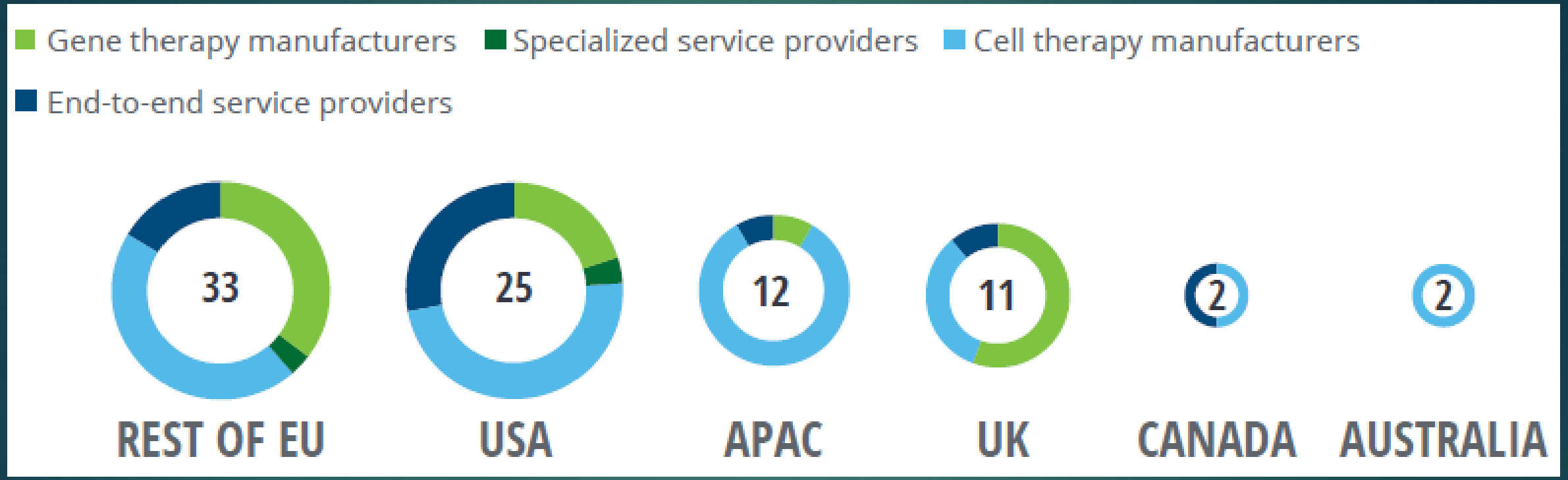
Cell & Gene Therapy



Source: Pharmaprojects

50+ Companies Compete in the Cell and Gene Global Marketplace(1)

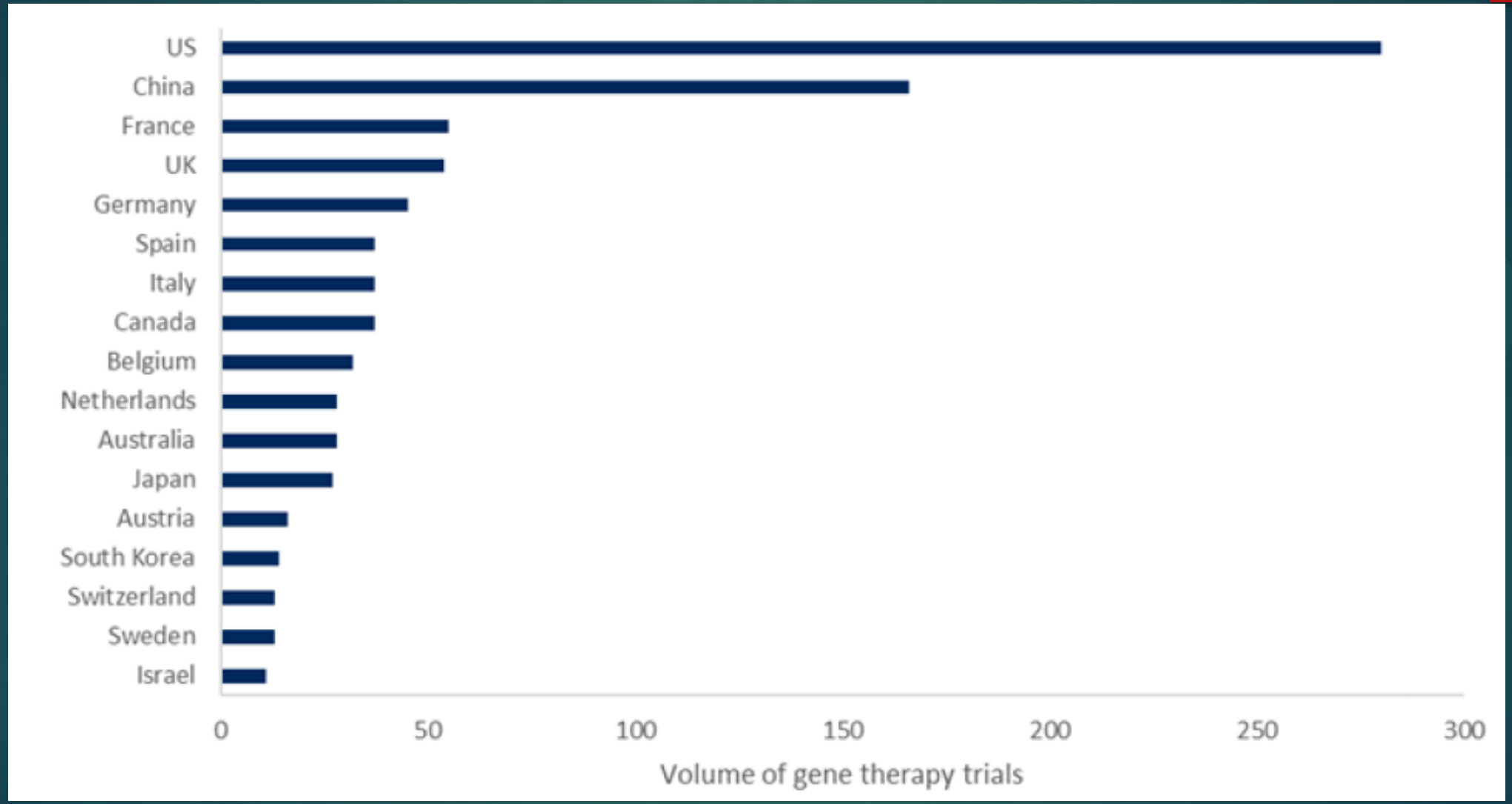
Cell & Gene Therapy



[1]2020 global life sciences outlook: Creating new value, building blocks for the future. Deloitte 2020 (https://documents.deloitte.com/insights/2020globallifesciencesoutlook

Most gene therapy clinical trial activity is in the US

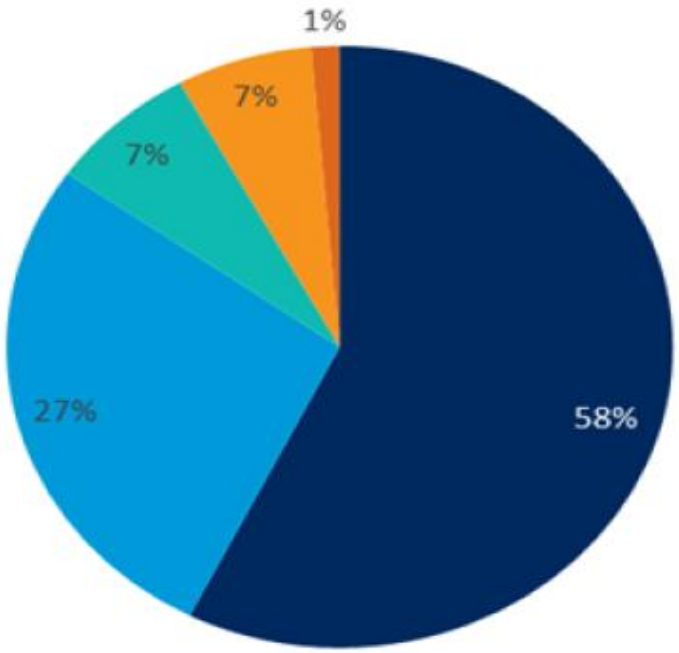
Cell & Gene Therapy



Source: Trialtrove

Completed Gene Therapy Trials are Largely Successful; Trials by Outcomes

Cell & Gene Therapy



Notes: The figure covers worldwide, industry-sponsored, completed Phase I–IV trials. The "unknown" category is for those trials where the primary endpoint results were not available, or only interim or pooled results have been reported. The "indeterminate" category is for those trials where the final results are available, but it is not readily apparent whether the results represent a positive or negative outcome.

Source: Trialtrove

CGT's Potential to Transform[1]

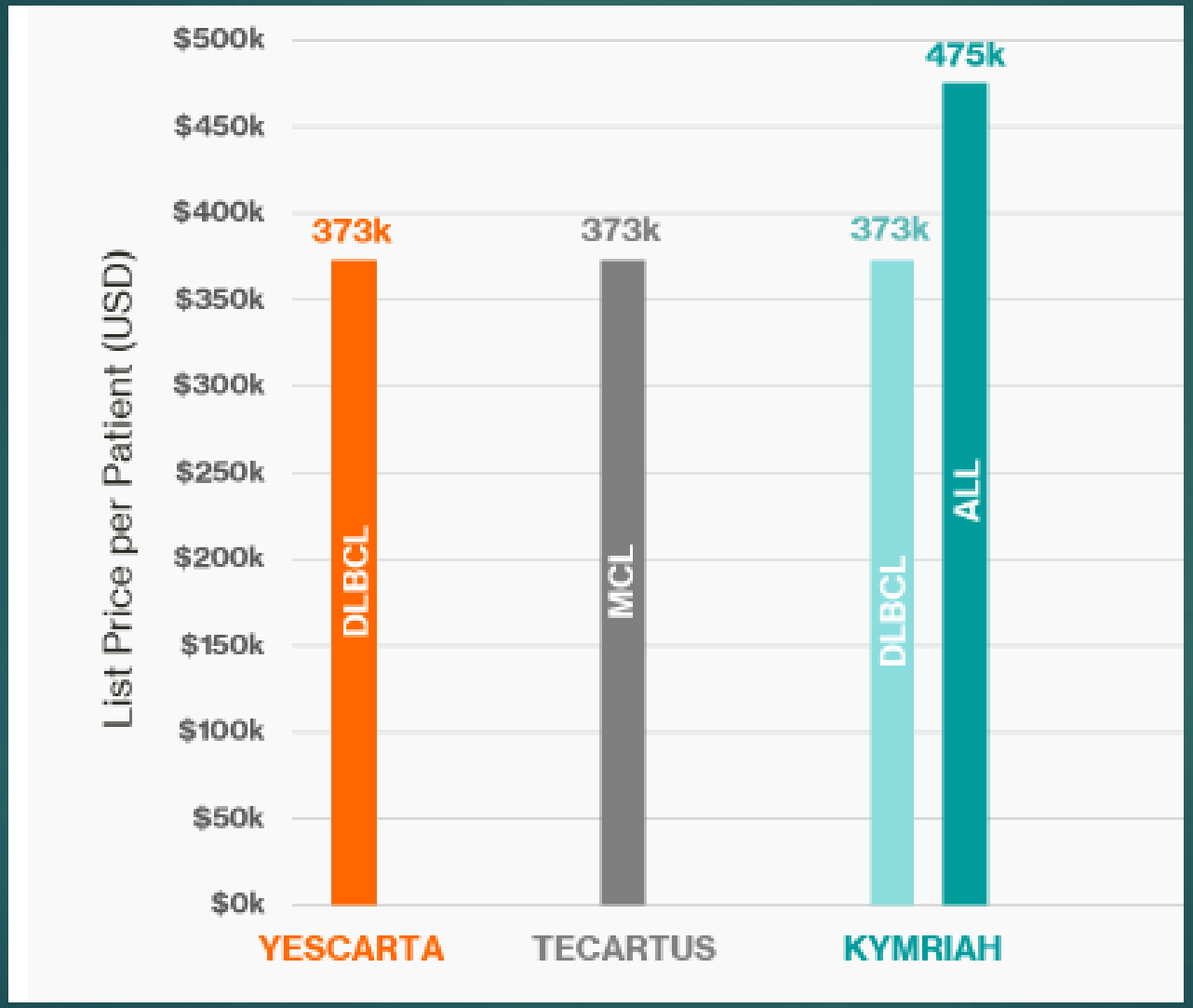
Cell & Gene Therapy

- Scientific development of CGT is booming and unlikely to slow down
  - Novartis opened the market in 2017 with Kymriah, followed a few months later by Gilead's Yescarta
  - The FDA predicts it will be approving 10 to 20 gene therapy products a year by 2025.
- Biggest hurdles to CGT commercialization
  - Manufacturing and logistics of getting treatment to the patients
  - These translate into untenable prices
- Payers are struggling to approve them because of their high treatment cost
  - $400,000 - $1,000,000 per patient
  - Kymriah: $475,000
  - Yescarta: $373,000
  - Luxturna (per eye): $425,000

[1]The Future of Cell and Gene Therapy Manufacturing Just Got Brighter. Amadeus Capital Partner, Blog by Pierre Socha, Jan 9, 2020 (https://www.amadeuscapital.com/the-future-of-cell-and-gene-therapy-manufacturing-just-got-brighter/)

Payers Struggling to Approve High Price of CAR-T Therapies(1)

Cell & Gene Therapy



ALL : Acute Lymphoblastic Leukaemia
DLBCL : Diffuse Large B-Cell Lymphoma
MCL : Mantle Cell Lymphoma

[1]CAR-Ts: Barriers and Opportunities for the Migration into Earlier Lines of Therapy in the USA. CB Partners, Sept 2020 (https://www.cbpartners.com/car-ts-barriers-and-opportunities-in-the-migration-into-earlier-lines-of-therapy-in-the-usa/)

Rregistered Gene Therapy in KSA :

Cell & Gene Therapy

Scientific Name	Trade Name	Strength	Doesage Form	Price	Details
TISAGENLECLEUCEL	Kymriah	6	Dispersion for infusion	1633500	Details

Scientific Name	Trade Name	Strength	Doesage Form	Price	Details
VORETIGENE NEPARVOVEC	Luxturna	5e+12	Concentrate and solvent for solution for injection	1759274.324	Details

SFDA
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

https://www.sfda.gov.sa/en/drugs-list

Trends Driving the Pharma Industry

Patient Centricity & Engagement

Biosimilars

Value-based Care & Access

Cell & Gene Therapy

Real World Evidence

Diagnostics

Digital & AI

Patient Centricity & Engagement:

5 Important Elements[1]

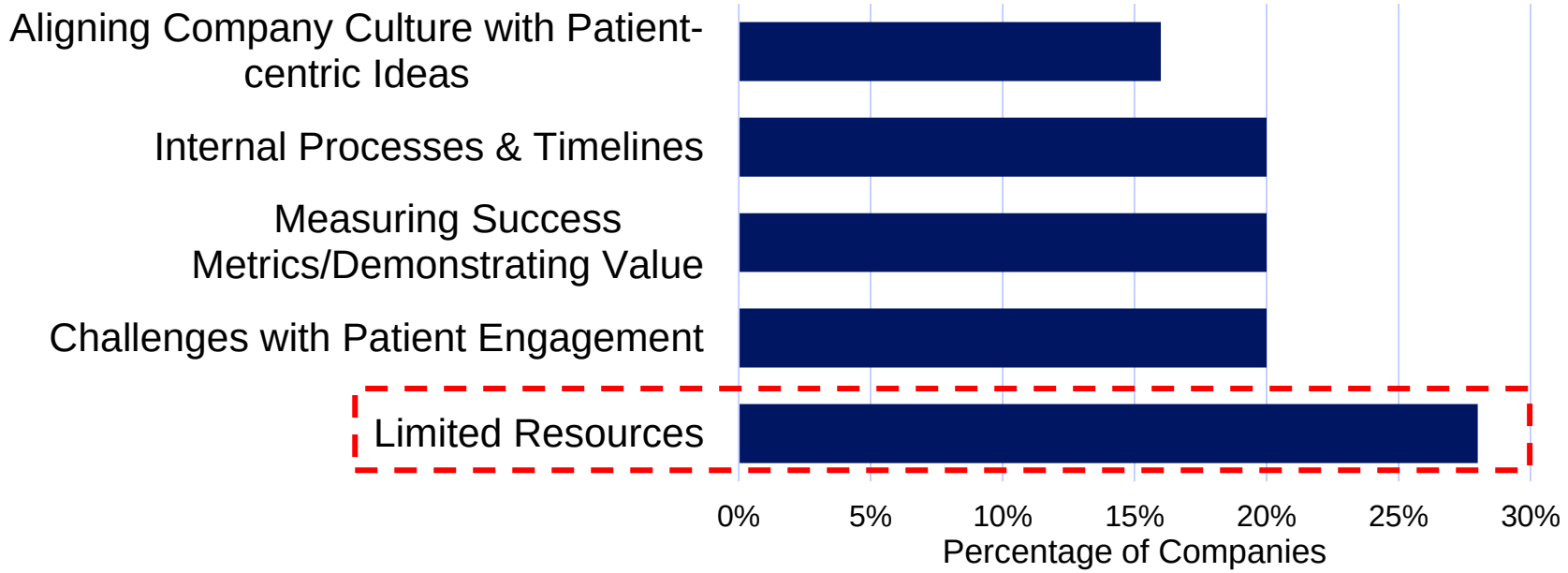
Patient Centricity & Engagement

1Patient Engagement: New Strategies for a New Era. Pharma Voice, Sept 2017

http://www.pharmavoice.com/article/2017-9-patient-engagement-strategies

Obstacles To Achieving Patient-Centricity[1]:

Patient Centricity & Engagement

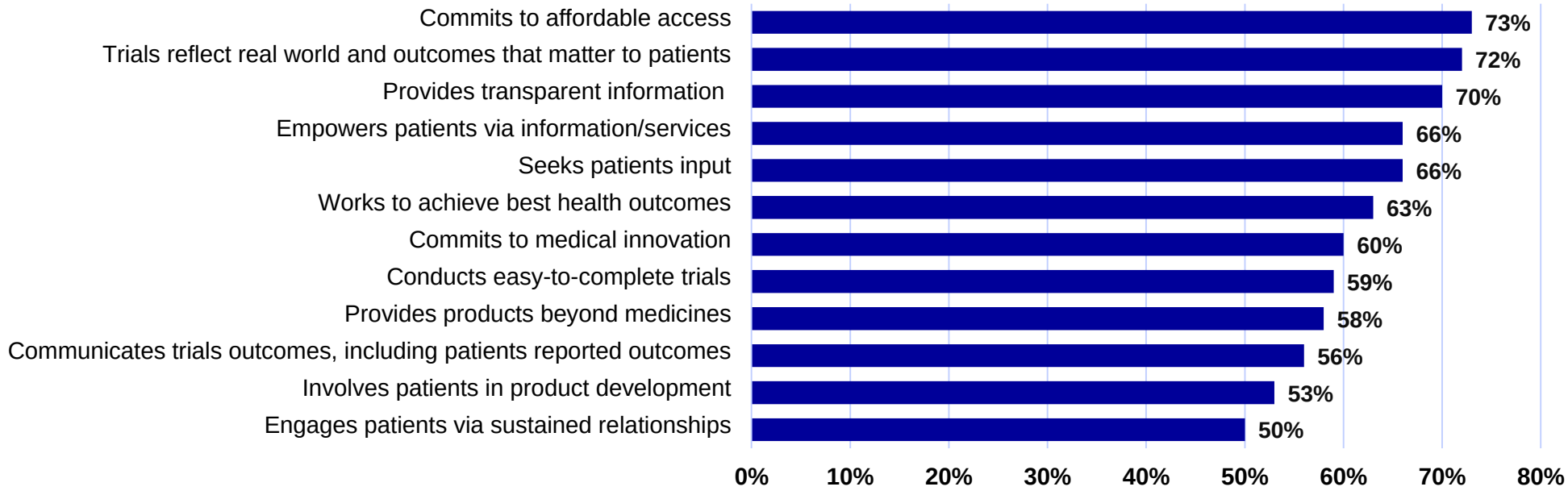


[1]Defining Patient-Centricity Success Metrics & Demonstrating Initiative Value. Cutting Edge Information, September 28, 2016 (http://www.marketwired.com/press-release/defining-patient-centricity-success-metrics-demonstrating-initiative-value-2162138.htm),

Attributes that Matter Most to Patients[1]:

Patient Centricity & Engagement

Respondents Rating Importance of Attribute at 8 or more (Out of 10)
N = 3,230

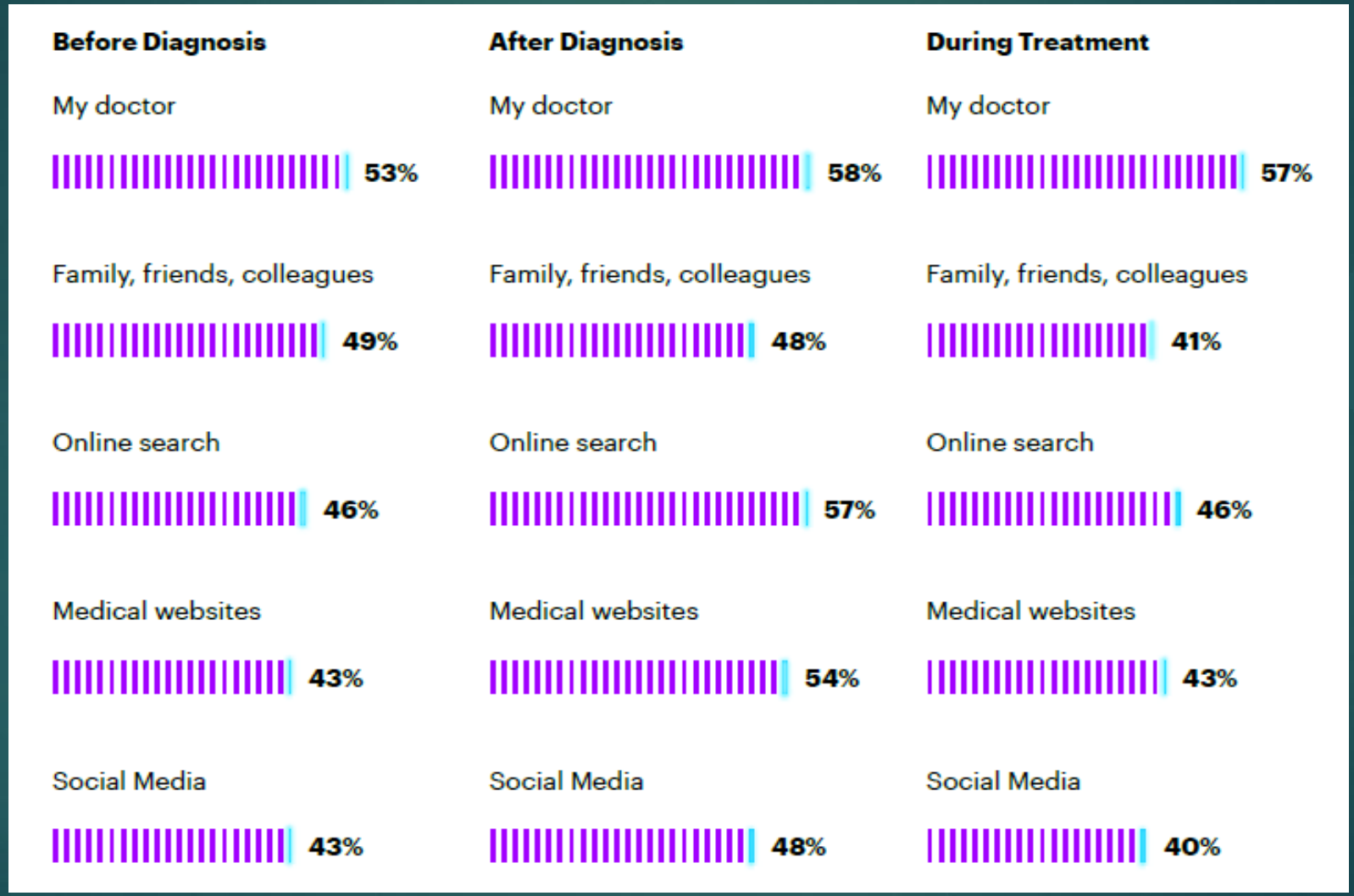


[1] What Do Patients Want, and Is Pharma Delivering? BCG July 2020

https://www.bcg.com/publications/2020/what-patients-want-is-pharma-delivering

Patients Seek Information from Digital Channels Nearly as Much as from Doctors[1]:

Patient Centricity & Engagement



[1]Boosting Move the Needle. Accenture January 2021

https://www.accenture.com/_acnmedia/PDF-145/Accenture-Global-Patient-Services-Survey.pdf#zoom=50

How to Build Strong Patient-Centric Communications[1]:

Patient Centricity & Engagement

- Develop and own patient centric communication program.
- Engage patient advocacy groups; SHCs.
- Support patient education.
- Structure formal channels of communication.
- Monitor progress, evaluate and adjust.

It's trending *– More focus is being placed on* ***Smart Health Communities*** *(SHCs) – groups of public, nonprofit, and commercial enterprises, as well as non-traditional players—who are focused on addressing disease prevention and well-being and work together on a sustained basis, all while operating largely outside of the traditional health care system.*[1]

[1]Boosting Move the Needle. Accenture January 2021

https://www.accenture.com/_acnmedia/PDF-145/Accenture-Global-Patient-Services-Survey.pdf#zoom=50

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Real World Evidence

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USFDA Definition of RWE :

Real World Evidence

Researchers from the US Food and Drug Administration (FDA) define real-world evidence (RWE) as: "Healthcare information derived from multiple sources outside of typical clinical research settings, including electronic medical records (EMRs), claims and billing data, product and disease registries, and data gathered by personal devices and health applications." They acknowledge that these data sets can "effectively complement the knowledge gained from "traditional" clinical trials.

Real-world evidence: From activity to impact in healthcare decision making | McKinsey

RWE Status and Challenges[1,2]:

Real World Evidence

Current Status:

- Developed countries are making significant moves towards RWE.
- Developing countries are in the earliest stages of establishing RWE.

Challenges

- Limitation of EMR (Electronic Medical Record) data system and complexity.
- Lack of standards and data integration from different sources.
- Collaborating with numerous stakeholders holding the data.
- Complying with regulatory requirements.
- Achieving medical-level accuracy.
- Low level of cooperation by pharma.
- Low awareness among HCPs.
- Varied stakeholder needs.
- High costs.

[1]The evolving landscape for Real World Evidence in Poland: Physician's' perspective. JHPOR 2015;1:15-33 (http://www.jhpor.com/index/artykul/pokaz/the_evolving_landscape_for_real_world_evidence_in_poland_physicians_perspective), ;

[2]Real-world evidence: From activity to impact in healthcare decision making. McKinsey & Company, May 2018

(https://www.mckinsey.com/industries/Pharmaceuticals-and-medical-products/our-insights/real-world-evidence-from-activity-to-impact-in-healthcare-decision-making)

Several Developed Countries Are Accumulating High-Value RWE Pools[1]:

Real World Evidence

	Database[1]		Lives covered (Millions)	Industry access
Japan	MHLW	National claims database	126	Possible through academics, often requires significant data cleaning
US	CMS	Medicaid/Medicare claims databases	120	Possible through academics, but with limitations
France	SNIIRAM	National claims database	60	None, limited to academics and health policy experts only
	PMSI	National hospital claims database	60	Through academics only, but future unclear due to privacy concerns
UK	CPRD	Electronic medical record (EMR) data from 10% GPs	53	Open, 80% of pharma companies purchase access to raw data
	HES	English hospital EMR database	15	None, raw data previously available before "care.data" concerns
Germany	AOK, WIdO	Regional public sickness funds claims data	24	Possible through academics but long wait times and reluctant to share with industry
	Barmer GEK		9	
	TK, Wineg		7	
Denmark	sundhed.dk	National cross-linked healthcare databases	6	Possible through academics, but time consuming

[1] Real-world evidence: From activity to impact in healthcare decision making. McKinsey & Company, May 2018

https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/real-world-evidence-from-activity-to-impact-in-healthcare-decision-making

RWE Involvement Across the Product Life Cycle[1]:

Real World Evidence

Typical RWE applications

Research	Development	Launch	In market
Support the understanding of diseases and unmet needs	Reduce clinical-development cycle time and costs	Support pricing and demonstrate value	Improve commercial spending and effectiveness
		Support pharmacovigilance and label extension	

[1] COVID-19 Opens a New Era for Real-World Evidence in Pharma. BCG Nov 2020 (https://www.bcg.com/publications/2020/covid-19-opens-a-new-era-for-real-world-evidence-in-pharma),

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Top Diagnostics Segments and Trends:

- Main segments: MDx, CDx, POC
  - Molecular diagnostics (MDx) drive precision medicine ($9.2 Bil 2019)
  - Companion diagnostics (CDx) move beyond oncology ($3.7 Bil 2020)
  - Point of care diagnostics (POC) will rise faster due to COVID inflection point ($24.8 Bil 2021)
- Immunoassays will remain predominant in healthcare.

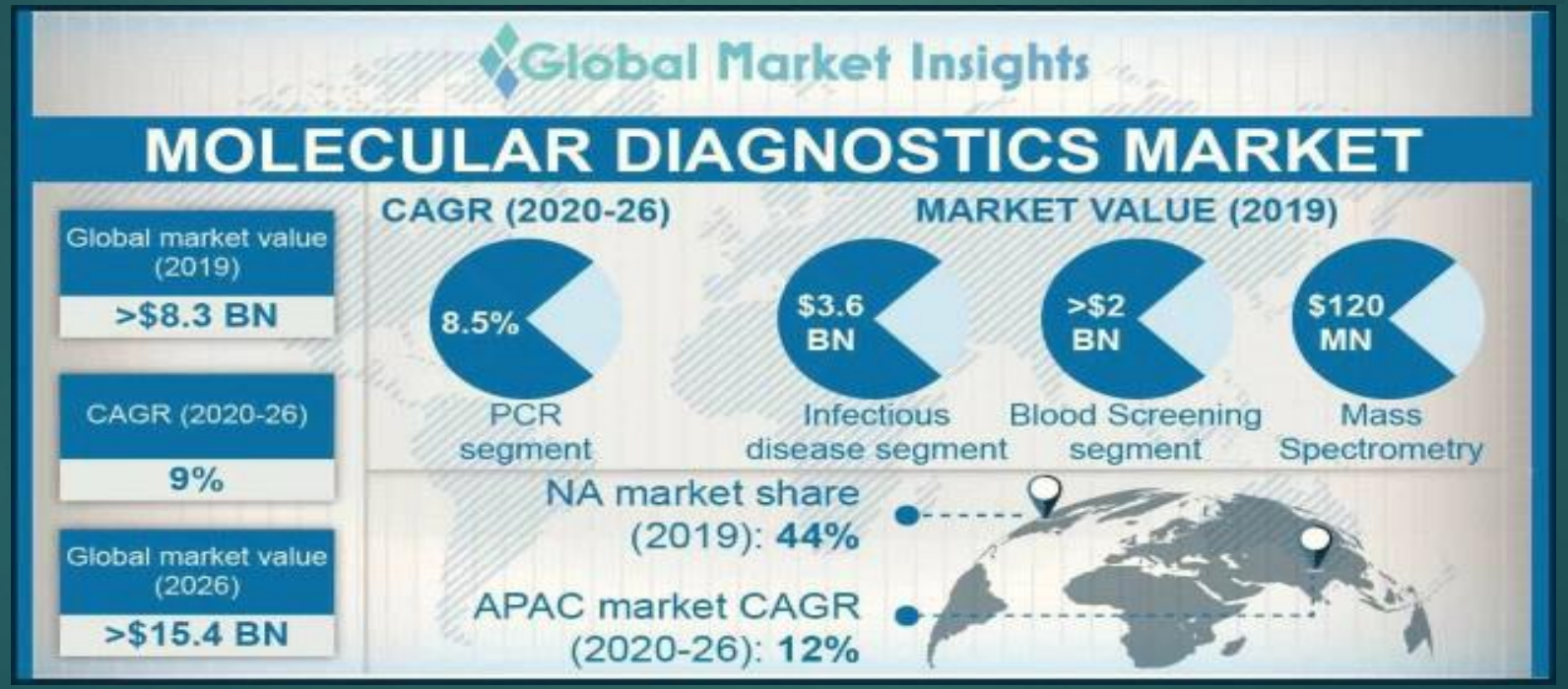
[1]Molecular Diagnostics Market Size, Share & Trends Analysis Report By Product (Instruments, Reagents), By Test Location, By Technology, By Application, By Region, And Segment Forecasts, 2020 – 2027. Grand View Research, Feb 2020 (https://www.grandviewresearch.com/industry-analysis/molecular-diagnostics-market); [2]Companion Companion Diagnostics Market by Product & Service (Assay, Kit, Software & Service), Technology (PCR, NGS, ISH, IHC), Indication (Breast, Lung & Gastric Cancer, Neurological Disease), End-User (Pharma Companies, CRO), Region - Global Forecast to 2025, Marker and Market (https://www.marketsandmarkets.com/Market-Reports/companion-diagnostics-market-155571681.html); [3]Point of Care/Rapid Diagnostics Market by Product (Glucose, Infectious Disease (Hepatitis C, Influenza), Coagulation), Platform (Microfluidics, Immunoassay), Mode of Purchase (Prescription, OTC), Enduser (Hospital, e-comm, Home Care) - Global Forecast to 2025. Markets and Markets Research. (https://www.marketsandmarkets.com/Market-Reports/point-of-care-diagnostic-market-106829185.html),

Molecular Diagnostics (MDx) :

Diagnostics

Molecular diagnostics is a rapidly evolving field in healthcare that uses nucleic acid-based tests to detect and characterize the genetic content of diseases. It helps in the early diagnosis of disease and can guide personalized treatment decisions.

The global molecular diagnostics market size is expected to reach USD **50.94 Billion** in 2030.



The high cost of molecular diagnostics tests is a major factor restraining the growth of the market.

https://www.researchandmarkets.com/reports/5623680/molecular-diagnostics-market-size-share-trends?gclid=EAIaIQobChMI5__IrYLg-wIVKe_tCh2FEgd5EAAYASAAEgJDzfD_BwE

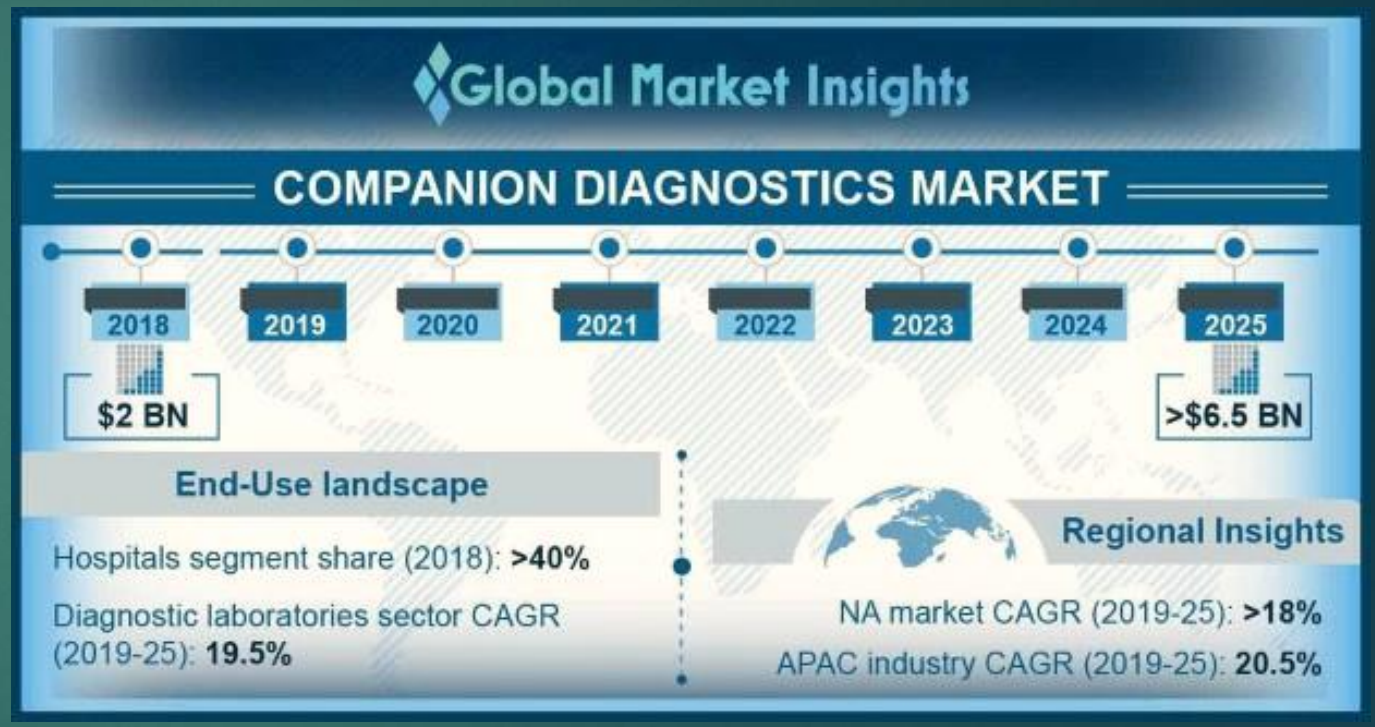
Companion Diagnostics (CDx) :

Diagnostics

A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product.(1)

Companion diagnostics can (1) **:**

1. Identify patients who are most likely to benefit from a particular therapeutic product;
2. Identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or
3. Monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness.



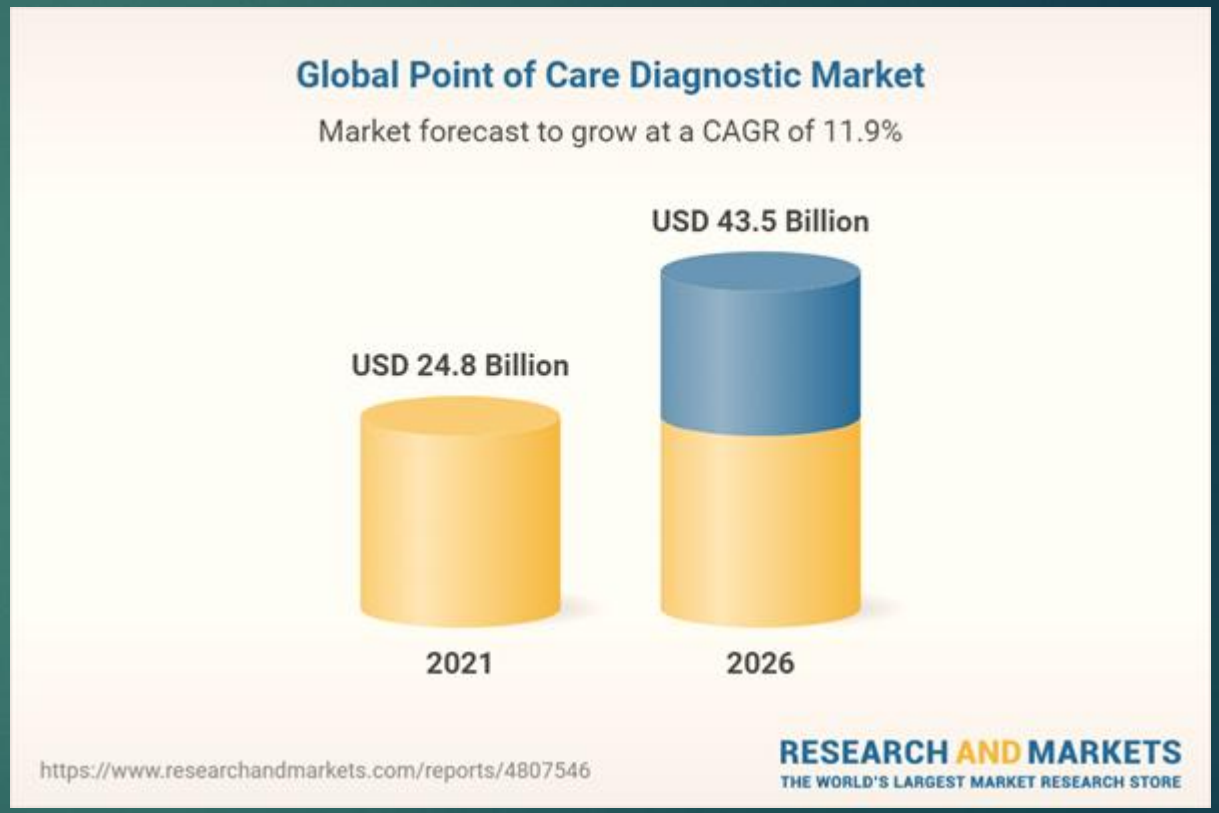
The prominent companies thriving in the companion diagnostics market are Sysmex Corporation, Almac Group, Arup Laboratories, Biocartis, Abbott Laboratories, bioMerieux, GE Healthcare, Genomic Health, Danaher Corporation, Illumina Inc, Myriad Genetics, Qiagen, Roche Diagnostics, Thermo Scientific, and Agilent.(2)

1. https://www.fda.gov/medical-devices/in-vitro-diagnostics/companion-diagnostics#:~:text=A%20companion%20diagnostic%20is%20a,corresponding%20drug%20or%20biological%20product.
2. https://www.researchandmarkets.com/reports/5651299/global-companion-diagnostics-market-2022-2028#src-pos-2

Point of Care Diagnostics (POC) :

Diagnostics

Point-of-care testing, often abbreviated to POC testing, is medical testing done at or near the point of care. In this context, POC refers to the location of the patient.(1)



KEY COMPANIES PROFILED

SIEMENS | ThermoFisher SCIENTIFIC | Roche | Abbott | ThermoFisher SCIENTIFIC

COVID-19 Impact on Diagnostics[1] :

Diagnostics

448
COVID-19-related diagnostics launched in market or in development

232
Focused on viral in-vitro diagnostics

219
FDA-cleared COVID-19 Tests

148
Antibody in-vitro diagnostics

[1] Pulse of the Industry, Medical Technology Report 2020, EY 2020 (https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-pulse-2020-report.pdf)

Trends Driving the Pharma Industry

Digital & AI

Biosimilars

Value-based Care & Access

Cell & Gene Therapy

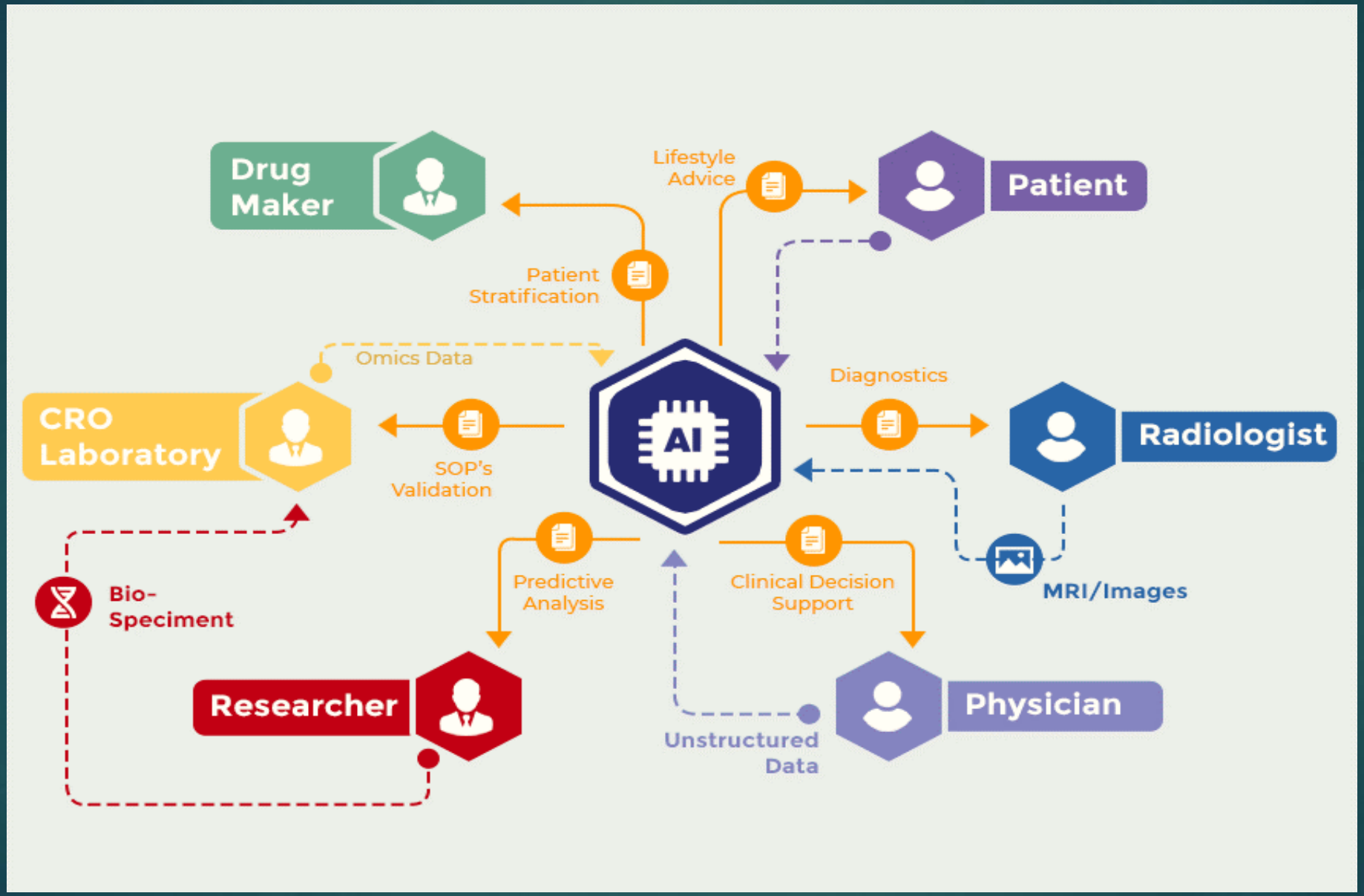
Patient Centricity & Engagement

Real World Evidence

Diagnostics

Digital and AI in Pharma and Healthcare[1]:

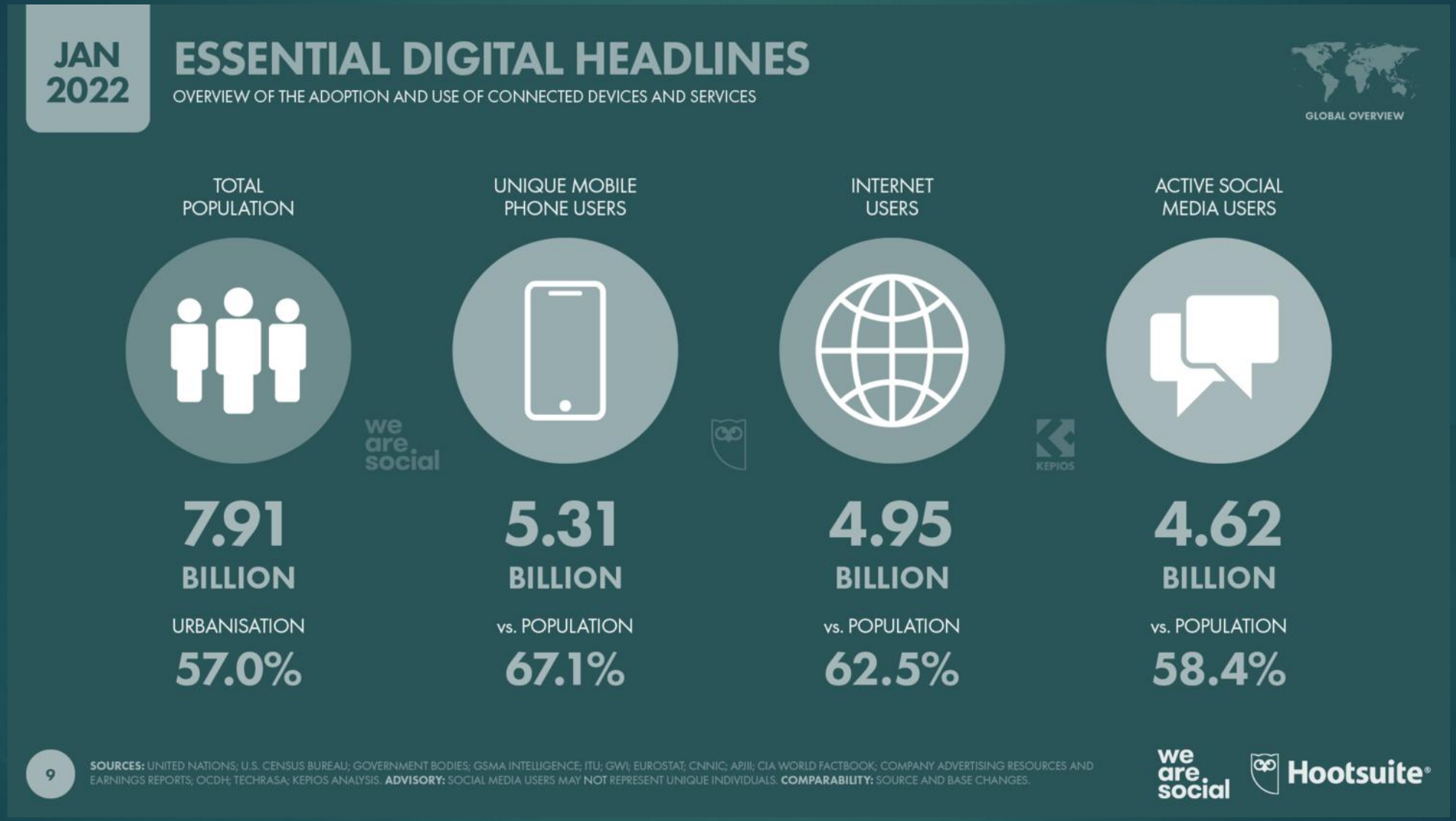
Digital & AI



[1] https://mobisoftinfotech.com/resources/blog/artificial-intelligence-in-the-pharmaceutical-industry/

Digital Around the World[1]:

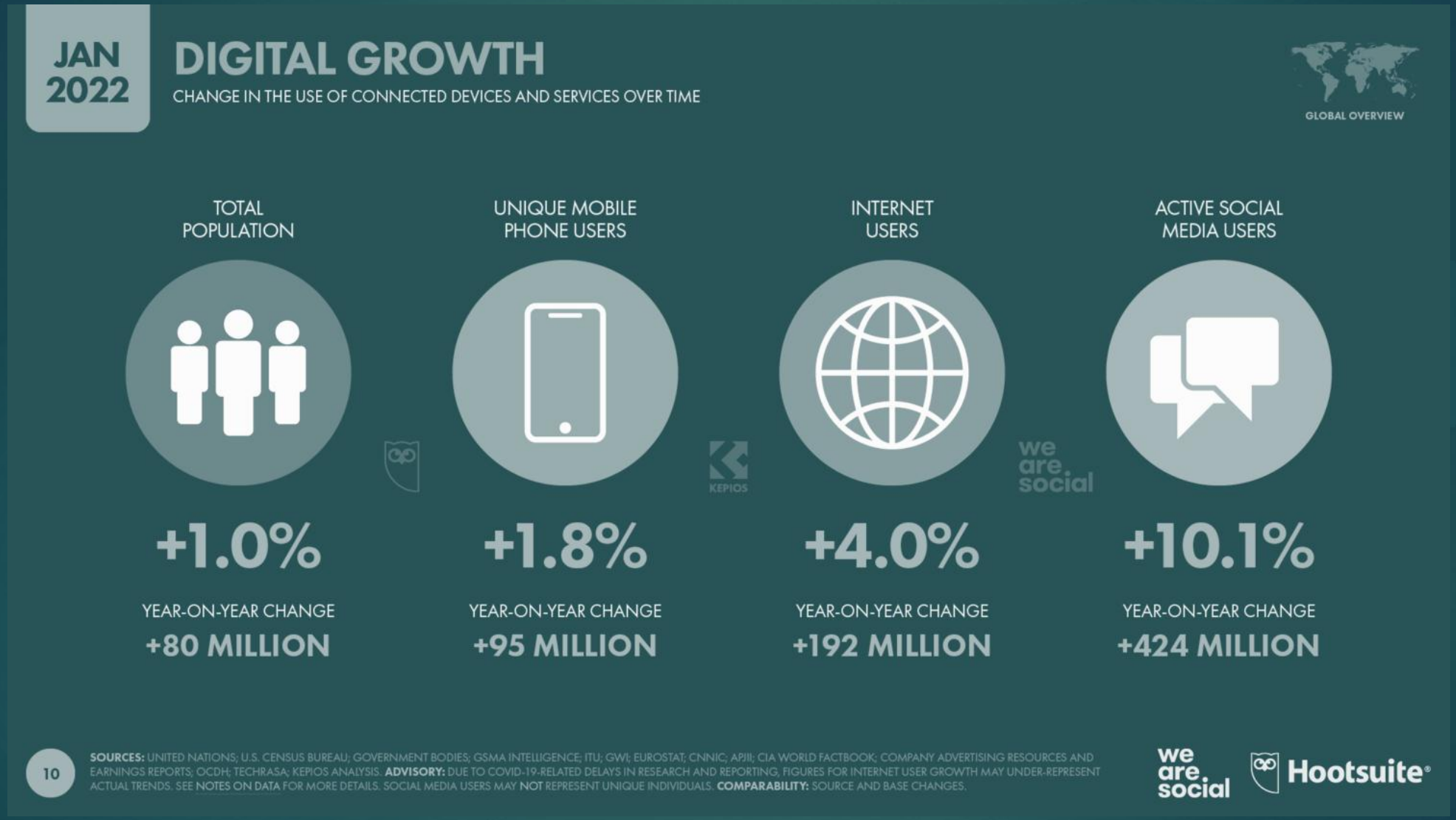
Digital & AI



[1] https://datareportal.com/reports/digital-2022-global-overview-report

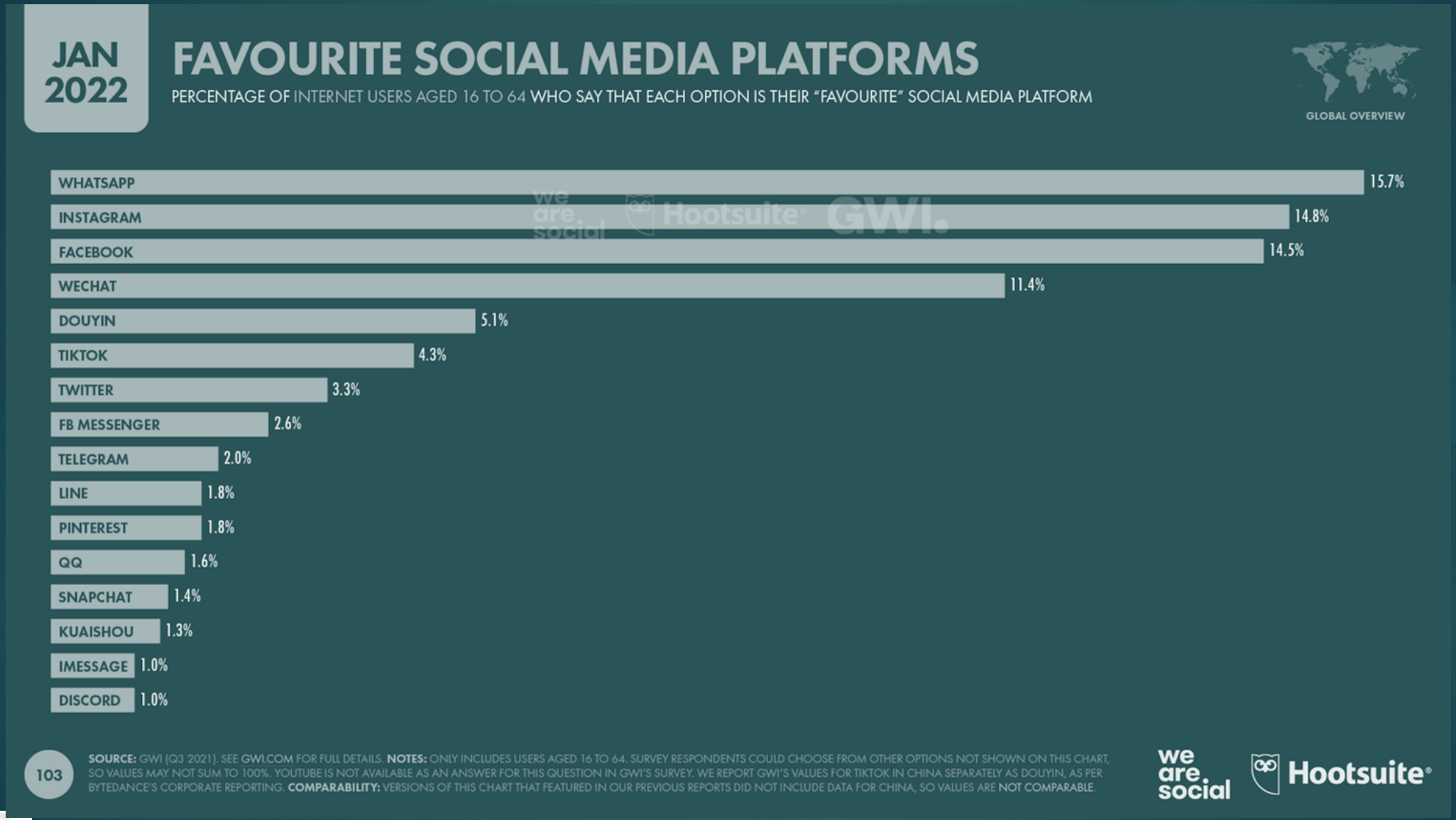
Digital Growth[1]:

Digital & AI



[1] https://datareportal.com/reports/digital-2022-global-overview-report

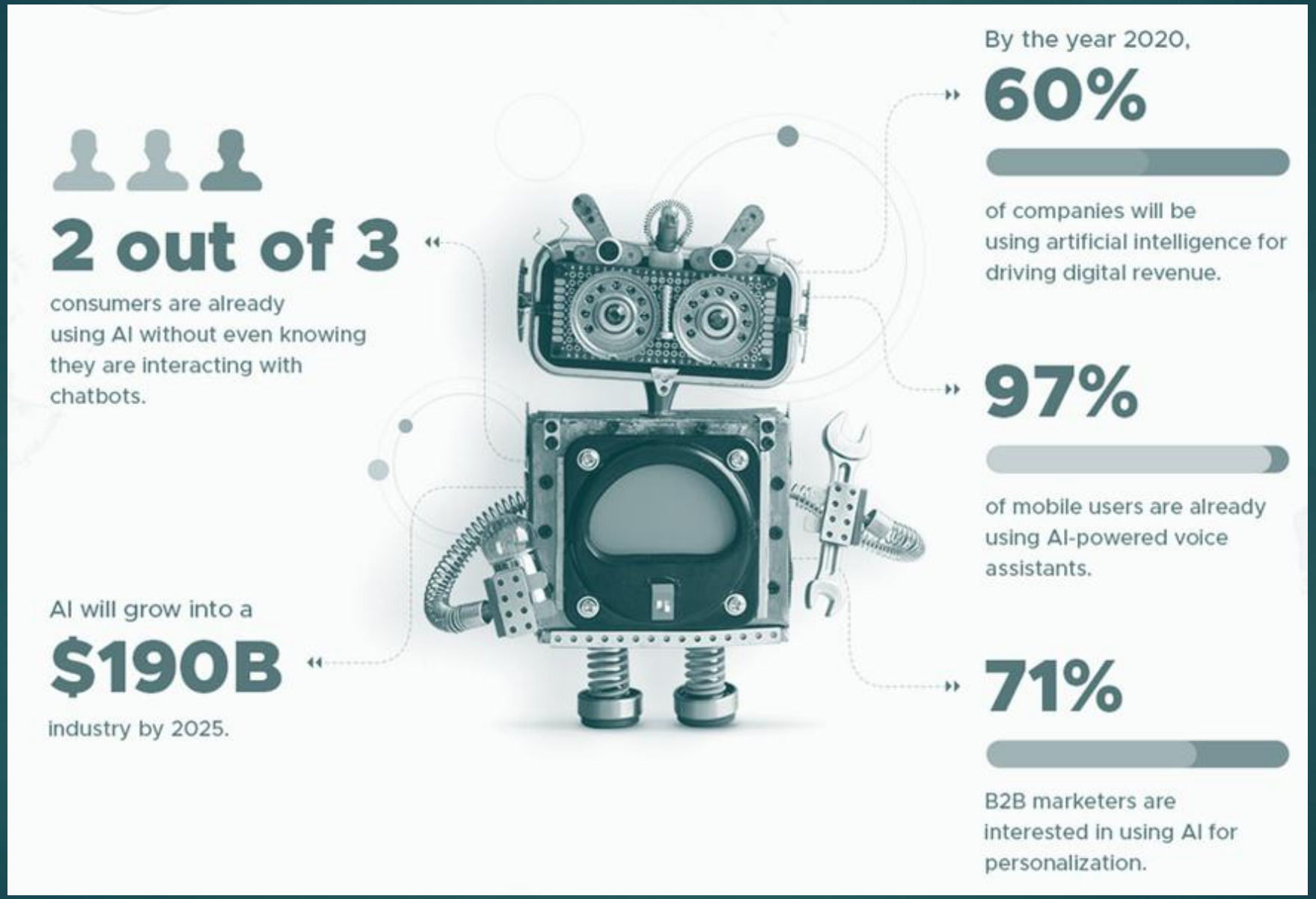
Social Media Platforms[1]:



[1] https://datareportal.com/reports/digital-2022-global-overview-report

Where is AI Right Now?[1]

Digital & AI



[1] Top AI Trends in Marketing [Infographic]. SingleGrain. https://www.singlegrain.com/artificial-intelligence/ai-trends-in-marketing-for-2019-infographic/

AI in Pharma Industry[1,2]

Digital & AI

- Application of AI with machine learning can make healthcare processes
  - Seamless
  - Cost-effective
  - Efficient
  - Hassle-free
- And become a driving force behind many communication services
  - Basic communication
  - Product recommendations
  - Content creation
  - Email personalization
  - E-commerce transactions

[1] Artificial Intelligence in the Pharmaceutical Industry – An Overview of Innovation. Mobisoft, Blog by Shailendra Sinhasane, Oct 4, 2019 (https://mobisoftinfotech.com/resources/blog/artificial-intelligence-in-the-pharmaceutical-industry/),
[2] 42 Digital Marketing Trends You Can't Ignore in 2021. Dec 6, 2019 (https://mobisoftinfotech.com/resources/blog/artificial-intelligence-in-the-pharmaceutical-industry/),

Important Links :

- https://www.gabionline.net/
- https://www.centerforbiosimilars.com/
- https://pharmaintelligence.informa.com/searchlisting?searchtext=biosimilars

Thank You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