Digital Health

Spring 2025

UNIVERSIDAD POLITÉCNICA DE MADRID

#9

Biotech, diagnostics, therapeutics, medical device, pharma, clinical research, genomic profiling

Agenda

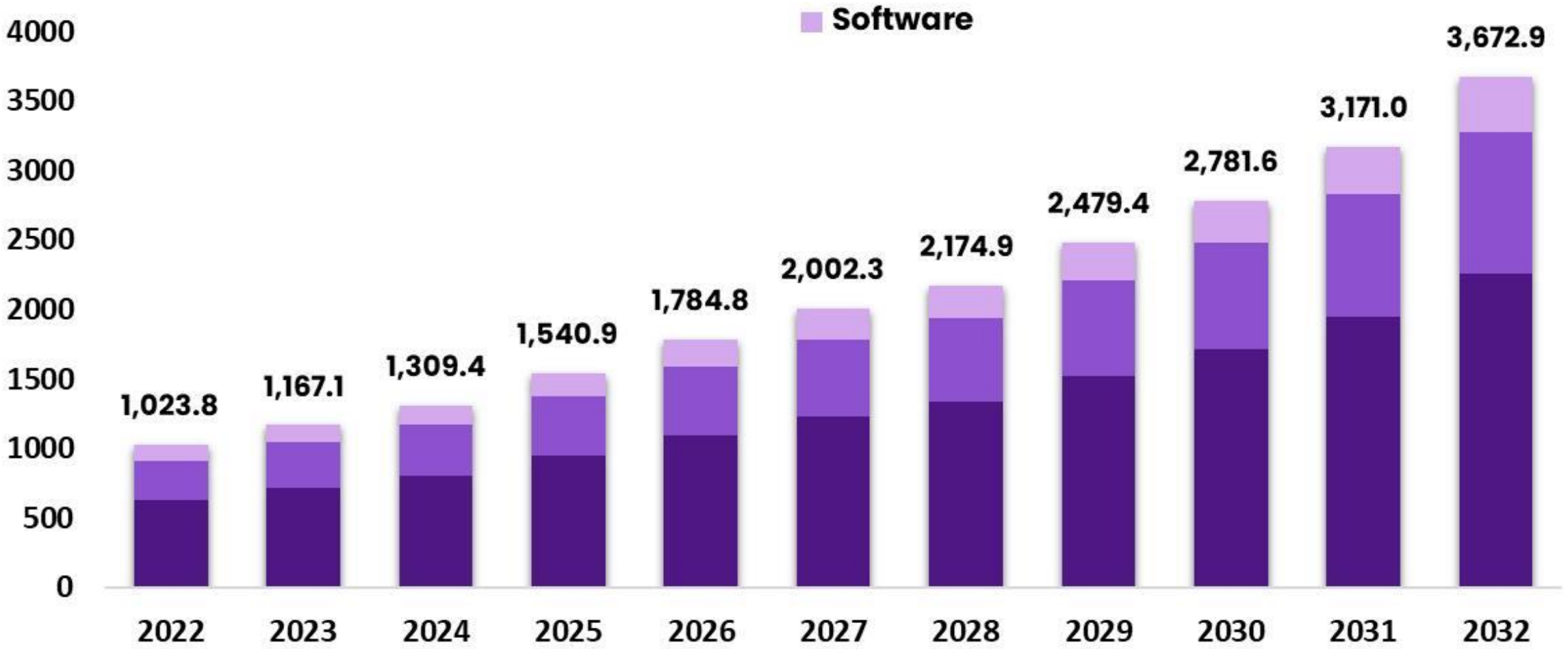
- Questions from last week?
- Learning objectives: Discipline literacy, critical analysis skills, applied and integrative learning, written communications, soft skills
- Icebreaker: Why is the sky blue?
- Lecture, videos, case study, discussion questions
- Guest lecture
- Next week: Challenges in Digital Health; Midterm exam due

Biotech, diagnostics, therapeutics, pharma, medical device, clinical research

- Biotechnology and pharmaceutical companies are involved with the research, development, and manufacturing of drugs, medical diagnostics, and medical devices.
- Building on basic science, biotechnology companies use applied research to develop and commercialize cutting-edge products and technologies.

Global Biotechnology Market

Size, by product type, 2022-2032 (USD Billion)



The Market will Grow At the CAGR of: 14%

The forecasted market size for 2032 in USD: $3672.9B

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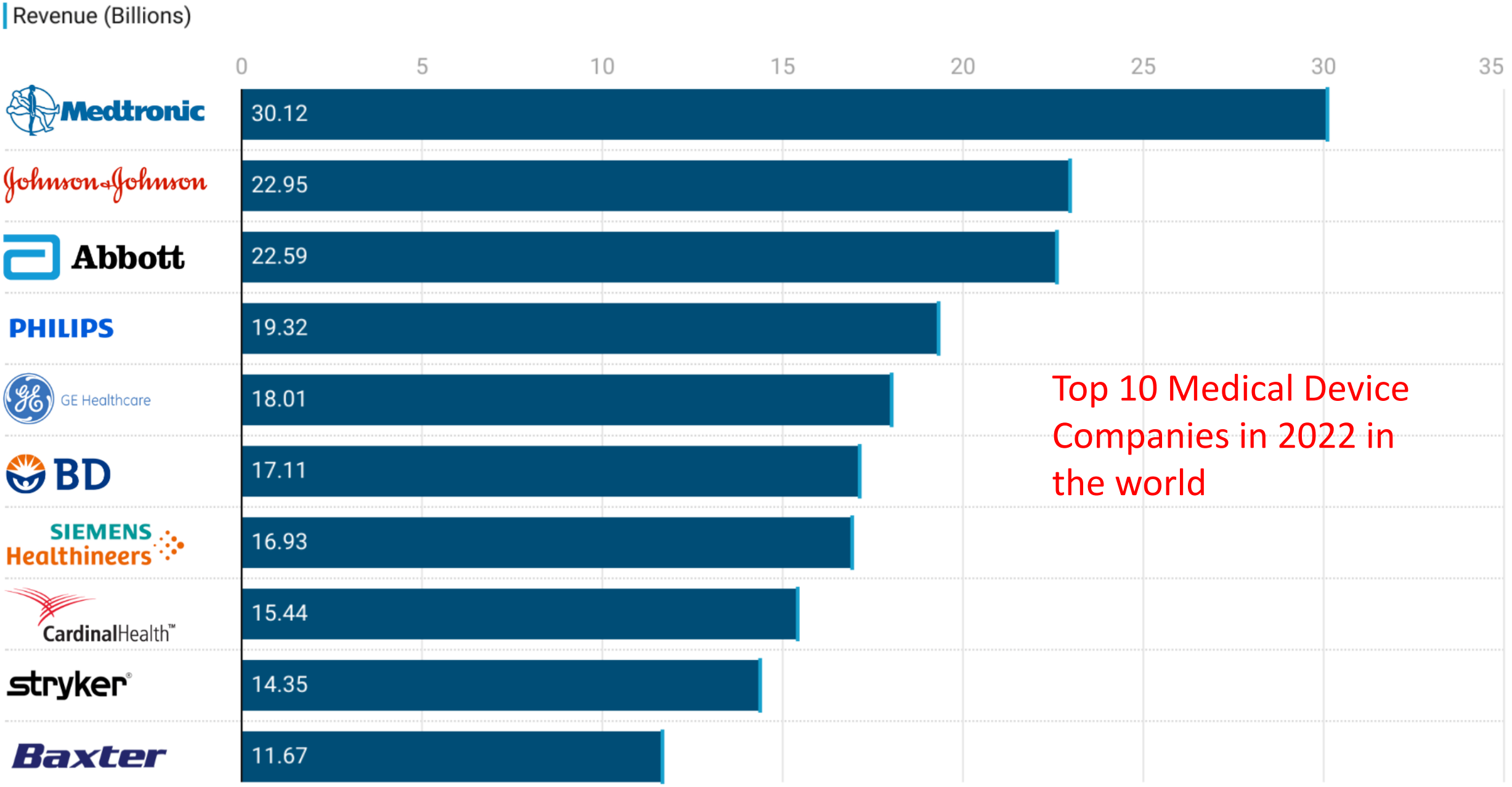
Biotechnology

Explosive growth in biotech in recent years due to COVID-19 vaccine development.

Balance scientific ambition with financial limitations while driving innovations forward

eg, 23andMe, DNA testing company about your ancestry went bankrupt

AI has great potential to accelerate drug and device development.



Top 10 Medical Device Companies in 2022 in the world

Biotech: Digital Diagnostics

- Diagnosis: determining which disease or medical condition explains a person's symptoms and signs
  - a complex process involving gathering patient information, clinical reasoning and now smart tools.
- Error in diagnosis may harm patients
  - by preventing or delaying appropriate treatment,
  - by providing unnecessary or harmful treatment
  - or resulting in psychological or financial consequences.

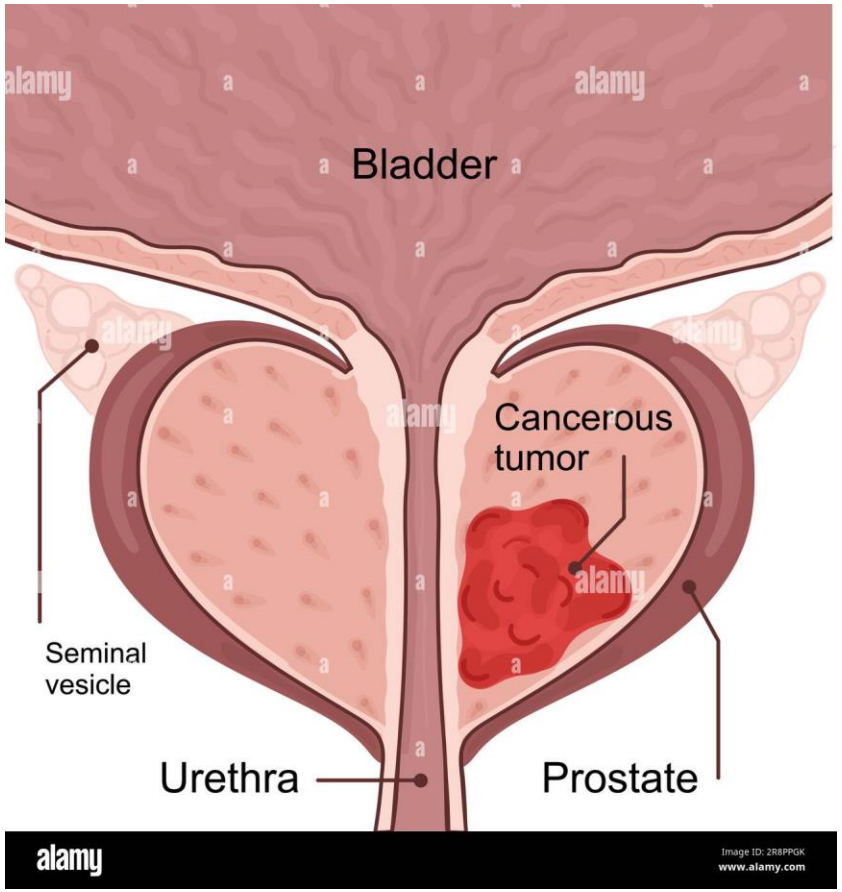
Biotech: Digital Diagnostics

- Digital diagnostic tools like medical algorithms are used to diagnose patients and provide treatment recommendations.
- Some algorithms are simple
  - Calculating a body mass index (BMI) from a patient's height and weight
  - Basic decision tree (if symptoms A, B and C are evident, then this is the probable diagnosis).
- Or algorithms can be as complex as AI to examine mammograms, eg, breast cancer.

Biotech

- Digital Diagnostics: 3 Examples
  - Prostate Cancer
  - Huntington’s Disease
  - Parkinson’s Disease

Digital Diagnostics: Prostate Cancer

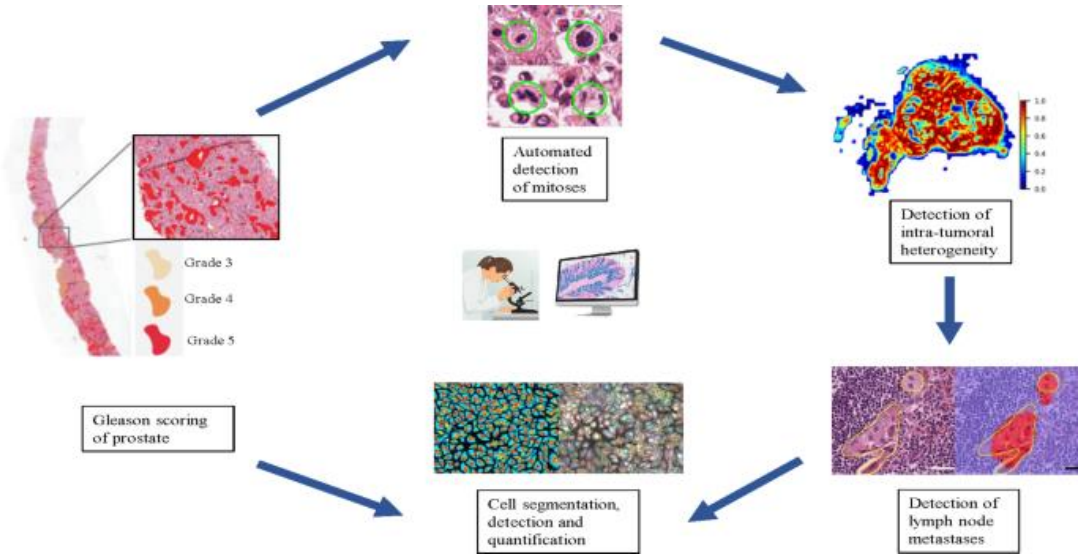


Digital Diagnostics: Prostate Cancer

Examining biopsies

- Men with high blood levels of prostate-specific antigen (PSA) have a biopsy.
- Tissue samples are taken and examined by a pathologist to determine if cancer cells are there.
  - A Gleason score (somewhat subjective) is assigned based on how aggressive the cancer is. Vary between pathologists.
- Now an FDA-approved AI software called Paige Prostate detects the presence of cancer by training on prostate samples that pathologists have identified as cancer.
- Watch this. Introducing FDA-Approved Paige Prostate

AI in Digital Diagnostics



- Benefits:
  - Improve diagnostic workflows
  - Eliminate human errors
  - Increase inter-observer reproducibility
  - Make predictions
- Challenges:
  - Clinical practice has lagged because of issues related to interpretability, clinical validation, regulation, generalizability, and cost.
- Future:
  - Personalized medicine or personalized cancer care
  - Used by human pathologists

Digital Diagnostics: Huntington's Disease

Rare inherited condition that causes brain cells to decay over time

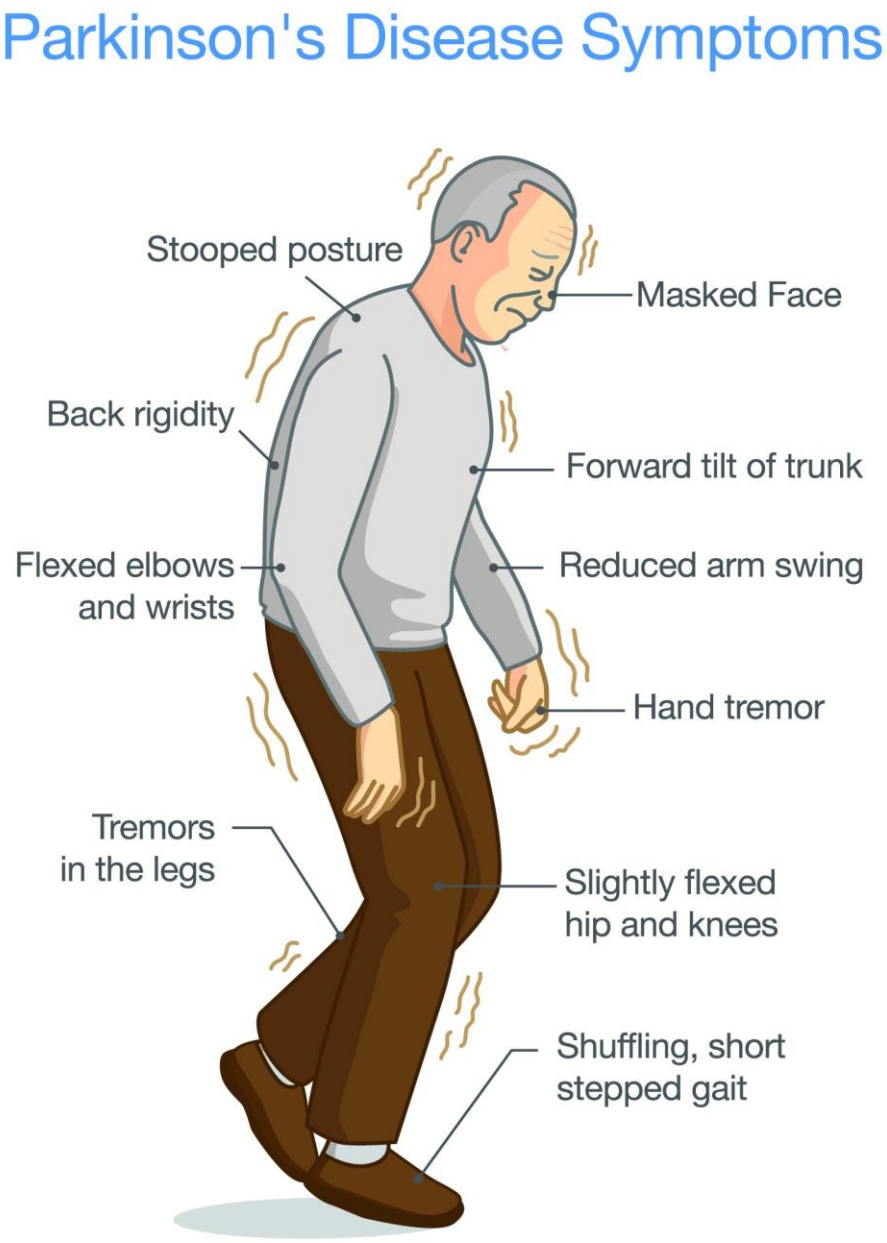
Digital Diagnostics: Huntington's Disease

- Measure involuntary movements and disease characteristics like trunk sway or sleep patterns/movements
  - Using wearable/portable devices to identify patient's condition to modify treatment.

- The use of wearable/portable digital sensors in Huntington's disease: A systematic review (2021)
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7957324/#:~:text=The%20use%20of%20wearable%2Fportable%20sensors%20allows%20the%20collection%20of,precise%20picture%20of%20disease%20manifestations.

Examples of wearable/portable sensors used in Huntington's disease

Parkinson’s Disease



Digital Diagnostics: Parkinson's Disease

- Most famous patient: Michael J. Fox, actor, Back to the Future
- Watch: (3 min) What is PD?
- parkinson's disease - Google Search
- https://www.google.com/search?q=parkinson%27s+disease&sca_esv=6c1772c741fb3aa7&sca_upv=1&rlz=1C1JZAP_enUS848US849&biw=1280&bih=585&tbm=vid&sxsrf=ADLYWILauNLb_WiMBF6xILiUZ8sVTrMJPA%3A1715834939672&ei=O5BFZqzQKLPh0PEP7vaviAM&ved=0ahUKEwjs2cmgr5GGAxWzMDQIHW77CzEQ4dUDCA4&uact=5&oq=parkinson%27s+disease&gs_lp=Eg1nd3Mtd2l6LXZpZGVvIhNwYXJraW5zb24ncyBkaXNlYXNlMgYQABgHGB4yBhAAGAcYHjIFEAAYgAQyBRAAGIAEMgsQABiABBiGAxiKBTILEAAYgAQYhgMYigUyCBAAGIAEGKIEMggQABiABBiiBDIIEAAYgAQYogQyCBAAGIAEGKIESPscUOsEWO4McAB4AJABAJgBmQGgAb8LqgEEMC4xMrgBA8gBAPgBAZgCA6ACtQPCAgcQIxgnGK4CwgIHECMYsAIYJ5gDAIgGAZIHAzAuM6AHplE&sclient=gws-wiz-video#fpstate=ive&vld=cid:ada8aea1,vid:lF0bdhZXqJw,st:0

Digital Diagnostics: Parkinson's Disease

- Body-worn sensors monitor patients, such as motor fluctuations, dyskinesia, tremor, bradykinesia, freezing of gait or gait disturbances.

- These sensors offer new opportunities for improving management in Parkinson's
  - (1.2 million patients in Europe).

- Watch (2 min)

- wearable sensors in parkinson's disease - Google Search
  https://www.google.com/search?sca_esv=6c1772c741fb3aa7&sca_upv=1&rlz=1C1JZAP_enUS848US849&sxsrf=ADLYWIIUVkW2TxQUolYnFxheOEGCeglPzw:1715834296964&q=wearable+sensors+in+parkinson%27s+disease&tbm=vid&source=lnms&prmd=ivnsbmt&sa=X&ved=2ahUKEwjP_43urJGGAxUMJzQIHUVaBooQ0pQJegQIEhAB&biw=1280&bih=585&dpr=3#fpstate=ive&vld=cid:d09fa244,vid:s5fnu1t4NQI,st:0

- https://nature.com/articles/s41531-023-00585-y#:~:text=Nowadays%2C%20there%20are%20various%20body,patients'%20management%20or%20research%20purpose.

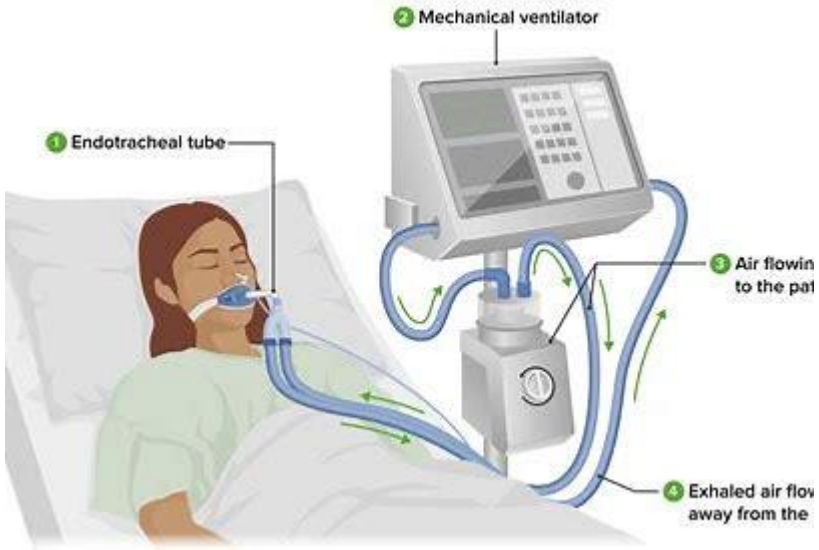
Digital Diagnostics Discussion Questions

- If you were a patient with one of these diseases, would you try these digital devices?
- Should biomedical engineers who understand this technology be on the team taking care of a patient?

Biotech: Digital Therapeutics

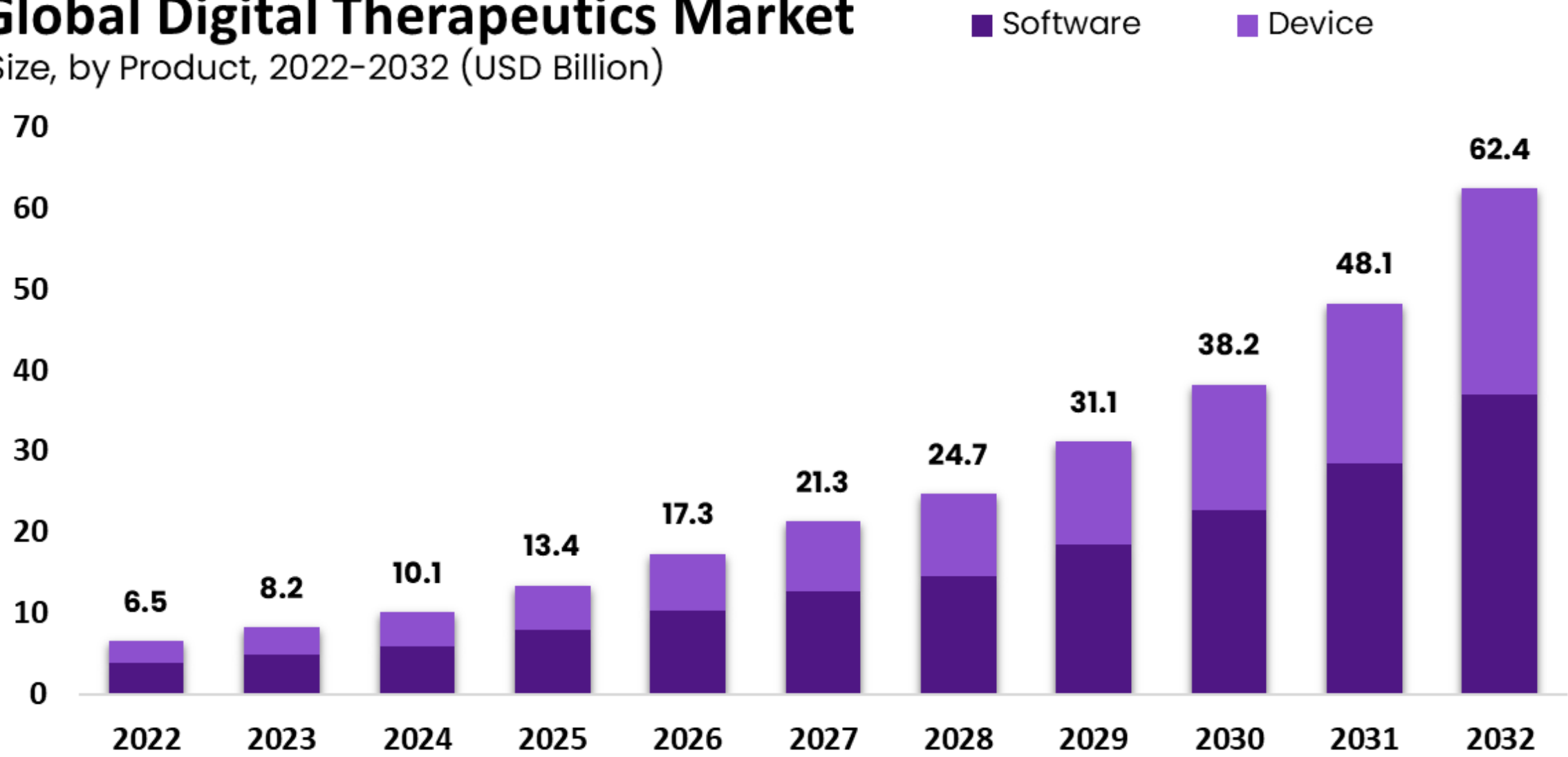
- Definition: Evidence-based therapy for patients using high quality software to prevent, manage, or treat physical, mental, and behavioral conditions.

- Example: Using AI to adjust the settings of mechanical ventilators in patients with respiratory failure



Global Digital Therapeutics Market

Size, by Product, 2022-2032 (USD Billion)



The Market will Grow At the CAGR of **26.1%** **The forecasted market size for 2032 in USD** **$62.4 B**

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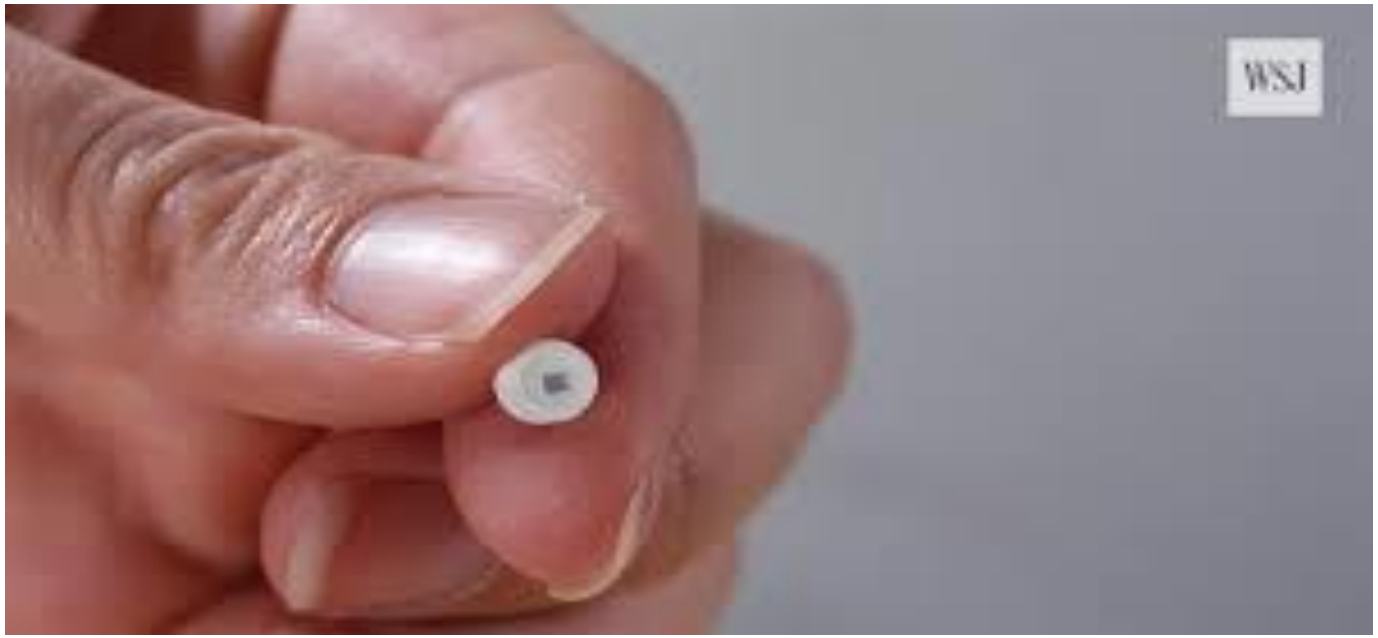
Have you heard of the Digital Pill?



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9578571/

The Digital Pill

Patients swallow a capsule with a sensor. Examples: chemotherapy in colon cancer, antipsychotics for schizophrenia

The sensor activates when it gets wet in the stomach (gastric acid) and then pings a signal to a patch that patients wear on their torso.

That transmits data on the dose size, the time and the drug taken to an online portal that a patient can view.

If a patient allows, the information is sent to his/her physician or pharmacist.

The Digital Pill

- The Digital Pill (ingestible event marker) is available, the goals are….
  - to better ensure adherence to medication and treatment guidelines
  - to improve health outcomes, and
  - to increase sales of drug companies?

- Common digital pill is Abilify, antipsychotic
  - Watch Bing Videos 3 min

Digital Diagnostics Discussion Questions

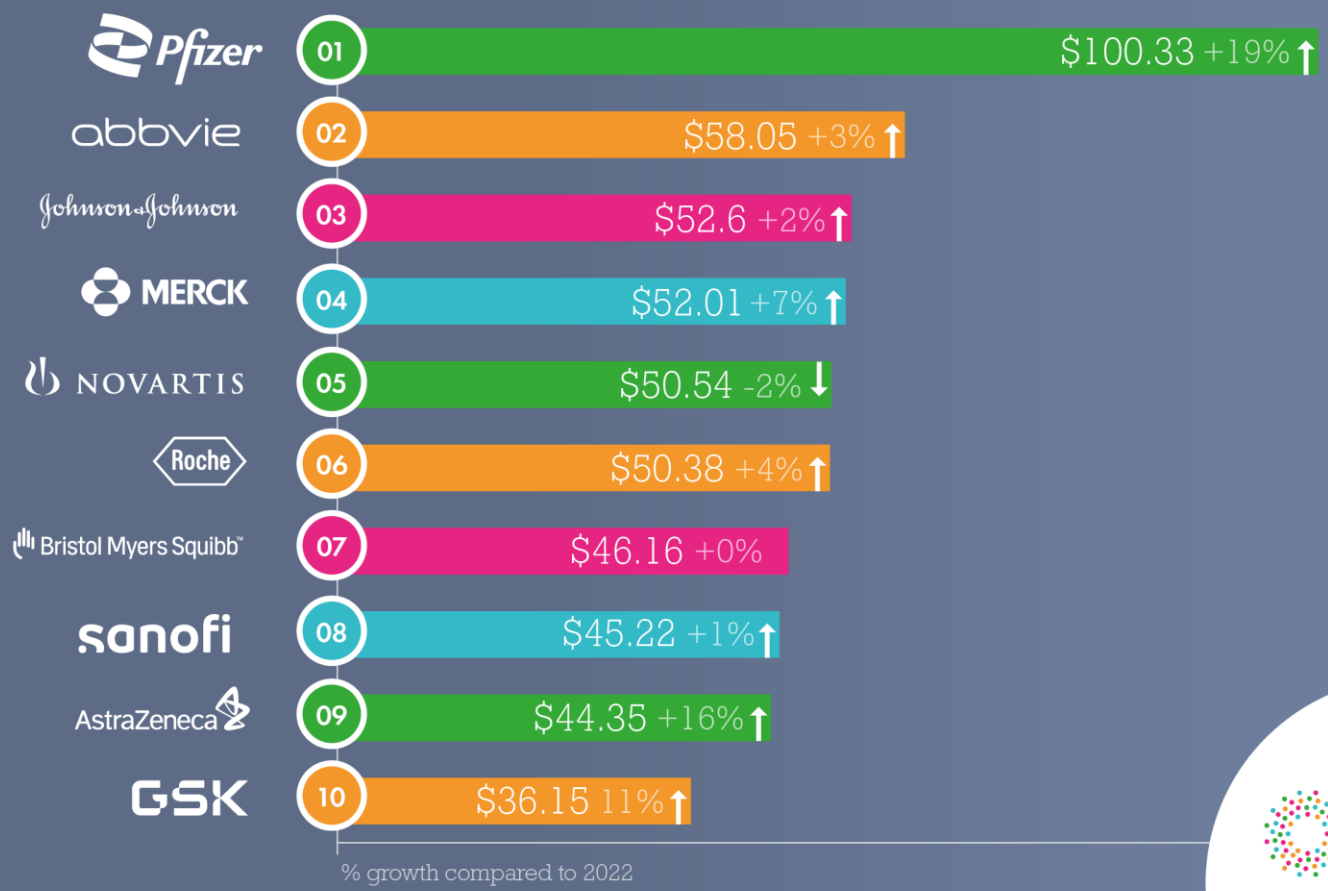
- The Digital Pill
- Is this a good idea?
- If you were a doctor, would you prescribe Abilify to your patient?
- What are the benefits and concerns?
- Who and how should the data be used?

Pharma: Global Pharmaceutical Industry

$1.6 trillion industry in 2023

Who are the top 10 pharmaceutical companies in the world? (2023)

Total revenue from pharmaceuticals (USD billions)



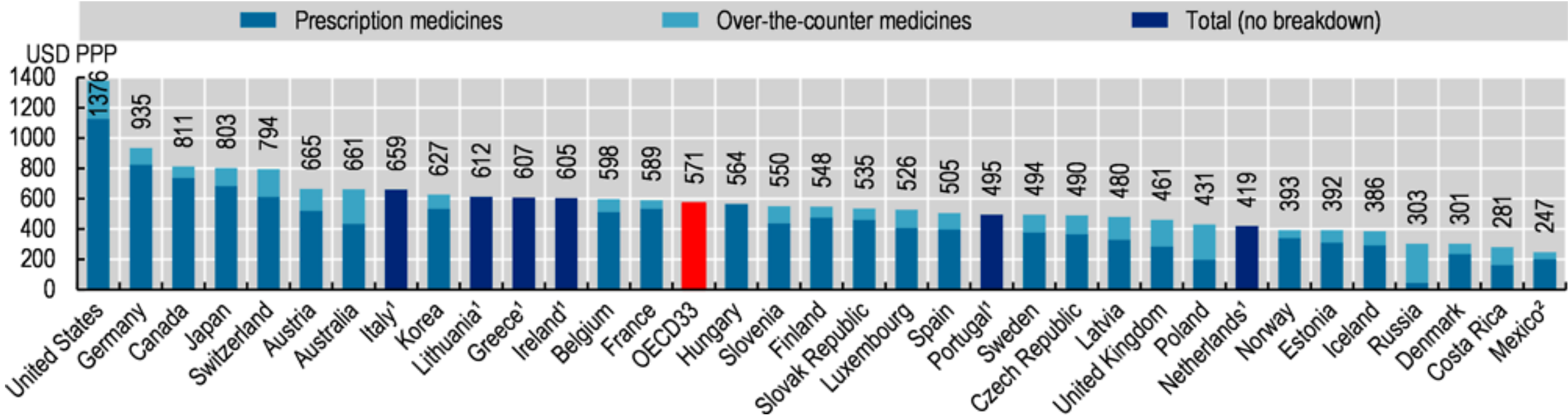
Proclinical
Part of Acacium Group

Cost of drugs: How much do people spend around the world (2022)?

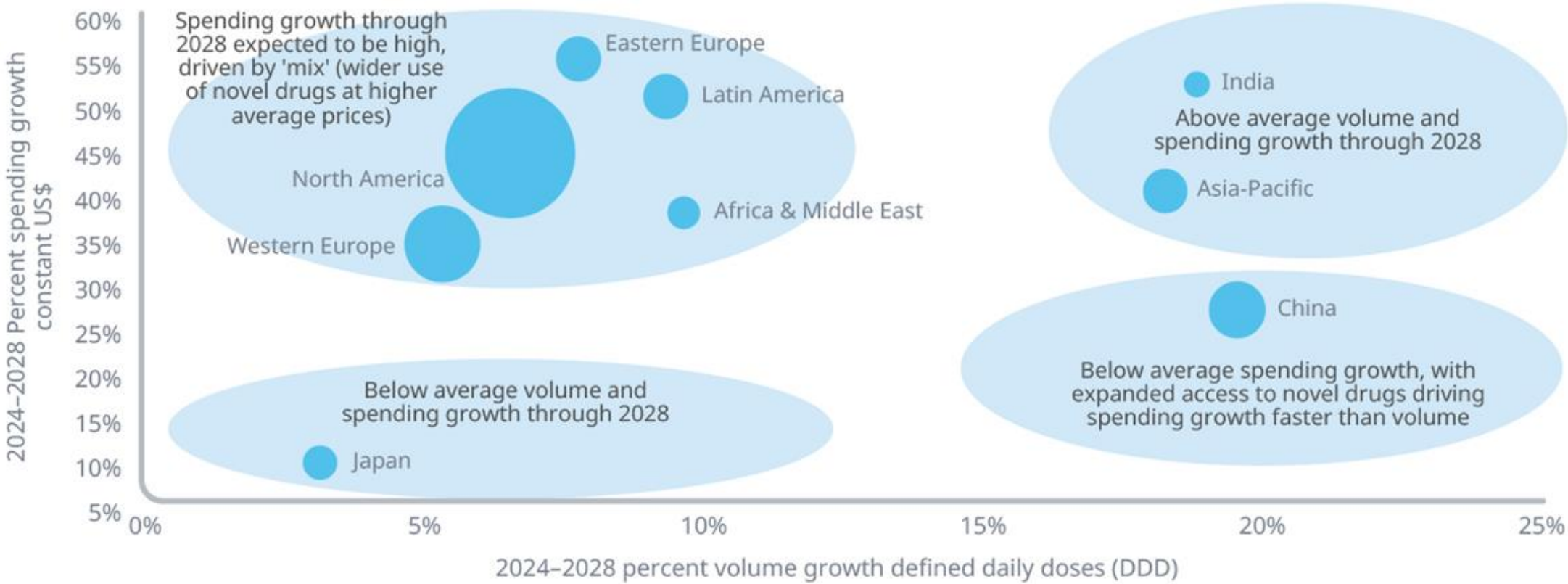
U.S.A: $1432
Germany: $1042
Canada: $914
Korea: $803
Switzerland: $803
France: $766
Austria: $765
Italy: $748
Greece: $740

https://www.statista.com/statistics/266141/pharmaceutical-spending-per-capita-in-selected-countries/

Pharma Spending per capita (OECD, 2021)

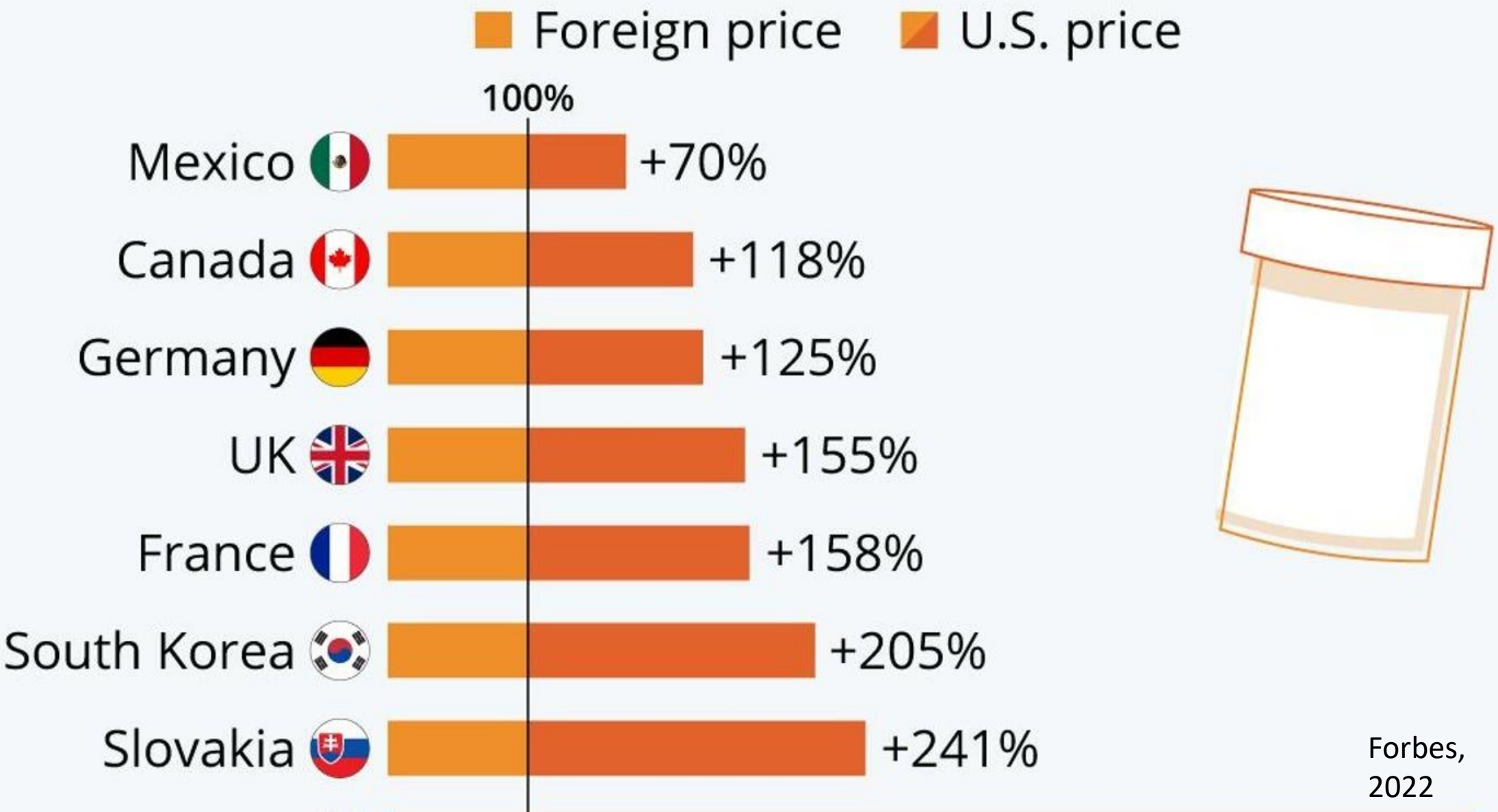


Spending and volume growth by region



Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Dec 2023.
Notes: Spending growth in constant US$ and reflecting 5-year aggregate growth. Volume growth in defined daily doses (DDD) (see methodology).
Bubble size reflects spending in 2028, see Exhibit 21 for relevant values.
Report: Global Use of Medicines 2024: Outlook to 2028. IQVIA Institute for Human Data Science, January 2024.

Percentage by which the prices of U.S. prescription drugs surpass those in other selected countries



Forbes, 2022

List prices: Elevidys, Lyfgenia, Roctavian, Casgevy and Veopoz more that $1,000,000 annually

U.S. 20 highest-priced drugs launched in 2023

Pharmaceutical companies launched new drugs in the United States at record-high prices last year, a Reuters survey has found.

Drug	Treats	Company	Annual list price ($)	FDA approved
Elevidys	Muscular dystrophy	Sarepta	$3,200,000	22 June 2023
Lyfgenia	Sickle cell disease	Bluebird	$3,100,000	8 December 2023
Roctavian	Hemophilia A	BioMarin	$2,900,000	30 June 2023
Casgevy	Sickle cell disease	Vertex/CRISPR	$2,200,000	8 December 2023
Veopoz	CHAPLE disease	Regeneron	$1,799,980	18 August 2023
Altuviiio	Hemophilia A	Sanofi	$970,000	23 February 2023
Lamzede	Rare disease	Chiesi	$655,200	16 February 2023
Pombiliti	Pompe disease	Amicus	$650,000	28 September 2023
Sohonos	Rare bone disease	Ipsen	$624,000	16 August 2023
Rivfloza	Rare kidney disease	Novo Nordisk	$603,648	29 September 2023
Daybue	Rett syndrome	Acadia	$575,000	10 March 2023
Joenja	Immune disorder	Pharming	$566,640	24 March 2023
Fabhalta	Blood disease	Novartis	$550,000	5 December 2023
Wainua	Amyloidosis	AstraZeneca	$499,000	21 December 2023
Elrexfio	Cancer	Pfizer	$498,000	14 August 2023
Zilbrysq	Myasthenia gravis	UCB	$382,155	17 October 2023
Skyclarys	Friedrich's ataxia	Reata/Biogen	$370,000	28 February 2023
Elfabrio	Fabry disease	Chiesi/Protalix	$364,717	9 May 2023
Talvey	Cancer	Johnson & Johnson	$360,000	9 August 2023
Columvi	Cancer	Roche	$350,000	15 June 2023

Note: Survey of manufacturers conducted by Reuters. Excludes vaccines, medications used intermittently, blood products, imaging agents, products used as part of bundled reimbursement in a hospital setting and drugs that have not yet been launched commercially. Some prices are the midpoint of a dose range determined by body weight and other factors.

Source: Reuters survey of companies receiving FDA approval of a new drug in 2023

The OZEMPIC craze…

- Novo Nordisk (Denmark) manufactures Ozempic, an injectable medication used to manage blood sugar and obesity and Wegovy, another weight-loss drug.

Bing Videos – Watch an Ozempic ad. States not approved for weight loss

Developing a New Drug

- Studies of the cost of designing a drug and navigating clinical trials to final approval vary widely.
- Total expense is estimated at $1 - 2 billion on average.
- Takes 10 to 15 years.
- Nearly 90% of the candidate drugs that enter human clinical trials fail, usually for lack of efficacy or unforeseen side effects.

AI in Pharma/Drug Development

- Goal: Harness A.I. to produce more effective drugs, faster and cheaper.
- Process: Using molecular information, protein structures and measurements of biochemical interactions.
  - The A.I. learns from patterns in the data to suggest possible useful drug candidates.
  - Digitally design a drug molecule.

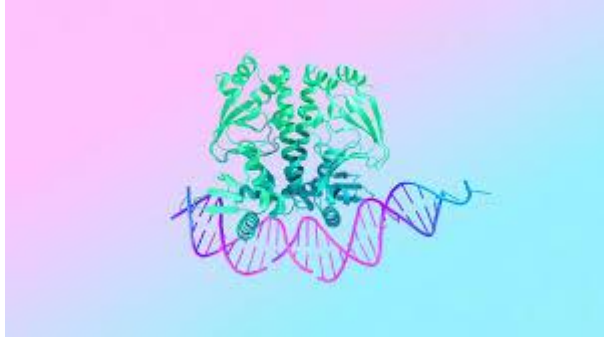
- The company, Terray is doing high speed biochemical screens
  - Lohr, S. The New York Times: How AI is revolutionizing Drug Development, June 17, 2024

AI in Pharma/Drug Development

Check out some of these companies exploring AI in all phases of the drug discovery and production process

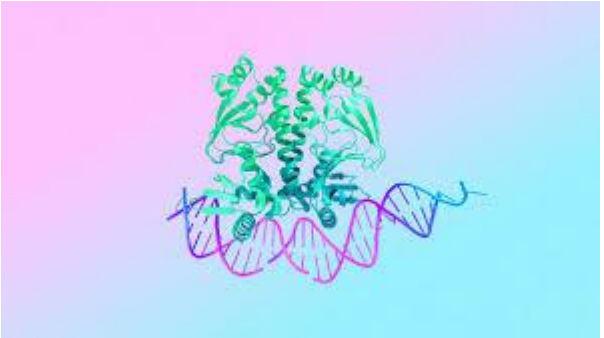
Areas	Usage Scenarios	AI Related Technologies	Companies in the Industry Chain	Intelligent Technology Service Providers
Drug R&D	Drug Discovery	Data Mining, NLP, Neural Network	Pfizer, IBM	BioSymetrics, CytoReason
	Preclinical Research	Neural Network, Reinforcement Learning	Bayer, Charles River	Cyclica, Peptone, BenchSci, Novoheart
	Clinical Research	Image Recognition, NLP	Merck, QuintilesIMS	Deep 6 AI, PathAI, AiCure, Biovista
	Approval Process	NLP, Data Mining	Roche, LabCorp	sciNote, Deep Intelligent Pharma
Drug Market	Pharmaceutical Logistics	Machine Learning, Blockchain, IoT	Suzuken, DHL	MediLedger, S.F. Express
	Medical Robots	Robotics, Speech Interaction, NLP	Mayo Clinic, CVS, Panasonic	Rowamax, PillPack
	Intelligent Device/Software	Face ID, Sensor, IoT	Cleveland Clinic, Rite Aid	ARxIUM, Xiaohe Intelligent Technology
	Medical Data Service	Data Mining, NLP	Novartis, WuXi AppTec	Medscape, Drugbank

AI in Pharma/Drug Development



- Other companies working in this area: Isomorphic Labs
- Based in London and Lausanne, Switzerland
- Drug discovery spinout from Google Deep Mind using a computational approach
- AlphaFold3 – predicts the shapes of amino acids folding into proteins in the human body with high accuracy allowing researchers to find new target pathways for drug delivery.

- Lohr, S. The New York Times: How AI is revolutionizing Drug Development, June 17, 2024



Discussion Questions

- Will traditional pharmaceutical companies and digital therapy companies merge because therapy will blend for patients?

- In other words, will all pharma companies become digital technology companies?

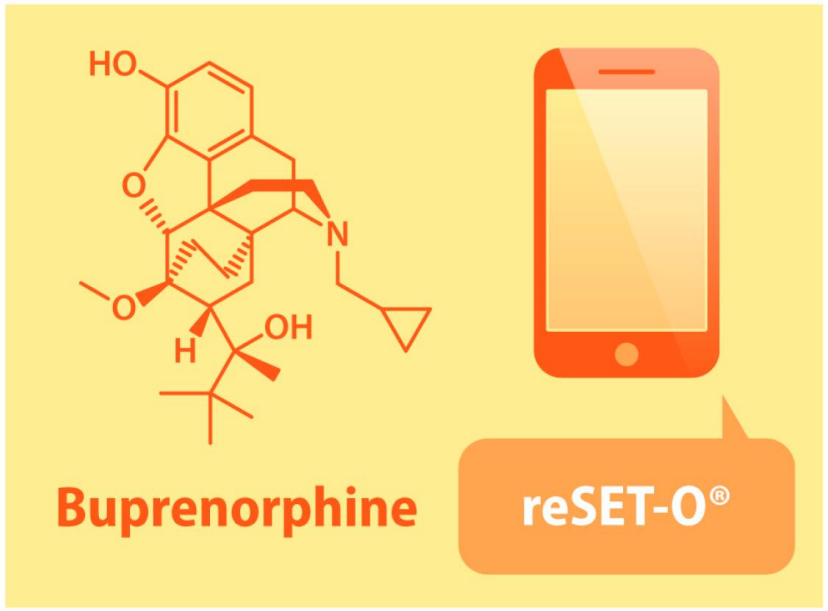
Pharma, Digital Therapeutics and Medical Device Industry Blur or Merge

- Innovative products that adhere to better patient compliance, improve product safety and utilize unique drug delivery methods.

- Johnson and Johnson acquires Abiomed, Inc. develops and manufactures temporary external and implantable mechanical circulatory support devices
- Thermo Fisher (lab equipment) acquired UK-based the Binding Site Group that makes blood tests for multiple myeloma.
- Amgen acquires Horizon Therapeutics (Ireland) treats rare diseases

Examples of Drug + Digital Combination Therapies

ADJUNCT DTx

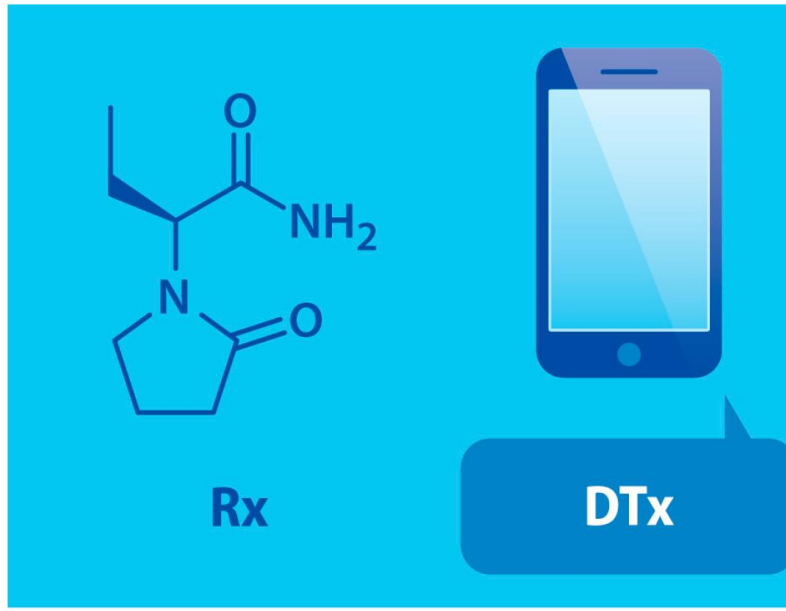


Opioid addiction
Cognitive behavioral therapy

COMPANION APP

Rheumatoid arthritis

DRUG-DEVICE COMBINATION PRODUCT



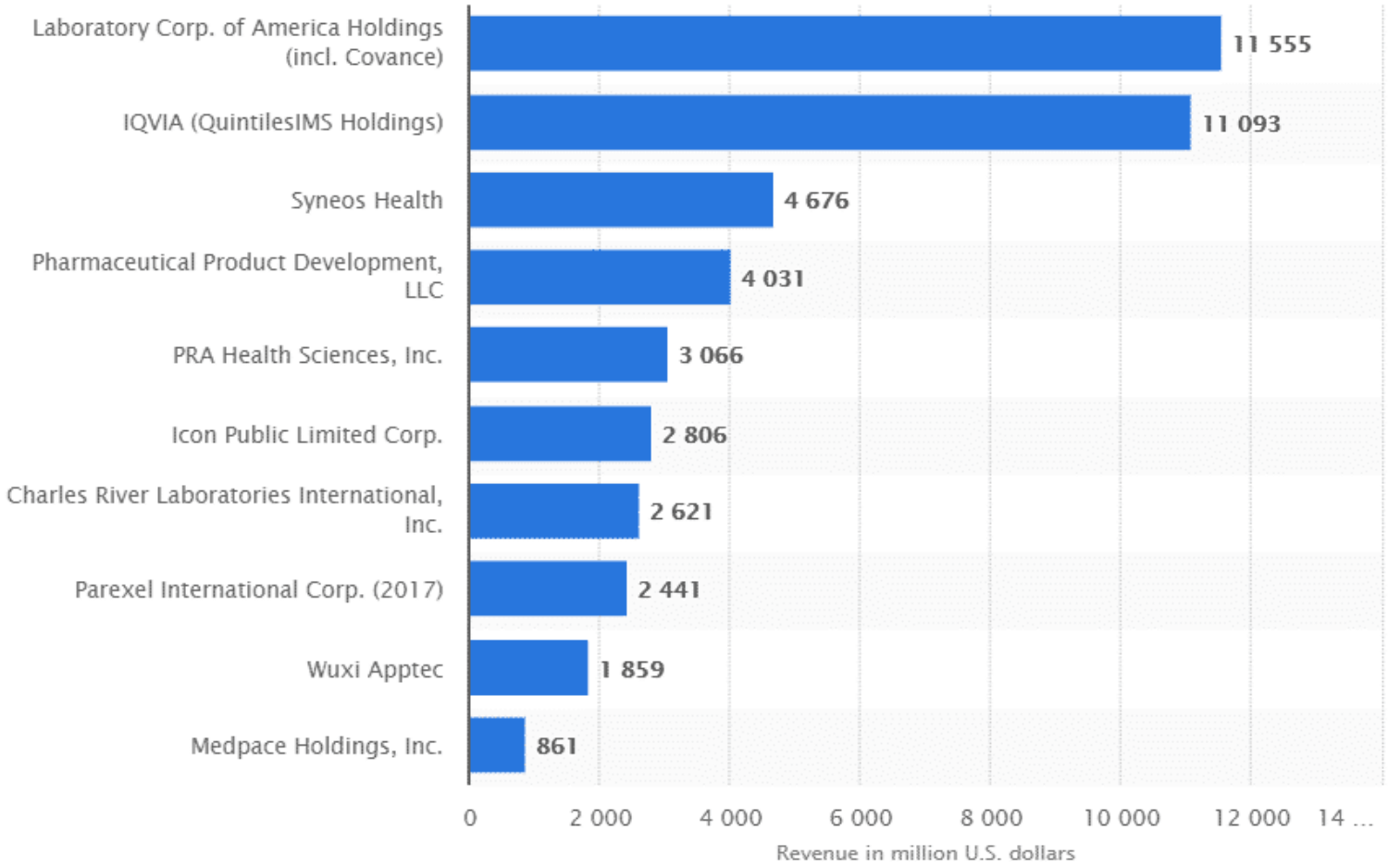
Biotech: Digital Therapeutics

- More examples of blending or merging…
- Sanofi, giant pharma company
  - Partners with Dario - smartphone application that links blood glucose monitoring with tracking, education, and support features, such as pop-up notifications and human coaches.
  - Partners with Happify - mental health digital tools for patients with multiple sclerosis
- Digital Therapeutics Alliance
  - https://www.dtxalliance.org/about-dta/
  - News of the industry

Clinical research organizations (CRO)

- Organizations that determine the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use.
- CRO companies are used by biotechnology, medical manufacturing and pharmaceutical industries to manage clinical trials in clinical research.

Top CRO companies globally

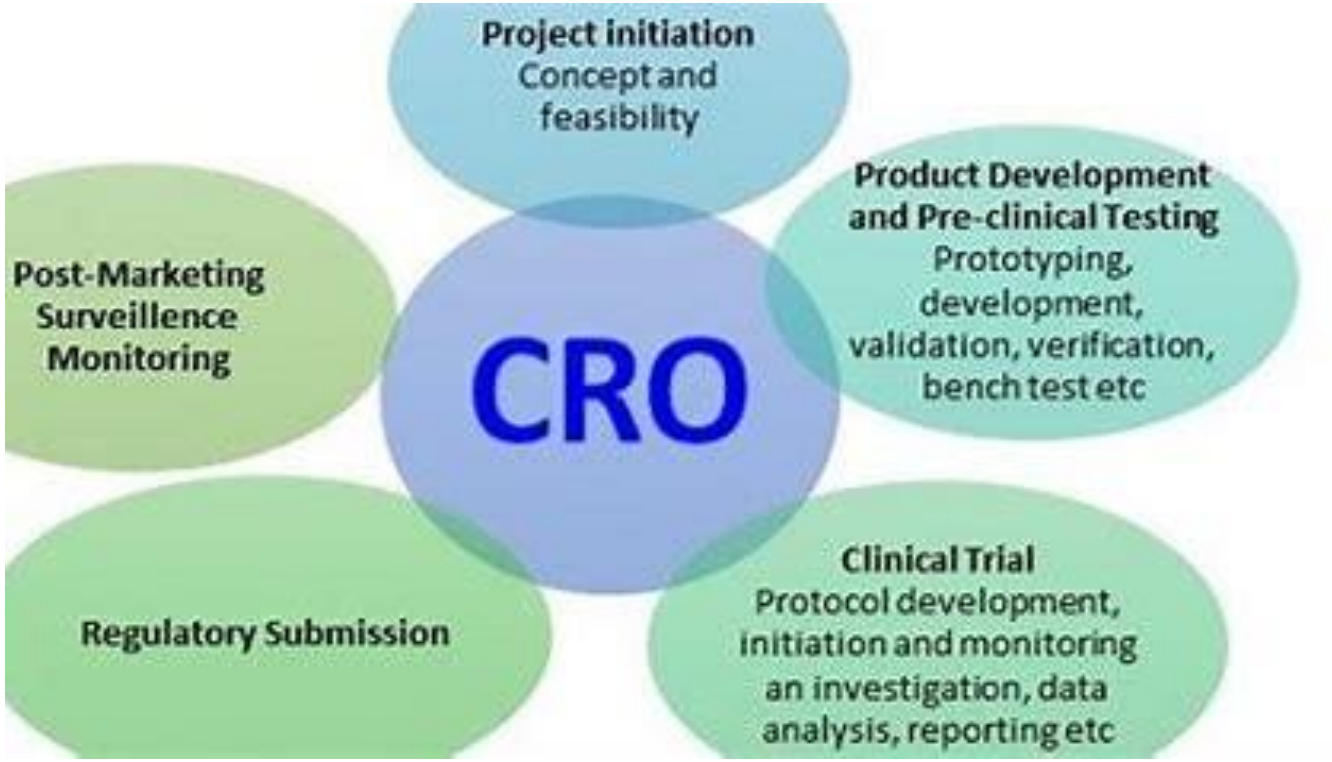


Clinical research organizations

Largest CROs worldwide were IQVIA (multinational and largest) Thermo Fisher Scientific Inc., Labcorp, ICON, and WuXi Clinical

Based on 2022 annual revenues in a 2023 Statista Report.

CRO Services



Clinical research organizations- Services

- Drug discovery
- Preclinical studies - determine toxicity
- Phase I - test basic safety and pharmacology
- Phase II - efficacy evaluation
- Phase III - advanced efficacy and safety testing
  - to provide data for statistical conclusions required by the regulatory authority
- Phase IV - continuous testing following the approval for marketing
- Other services including pharmacovigilance, bio-statistics, clinical data management, site management, monitoring, regulatory services, protocol development, and medical writing

Genomic profiling, genomic sequencing or genomic characterization

- A laboratory method that is used to learn about genes in a person or in a cell type, and the way those genes interact with each other and with the environment.
- Genomic profiling may be used to find out why some people get certain diseases while others do not, or why people react in different ways to the same drug.
- Genomic profiling may also be used to help develop new ways to diagnose, treat, and prevent diseases.
- Personalized medicine arises.

  - From the U.S. National Cancer Institute.

Genomic profiling

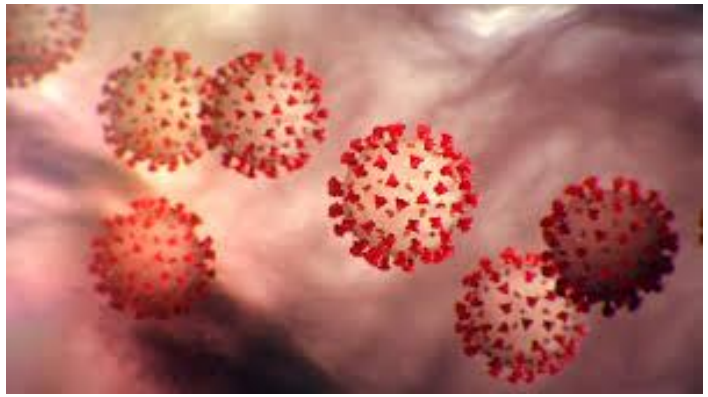
- Saving babies –
  - Fast DNA Sequencing Can Offer Diagnostic Clues for inborn errors of metabolism
  - For example, thalassemia where reduced hemoglobin is produced
  - Changes medical management by identifying newborns who need intensive care, determines prognosis and becomes a best practice in neonatal intensive care.

- Interesting Article: 33 studies document effectiveness
- The Role of Genome Sequencing in the NICU - PMC

Genomic profiling

- Think about the importance of genomic profiling during this corona virus pandemic and with the new variants.

- Watch this explanation of the pandemic (5 min).
- https://www.youtube.com/watch?v=RvyQJHKicXk



Genomic Profiling Examples

- Cure for cystic fibrosis (mutation causes severe respiratory problems)
- Cure for Duchenne muscular dystrophy (mutation causes muscle contraction difficulties)
- Modify drug treatment for colon cancer based on DNA

Discussion Questions

- Should the public understand genomic sequencing? Why does the public need to know about science?
  - News in the U.S. reported that people were afraid to take the Covid vaccine because they thought it might alter their DNA.
- How does genomic profiling really support the future of a healthy population?

Companies in biotech, diagnostics, therapeutics, pharma, medical device - Grifols

- Grifols is a global healthcare company founded in Barcelona, with more than 100 years of history, dedicated to improving the health and well-being of people around the world.

24,000 employees in 30 countries
Sites in Bilbao, Murcia, San Sebastian and Barcelona

Companies in biotech, digital diagnostics, digital therapeutics and genomic profiling

1. Sweden: Natural Cycles' birth control app

- https://www.naturalcycles.com/en/about

2. Germany: Gaia AG, digital therapeutics for depression, epilepsy and other conditions.

- https://gaia-group.com/en/

3. U.S.: Click Therapeutics for major depressive disorder and smoking cessation. Software as treatments.

- https://www.clicktherapeutics.com/

4. Japan: Otsuka/Proteus Abilify MyCite, drug/sensor for serious mental illness

- https://www.proteus.com/press-releases/otsuka-and-proteus-announce-the-first-us-fda-approval-of-a-digital-medicine-system-abilify-mycite/

5. U.S.: Dthera Sciences, digital therapeutics focused on neurodegenerative diseases such as Alzheimer's disease.

- https://dthera.com/

Companies in biotech, digital diagnostics, digital therapeutics and genomic profiling

6. U.S.: Pear Therapeutics, for psychiatric and neurologic conditions
- https://peartherapeutics.com/about-us/who-we-are/

7. U.S.: Akili Interactive, trials to treat pediatric ADHD
- https://www.akiliinteractive.com/

8. India: qure.ai, medical algorithms for diagnostic imaging
- https://qure.ai/

9. France: Voluntis, oncology products
- https://www.voluntis.com/

10. Spain: Salumedia, lifestyle and wellness digital products
- https://www.salumedia.com/solution
- Acquired by Adhera Health

11. The Netherlands: Xilloc, patient specific bone reconstruction.
- www.xilloc.com

Companies in biotech, diagnostics, therapeutics, pharma, medical device

- Around the world, companies are trying to capitalize on the opportunities in biotech, digital diagnostics and therapeutics and genomic profiling to create profitable enterprises.
- Think about some of these companies.
- Would you like to work for one of these companies?
- How do you evaluate their mission, vision and culture?
- How do you know what the future looks like for the company?

Case Study: Medtronic, Healthcare technology for the digital age. https://www.medtronic.com/us-en/index.html

- Medtronic plc is an Irish medical device company. The company's operational and executive headquarters are in Minneapolis, Minnesota, USA.
- Operates in more than 150 countries and employs over 90,000 people. It develops and manufactures healthcare technologies and therapies.
- Pacemakers, laparoscopic surgical instruments, nutrition-related data services and analytics, titanium spine implants, diabetes therapy management, computer assisted surgery, renal care solutions.
- Annual revenues of $32 billion

Case Study: Medtronic - check out the web site

- As the new CEO…
- If Medtronic wanted to buy another company, describe this new company. The product or service? ...
- What new products or services would you try to develop?
- What future challenges does Medtronic have?
- What trends point to the continued success of Medtronic?

Summary

- Innovations pursued by biotech, diagnostics, therapeutics, medical device, pharma, clinical research, and genomic profiling companies
- Size of this industry – companies working in this area
- Use of AI in this industry
- Benefits to mankind of innovations in this industry

Next session:

Confidentiality, privacy, interoperability, interconnectivity, cybersecurity, regulations

- Challenges in Digital Health
- Work on midterm exam. Due next week.