



BIOPHARMA & DIGITAL HEALTH

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AMGEN



World's largest independent biotech firm

- Sixth largest biopharma company by market capitalization

Founded 1980, 20K employees, \$23B revenues

Headquartered in Thousand Oaks

- Presence in 55 countries, Cambridge, & 100 other countries

“Biology first” approach targets serious diseases that are challenging to treat

- Cardiovascular, Oncology, Neurosciences, Bone, Inflammation, Nephrology

DEFINITION

Digital Health

The development of **interconnected health systems** to improve the use of **computational technologies, smart devices, analytics, and communications systems** to help healthcare professionals and patients understand and manage illnesses and health risks, as well as promote well-being.

Adapted from Wikipedia

CURRENT TRENDS



HEALTHCARE LANDSCAPE



Patients

- Pull information from internet, resist information pushed at them
- Are empowered, demanding, value buying experience, will trade PHI for free services

Healthcare providers

- Pull information from internet, resist information pushed at them
- Go online (67%), use social media (50%), from episodic to continuous care, operate increasingly under value-based reimbursement and data-driven medical care

Payers

- Believe clinical trials are necessary, but not sufficient, to justify high cost of medicines
- Require real-world evidence of value, positive socioeconomic impact

LIFE SCIENCES LANDSCAPE



Performance of industry

- 2014 AGR of top 25 life sciences firms was only 1%
- Average cost of new drug is \$2.6B, due to 10% success rate of P1 candidates

Value delivered

- Patients value functional ability more than clinical efficacy
- Minimal package is becoming Drug + Digital (to enhance drug efficacy)

Drug approval revamped

- Prescription Drug User Fee Act (PDUFA) \Rightarrow FDA to accept patient input
- 21st Century Cures Act \Rightarrow FDA required to consider non-clinical trial data

DIGITAL HEALTH LANDSCAPE



Mobile health market predicted to be \$21B in 2018

Wearables market projected to be \$32B in 2019

Experimentation poses a low barrier and minimal risk

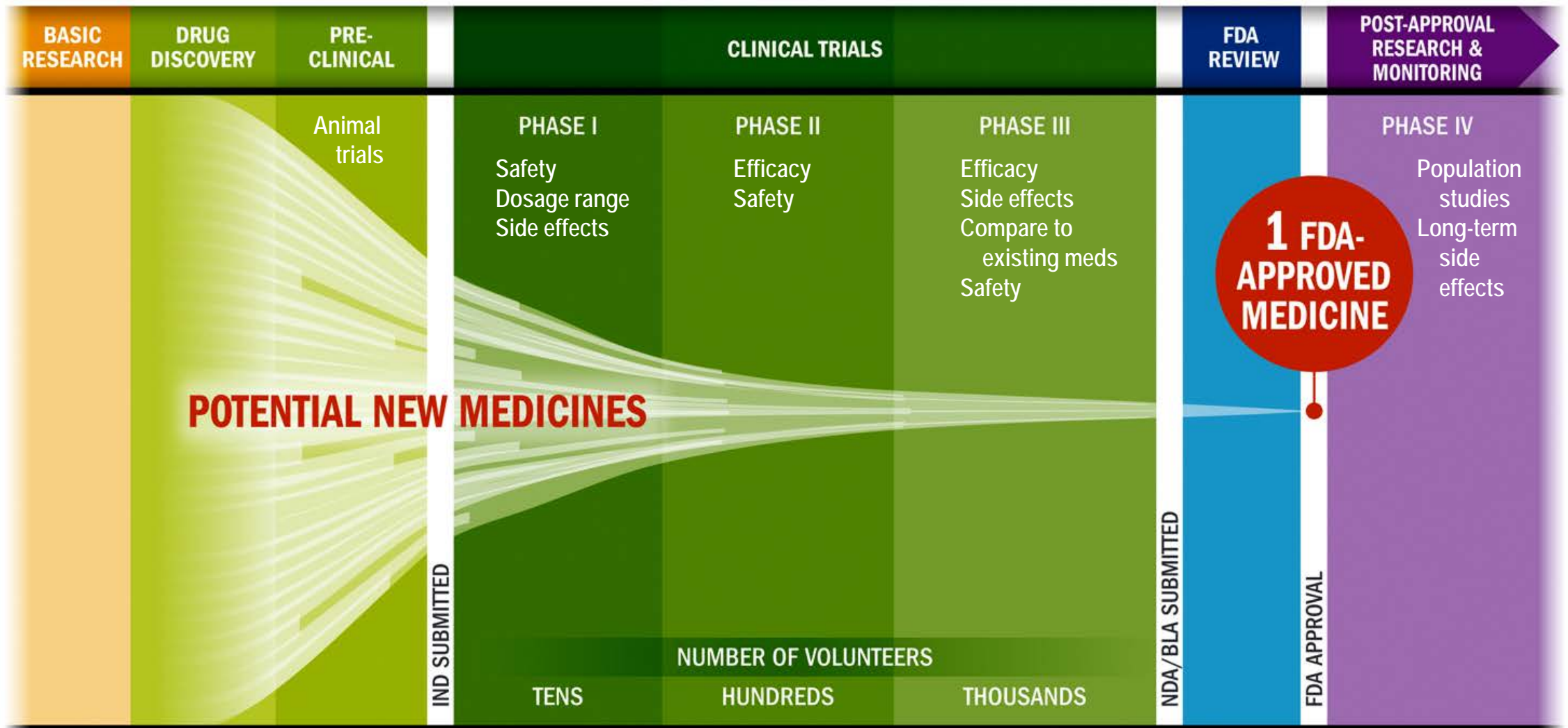
Creation of massively big data

Need for machine learning and predictive analytics

Proliferation of new healthcare technologies from a variety of domains

HOW IS BIOPHARMA EVOLVING?





Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

TRADITIONAL MODEL



Drug development is slow, extremely costly, and risky

Clinical trials cost \$30-40M pre-approval, \$30-40M post-approval

New drug pipelines are drying up

Inability to precisely target the right patients in the real world

Payers are pushing back against the high cost of new drugs

Payers want evidence of real-world benefit

NEW BUSINESS MODEL



Priorities:

- Provide a more holistic, complete, and safer data-driven solution to patients
- Make drug development more efficient and cost-effective
- Demonstrate real-world value to patients, providers, and payers

Solution: create a **digital health ecosystem** around the medicine

- Transition to virtual clinical trials and automation where appropriate
- Develop more precise patient targeting for products
- Improve recruitment, retention, and adherence through patient engagement
- Deliver benefits that truly matter to patients, providers, and payers

DIGITAL HEALTH TECHNOLOGIES

Telemedicine

Mobile apps

Big data, analytics, & AI

Infrastructure systems

Cybersecurity

Alerting/warning systems

Medication compliance

Wearable sensors

Specialized sensors

Ingestible sensors

Implantable sensors

Smart pills

Next-gen clinical tools

Simulation & modeling

New user interfaces

Augmented reality

Virtual reality

Robots

Environmental sensors

3D bioprinting

Social media & engagement

Behavioral therapy

Genomics

Bionics

PHARMA EXPLORES DIGITAL HEALTH

- **Mobile apps, devices, wearables** (top 12 pharmas released 700 apps/5 years)
- **Social media** (Novartis Target My Hives app, startups)
- **Clinical trial streamlining, recruiting, engagement, adherence** (Science 37)
- **M&As, digital health investments** (28/325 deals digital health 2014-16)
- **New business models** (data-driven outcomes pricing, risk sharing, open sourcing)
- **Accelerators & startup networks** (JLABS, Janssen, Amgen)
- **Crowdsourcing & open innovation** (Innocentive, Indiegogo)
- **Nontraditional alliances** (Verily, Apple, Qualcomm, IBM Watson)
- **Manufacturing** (Spritam, 3D-printed pill for epilepsy)

AMGEN'S EXPERIENCE



DIGITAL HEALTH INITIATIVES



- Patient Centricity initiative
- Technical proof of concept
- Virtual/hybrid clinical studies
- Wearables in clinical trials
- Technology assessment
- Venture funding
- QB3 startup incubator



Q & A