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FDA's COVID-19 Activities

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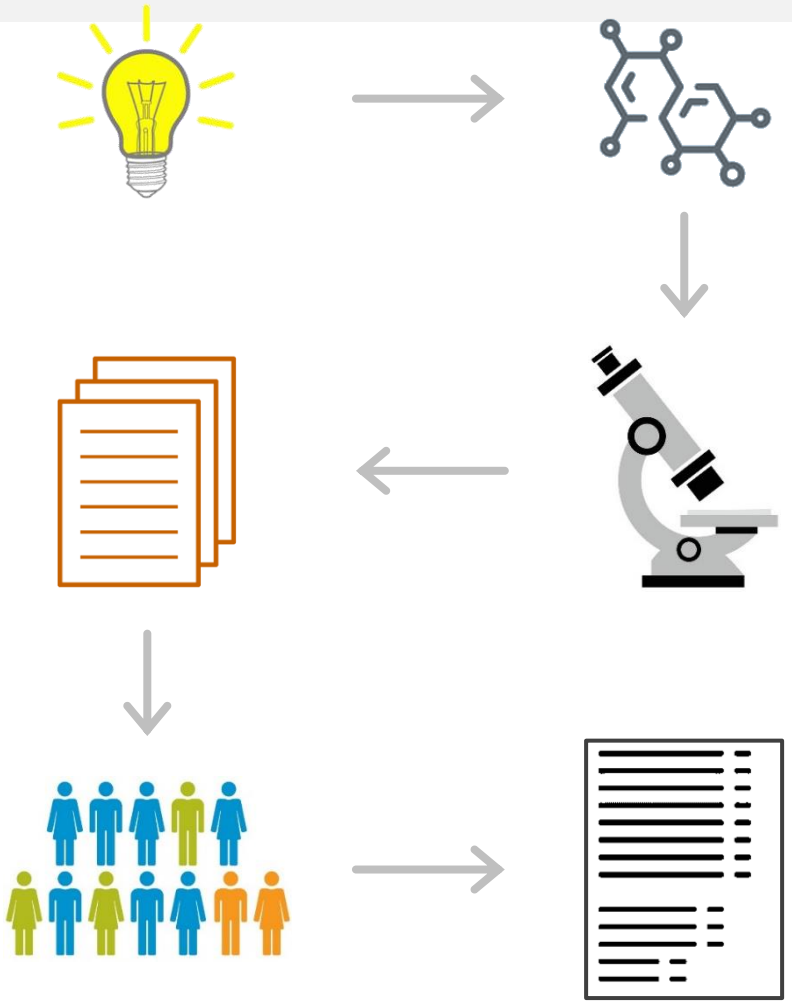
Learning Objectives

1. Learn about FDA's regulatory pathways for the approval of products intended for the prevention, diagnosis, and treatment of COVID-19
2. Understand actions FDA has taken to assist industry during the COVID-19 pandemic
3. Learn about FDA COVID-19 enforcement

From Idea to Market



- The idea
- The search for compounds
- Preclinical studies
- Submission of IND
- Clinical trials
- Submission of NDA

Diagnostic Tests

Vaccines

Therapeutics

Ventilators

Compounded drugs

OTC products

Convalescent plasma

PPE

Center for Drug Evaluation and Research Response to COVID-19

FDA

Timeline: January 1, 2020 – September 30, 2021

COVID-19 Therapeutic Development:

- 640+ drug development programs in planning stages
- 470+ trials reviewed by FDA
- 11 treatments currently authorized for emergency use
- 1 treatment currently approved by FDA

Regulatory Flexibility: Proactively issued temporary policies to address the pandemic and provide regulatory flexibility on:

- Certain drugs compounded for hospitalized patients with COVID-19
- Repackaging or combining Propofol
- Prescription Drug Marketing Act requirements for distributing prescription drug samples
- Drug Supply Chain Security Act requirements

Generic Drug Approvals (Abbreviated New Drug Applications):
Approved 1,000+ original and supplemental generic applications for COVID-19 related treatments and supportive therapies

Addressing Fraud:
Took action against sellers of **fraudulent products** for the treatment or prevention of COVID-19, and issued more than **120 warning letters**

Internet Pharmacies:
Issued **17 warning letters** to operators of websites that sell unapproved and misbranded COVID-19 products

Hand Sanitizer:
Published a list with more than **250 listings** of hand sanitizers consumers should not use, including those containing potentially dangerous contaminants

Shortage Mitigation Activities:
Continued outreach to more than **180 manufacturers** relating to manufacturing capacity and supply chain for both COVID-19 and non-COVID-19 treatments

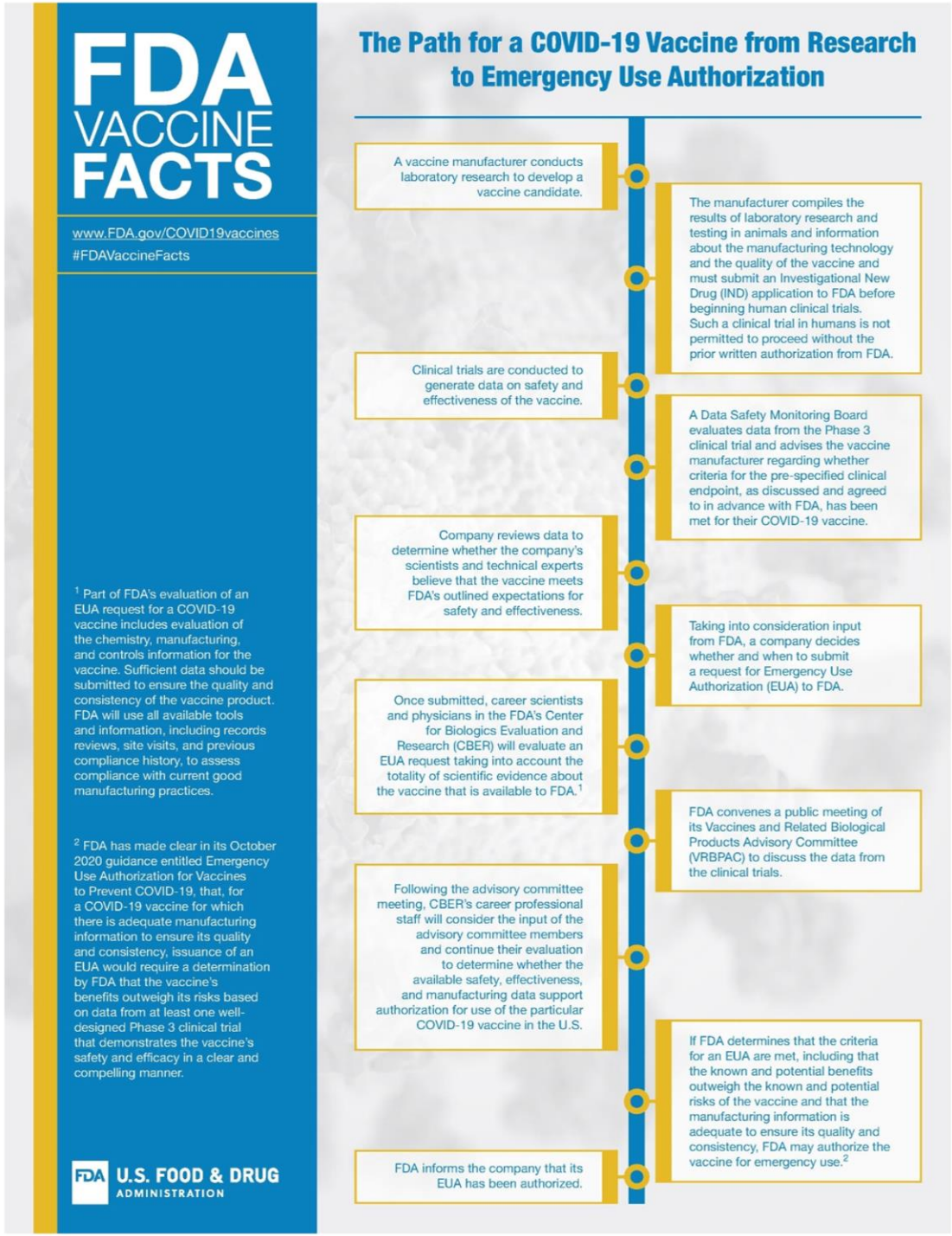
Surveillance and Epidemiology:
Examined and analyzed data across at least **15 data sources**, including **55,000 adverse event reports** to monitor drug safety and medication errors

U.S. Public Health Service Corps Deployment:
Approximately **364 CDER Commissioned Corps officers** fulfilled **623 deployment requests** in support of the COVID-19 mission

Engagement With Stakeholders:
CDER fielded **23,515 COVID-19 drug related inquiries** from the general public, including health care providers, consumers and manufacturers

For more information, please visit **https://www.fda.gov/drugs**

https://www.fda.gov/drugs/coronavirus-covid-19-drugs/center-drug-evaluation-and-research-response-coronavirus-covid-19-infographic



https://www.fda.gov/media/143890/download

FDA Covid-19 Response Toolkit

Operation Warp Speed	Coronavirus Treatment Acceleration Program (CTAP)	Emergency Use Authorization	The PREP Act

Emergency Use Authorizations

- Public health emergencies
- FDA criteria
  - Reasonable belief product “may be effective”
  - Benefits outweigh the risks
  - No alternatives available
- Subject to revocation
  - Operation Quack Hack

How is an EUA different?

- Both rely on data regarding safety and effectiveness and require a conclusion that potential benefits outweigh any potential risks

- Main difference is the ***quantity*** of data and the review ***timeline***

POLLING QUESTION

What other health crises might have triggered an EAU?

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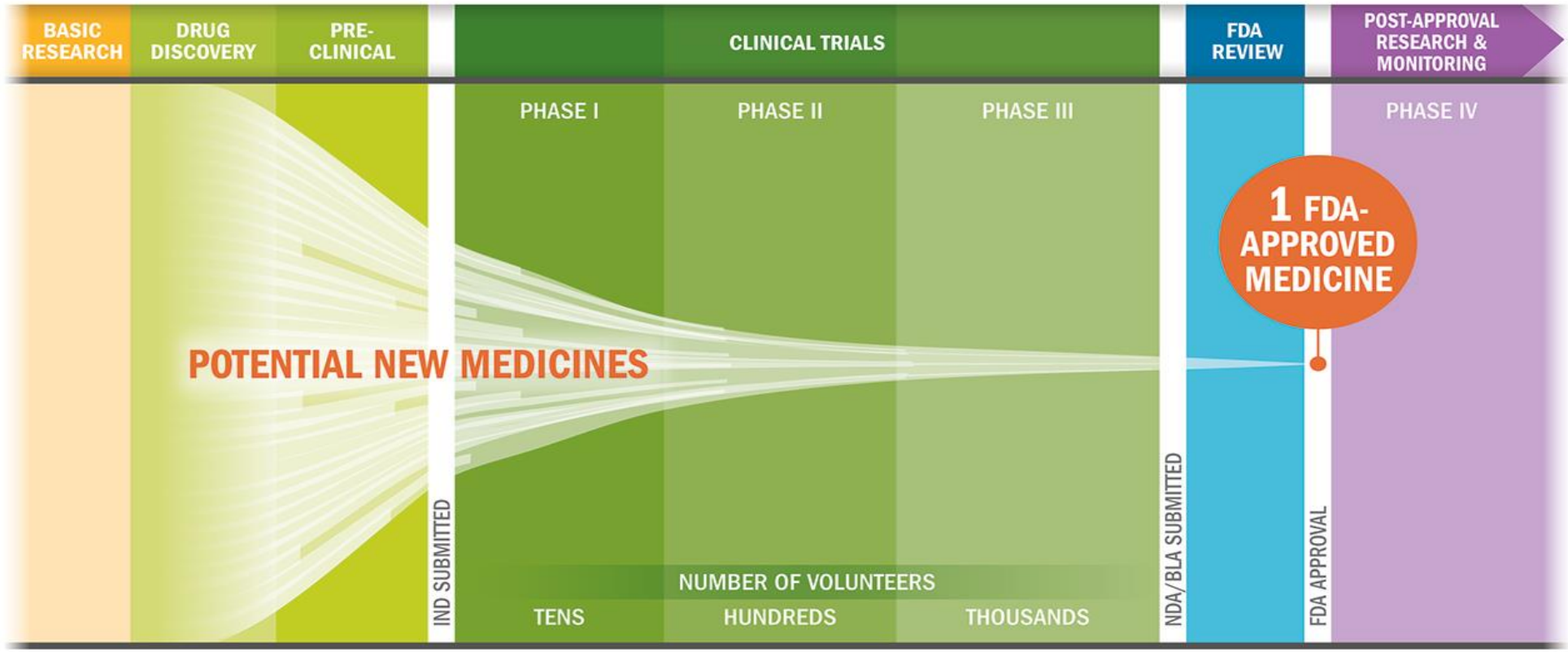
- Spanish flu (1918)
- Swine flu (1976)
- AIDS epidemic (1980s)
- Avian flu (2005)
- Anthrax (2001)
- H1N1 swine flu (2009)
- MERS (2012)
- Ebola (2013)
- Zika (2015)

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of $2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.

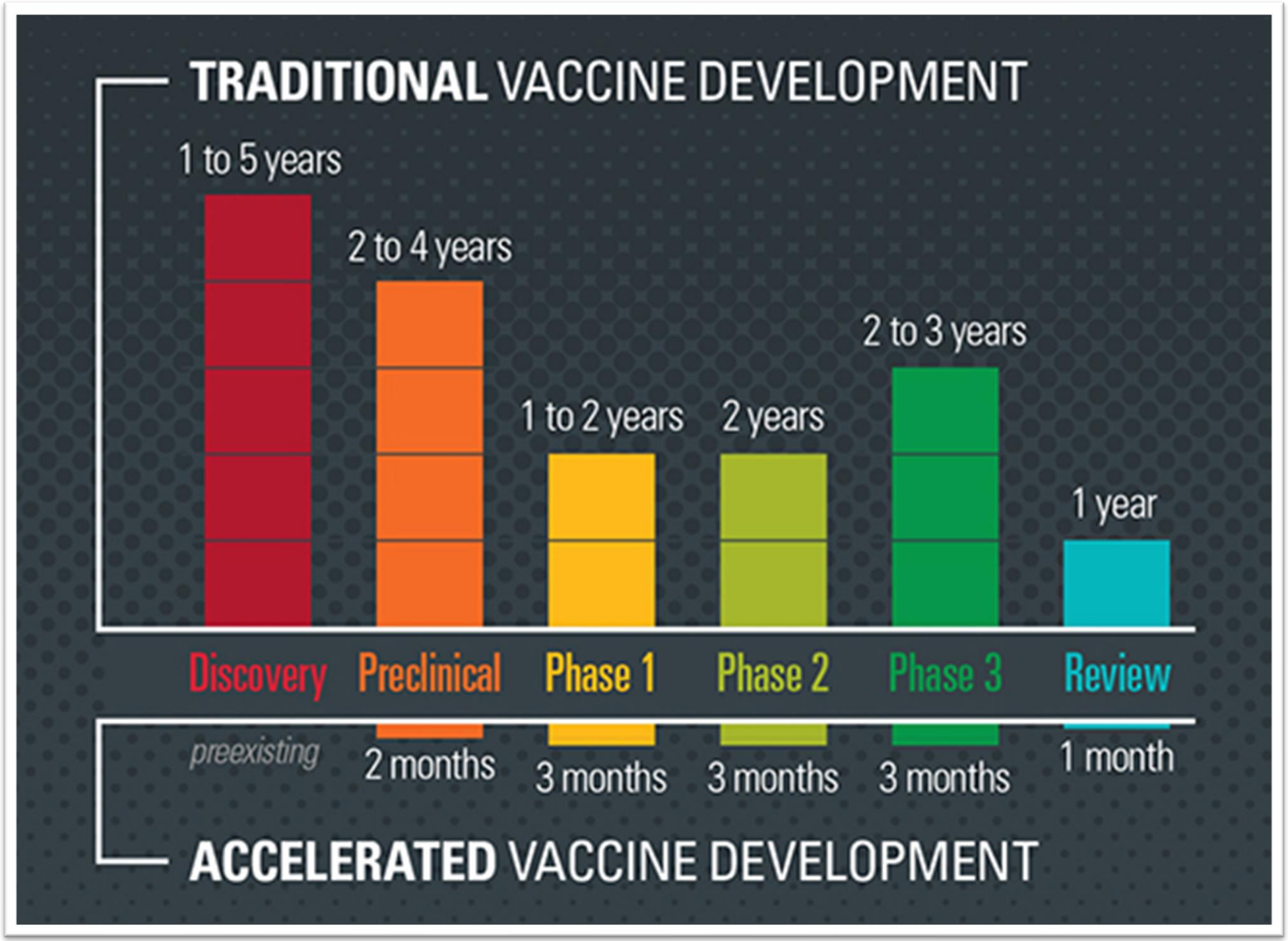


Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* 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.

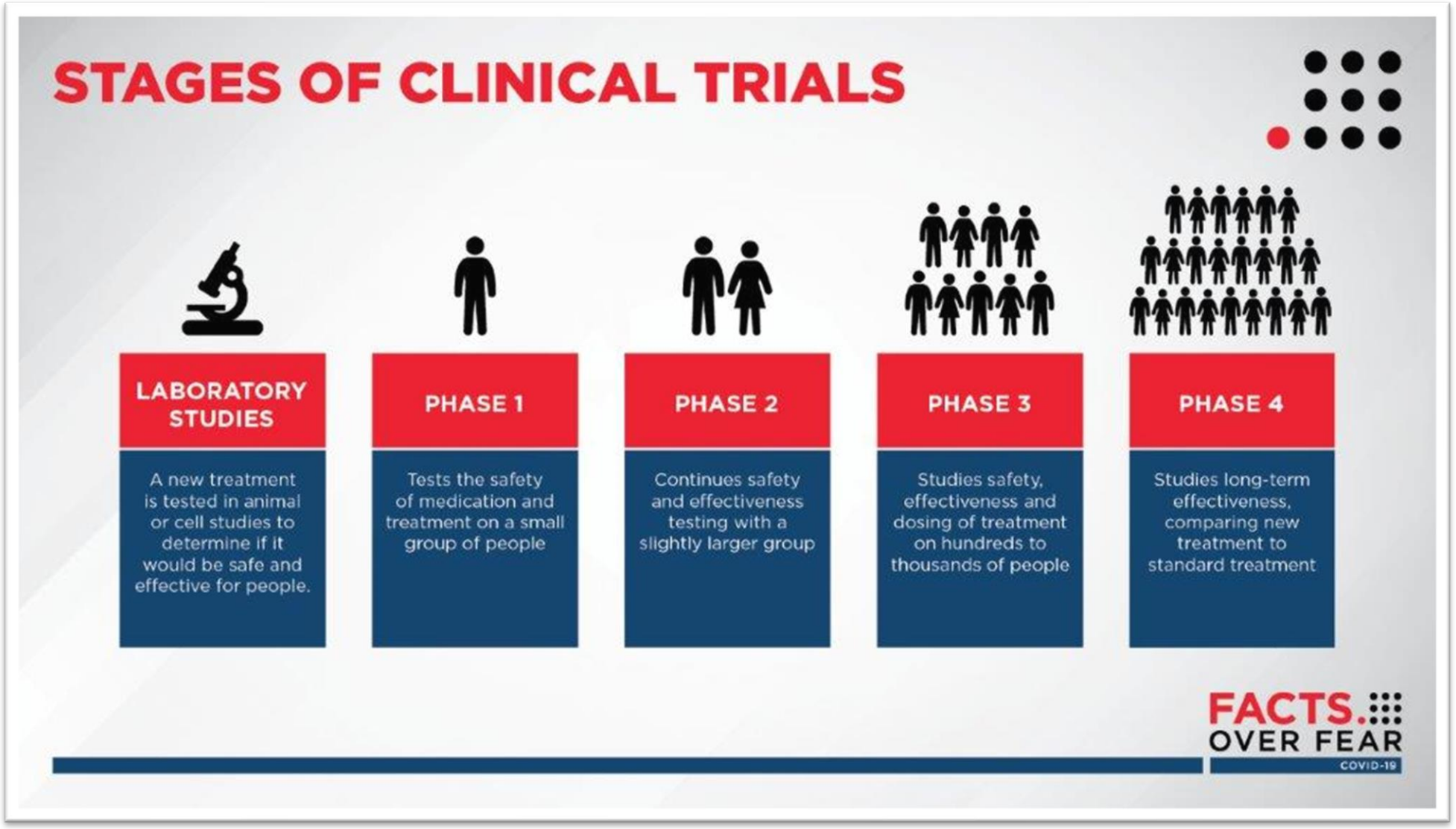
Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf (accessed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

Source: Pharmaceutical Research and Manufacturers of America



https://www.nebraskamed.com/COVID/were-the-covid-19-vaccines-rushed

CLINICAL TRIALS



www.
sanfordhealth.org

LOGISTICS

- Manufacturing
- Facility inspections
- Supply chain requirements

SAFETY MONITORING

- Risk Evaluation and Mitigation Strategy (REMS)
- Vaccine Adverse Event Reporting System (VAERS)

FDA ENFORCEMENT ACTIONS

- Over **1486** reports of fraudulent products related to Covid-19
- **180** warning letters
- **312** reports sent to online marketplace
- **299** abuse complaints sent to domain registrars

Source: FDA Covid-19 Response At-A-Glance, https://www.fda.gov/media/137005/download

THE PREP ACT

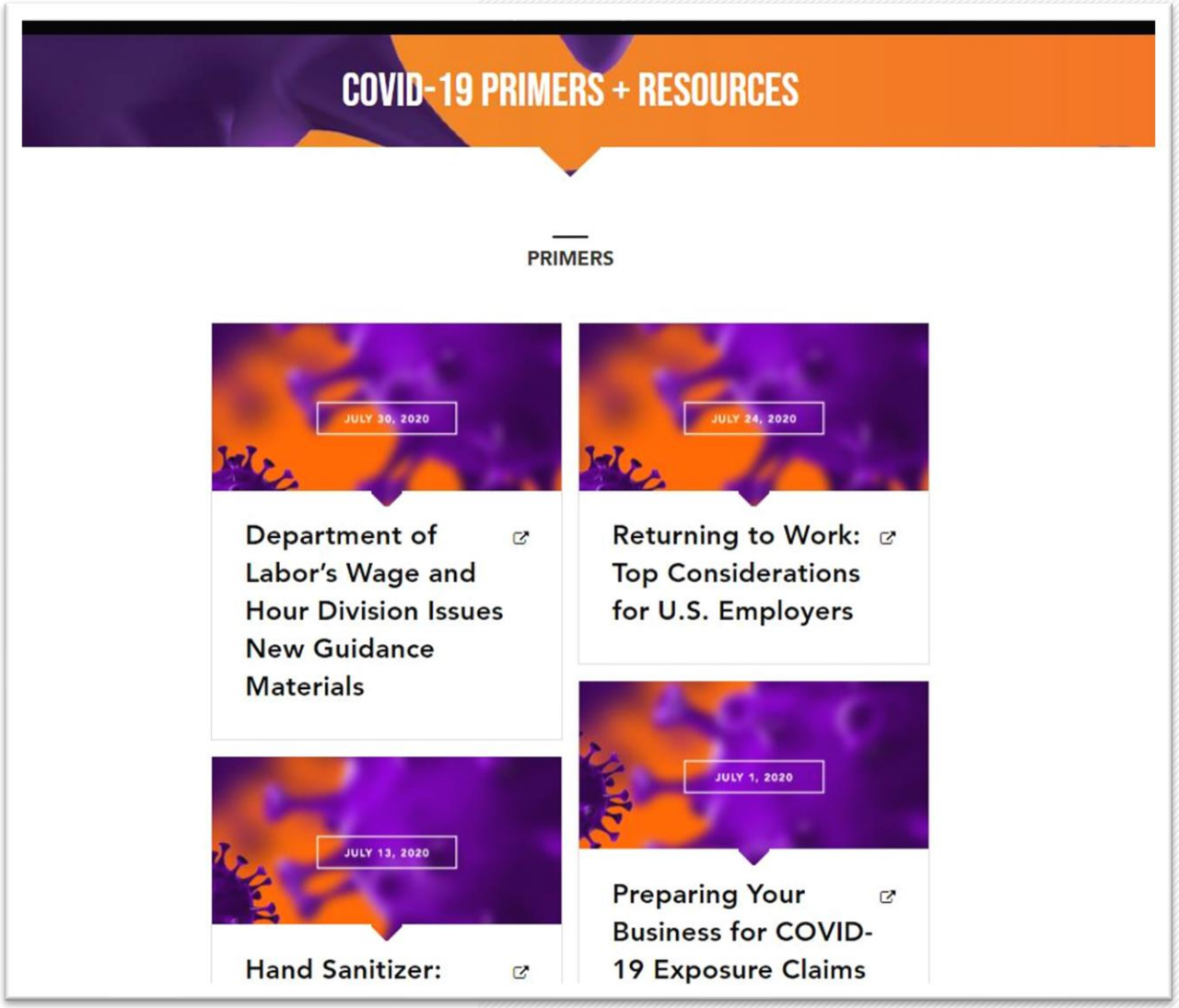
- Protects **entities and individuals** who manufacture, distribute, or administer covered **medical countermeasures**.

DISCUSSION

Issues Related to Diversity

Additional Resources

- https://www.shb.com/covid-19-resources



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