

CLINICAL TRIALS

IN THE AGE OF CORONAVIRUS

11 MONTHS FOR A COVID-19 VACCINE ROLL OUT FROM CONCEPTION TO APPROVAL

The first approved COVID-19 vaccine took **218 DAYS** from study start to regulatory approval

In 2003, developing an H1N1 vaccine **TOOK 5-6 MONTHS**

Knowledge and infrastructure for flu vaccines was already in place

Clinical trial requirements were brief or waived entirely based on extensive study of existing seasonal flu vaccines

The fastest vaccine developed until this year from scratch was the **MUMPS VACCINE** **TAKING JUST 4 YEARS**

CREATING A VACCINE

In the U.S., it typically takes a new drug

12 YEARS

to reach the market

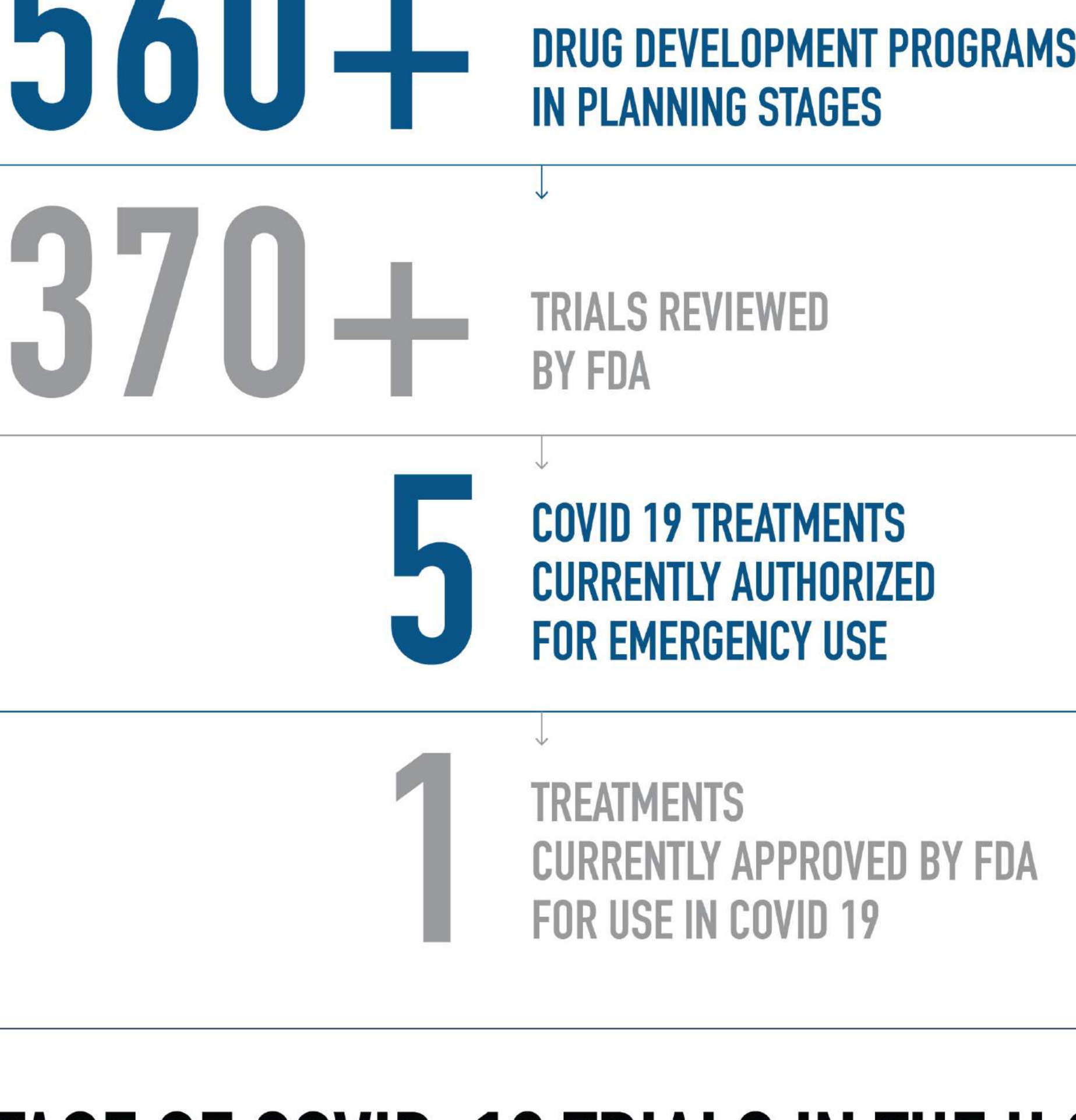


THE FASTEST WAY TO CURE A DISEASE IS TO TEST AS MANY OPTIONS AS POSSIBLE

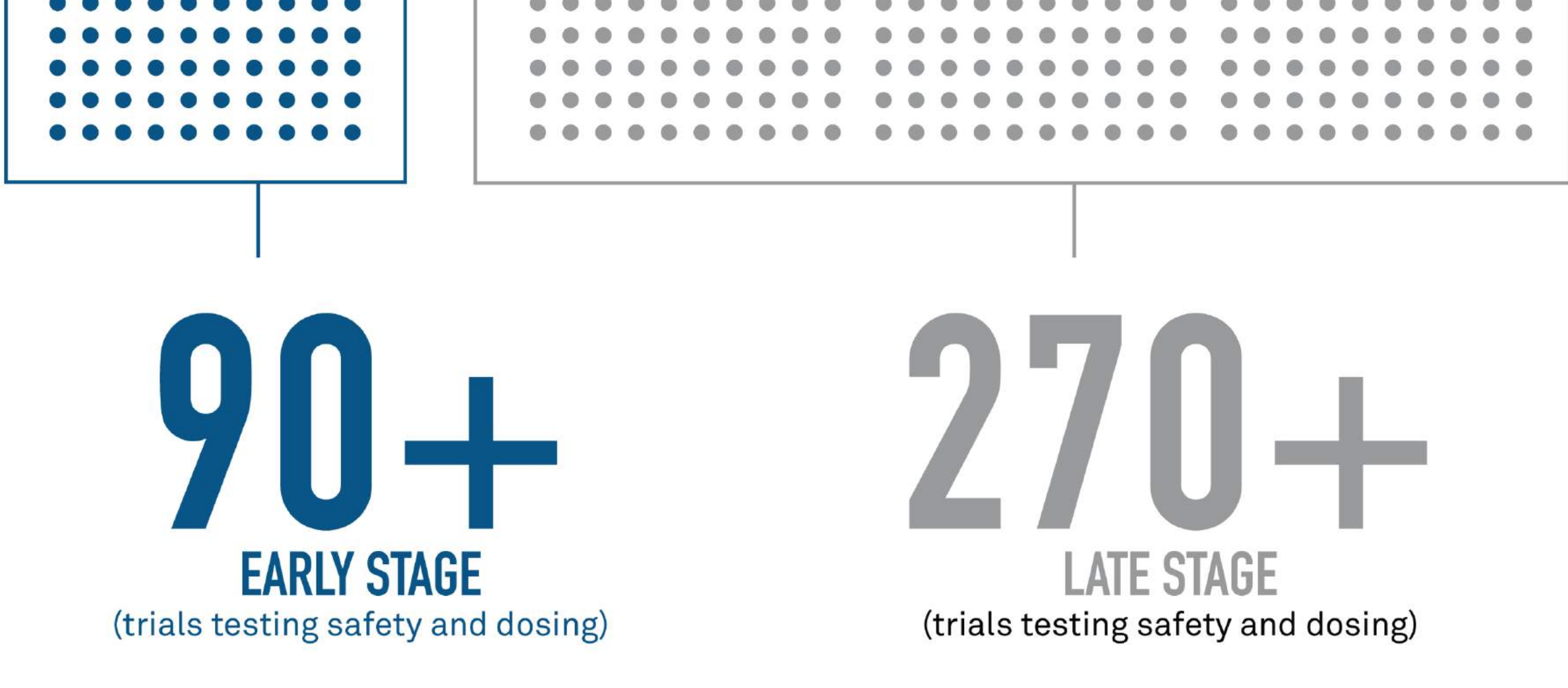
THE CLINICAL TRIAL PROCESS

Updated as of Nov. 17, 2020

CORONAVIRUS TREATMENT ACCELERATION PROGRAM (CTAP) DASHBOARD

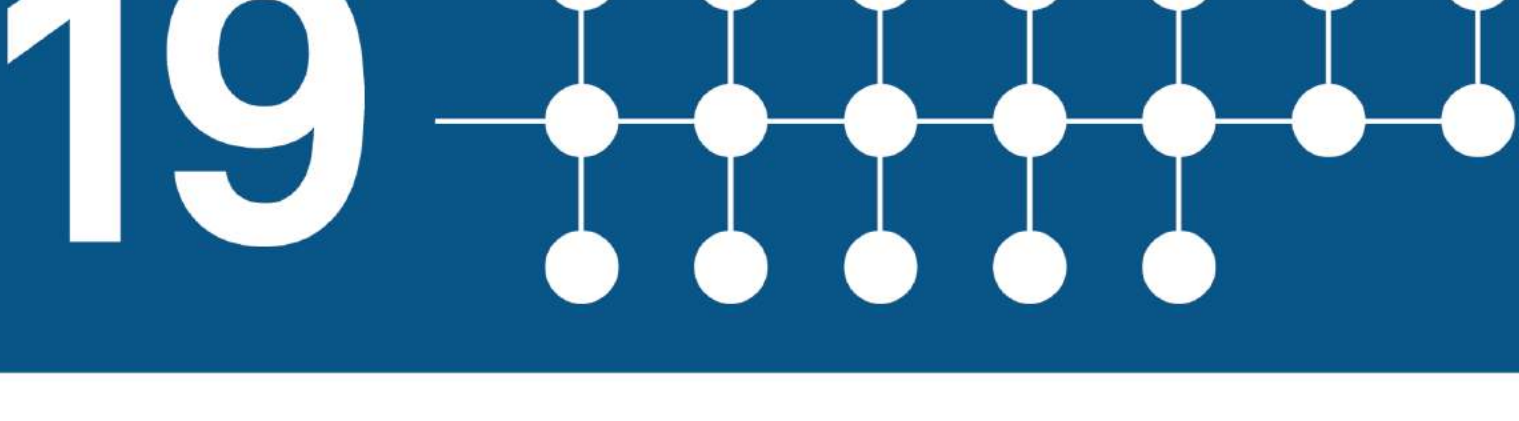


STAGE OF COVID-19 TRIALS IN THE U.S.



CLINICAL TRIAL PHASES

Currently there are 19 COVID-19 **VACCINES IN PRE-CLINICAL TRIALS**

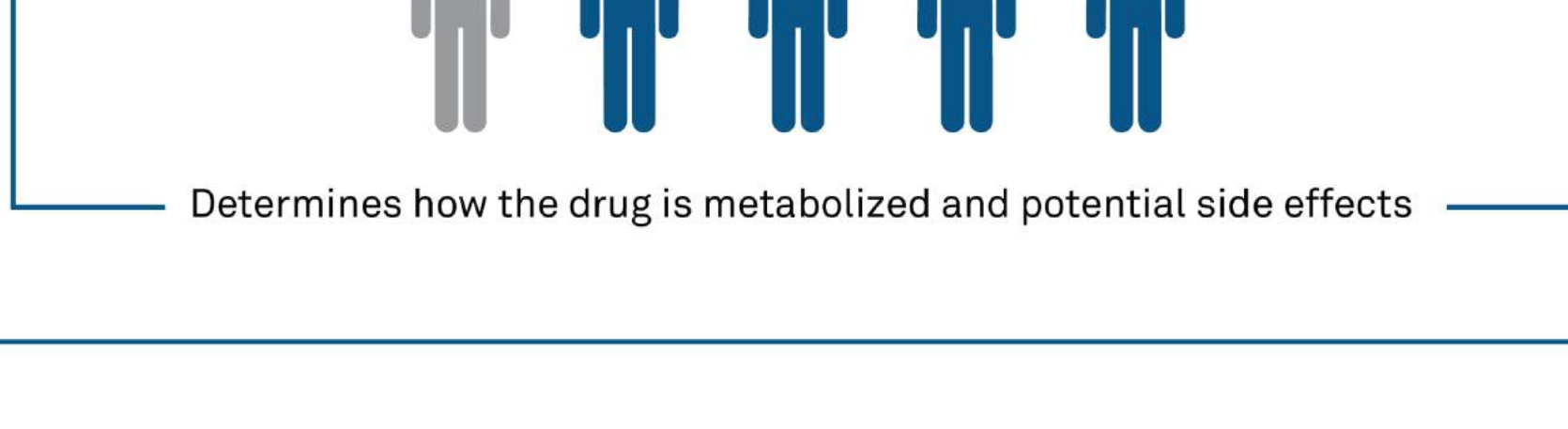


PHASE I TRIALS

SAFETY & DOSAGE

20-100 healthy volunteers receive increasing doses until side effects appear

Approximately 70% of drugs move to the next phase

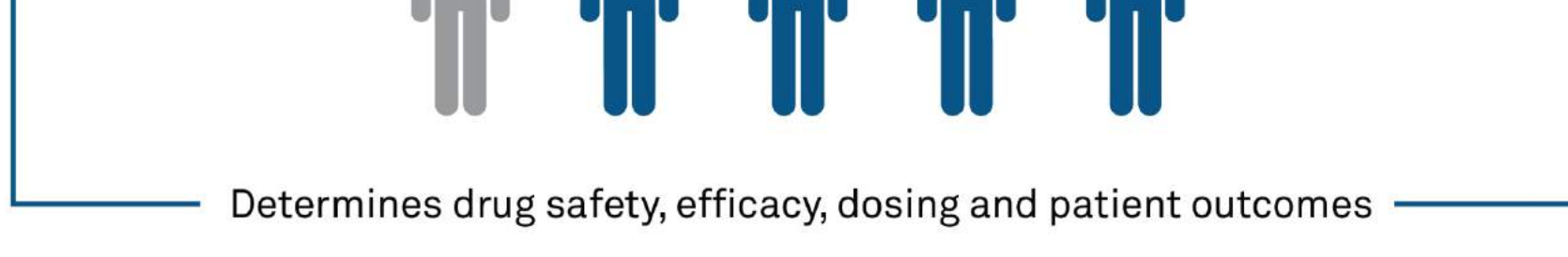


PHASE II TRIALS

EFFICACY & SIDE EFFECTS

100-500 affected patients are given the drug to observe its effects

Approximately 33% of drugs move to the next phase

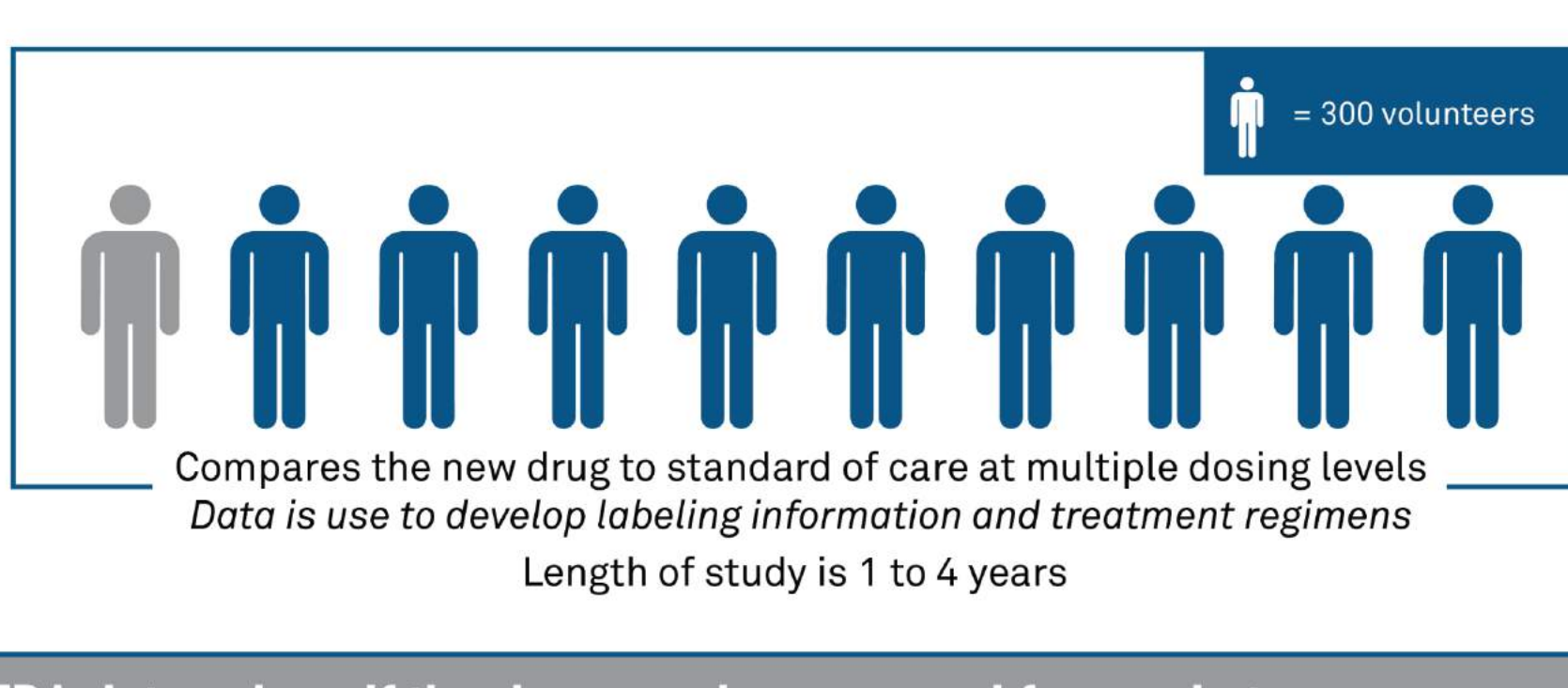


PHASE III TRIALS

EFFICACY AND MONITORING OF ADVERSE REACTIONS

300-3,000 volunteers are given the drug or a placebo Patients and doctors don't know who receives the new drugs

Approximately 25-30% of drugs move to the next phase



After phase 3 trials, the FDA determines if the drug can be approved for market

PHASE IV TRIALS

Continue to monitor long term safety and efficacy using real world data Such as anonymized insurance claims and electronic health records

Researchers may begin to explore possible uses of the drug for other indications When repurposing an already tested and approved drug, researchers can often bypass phase 1 trials



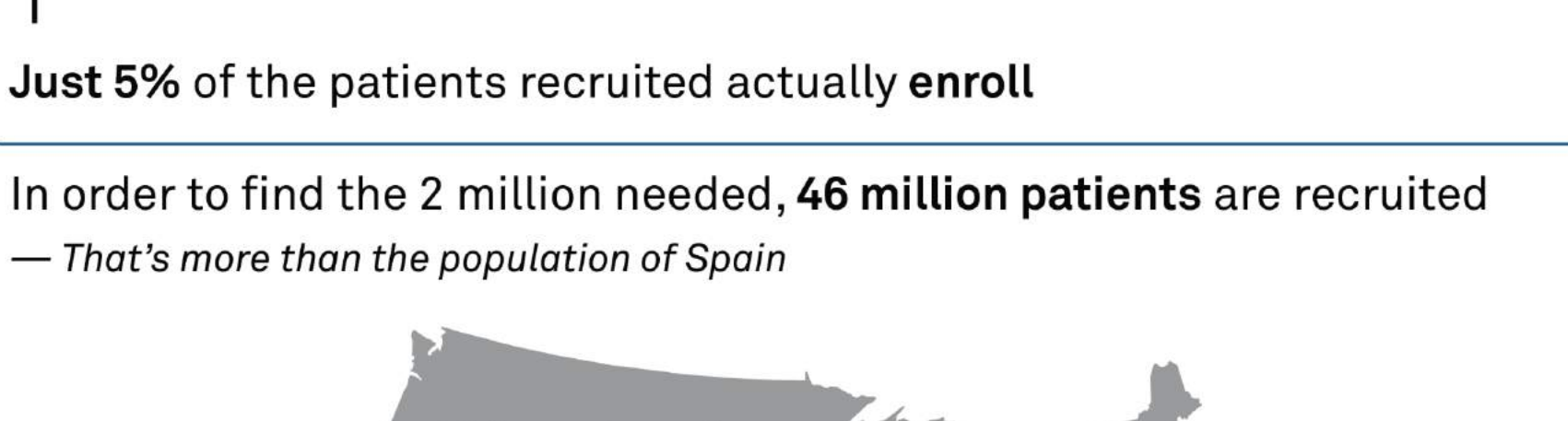
The FDA has promised to expedite development timelines for prevention and treatment options for COVID-19 Including emergency authorizations for existing drugs used to treat other diseases

CHALLENGES

For Clinical Trials

LOW ENROLLMENT

More than **two million patients** are needed for clinical trials every year



LACK OF DIVERSITY

Both drugs and diseases (including COVID-19) may affect diverse populations differently



Socioeconomic barriers and a history of victimization in medical experiments may contribute to minorities unwillingness to participate in clinical trials

Sources:

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Interested in joining a trial?

Visit **clinicaltrials.gov** or contact a patient advocacy group and start a conversation with your doctor

WE ALL BENEFIT FROM CLINICAL TRIALS

Now more than ever

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