COVID-19 Therapeutics and Vaccines

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Potential Therapeutics

Monoclonal antibodies are lab-made proteins that target and bind specific parts of a virus to prevent it from attacking the body.

The virus's **Spike Protein** region that binds the ACE-2 receptor in our lungs has been identified as the best target to prevent SARS-CoV-2 from entering and infecting cells.

Mesenchymal stem cell therapy (MSC) is a novel treatment in COVID-19 patients which may prevent lung tissue death and induce regeneration.

There are 24 clinical trials. The FDA has approved mesechymal stem cells for emergency or compassionate use in severe COVID-19 patients.

Convalescent plasma therapy is a solution where plasma containing disease-fighting antibodies is transferred from patients who have recovered to individuals who are exposed and/or are sick.

Studies in China showed alleviation of clinical symptoms and reduced mortality. The FDA approved convalescent plasma treatment for clinical investigations under the **Investigational New Drug Applications (IND).**

Off-Label Drug Use

Off-label drug use is important during a pandemic, allowing doctors to adapt their practice rapidly. Physicians should base off-label drug use in rigorous scientific evidence. Accelerated, flexible clinical trials and research consortiums can gather quality evidence supporting treatments at an expedited pace.

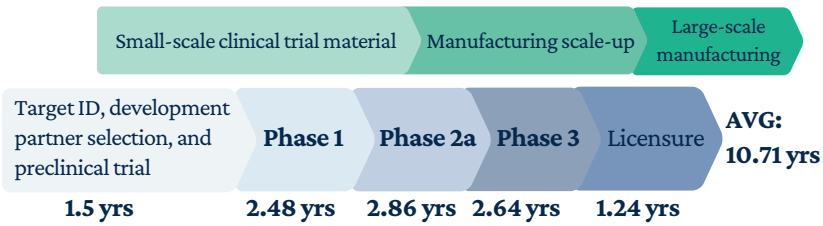
Safety Considerations

Drugs: Off-label drug use lacking strong scientific evidence led to significantly higher Adverse Drug Event rates compared to off-label use supported by strong scientific evidence and on-label use.

Vaccines: Some concerns arise in rapid vaccine development. There is no data on short-term or long-term safety for the candidates in animal models before trial in humans, as they are being conducted concurrently. This is further exacerbated by the fact that the safety profile of certain types of vaccines has not been well-established.

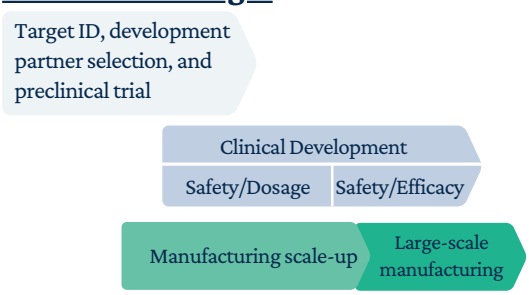
Timeline for Vaccines

Traditional Paradigm



- The average vaccine candidate takes over 10 years to come to market and, accounting for all the candidates that fail along the way, can cost upwards of 300 million dollars.

Outbreak Paradigm



- By executing multiple steps in parallel, and conducting large-scale manufacturing of preclinical candidates, the government hopes for a vaccine to be available for emergency use in 12-18 months.

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Created by students enrolled in a new course on COVID-19 at Yale School of Medicine led by Saad Omer, MBBS, MPH, PhD, FIDSA and Sheela Shenoi, MD, MPH, both of the Yale Institute for Global Health.