

SARS-Cov-2 Vaccines

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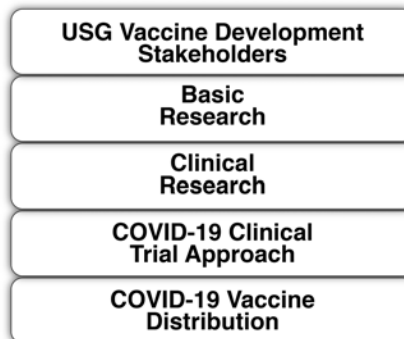


COVID-19 Vaccines: A View from NIAID

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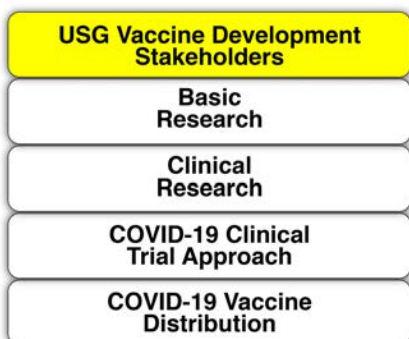


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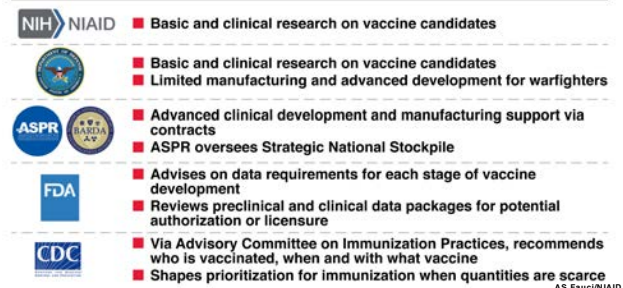
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Primary USG Vaccine Development Stakeholders



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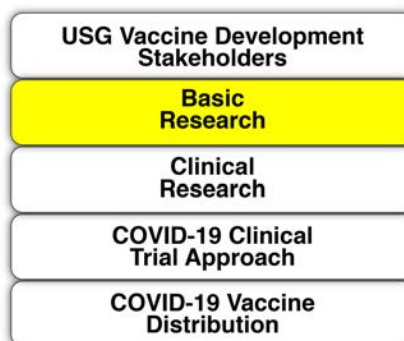
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Pre-COVID-19 USG Vaccine Development Model



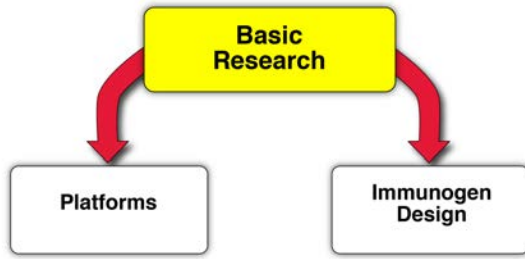
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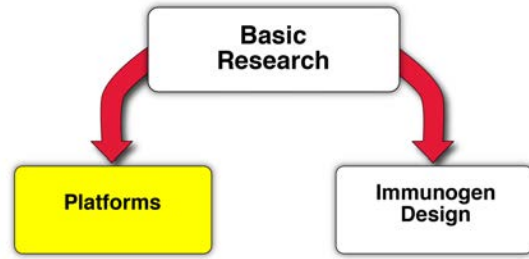
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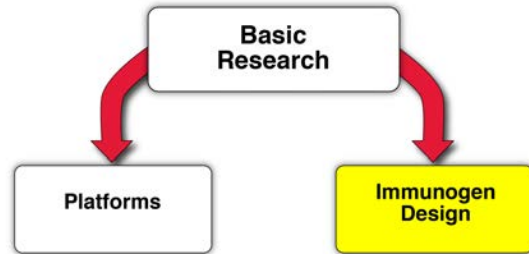
Vaccine Platform Technologies

<p>Genetic immunization (DNA and RNA vaccines) SARS, MERS, West Nile, Zika, RSV</p>	<p>Nanoparticles (viral protein on particle) Influenza, Malaria, RSV</p>
<p>Viral vector (e.g., VSV, adenovirus) Ebola, Marburg, Zika</p>	<p>Virus-like particle (VLP) (no RNA or DNA; non-infectious) Chikungunya, Zika, WEVEE</p>
<p>Recombinant protein Influenza, RSV</p>	<p>Adjuvants (e.g., AS01, MF59)</p>

Selected Examples

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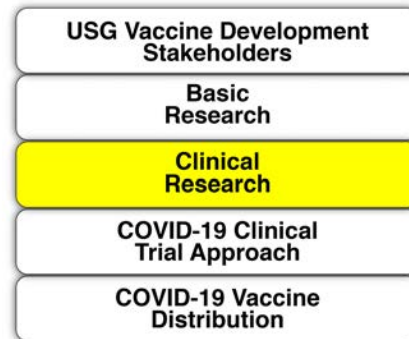
SARS-CoV-2 mRNA Vaccine Design Enabled by Prototype Pathogen Preparedness
KS Corbett, BS Graham et al.

Atomic-level structure of SARS-CoV-2 spike protein. Receptor binding domain is colored green.

Image source: Wrapp et al., Science 2020.

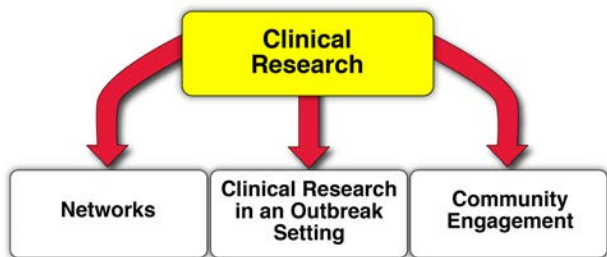
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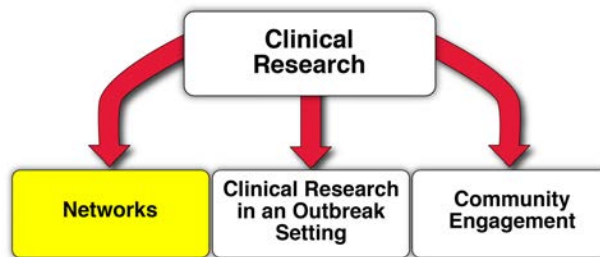
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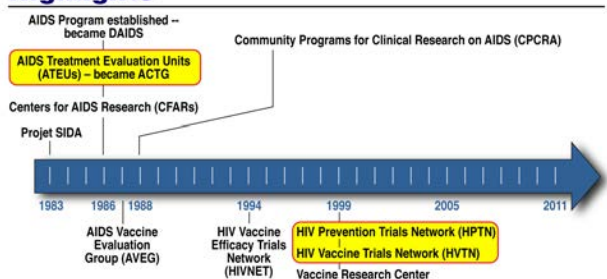
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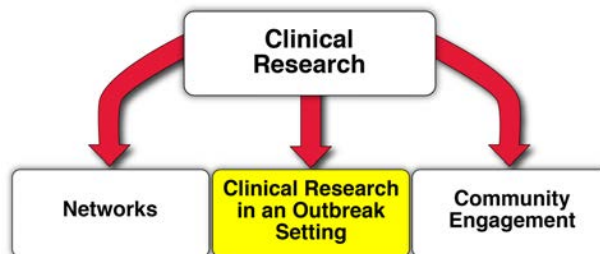
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Selected NIAID HIV/AIDS Programmatic Highlights



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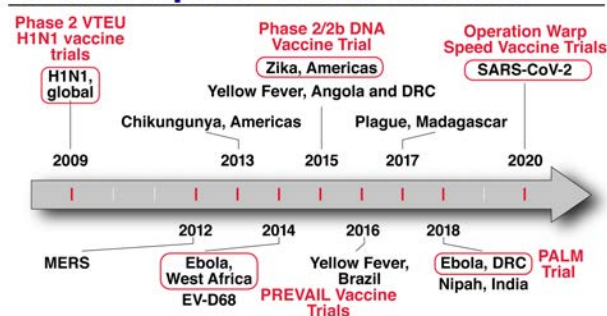
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Recent Response Clinical Research



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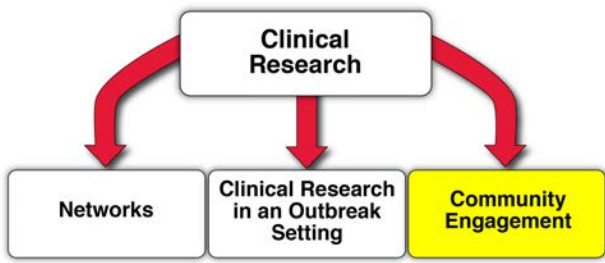
April 12, 2017 NAS Report on the Ebola Clinical Research Experience



- Core principles of science and ethics in conducting clinical research should not change during an epidemic
- RCTs ethical and appropriate: most efficient, reliable way to determine safety and efficacy
- Clinical research studies must have
 - Scientific and social value
 - Respect for/engagement with affected communities
 - Post-trial access to candidate products proved safe/effective

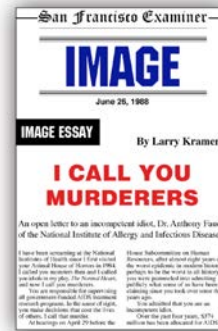
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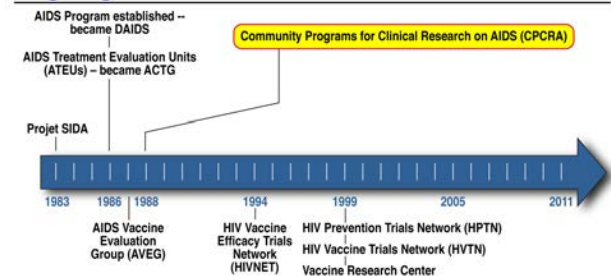
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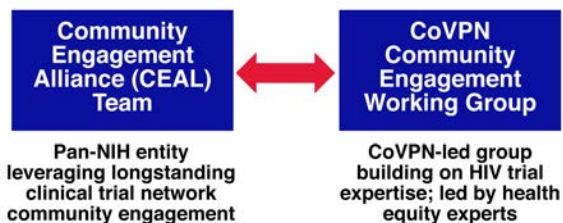
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Selected NIAID HIV/AIDS Programmatic Highlights



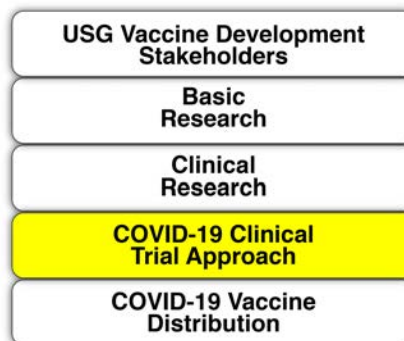
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Published online May 11, 2020

Science

A Strategic Approach to COVID-19 Vaccine R&D

L Corey, JR Mascola, AS Fauci & FS Collins

- Unprecedented collaboration and resources will be required to research and develop safe and effective vaccines for COVID-19 that can be manufactured and delivered in the scale of billions of doses to people globally.

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Selected COVID-19 Vaccine Candidates

Platform	Developer	Phase 1/2	Phase 2/3
Nucleic acid	moderna	Enrolled	Enrolled
	BIONTECH	Enrolled	Enrolled
Viral vector	OXFORD AstraZeneca	Enrolled	Ongoing
	janssen	Enrolled	Ongoing
	MERCK	Ongoing	--
Protein subunit	NOVAVAX	Ongoing	Ongoing
	gsk SANOFI	Ongoing	--

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Contains Nonbinding Recommendations

Development and Licensure of Vaccines to Prevent COVID-19

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
June 2020

“It is important for developers of COVID-19 vaccines to plan for pediatric assessments of safety and effectiveness, given the nature of the COVID-19 public health emergency... The epidemiology and pathogenesis of COVID-19, and the safety and effectiveness of COVID-19 vaccines, may be different in children compared with adults.”

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October 13, 2020

Will Kids Get a COVID-19 Vaccine? Pfizer to Expand Trial to Ages 12 and Up

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Pfizer News Release

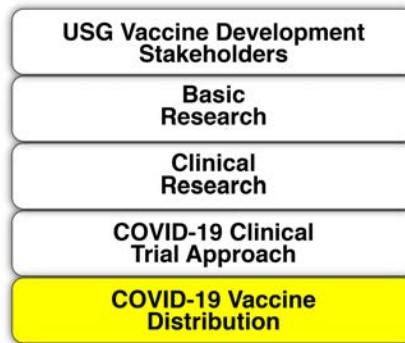
Monday, November 09, 2020

Pfizer and Biontech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis From Phase 3 Study

■ Point estimate of 90% efficacy against symptomatic COVID-19 in interim analysis

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NASEM Releases Final Framework for Distributing COVID-19 Vaccine



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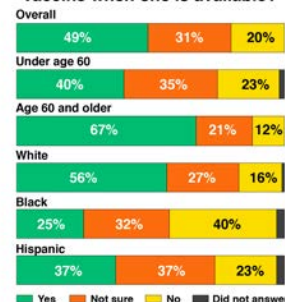
June 30, 2020

Science

Just 50% of Americans Plan to Get a COVID-19 Vaccine. Here's How to Win Over the Rest

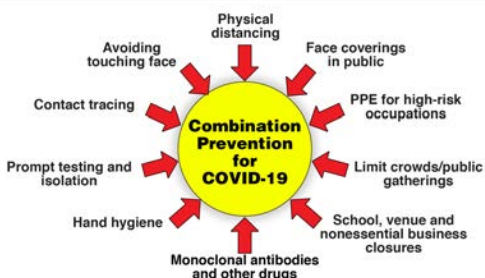
W Cornwall

Do you plan to get a coronavirus vaccine when one is available?



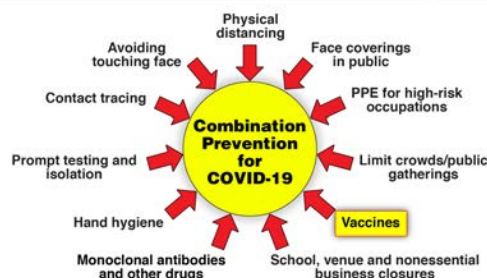
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Prevention of COVID-19 in the Absence of a Vaccine



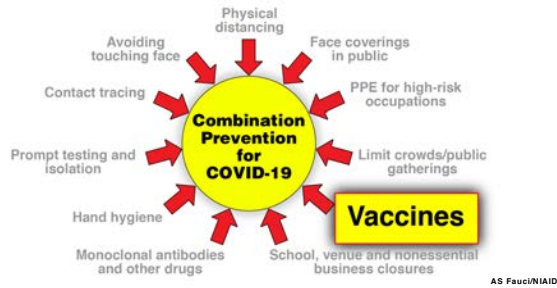
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Prevention of COVID-19 with a Moderately Effective Vaccine and Moderate Uptake



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Prevention of COVID-19 with a Highly Effective Vaccine and Widespread Uptake



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**Universal Coronavirus Vaccines:
The Time to Start Is Now**
LT Giurgea, A Han and MJ Memoli

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