National Institutes of Health Update

Claire Schuster, MPH
National Institute of Allergy and Infectious Diseases
National Institutes of Health

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National Institute of Allergy and Infectious Diseases

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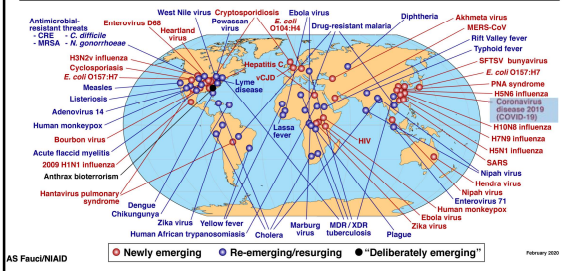
Global Examples of Emerging and Re-Emerging Infectious Diseases



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1

1

- Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease
- Develop diagnostics and assays
- Characterize and test therapeutics
- Develop safe and effective vaccines

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2

2

Adaptive COVID-19 Treatment Trial (ACTT)

- **ACTT-1:** NIH clinical trial of antiviral remdesivir to treat COVID-19
  - Preliminary report published online in New England Journal of Medicine (5/22/2020)
- **ACTT-2:** NIH clinical trial testing remdesivir plus anti-inflammatory baricitinib
  - Fully enrolled (n=1,034) as of 6/30/2020
- **ACTT-3:** NIH clinical trial testing remdesivir plus immunomodulator interferon beta-1a
  - NIAID announced study launch on 8/5/2020

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3

3

Remdesivir for the Treatment of Covid-19 — Preliminary Report

JH Beigel, HC Lane et al. for the ACTT-1 Study Group Members

- Patients who received remdesivir had a 32% faster time to recovery than those who received placebo (p<0.001)
- Results also suggested a survival benefit
- N=1,063 patients from 10 countries (U.S., Europe, Asia)

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4

4

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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5

5

The New England Journal of Medicine

published online July 14, 2020

An mRNA Vaccine against SARS-CoV-2 — Preliminary Report

LA Jackson, JH Beigel et al. for the mRNA-1273 Study Group

- **Experimental COVID-19 vaccine mRNA-1273 safe, immunogenic in healthy volunteers ages 18-55 years**
- **N=45**

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6

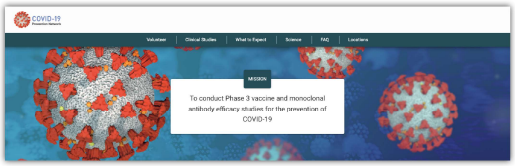
6

NIH National Institute of Allergy and Infectious Diseases

July 8, 2020

News Release

NIH Launches Clinical Trials Network to Test COVID-19 Vaccines and Other Prevention Tools



https://www.coronavirespreventionnetwork.org/

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7

7

Novel Coronavirus: SARS-CoV-2

NIH News
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
July, 2020

Phase 3 Clinical Trial of Investigational Vaccine for COVID-19 Begins

Multi-Site Trial to Test Candidate Developed by Moderna and NIH

Q&A with Dr. Collins and Dr. Fauci on COVID-19 Vaccines

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8

8

Clinical Trials of Monoclonal Antibodies to Prevent COVID-19 Now Enrolling

Phase 3 Trials Conducted in the NIAID COVID-19 Prevention Network

August 10, 2020

NOTE: People 18 years of age and older who are interested in participating in these trials should visit the COVID-19 Prevention Network. Please do not contact the NIAID Media phone number or email to inquire about enrolling in the trials.

Two Phase 3, randomized, placebo-controlled, double-blind clinical trials testing whether experimental monoclonal antibodies (mAbs) can prevent infection by SARS-CoV-2 coronavirus are now enrolling healthy adults at clinical trial sites in the United States. Many of the trial sites and study investigators are part of the COVID-19 Prevention Network (CoVPN), recently established by the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH). SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). The trials are enrolling adults who are at risk of infection due to close contact at work or home to persons with SARS-CoV-2 infection.

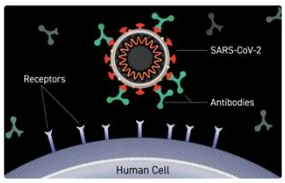

Illustration of an antibody binding to the surface of a virus, blocking entry into a human cell.

9

9

COVID-19: Pediatric Research

Study to determine the incidence of novel coronavirus infection in U.S. children begins

- NIH-funded study also will ascertain percentage of infected children who develop COVID-19
- The study, called Human Epidemiology and Response to SARS-CoV-2 (HEROS), will help determine what percentage of children infected with SARS-CoV-2 develop symptoms of the disease.

NIH-funded project seeks to identify children at risk for MIS-C

- MIS-C is thought to be a severe complication of COVID-19
- Up to $20 million will be awarded to successful research proposals over four years

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10

10

COVID-19: Pediatric Research

NIH Director's Blog

2020 July

What We know About COVID-19's Effects on Child and Maternal Health

Posted on July 30th, 2020 by Dr. Francis Collins

https://directorsblog.nih.gov/2020/07/

NIH-funded study to evaluate drugs prescribed to children with COVID-19

- Researchers will assess dosage, metabolism and other properties not yet determined in children
- Conducted in approximately 40 sites of the NICHD-funded Pediatric Trials Network
- Many study sites are located near diverse communities, given reports that COVID-19 disproportionately affects racial and ethnic minorities across all ages

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11

11

COVID-19 and Pregnancy

NIH-funded study to investigate pregnancy outcomes resulting from COVID-19 pandemic

- Multipronged study to understand the effects of the COVID-19 pandemic during and after pregnancy.
- The study will be conducted by researchers in the Maternal-Fetal Medicine Units (MFMU) Network funded by NIH's *Eunice Kennedy Shriver* NICHD

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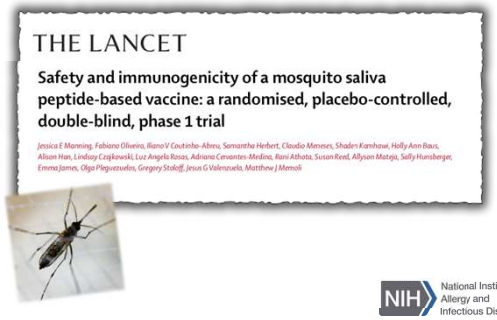
12

12

Vaccine to Protect Broadly Against Mosquito-Borne Diseases Appears Safe



13

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13