

Leveraging Clinical Research Capabilities to Support COVID-19 Vaccine Development



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11 FEB 2021

Bottom Line Up Front

- Developing strategies to defeat COVID required the research community to coordinate a major mission pivot.
- The ability to pivot requires enduring expertise, experience, and robust research support infrastructure.
- SUNY Upstate was making long-term investments in people and clinical research capabilities.
- *These strategic investments allowed Upstate to make significant contributions to the clinical development of the Pfizer/BioNTech COVID-19 vaccine.*

What is a Physician-Scientist?

- Physicians
 - Care for people
 - Prevention / wellness
 - Diagnosis and treatment
 - Observing events →
- Scientists
 - Ask and answer questions
 - Develop hypotheses explaining observations
 - Design and conduct experiments to generate facts
- Physician-Scientists
 - ***Advance knowledge towards tangible solutions***



ProMED
INTERNATIONAL SOCIETY
FOR INFECTIOUS DISEASES

Published Date: 2019-12-30 23:59:00

Subject: PRO/AH/EDR> Undiagnosed pneumonia - China (HU): RFI

Archive Number: 20191230.6864153

UNDIAGNOSED PNEUMONIA - CHINA (HUBEI): REQUEST FOR INFORMATION

A ProMED-mail post

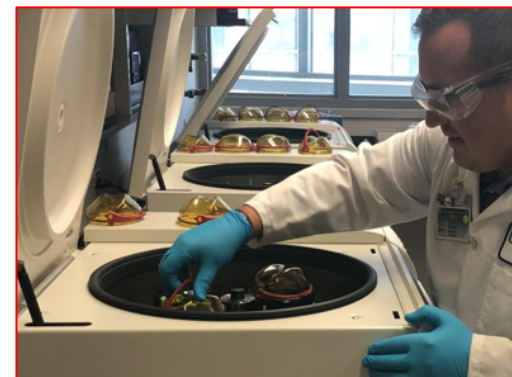
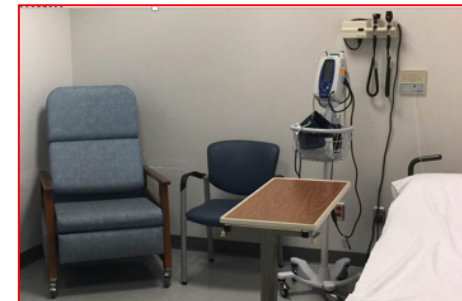
<http://www.promedmail.org>

ProMED-mail is a program of the
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What are clinical research capabilities?

- Teams of Teams (most valuable and most elusive)
 - Clinicians / Research Coordinators / Labratorians
 - Recruiters / Administrators / Vaccine preparers
 - Regulatory affairs / Quality Control / ...and more
- Physical infrastructure
 - Clinical Research Unit
 - Specimen management
- Research support personnel
 - Contracting, finance, compliance



What was our pre-COVID mission?

- Develop and advance vaccines, drugs, and diagnostics
 - DoD: dengue, rabies, malaria, zika
 - NIH: substance use disorders, influenza (CIVIC)
 - Pharma: dengue, chikungunya, HIV
 - NGO (Trudeau Institute): zika
- Actionable knowledge products
 - Citizen tick test program
- Service learning
 - Ecuador, Kenya



How did we pivot to a COVID mission?

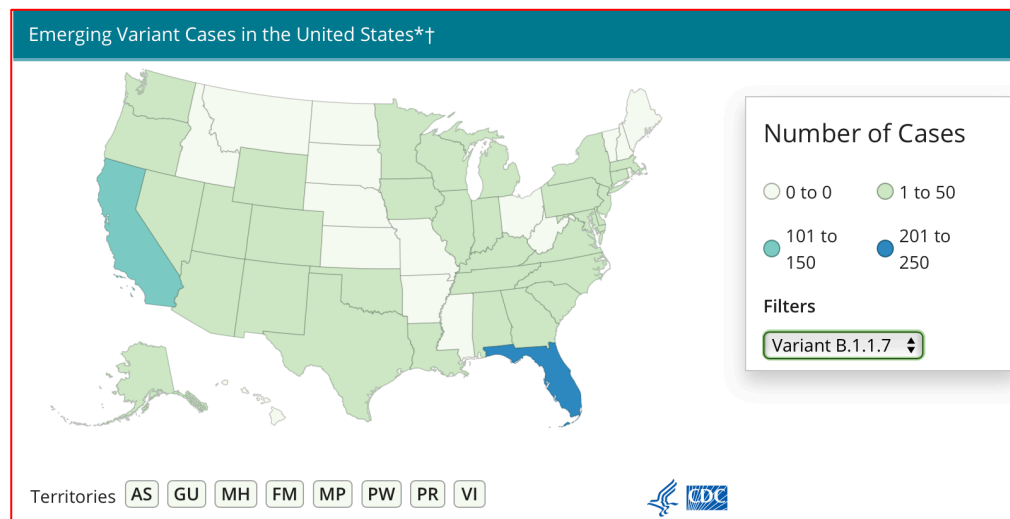
- Re-focused diverse skillsets / expertise
- Scaled operations to meet enrollment demand
- Developed new safety protocols
- Round the clock, global teams engagement
 - Pfizer, ICON, others
- Major recruiting effort
 - Overwhelming response
- Volunteer engagement 24/7
- Endless data entry / audits
- EUA in the middle of a trial



Colleen M. Gibbons, of Syracuse, was the first person to volunteer to participate in a study of an experimental Covid-19 vaccine at Upstate Medical University. Provided photo

What are we doing now?

- Unblinding placebo recipients eligible for vaccination
 - By 1 MAR all those 16 years will have 1st dose
- Vaccinating children down to 12 years
 - Cohort filled (>2,200 global / >70 at Upstate)
- Continuing to follow volunteers for natural infections
 - Watching for variants



Variant	US Cases	States Reporting
B.1.1.7	690	33
B.1.315	6	3
P.1	3	2

What are we doing now?

- Beginning new COVID-19 vaccine collaborations
 - GeneOne Life Sciences (DNA vaccine)
 - U of MD, NIH VTEU, and Operation Warp Speed
- Ramping up delayed / paused non-COVID work
 - Heroin vaccine trial
 - Universal flu vaccine
 - Dengue drug trial
 - Chikungunya vaccine trial
 - Staph aureus bacteremia
 - ...others

Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic



Distributed via the CDC Health Alert Network
December 17, 2020, 8:00 AM ET

Questions



IS THERE A DOCTOR IN THE FAMILY? Dr. Sri Narsipur, Upstate's professor and chair of Medicine and medical director of Nephrology, received his second covid vaccine dose from Sonia Narsipur—his daughter! Sonia is a fourth-year medical student at Upstate, and is interested in family medicine so she can advocate for and help patients of all ages. Sonia comes from a family of doctors, as her mom—Dr. Sonia Y. Kragh—is also a physician.

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