

**From:** [Caliguiri, Laura](#)  
**To:** [Kimberly, Brad](#); [Lynch, Sarah](#); [Capobianco, Abigail](#)  
**Subject:** FW: What You Need To Know | President Trump's Coronavirus Response Efforts  
**Date:** Tuesday, March 31, 2020 8:53:05 PM

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**From:** Mitchell, Austin A. EOP/WHO (b) (6)@who.eop.gov>  
**Sent:** Tuesday, March 31, 2020 8:51 PM  
**Subject:** What You Need To Know | President Trump's Coronavirus Response Efforts

## What You Need To Know | President Trump's Coronavirus Response Efforts

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*President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.*

### WHOLE-OF-GOVERNMENT APPROACH

- The President signed the CARES Act, providing unprecedented and immediate relief to American families, workers, and businesses.
- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- President Trump signed initial legislation securing \$8.3 billion for coronavirus response.
- President Trump signed the Families First Coronavirus Response Act, ensuring that American families and businesses impacted by the virus receive the strong support they need.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.
- At the request of President Trump, FEMA is leading federal operations on behalf of the White House Coronavirus Task Force.
- FEMA's National Response Coordination Center has been activated to its highest level in support of coronavirus response.
- The President held a teleconference with other G20 leaders to coordinate

coronavirus response.

- President Trump signed an executive order giving the DoD and DHS the authority to activate the ready reserve components of the armed forces to assist with coronavirus response.

### **SUPPORTING STATE AND LOCAL EFFORTS**

- President Trump issued a letter informing our nation's governors that the Administration is developing new guidelines for state and local policy makers.
- Through the CARES Act, we more than doubled the funds available through the President's Emergency and Disaster Declarations to help State, local, and tribal leaders effectively respond.
- The President has approved major disaster declarations for heavily impacted states.
- The Administration is covering costs of deploying National Guard units to assist with response efforts in hard hit states, while ensuring governors remain in command.
- The President has held multiple teleconferences with our nation's governors to coordinate response efforts and offer his full support.

### **TRAVEL RESTRICTIONS**

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.
- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The United States reached mutual agreements with Mexico and Canada to restrict non-essential travel across our northern and southern borders.
- The Administration announced it will expeditiously return aliens who cross between ports of entry or are otherwise not allowed to enter the country, as the facilities in which these aliens would be held cannot support quarantine for the time needed to assess potential cases.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.
- The State Department issued a global level 4 travel advisory, urging Americans to avoid all international travel due to the coronavirus outbreak worldwide.

- The State Department has worked to safely repatriate thousands of Americans from around the world.

### **EXPANDING TESTING ACCESS**

- The FDA has issued emergency approval for multiple new commercial coronavirus tests, including some that deliver results to healthcare providers within minutes.
- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration worked with Apple to launch an app and website to help Americans determine if they should seek care for coronavirus, and provide them guidance on next steps.
- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.
- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.
- The Department of Defense has set up 15 coronavirus testing sites worldwide.
- The President signed legislation requiring more reporting from state and private labs to ensure our public health officials have the data they need to respond to this outbreak.
- DoD and HHS worked to airlift hundreds of thousands of swabs and sample test kits from Italy to the United States.

### **HELPING FAMILIES AND WORKING AMERICANS**

- President Trump signed historic legislation to provide direct payments to Americans, significantly expand unemployment benefits, and more.
- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.
- The Department of Labor issued guidance to help inform Americans about the paid family and medical leave available to them.
- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.

- The Treasury Department moved tax day from April 15 to July 15.
- President Trump signed legislation providing funding and flexibility for emergency nutritional aid for senior citizens, women, children, and low-income families.
- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.
- USDA launched a partnership with Panera Bread and the Children's Hunger Alliance to provide meals to children across Ohio, with more states to come.
- HHS has announced \$250 million in grants to help communities provide meals for seniors.
- The Administration is halting foreclosures and evictions for families with FHA-insured mortgages.
- The Department of Labor announced up to \$100 million in dislocated worker grants in response to the coronavirus national health emergency.
- The White House worked with the private sector to launch a central website where families, students, and educators can access online education technologies.
- President Trump signed legislation to provide continuity in educational benefits for veterans and their families who attend schools that have had to switch to online learning.
- The Department of Education has given broad approval to colleges and universities to allow them to more easily move their classes online.
- The Department of Education set interest rates on all federally-held student loans to 0% for at least 60 days.
- The Department of Education announced borrowers will have the option to suspend their payments on federally-held student loans for at least two months.
- The Department of Education is providing waivers for federal testing requirements to states that have had to close schools.

### **SUPPORTING IMPACTED BUSINESSES**

- President Trump signed legislation providing almost \$350 billion in loans for small businesses and much needed payroll tax relief.
- The President secured legislation giving the Treasury and Federal Reserve \$500

billion to provide liquidity and purchase business, municipal, and State debt.

- Thanks to legislation signed by President Trump, the Federal Reserve can leverage more than \$4 trillion in funds if needed during this crisis.
- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- SBA relaxed criteria for disaster assistance loans – expanding small businesses’ access to economic assistance.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held calls and meetings with business leaders from the pharmaceutical industry, airlines, health insurers, grocery stores, retail stores, banks, and more.
- The Treasury Department approved the establishment of the Money Market Mutual Fund Liquidity Facility to provide liquidity to the financial system.
- The Export-Import Bank announced four new temporary relief programs to provide maximum financing flexibility and inject liquidity into the market.

### **INFORMING THE PUBLIC**

- The Administration launched a website – [coronavirus.gov](https://www.coronavirus.gov) – to keep the public informed about the outbreak.
- The President announced he is extending CDC guidelines for 30 days to slow the spread of the virus.
- The President launched a partnership with the Ad Council, media networks, and digital platforms to communicate public services announcements about the coronavirus.
- The President announced guidelines for Americans to follow and do their part to stem the spread of the virus.
- The Task Force is holding nearly daily press conferences to provide the American people with the latest information.
- The Task Force recommended mitigation strategies to heavily impacted communities, like those in New York, Washington, and California.
- CMS announced guidance to protect vulnerable elderly Americans and limit medically unnecessary visits to nursing homes.
- President Trump’s PREVENTS initiative started a new public awareness campaign to promote emotional wellbeing for veterans during the coronavirus pandemic.

## **SUPPORTING PATIENTS AND HEALTHCARE PROVIDERS**

- The President worked with Congress to secure \$100 billion for out healthcare providers.
- In January, the Administration declared the coronavirus to be a public health emergency.
- The President donated his fourth-quarter 2019 salary to the Department of Health and Human Services for coronavirus response efforts.
- The Army Corps of Engineers and FEMA are helping to build temporary hospitals and medical facilities in hard hit areas.
- The Vice President penned a letter to hospital administrators asking hospitals to report testing data to HHS to help inform policies.
- The President took action to give HHS authority to waive rules and regulations so that healthcare providers have maximum flexibility to respond to this outbreak.
- CMS issued sweeping regulatory changes to increase hospital capacity, rapidly expand the healthcare workforce, and cut paperwork so doctors can put patients first.
- HHS is providing funding to help healthcare systems across the country quickly prepare for a surge in coronavirus patients.
- CMS is giving flexibility to Medicare Advantage and Part D plans to waive cost-sharing for coronavirus tests and treatment.
- The President announced that Humana and Cigna will waive co-pays, coinsurance, and deductibles for coronavirus treatments.
- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.
- The White House Office of Science and Technology Policy coordinated with the NIH, the tech industry, and non-profits to release a machine readable collection of 29,000 coronavirus-related research articles, which will help scientists discover insights to virus' genetics, incubation, treatment, symptoms, and prevention.
- The White House launched a new public-private consortium to help provide coronavirus research projects access to powerful supercomputer resources.
- The Administration announced that health plans with health savings accounts will be able to cover coronavirus testing and treatment without co-payments.
- CMS dramatically expanded telehealth for Medicare beneficiaries, ensuring more patients can access their doctors remotely while avoiding exposure.

- HHS lifted HIPAA penalties to enable healthcare providers to expand telehealth access for patients.
- The FDA took action to allow expanded use of devices to monitor patients' vital signs remotely, reducing hospital visits and minimizing risks of exposure.
- The VA established 19 emergency operations centers across the country and put in place visitation restrictions to limit patients' exposure.
- Thanks to a waiver from the Office of Personnel Management, the VA is working to rehire retired medical personnel during the coronavirus outbreak.
- CMS and the VA are working to limit nonessential, elective medical procedures to free up healthcare resources.
- The Department of Defense issued guidance to delay elective medical procedures at military facilities in order to preserve healthcare resources.
- The Navy deployed two medical ships to help support impacted areas.
- The President announced Carnival Cruise Lines will be making ships available for hospitals to use for non-coronavirus patients.

#### **STRENGTHENING ESSENTIAL MEDICAL SUPPLIES**

- The Administration mobilized a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk.
- FEMA is working to distribute ventilators and other critical supplies to hard hit states.
- FEMA launched Project Airbridge to help quickly airlift critical supplies across the country.
- The President invoked the Defense Production Act, providing a number of authorities that can be used as needed.
- The President took action under the Defense Production Act to compel General Motors to accept, perform, and prioritize Federal contracts for ventilators.
- President Trump signed an executive order providing HHS and DHS with the full authorities available under the Defense Production Act to respond to this outbreak.
- The President urged the private sector to bolster response efforts, leading companies across the country to produce more critical supplies like masks, ventilators, and hand sanitizer.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the

Strategic National Stockpile.

- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.
- The Department of Defense is procuring 8,000 ventilators worth an estimated \$84.4 million
- The President signed legislation removing restrictions that prevented manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.
- The FDA gave emergency approval to a new system to sterilize N95 masks, helping hospitals get the most use out of their masks.
- The President signed an executive order to prevent hoarding and price-gouging of critical medical supplies.
- The Department of Justice has taken action to combat coronavirus related fraud.

#### **DEVELOPING VACCINES AND THERAPEUTICS**

- The Administration is working to help accelerate the development of therapeutics and a vaccine to combat the coronavirus.
- The FDA is evaluating existing drugs that could serve as potential therapeutics for coronavirus patients.
- The FDA approved emergency use of convalescent plasma treatments for seriously ill coronavirus patients.
- HHS accepted 30 million doses of hydroxychloroquine sulfate donated by pharmaceutical companies.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.
- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

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**From:** [Caliguiri, Laura](#)  
**To:** [Lynch, Sarah](#); [Capobianco, Abigail](#); [Kimberly, Brad](#)  
**Subject:** FW: What You Need To Know | President Trump's Coronavirus Response Efforts  
**Date:** Tuesday, March 24, 2020 8:36:17 PM

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**From:** Mitchell, Austin A. EOP/WHO (b) (6)@who.eop.gov>  
**Sent:** Tuesday, March 24, 2020 8:35 PM  
**Subject:** What You Need To Know | President Trump's Coronavirus Response Efforts

## **What You Need To Know | President Trump's Coronavirus Response Efforts**

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*President Trump and his Administration are working every day to protect the health and wellbeing of Americans and respond to the coronavirus.*

### **WHOLE-OF-GOVERNMENT APPROACH**

- President Trump declared a national emergency, inviting States, territories, and tribes to access over \$42 billion in existing funding.
- President Trump signed legislation securing \$8.3 billion for coronavirus response.
- President Trump signed the Families First Coronavirus Response Act, ensuring that American families and businesses impacted by the virus receive the strong support they need.
- To leverage the resources of the entire government, the President created a White House Coronavirus Task Force to coordinate response.
- The Vice President named Dr. Deborah Birx to serve as the White House Coronavirus Response Coordinator.
- At the request of President Trump, FEMA is leading federal operations on behalf of the White House Coronavirus Task Force.
- FEMA's National Response Coordination Center has been activated to its highest level in support of coronavirus response.

### **SUPPORTING STATE AND LOCAL EFFORTS**

- The President has approved major disaster declarations for impacted states like New York, Washington, and California.

- The Administration is covering costs of deploying National Guard units to assist with response efforts in hard hit states, while ensuring governors remain in command.
- The President has held multiple teleconferences with our nation's governors to coordinate response efforts and offer his full support.

### **TRAVEL RESTRICTIONS**

- In January, President Trump reacted quickly to implement travel restrictions on travel from China, buying us valuable time to respond to the virus.
- The President has announced further travel restrictions on global hotspots, including Europe, the United Kingdom and Ireland, and Iran.
- American citizens returning from travel-restricted countries are being routed to specific airports, where they can be screened and isolated as needed.
- The United States reached mutual agreements with Mexico and Canada to restrict non-essential travel across our northern and southern borders.
- The Administration announced it will expeditiously return aliens who cross between ports of entry or are otherwise not allowed to enter the country, as the facilities in which these aliens would be held cannot support quarantine for the time needed to assess potential cases.
- The Administration raised travel warnings to their highest level for other hot spot locations, like Japan and South Korea.
- The President has expanded airport screenings to identify travelers showing symptoms and instituted mandatory quarantines.
- The State Department issued a global level 4 travel advisory, urging Americans to avoid all international travel due to the coronavirus outbreak worldwide.
- The State Department has worked to safely repatriate 9,000 Americans from 28 countries around the world.

### **EXPANDING TESTING ACCESS**

- The FDA has issued emergency approval for multiple new commercial coronavirus tests to significantly expand testing across the country.
- The President secured legislation that will ensure Americans are able to be tested for free.
- The Administration is working with state and local partners and the private sector to open up drive-through testing sites.
- The Administration is working with the private sector to develop a website that Americans can utilize to determine whether they need a test and, if so, where to

get it.

- HHS is providing funding to help accelerate the development of rapid diagnostic tests for the coronavirus.
- The FDA cut red tape to expand testing availability.
- Admiral Brett Giroir – the Assistant Secretary for Health and head of the Public Health Service – has been appointed to coordinate coronavirus testing efforts.
- The FDA is empowering states to authorize tests developed and used by laboratories in their states.
- The Department of Defense has set up 15 coronavirus testing sites worldwide.
- The President signed legislation requiring more reporting from state and private labs to ensure our public health officials have the data they need to respond to this outbreak.
- DoD and HHS worked to airlift hundreds of thousands of swabs and sample test kits from Italy to the United States.

#### **SUPPORTING IMPACTED BUSINESSES**

- The Small Business Administration has announced disaster loans which provide impacted businesses with up to \$2 million.
- SBA relaxed criteria for disaster assistance loans – expanding small businesses' access to economic assistance.
- The President directed the Energy Department to purchase large quantities of crude oil for the strategic reserve.
- President Trump has held calls and meetings with business leaders from the pharmaceutical industry, airlines, health insurers, grocery stores, retail stores, banks, and more.
- The Treasury Department approved the establishment of the Money Market Mutual Fund Liquidity Facility to provide liquidity to the financial system.

#### **HELPING FAMILIES AND WORKING AMERICANS**

- The Administration negotiated legislation which will provide tax credits for eligible businesses that give paid leave to Americans affected by the virus.
- The Administration took action to provide more flexibility in unemployment insurance programs for workers impacted by the coronavirus.
- The Treasury Department moved tax day from April 15 to July 15.
- President Trump signed legislation providing funding and flexibility for emergency nutritional aid for senior citizens, women, children, and low-income families.

- USDA announced new flexibilities to allow meal service during school closures.
- USDA announced a new collaboration with the private sector to deliver nearly 1,000,000 meals a week to students in rural schools closed due to the coronavirus.
- HHS has announced \$250 million in grants to help communities provide meals for seniors.
- The Administration is halting foreclosures and evictions for families with FHA-insured mortgages.
- The Department of Labor announced up to \$100 million in dislocated worker grants in response to the coronavirus national health emergency.
- The White House worked with the private sector to launch a central website where families, students, and educators can access online education technologies.
- President Trump signed legislation to provide continuity in educational benefits for veterans and their families who attend schools that have had to switch to online learning.
- The Department of Education has given broad approval to colleges and universities to allow them to more easily move their classes online.
- The Department of Education set interest rates on all federally-held student loans to 0% for at least 60 days.
- The Department of Education announced borrowers will have the option to suspend their payments on federally-held student loans for at least two months.
- The Department of Education is providing waivers for federal testing requirements to states that have had to close schools.

### **INFORMING THE PUBLIC**

- The Administration launched a website - coronavirus.gov - to keep the public informed about the outbreak.
- The President launched a partnership with the Ad Council, media networks, and digital platforms to communicate public services announcements about the coronavirus.
- The President announced guidelines for Americans to follow and do their part to stem the spread of the virus.
- The Task Force is holding nearly daily press conferences to provide the American people with the latest information.

- The Task Force has recommended mitigation strategies to heavily impacted communities, like those in New York, Washington, and California.
- CMS announced guidance to protect vulnerable elderly Americans and limit medically unnecessary visits to nursing homes.

### **SUPPORTING PATIENTS AND HEALTHCARE PROVIDERS**

- In January, the Administration declared the coronavirus to be a public health emergency.
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- CMS created new billing codes for coronavirus tests to promote better tracking of the public health response.
- The White House Office of Science and Technology Policy coordinated with the NIH, the tech industry, and non-profits to release a machine readable collection of 29,000 coronavirus-related research articles, which will help scientists discover insights to virus' genetics, incubation, treatment, symptoms, and prevention.
- The White House launched a new public-private consortium to help provide coronavirus research projects access to powerful supercomputer resources.
- The Administration announced that health plans with health savings accounts will be able to cover coronavirus testing and treatment without co-payments.
- CMS dramatically expanded telehealth for Medicare beneficiaries, ensuring more patients can access their doctors remotely while avoiding exposure.
- HHS lifted HIPAA penalties to enable healthcare providers to expand telehealth access for patients.
- The FDA took action to allow expanded use of devices to monitor patients' vital signs remotely, reducing hospital visits and minimizing risks of exposure.
- The VA established 19 emergency operations centers across the country and put in place visitation restrictions to limit patients' exposure.

Thanks to a waiver from the Office of Personnel Management, the VA is working to rehire retired medical personnel during the coronavirus outbreak.

- CMS and the VA are working to limit nonessential, elective medical procedures to free up healthcare resources.
- The Department of Defense issued guidance to delay elective medical procedures at military facilities in order to preserve healthcare resources.
- The Navy will be deploying two medical ships to help support impacted areas.
- The President announced Carnival Cruise Lines will be making ships available for hospitals to use for non-coronavirus patients.

### **STRENGTHENING ESSENTIAL MEDICAL SUPPLIES**

- The President announced he is invoking the Defense Production Act.
- The President has urged companies to bolster response efforts, leading companies across the country to step up and produce more critical supplies like face masks and hand sanitizer.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the Strategic National Stockpile.
- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.
- The President signed legislation removing restrictions that prevented manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.
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- The FDA is evaluating existing drugs that could serve as potential therapeutics for coronavirus patients.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.

- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

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**From:** [Caliguiri, Laura](#)  
**To:** [Lynch, Sarah](#); [Kimberly, Brad](#); [Capobianco, Abigail](#)  
**Subject:** FW: What You Need To Know | President Trump's Coronavirus Response Efforts  
**Date:** Thursday, March 26, 2020 8:08:24 PM

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**From:** Mitchell, Austin A. EOP/WHO (b) (6)@who.eop.gov>  
**Sent:** Thursday, March 26, 2020 7:56 PM  
**Subject:** What You Need To Know | President Trump's Coronavirus Response Efforts

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- The Navy will be deploying two medical ships to help support impacted areas.
- The President announced Carnival Cruise Lines will be making ships available for hospitals to use for non-coronavirus patients.
- The Army Corps of Engineers is helping to build temporary hospitals and medical facilities in states like New York and Washington.

### **STRENGTHENING ESSENTIAL MEDICAL SUPPLIES**

- The Administration mobilized a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk.
- FEMA is working to distribute ventilators and other critical supplies to hard hit states like New York.
- The President invoked the Defense Production Act, providing a number of authorities that can be used if needed.
- The President urged the private sector to bolster response efforts, leading companies across the country to produce more critical supplies like masks, ventilators, and hand sanitizer.
- The President signed a memorandum directing his Administration to make general-use face masks available to healthcare workers.
- HHS announced it will be purchasing 500 million N95 respirators for the Strategic National Stockpile.
- The Department of Defense announced it will be providing 5 million respirator masks and 2,000 specialized ventilators to assist.

- The President signed legislation removing restrictions that prevented manufacturers from selling industrial masks – which can readily protect healthcare workers – directly to hospitals.
- The President signed an executive order to prevent hoarding and price-gouging of critical medical supplies.
- The Department of Justice has taken action to combat coronavirus related fraud.

#### **DEVELOPING VACCINES AND THERAPEUTICS**

- The Administration is working to help accelerate the development of therapeutics and a vaccine to combat the coronavirus.
- The FDA is evaluating existing drugs that could serve as potential therapeutics for coronavirus patients.
- The Trump Administration is actively working with drug manufacturers to monitor any potential drug supply chain issues.
- The Administration is expanding research and consulting with experts to better understand the transmission of coronavirus.
- The National Institutes of Health has announced the beginning of a clinical trial for a coronavirus vaccine candidate.

###

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**From:** Droegemeier, Kelvin K. EOP/OSTP [(b) (6)]@ostp.eop.gov]  
**Sent:** 4/3/2020 11:05:14 AM  
**To:** Holt, Brandon T. EOP/NSC [(b) (6)]@nsc.eop.gov; Clancy, Carolyn [Carolyn.Clancy@va.gov]; Klote, Mary M. [Mary.Klote@va.gov]; Justice, Amy [Amy.Justice2@va.gov]; Bates, Jack (BISL) [Jack.Bates@va.gov]; Francis, Joe [Joe.Francis@va.gov]; Quinn, John F. (NDS) [John.Quinn@va.gov]; Box, Tami [Tamara.Box@va.gov]; Ramoni, Rachel [Rachel.Ramoni@va.gov]; Muralidhar, Sumitra [Sumitra.Muralidhar@va.gov]; Brouillette, Dan [dan.brouillette@hq.doe.gov]; Dabbar, Paul [paul.dabbar@hq.doe.gov]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Watson, Ian D. EOP/OSTP [(b) (6)]@ostp.eop.gov; Waterman, Paige E. EOP/OSTP [(b) (6)]@ostp.eop.gov; Pottinger, Matthew F. EOP/WHC [(b) (6)]@who.eop.gov; Fabina, Lauren C. EOP/NSC [(b) (6)]@nsc.eop.gov; Ruggiero, Anthony J. EOP/NSC [(b) (6)]@nsc.eop.gov; Tully, Ryan M. EOP/NSC [(b) (6)]@nsc.eop.gov; Kratsios, Michael J. EOP/OSTP [(b) (6)]@ostp.eop.gov; Parker, Lynne E. EOP/OSTP [(b) (6)]@ostp.eop.gov  
**CC:** Hennessey, Millicent S. EOP/NSC [(b) (6)]@nsc.eop.gov; Ferro, Phil J. EOP/NSC [(b) (6)]@nsc.eop.gov  
**Subject:** RE [(b) (5)] Coordination Call between EOP, VA, DoE and FDA

Hi all,

I'm adding Michael Kratsios and Lynne Parker re [(b) (5)]

Kelvin

---

**From:** Holt, Brandon T. EOP/NSC <[(b) (6)]@nsc.eop.gov>  
**Sent:** Friday, April 3, 2020 10:36 AM  
**To:** Clancy, Carolyn <Carolyn.Clancy@va.gov>; Klote, Mary M. <Mary.Klote@va.gov>; Justice, Amy <Amy.Justice2@va.gov>; Bates, Jack (BISL) <Jack.Bates@va.gov>; Francis, Joe <Joe.Francis@va.gov>; Quinn, John F. (NDS) <John.Quinn@va.gov>; Box, Tami <Tamara.Box@va.gov>; Ramoni, Rachel <Rachel.Ramoni@va.gov>; Muralidhar, Sumitra <Sumitra.Muralidhar@va.gov>; Brouillette, Dan <dan.brouillette@hq.doe.gov>; Dabbar, Paul <paul.dabbar@hq.doe.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Watson, Ian D. EOP/OSTP [(b) (6)]@ostp.eop.gov; Waterman, Paige E. EOP/OSTP [(b) (6)]@ostp.eop.gov; Droegemeier, Kelvin K. EOP/OSTP <[(b) (6)]@ostp.eop.gov>; Pottinger, Matthew F. EOP/WHO [(b) (6)]@who.eop.gov; Fabina, Lauren C. EOP/NSC [(b) (6)]@nsc.eop.gov; Ruggiero, Anthony J. EOP/NSC [(b) (6)]@nsc.eop.gov; Tully, Ryan M. EOP/NSC [(b) (6)]@nsc.eop.gov  
**Cc:** Hennessey, Millicent S. EOP/NSC [(b) (6)]@nsc.eop.gov; Ferro, Phil J. EOP/NSC [(b) (6)]@nsc.eop.gov  
**Subject:** RE: Big [(b) (5)] Coordination Call between EOP, VA, DoE and FDA

Good morning all,

Could we please lock in this call for 12:30pm? Please see call-in information below. Thank you!

Participant Dial-In: (202) 395-6392

Participant Code [(b) (6)]

Best,  
Brandon

**Brandon T. Holt**

Office of the National Security Advisor

D[(b) (6)]

**From:** Ferro, Phil J. EOP/NSC (b) (6) @nsc.eop.gov>

**Sent:** Friday, April 3, 2020 10:30 AM

**To:** Clancy, Carolyn <Carolyn.Clancy@va.gov>; Klote, Mary M. <Mary.Klote@va.gov>; Justice, Amy <Amy.Justice2@va.gov>; Bates, Jack (BISL) <Jack.Bates@va.gov>; Francis, Joe <Joe.Francis@va.gov>; Quinn, John F. (NDS) <John.Quinn@va.gov>; Box, Tami <Tamara.Box@va.gov>; Ramoni, Rachel <Rachel.Ramoni@va.gov>; Muralidhar, Sumitra <Sumitra.Muralidhar@va.gov>; Brouillette, Dan <dan.brouillette@hq.doe.gov>; Dabbar, Paul <paul.dabbar@hq.doe.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Watson, Ian D. EOP/OSTP (b) (6) @ostp.eop.gov>; Waterman, Paige E. EOP/OSTP (b) (6) @ostp.eop.gov>; Droegemeier, Kelvin K. EOP/OSTP <(b) (6) ostp.eop.gov>; Pottinger, Matthew F. EOP/WHO (b) (6) @who.eop.gov>; Fabina, Lauren C. EOP/NSC (b) (6) @nsc.eop.gov>; Ruggiero, Anthony J. EOP/NSC (b) (6) @nsc.eop.gov>; Tully, Ryan M. EOP/NSC (b) (6) @nsc.eop.gov>

**Cc:** Holt, Brandon T. EOP/NSC <(b) (6) nsc.eop.gov>; Hennessey, Millicent S. EOP/NSC (b) (6) @nsc.eop.gov>

**Subject:** (b) (5) Coordination Call between EOP, VA, DoE and FDA

Good Morning Colleagues,

First off, thank you for your robust support to get this initiative off the ground as quickly as possible. (b) (5)

We would like to convene a call this afternoon to coordinate efforts. Brandon Holt who works for APDNSA Pottinger will work with you and your staff to schedule this call. To this end, please feel free to have your staff respond to Brandon. We will send out an agenda shortly.

Please let me know if you have any questions or if I may be of assistance.

All the best,

Phil

Philip J. Ferro, PhD, MS  
Director for Countering Biological Threats  
National Security Council  
202.456.1222 (O) (b) (6) (cell)  
Philip.J.Ferro@nsc.eop.gov

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 11:47:21 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; (b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,,, (b) (6)  
**Start:** 3/21/2020 12:00:00 PM  
**End:** 3/21/2020 12:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 10:04:25 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; (b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,, (b) (6)  
**Start:** 3/21/2020 11:30:00 AM  
**End:** 3/21/2020 12:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 11:44:54 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];  
(b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,,, (b) (6)  
**Start:** 3/21/2020 12:30:00 PM  
**End:** 3/21/2020 1:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 11:20:47 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];  
(b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,,, (b) (6)  
**Start:** 3/21/2020 11:45:00 AM  
**End:** 3/21/2020 12:15:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter (b) (6) who.eop.gov

Please note updated start time of 11:45 AM. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];  
(b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,, (b) (6)  
**Start:** 3/21/2020 12:00:00 PM  
**End:** 3/21/2020 12:30:00 PM  
**Show Time As:** Tentative  
  
**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/23/2020 9:01:29 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Liddell, Christopher P. EOP/WHO [(b) (6) who.eop.gov]  
**CC:** Grogan, Joseph J. EOP/WHO [(b) (6) who.eop.gov]; CMS SV1 [(b) (6) cms.hhs.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Re: Oracle Platform

Hi Chris - Working

---

**From:** Hahn, Stephen <(b) (6)@fda.hhs.gov>  
**Sent:** Monday, March 23, 2020 8:59 AM  
**To:** Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>  
**Cc:** Grogan, Joseph J. EOP/WHO <(b) (6)@who.eop.gov>; CMS SV1 <(b) (6)@cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)@niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)@od.nih.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: Oracle Platform

Chris,  
Amy is working on this in real time. We'll get this to you.  
Steve

---

**From:** Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>  
**Date:** March 22, 2020 at 5:31:29 PM EDT  
**To:** Hahn, Stephen <(b) (6)@fda.hhs.gov>  
**Cc:** Grogan, Joseph J. EOP/WHO <(b) (6)@who.eop.gov>; CMS SV1 <(b) (6)@cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)@niaid.nih.gov>; Collins, Francis S (NIH)

<(b) (6) od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

**Subject:** Re: Oracle Platform

Steve

Do you have a presentation from (b) (5)

Thanks

Chris

On Mar 22, 2020, at 4:00 PM, Hahn, Stephen (b) (6) @fda.hhs.gov wrote:

Thanks, Chris. Please let me know if you have any questions.

Steve

---

**From:** Grogan, Joseph J. EOP/WHO (b) (6) who.eop.gov>

**Date:** March 21, 2020 at 7:29:35 PM EDT

**To:** CMS SV1 <SV1@cms.hhs.gov>

**Cc:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <(b) (6) niaid.nih.gov>, Collins, Francis S (NIH) <(b) (6) od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO <(b) (6) who.eop.gov>

**Subject:** Re: Oracle Platform

Cc'ing deputy cos Chris Liddell who can help with any technical issues and can enlist US digital services if necessary.

Sent from my iPhone

On Mar 21, 2020, at 7:02 PM, CMS SV1 <SV1@cms.hhs.gov> wrote:

Amy, please work through Brady Brookes for CMS issues.

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Sent:** Saturday, March 21, 2020 6:59 PM

**To:** Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6) niaid.nih.gov>; Hahn, Stephen <(b) (6) fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; CMS SV1 <(b) (6) cms.hhs.gov>

**Cc:** Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <(b) (6) who.eop.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6) niaid.nih.gov>; Collins, Francis (NIH/OD) [E] <(b) (6) od.nih.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>

**Subject:** Re: Oracle Platform

Thanks, All.

I am in touch with John Brooks and will connect with Cliff Lane as well.

(b) (5) will be ready for the 5pm deadline.

Take care,

Amy

---

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: 240-429-7034

Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

---

**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Sent:** Saturday, March 21, 2020 6:53 PM

**To:** Fauci, Anthony S (NIH) <(b) (6) [niaid.nih.gov](mailto:niaid.nih.gov)>; Hahn, Stephen <(b) (6) [fda.hhs.gov](mailto:fda.hhs.gov)>; Redfield, Robert R (CDC) <[olx1@cdc.gov](mailto:olx1@cdc.gov)>; Abernethy, Amy <[Amy.Abernethy@fda.hhs.gov](mailto:Amy.Abernethy@fda.hhs.gov)>; (b) (6) [cms.hhs.gov](mailto:cms.hhs.gov) <(b) (6) [cms.hhs.gov](mailto:cms.hhs.gov)>

**Cc:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Joe Grogan <[Joseph.J.Grogan@who.eop.gov](mailto:Joseph.J.Grogan@who.eop.gov)>; Verma, Seema (CMS) <[Seema.Verma@cms.hhs.gov](mailto:Seema.Verma@cms.hhs.gov)>; Lane, Henry C (NIH) <(b) (6) [niaid.nih.gov](mailto:niaid.nih.gov)>; Collins, Francis S (NIH) <(b) (6) [od.nih.gov](mailto:od.nih.gov)>

**Subject:** RE: Oracle Platform

+ Seema

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**From:** Fauci, Anthony (NIH/NIAID) [E] <(b) (6) [niaid.nih.gov](mailto:niaid.nih.gov)>

**Sent:** Saturday, March 21, 2020 6:50 PM

**To:** Hahn, Stephen <(b) (6) [fda.hhs.gov](mailto:fda.hhs.gov)>; Redfield, Robert R (CDC) <[olx1@cdc.gov](mailto:olx1@cdc.gov)>; Abernethy, Amy <[Amy.Abernethy@fda.hhs.gov](mailto:Amy.Abernethy@fda.hhs.gov)>

**Cc:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Joe Grogan <(b) (6) [who.eop.gov](mailto:who.eop.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Verma, Seema (CMS) <[Seema.Verma@cms.hhs.gov](mailto:Seema.Verma@cms.hhs.gov)>; Lane, Henry C (NIH) <[clane@niaid.nih.gov](mailto:clane@niaid.nih.gov)>; Collins, Francis S (NIH) <[collinsf@od.nih.gov](mailto:collinsf@od.nih.gov)>

**Subject:** RE: Oracle Platform

Steve:

Thanks for the note. Cliff Lane will be my designated person to work with Amy, and if there are other areas of expertise where NIH can contribute such as a person from National Library of Medicine (NLM) and/or the National Center for Advancing Translational Science (NCATS), Cliff will work with me and Dr. Francis Collins (NIH Director) to provide a name and contact information for such a person. I am also copying Dr. Collins on this e-mail.

Best regards,

Tony

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**From:** Hahn, Stephen <(b) (6)@fda.hhs.gov>

**Sent:** Saturday, March 21, 2020 4:31 PM

**To:** Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>

**Cc:** Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan (b) (6)@who.eop.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>

**Subject:** Oracle Platform

Tony and Bob,

This email is in follow up to our conversation an hour ago regarding the Oracle Platform. I am adding Dr. Amy Abernathy who is the Principle Deputy Commissioner of FDA. CMS Administrator Verma, Joe Grogan, Stacy Amin, Chief Legal Counsel for FDA, and Keagan Lenihan, my Chief of Staff are copied.

We have a 5 pm deadline tomorrow to deliver a plan for (b) (5). Amy will lead this effort and coordinate with your agencies. I know that you will be designating participants to work with Amy. I've discussed with Amy and she has heard about the details of our conversation earlier today. (b) (5)

The questions are:

1. What are the disclosure, consent, and HIPAA considerations for the platform. We'll need to run the legal traps around this. Stacy, Keagan and I have a call into to you so that we can read you into the details.
2. What are the issues around engagement and communication with the physician community?
3. Do we have the appropriate data fields and who should review them to ensure that we are collecting what we need, balanced with burden on physicians/providers?

The White House had made it clear that they will help us remove any barriers. If you encounter any obstacles, please funnel them to me (cel (b) (6)) and I'll pass them along to the WH. Administrator Verma has agreed to look into any coverage issues that might arise.

Thanks.

Steve

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];  
(b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,, (b) (6)  
**Start:** 3/21/2020 12:30:00 PM  
**End:** 3/21/2020 1:00:00 PM  
**Show Time As:** Tentative  
  
**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Woodcock, Janet [Janet.Woodcock@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; (b) (6) who.eop.gov  
**CC:** Rom, Colin [Colin.Rom@fda.hhs.gov]

**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,,, (b) (6)

**Start:** 3/21/2020 11:45:00 AM  
**End:** 3/21/2020 12:15:00 PM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note updated start time of 11:45 AM. Thank you.

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; (b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,, (b) (6)  
**Start:** 3/21/2020 11:30:00 AM  
**End:** 3/21/2020 12:00:00 PM  
**Show Time As:** Tentative  
  
**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];  
(b) (6) who.eop.gov  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Telecon: Coronavirus Treatment Acceleration Program  
**Location:** 1-877-465-7975,, (b) (6)  
**Start:** 3/21/2020 11:45:00 AM  
**End:** 3/21/2020 12:15:00 PM  
**Show Time As:** Busy  
  
**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note updated start time of 11:45 AM. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/21/2020 8:01:07 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Woodcock, Janet [Janet.Woodcock@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; (b) (6) who.eop.gov  
**CC:** Rom, Colin [Colin.Rom@fda.hhs.gov]

**Subject:** Telecon: Coronavirus Treatment Acceleration Program

**Location:** 1-877-465-7975,, (b) (6)

**Start:** 3/21/2020 11:30:00 AM

**End:** 3/21/2020 12:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 4/2/2020 4:38:49 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: First coronavirus blood test gets FDA emergency authorization

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**From:** POLITICO Pro <politicoemail@politicopro.com>  
**Date:** April 2, 2020 at 1:23:31 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** First coronavirus blood test gets FDA emergency authorization

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/31/2020 1:35:01 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]  
**Subject:** Fwd: Confidential Draft Press Release  
**Attachments:** Confidential Draft Release.docx

FYI

---

**From:** Daniel O'Day <daniel.oday@gilead.com>  
**Date:** March 31, 2020 at 1:34:12 PM EDT  
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Brett Pletcher <Brett.Pletcher@gilead.com>  
**Subject:** Confidential Draft Press Release

Dear Janet and Steve,

Janet, as mentioned briefly yesterday, I am writing to share with you a draft announcement we would like to issue later this week, which at a high level commits to donating (b) (4) of remdesivir at no cost. As public and government interest increases daily, and concerns about cost during the peak of this pandemic are top of mind, I feel a responsibility to communicate this commitment even ahead of clinical data or a regulatory authorization of any kind. At the same time, because existing supply is limited, we also want to communicate our expansive efforts to increase supply as rapidly as possible, through our own efforts and partnerships with external pharmaceutical and chemical manufacturing companies. This is critical to assuring a coordinated effort across the globe that can maximize the production of remdesivir if needed, and is time sensitive.

The point of this communication is to assure the public of our view – that this is an extraordinary time and we will take extraordinary measures to ensure access to remdesivir, through current expanded access programs, and through other mechanisms when and if data supports broader access. This is also a follow-on to my open letter this past weekend on the Gilead website about our Compassionate use and Expanded access efforts, and consistent with our commitment to transparency.

We are sharing this draft press release in parallel with the review team at FDA, following the process my regulatory team follows for standard submissions and discussion. I appreciate you helping us to keep this information confidential, and also appreciate you letting me know your thoughts by the end of the day if possible.

We would also intend to share this with members of the Coronavirus task force, and the white house as a second step tomorrow prior to release.

Please call or email at any time. Cell (b) (6)

Best,  
Dan



**CONTACTS:** Douglas Maffei, PhD, Investors  
(650) 522-2739

Sonia Choi, Media  
(650) 425-5483

*Confidential Draft – Not for Distribution*

(b) (4)

(b) (4)

*For more information about Gilead, please visit the company's website at [ HYPERLINK "http://www.gilead.com" ], follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/30/2020 12:01:51 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Updated CTAP Graphic  
**Attachments:** CTAP\_print\_combined\_v4\_3.30.20.pdf

We're putting it in landscape version but wanted you to see most recent version.  
Steve

---

**From:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>  
**Date:** March 30, 2020 at 11:55:11 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Updated CTAP Graphic

Dr. Hahn, please see an updated graphic attached. The following changes have been made:

- Data points have been added for the projected number of doses available for convalescent plasma and hyperimmune globulin.
- (b) (5)
- IL-6 Inhibitors are shown to have "Trials Ongoing" in April (since trials for one therapy are starting this month).
- The status of clinical trials/production of hyperimmune globulin now reads, "Working with manufacturers and on donor identification to ramp up production."

We'll have a formatted one-pager describing CTAP to you shortly.

--  
Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
Food and Drug Administration  
+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

(b) (5)

(b) (5), (b) (4)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/24/2020 6:30:58 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Summary of clinician feedback  
**Attachments:** Rapid Clinician impressions from Oracle COVID 032320docx.docx

Clinician feedback on the Oracle system

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Date:** March 24, 2020 at 9:30:07 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Subject:** Summary of clinician feedback

Hi - As per our discussion this morning, here is a quick summary of the feedback from 30 clinicians who used the Oracle COVID-19 system yesterday.

Take care,

Amy

---

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: 240-429-7034  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

(b) (4), (b) (5)

(b) (4), (b) (5)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/31/2020 12:35:17 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Please send to me  
**Attachments:** UPDATED\_CTAP\_print\_combined\_V8\_3.30.20.pdf; CTAP-handout-1col-draft3.pdf

---

**From:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>  
**Date:** March 31, 2020 at 12:06:13 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

If it's not too late (b) (5)

I've re-attached the bullets page as well.

--  
Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
Food and Drug Administration  
+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Guram, Jeet  
**Sent:** Tuesday, March 31, 2020 11:14 AM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

Here is the latest version of the graphic, and I've re-attached the bullets page as well.

--  
Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
Food and Drug Administration  
+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 11:05 AM  
**To:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

Ok thx

---

**From:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>  
**Date:** March 31, 2020 at 10:29:25 AM EDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

Got it, (b) (5)

I'll send the version of the graphic with the larger font size as soon as it comes in, which should be later this morning.

--  
Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
Food and Drug Administration  
+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 10:25 AM  
**To:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

(b) (5)

---

**From:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>  
**Date:** March 31, 2020 at 9:50:15 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

(b) (5)

--  
Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
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+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Guram, Jeet  
**Sent:** Tuesday, March 31, 2020 9:17 AM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Please send to me

Here are the documents – the team is working on making the font larger for the graphics document, I'll check on the status of that.

(b) (5)

(b) (5)

Jeet Guram, M.D.  
Senior Advisor, Office of the Commissioner  
Food and Drug Administration  
+1 (202) 230-0451 | [jeet.guram@fda.hhs.gov](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>  
**Sent:** Tuesday, March 31, 2020 9:03 AM  
**To:** Guram, Jeet <[Jeet.Guram@fda.hhs.gov](mailto:Jeet.Guram@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>  
**Cc:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Rom, Colin <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>  
**Subject:** Please send to me

The 3 pager CTAP document  
Page 1 the bullet points about the program  
Pages 2-3 graphics of pipeline

The Secretary wants this (b) (5) . When can you get this to me?  
Thanks  
Steve

(b) (5)

(b) (5), (b) (4)

(b) (5)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/27/2020 7:06:45 AM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** For our 7:45 am call: Draft March 27 2020 Commissioner CTAP TP.docx  
**Attachments:** Draft March 27 2020 Commissioner CTAP TP.docx

(b)

(5)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/27/2020 2:00:02 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]  
**Subject:** Fwd: Chinese convalescent plasma pre-print in BMJ  
**Attachments:** The feasibility of convalescent plasma therapy in severe COVID19 patients --a pilot study.2020.03.16.20036145v1.full.pdf

---

**From:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Date:** March 26, 2020 at 4:37:31 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Chinese convalescent plasma pre-print in BMJ

Dear Dr. Hahn,

Colin had asked if I could forward the BMJ preprint on convalescent plasma from the early Chinese experience – it is attached.

Please let us know if you have any questions or need anything else on this.

Thanks,

Julie

**Julia C. Tierney, JD**  
*Chief of Staff*

Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
(301) 796-8602 (direct)  
[Julia.Tierney@fda.hhs.gov](mailto:Julia.Tierney@fda.hhs.gov)



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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/24/2020 5:23:15 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: FDA encourages use of experimental coronavirus treatment made from survivors' blood

This is really good work.

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Date:** March 24, 2020 at 5:09:53 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** FDA encourages use of experimental coronavirus treatment made from survivors' blood

### **FDA encourages use of experimental coronavirus treatment made from survivors' blood**

By Arthur Allen

03/24/2020 05:08 PM EDT

FDA today encouraged researchers to study the experimental treatment of desperately ill Covid-19 patients with convalescent serum, a 130-year-old therapy that medicine periodically retrieves from its black bag with mixed success during pandemics.

The agency also said it would approve emergency use of the treatment — plasma rich with coronavirus antibodies, taken from the blood of people who have recovered from the disease — on severely ill patients. FDA said it would require donors' blood be carefully screened to make sure there was no residual coronavirus or other contaminants.

Convalescent serum was used to treat a variety of infections from the 1890s until around World War II. The 1925 dogsled trek that brought diphtheria "antitoxin" to save children in Nome, Alaska, is memorialized in the Balto movies and the annual Iditarod dog race.

More recently, Chinese doctors gave convalescent plasma to 21 patients during the 2009 swine flu pandemic; a fifth died, compared to 55 percent in a control group. The serum had almost no impact in Guinea when used in a group of Ebola patients in 2014. Chinese doctors have also employed human serum against coronavirus in the current pandemic.

Antibody therapy is most effective when used to prevent disease rather than in treatment, according to an article published last week by experts Arturo Casadevall of Johns Hopkins University and Liise-anne Pirofski of the Albert Einstein College of Medicine, who are organizing a trial to test the serum.

In contrast to the FDA, which said it would only give permission for emergency use in the sickest patients, Casadevall and Pirofski write that the serum might be most appropriate to temporarily boost protection in infected health care workers who would otherwise need to go into quarantine.

FDA provided emergency numbers for doctors to reach officials at the agency who can approve use of the therapy at short notice in the most desperate cases.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/03/fda-encourages-use-of-experimental-coronavirus-treatment-made-from-survivors-blood-3978431>

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/24/2020 5:03:19 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** FW: Gilead FDA material  
**Attachments:** protocol GS-US-540-5821\_Approved.pdf; CU Update for FDA\_final.pptx

---

**From:** Daniel O'Day <daniel.oday@gilead.com>  
**Date:** March 23, 2020 at 3:48:06 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>  
**Subject:** FW: Gilead FDA material

Dear Deborah and Steve,

Steve, I thought I would share the attached with Deborah as well, as we have not had a chance to connect yet today, and I know how busy you both are! (and should we connect I wanted Deborah to have the material in front of her) I know Steve's team at FDA and our Clinical team discussed the protocol (first attachment) and are well on the way to implementation.

The bigger issue is the CU update deck attached (second attachment). Please refer to slide 10. We believe this is of public health importance, and would like to discuss at your earliest convenience. We intend to discuss with European authorities and others tomorrow.

Best,  
Dan

From: Daniel O'Day <daniel.oday@gilead.com>  
Date: Sunday, March 22, 2020 at 10:37 PM  
To: "sh1@fda.hhs.gov" <sh1@fda.hhs.gov>  
Subject: Gilead FDA material

Hi Steve,

Please see attached the interim analysis for 53 CU patients and the draft expanded access treatment protocol.

These materials were sent to your team in preparation for a 9am call tomorrow morning between our teams to discuss.

Due to the nature of the interim analysis, I believe it would be helpful to have a discussion with you and Dr. Birx tomorrow when possible in addition to the team discussion. Can you let me know if you agree, and if you support me sharing the interim analysis with Dr. Birx?

If possible, I would prefer that we speak prior to this data being shared beyond FDA and Dr. Birx.

Please let me have your thoughts. I look forward to seeking your advice on next steps.

Best,  
Dan

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/8/2020 9:15:07 AM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Serology Question Follow Up - BD

For the top of your inbox.  
This request for help with respect to challenges faced in China.  
Thanks, Joe

---

**From:** Dave Hickey <Dave\_Hickey@bd.com>  
**Date:** April 6, 2020 at 9:31:04 PM EDT  
**To:** Whitaker, Scott <SWhitaker@AdvaMed.org>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** RE: Serology Question Follow Up - BD

Scott,

Thanks for forwarding

Dr Hahn – thank you again for taking time on the call today and for listening to our questions / asks and for the guidance from you and your team. Very much appreciated.

Dave.



**Dave Hickey**  
*President, Integrated Diagnostic Solutions*

[Dave.Hickey@bd.com](mailto:Dave.Hickey@bd.com)

7 Loveton Circle,  
Sparks, Maryland 21152  
US  
**t:** 4103164121  
**c:** (b) (6)

[bd.com](http://bd.com)

---

**From:** Whitaker, Scott <SWhitaker@AdvaMed.org>  
**Sent:** Monday, April 6, 2020 9:26 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Dave Hickey <Dave\_Hickey@bd.com>  
**Subject:** Fwd: Serology Question Follow Up - BD

Do you recognize this sender? This email came from an external source. Use caution when opening attachments or clicking links.

Dr. Hahn,

Per our earlier discussion, see below an email from Dave Hickey, President BD Integrated Diagnostic Solutions, outlining (b) (4). Thanks for your consideration.

Scott

Sent from my iPad

Scott, please find below an email to Commissioner Hahn to follow-up on the issue that I raised during today's AdvaMedDx Board discussion. As he requested, if you could feed this into him it would be really appreciated.

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Commissioner Hahn,

Last week, we announced a partnership with BioMedomics and Henry Schein to bring a high quality serology test to the U.S. market (see release below). This will meet a critical need for new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes. (b) (4)

[REDACTED]

(b) (4)

We look forward to working with you to ensure appropriate access to these critical tests.

Dave

## BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

**Point-of-care blood test detects evidence of present or past exposure in 15 minutes**

FRANKLIN LAKES, N.J. and MORRISVILLE, N.C., March 31, 2020 /PRNewswire [prnewswire.com]/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.

The new test, developed and manufactured by BioMedomics, will be available through BD and distributed exclusively by Henry Schein, Inc. to health care providers throughout the United States.

The test does not require special equipment and may be used in a laboratory or at the point of care. The test detects antibodies in the blood that are produced by the body in response to coronavirus infection. These antibodies are

typically present in the middle to later stages of COVID-19 infection, but may remain present after exposure, which helps clinicians determine who has been exposed to the coronavirus, even if a person didn't exhibit any symptoms of the COVID-19 disease. Data on past exposure is important for researchers to more accurately understand the likely true occurrence of SARS-CoV-2 infection across a population. This information will be helpful in informing future strategies for combatting COVID-19.

"Serology tests are important because they provide an additional piece of information to aid in characterizing possible prior exposure to SARS-CoV-2, especially since many infections are mild or asymptomatic in severity," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Initial evidence suggests that nearly all patients infected with SARS-CoV-2 will have developed a detectable antibody response within days of symptom onset, at which time a negative serologic test, along with molecular diagnostics, could be helpful in ruling out COVID-19. Our agreement with BioMedomics adds a rapid serology test that can augment current tests already on the market, and we are pleased to collaborate in this effort with Henry Schein, which has extensive knowledge of the point-of-care test field."

The test is completed in four, simple steps. First, blood is collected through normal blood collection devices such as the BD Microtainer® Contact-Activated Lancet. A few drops of blood are then transferred to the test cartridge, followed by two to three drops of a buffer. The results can be read in 15 minutes, similar to how over-the-counter pregnancy tests show multiple lines for positive results and a single line for negative results.

"BioMedomics designed the test to be easy to use and provide results in minutes, with no special equipment necessary or the need to transport the sample to a laboratory for analysis," said Frank Wang, CEO of BioMedomics. "Our test has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and our published clinical data in the *Journal of Medical Virology* was one of the world's first for a COVID-19 serology test. It has been used widely in China during the COVID-19 outbreak and is now ready to help combat coronavirus in the U.S. through our collaboration with BD. We are committed to doing our part to battle this disease and are excited to have BD as a partner to help deliver our high-quality rapid test to those who need it most."

The test analyzes blood, serum or plasma samples for the presence of immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies associated with the coronavirus (SARS-CoV-2). IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high-affinity IgG responses for long-term immunity and immunological memory. The detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, and detection of COVID-19 IgG antibodies indicates a later stage of infection, so this combined antibody test could also provide information on the stage of the disease in patients. Current guidance from the U.S. Food and Drug Administration (FDA) recommends that results from antibody testing should not be used as the sole basis to diagnose or exclude coronavirus infection. Depending on the clinical scenario, additional testing, such as those used on the BD MAX™ System may be considered to further evaluate the possibility of SARS-CoV-2 infection.

"We look forward to working with such an outstanding company as BD to help make the antibody test part of the standard of care," said Stanley M. Bergman, Henry Schein's chairman of the board and chief executive officer. "The test will help to identify people who have developed antibodies to the virus, which may inform future strategies regarding COVID-19."

The test has not been reviewed by the FDA but is permitted for distribution and use under the public health emergency guidance issued by FDA on March 16, 2020, and BD expects to begin shipping tests in April. BD will have capacity to supply more than one million tests over the coming months, with the ability to scale up based on market demand and is working with medical products distribution company Henry Schein to make these tests available to medical care facilities throughout the United States. Health care providers can order the test and all collection devices needed to perform the test by contacting their BD or Henry Schein representatives.

### **About BD**

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](http://bd.com) [c212.net].

**About BioMedomics**

BioMedomics is a point-of-care diagnostics company that aims to provide novel, rapid point-of-care tests to aid in the diagnosis of critical diseases. The company uses cutting-edge technology to create life-saving diagnostic solutions and address global health care needs. Its diagnostic tests produce rapid and accurate clinical results at the point-of-care without requiring complex and expensive lab equipment — placing immediate health care knowledge in the hands of providers. With that knowledge comes the power to make treatment decisions and save lives. Please visit [biomedomics.com](http://biomedomics.com) [c212.net] for more information.



**Dave Hickey**  
*President, Integrated Diagnostic Solutions*

[Dave.Hickey@bd.com](mailto:Dave.Hickey@bd.com)

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Sparks, Maryland 21152  
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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/6/2020 1:35:46 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fw: Journal publisher raises red flags about French malaria drug study

FYI

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Date:** April 6, 2020 at 1:33:04 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fw: Journal publisher raises red flags about French malaria drug study

FYI. I think that the issue of patient selection is one that is going to come up over and over again, as per our conversation this morning.

---

**From:** POLITICO Pro Health Care <politicoemail@politico.com>  
**Sent:** Monday, April 6, 2020 1:31 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Journal publisher raises red flags about French malaria drug study

### **Journal publisher raises red flags about French malaria drug study**

By Sarah Oweremohle  
04/06/2020 01:30 PM EDT

The society that recently published a French study that suggested malaria drug hydroxychloroquine could help coronavirus patients has raised formal concerns about the research.

In a statement, the International Society of Antimicrobial Chemotherapy says it "shares the concerns" raised by critics of the study, which was published on March 20 in a society-run journal. Such statements of concern are often the first step towards retracting a scientific paper.

The small study, led by controversial French researcher Didier Raoult, helped fuel growing interest in the drugs in the United States. President Donald Trump has cited Raoult's work while championing hydroxychloroquine as having "very, very encouraging" early results against the coronavirus.

But the society, which runs the International Journal of Antimicrobial Agents, has now said that the French study does not meet their standards — citing its "lack of better explanations" for how study participants were chosen. Experts have pointed out that Raoult's team chose who would get the drug versus who would not, even though the gold standard for clinical trials is to assign patients to treatment groups randomly.

Raoult has not yet responded to a request for comment on the society's statement.

The results from other studies of hydroxychloroquine have been mixed, and the studies themselves have been small.

The president's focus on hydroxychloroquine has sparked divides within his administration, where several health officials feel there has been outsized attention on the drug even as other medicines are in trials.

The Food and Drug Administration last week authorized emergency use of the drug for severely ill patients but acknowledged there was still limited data about whether the treatment is effective.

*To view online:*

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**Sent:** 4/2/2020 4:40:30 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: First coronavirus blood test gets FDA emergency authorization

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**From:** POLITICO Pro <politicoemail@politicopro.com>  
**Date:** April 2, 2020 at 1:23:31 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** First coronavirus blood test gets FDA emergency authorization

### **First coronavirus blood test gets FDA emergency authorization**

By David Lim

04/02/2020 01:20 PM EDT

The FDA has granted its first emergency use authorization for a coronavirus test that analyzes antibodies in a person's blood to determine if they have been exposed to the virus.

Antibody tests, also known as serology tests, are powerful weapons to curb outbreaks because they can detect people who have recovered from infection, not just those who are currently ill.

The serology test that received FDA authorization Wednesday is manufactured by Cellex. The agency says that "it is reasonable to believe" that Cellex's antibody test "may be effective in diagnosing" the virus and that there is no "adequate, approved, and available alternative." By contrast, devices seeking approval under a premarket approval application must show evidence that "provides reasonable assurance" they are "safe and effective."

Under guidance updated in March, FDA is allowing firms that validate coronavirus serological tests to use them in certain circumstances before being reviewed by the agency. More than 50 serological tests are being offered under that policy, according to an FDA document. Such tests must disclose they have not been reviewed by the agency, cannot be used for home testing and results from them "should not be used as the sole basis to diagnose or exclude" coronavirus exposure.

Earlier this week, the California company Bodysphere falsely claimed in a press release that it already received authorization for a coronavirus antibody test. An agency spokesperson told POLITICO today that the Cellex test is the only one to receive such authorization from FDA to date.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/04/first-coronavirus-blood-test-gets-fda-emergency-authorization-3978844>

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Arlington, VA 22209

USA.

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/7/2020 8:24:49 AM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Serology Question Follow Up - BD

As per our discussion, this issue regarding the Chinese export ban was flagged by the President of BD.

FDA will address the waiver issue and will work closely with industry to make sure the tests are validated appropriately.

We do need help on the international issues.

Thanks

Steve

---

**From:** Whitaker, Scott <SWhitaker@AdvaMed.org>  
**Date:** April 6, 2020 at 9:25:55 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Hickey, David <Dave.Hickey@bd.com>  
**Subject:** Fwd: Serology Question Follow Up - BD

Dr. Hahn,

Per our earlier discussion, see below an email from Dave Hickey, President BD Integrated Diagnostic Solutions, outlining (b) (4) . Thanks for your consideration.

Scott

Sent from my iPad

Scott, please find below an email to Commissioner Hahn to follow-up on the issue that I raised during today's AdvaMedDx Board discussion. As he requested, if you could feed this into him it would be really appreciated.

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Commissioner Hahn,

Last week, we announced a partnership with BioMedomics and Henry Schein to bring a high quality serology test to the U.S. market (see release below). This will meet a critical need for new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes. (b) (4)

(b) (4)

(b) (4)

We look forward to working with you to ensure appropriate access to these critical tests.

Dave

## BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

**Point-of-care blood test detects evidence of present or past exposure in 15 minutes**

FRANKLIN LAKES, N.J. and MORRISVILLE, N.C., March 31, 2020 /PRNewswire [prnewswire.com]/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.

The new test, developed and manufactured by BioMedomics, will be available through BD and distributed exclusively by Henry Schein, Inc. to health care providers throughout the United States.

The test does not require special equipment and may be used in a laboratory or at the point of care. The test detects antibodies in the blood that are produced by the body in response to coronavirus infection. These antibodies are typically present in the middle to later stages of COVID-19 infection, but may remain present after exposure, which helps clinicians determine who has been exposed to the coronavirus, even if a person didn't exhibit any symptoms of the COVID-19 disease. Data on past exposure is important for researchers to more accurately understand the likely true occurrence of SARS-CoV-2 infection across a population. This information will be helpful in informing future strategies for combatting COVID-19.

"Serology tests are important because they provide an additional piece of information to aid in characterizing possible prior exposure to SARS-CoV-2, especially since many infections are mild or asymptomatic in severity," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Initial evidence suggests that nearly all patients infected with SARS-CoV-2 will have developed a detectable antibody response within days of symptom onset, at which time a negative serologic test, along with molecular diagnostics, could be helpful in ruling out COVID-19. Our agreement with BioMedomics adds a rapid serology test that can augment current tests already on the market, and we are pleased to collaborate in this effort with Henry Schein, which has extensive knowledge of the point-of-care test field."

The test is completed in four, simple steps. First, blood is collected through normal blood collection devices such as the BD Microtainer® Contact-Activated Lancet. A few drops of blood are then transferred to the test cartridge, followed by two to three drops of a buffer. The results can be read in 15 minutes, similar to how over-the-counter pregnancy tests show multiple lines for positive results and a single line for negative results.

"BioMedomics designed the test to be easy to use and provide results in minutes, with no special equipment necessary or the need to transport the sample to a laboratory for analysis," said Frank Wang, CEO of BioMedomics. "Our test has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and our published clinical data in the *Journal of Medical Virology* was one of the world's first for a COVID-19 serology test. It has been used widely in China during the COVID-19 outbreak and is now ready to help combat coronavirus in the U.S. through our collaboration with BD. We are committed to doing our part to battle this disease and are excited to have BD as a partner to help deliver our high-quality rapid test to those who need it most."

The test analyzes blood, serum or plasma samples for the presence of immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies associated with the coronavirus (SARS-CoV-2). IgM provides the first line of

defense during viral infections, followed by the generation of adaptive, high-affinity IgG responses for long-term immunity and immunological memory. The detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, and detection of COVID-19 IgG antibodies indicates a later stage of infection, so this combined antibody test could also provide information on the stage of the disease in patients. Current guidance from the U.S. Food and Drug Administration (FDA) recommends that results from antibody testing should not be used as the sole basis to diagnose or exclude coronavirus infection. Depending on the clinical scenario, additional testing, such as those used on the BD MAX™ System may be considered to further evaluate the possibility of SARS-CoV-2 infection.

"We look forward to working with such an outstanding company as BD to help make the antibody test part of the standard of care," said Stanley M. Bergman, Henry Schein's chairman of the board and chief executive officer. "The test will help to identify people who have developed antibodies to the virus, which may inform future strategies regarding COVID-19."

The test has not been reviewed by the FDA but is permitted for distribution and use under the public health emergency guidance issued by FDA on March 16, 2020, and BD expects to begin shipping tests in April. BD will have capacity to supply more than one million tests over the coming months, with the ability to scale up based on market demand and is working with medical products distribution company Henry Schein to make these tests available to medical care facilities throughout the United States. Health care providers can order the test and all collection devices needed to perform the test by contacting their BD or Henry Schein representatives.

### **About BD**

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](http://bd.com) [c212.net].

### **About BioMedomics**

BioMedomics is a point-of-care diagnostics company that aims to provide novel, rapid point-of-care tests to aid in the diagnosis of critical diseases. The company uses cutting-edge technology to create life-saving diagnostic solutions and address global health care needs. Its diagnostic tests produce rapid and accurate clinical results at the point-of-care without requiring complex and expensive lab equipment — placing immediate health care knowledge in the hands of providers. With that knowledge comes the power to make treatment decisions and save lives. Please visit [biomedomics.com](http://biomedomics.com) [c212.net] for more information.



### **Dave Hickey**

*President, Integrated Diagnostic Solutions*

[Dave.Hickey@bd.com](mailto:Dave.Hickey@bd.com)

7 Loveton Circle,  
Sparks, Maryland 21152  
US

t: 4103164121

c: (b) (6)

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Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/7/2020 7:44:46 AM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Question

FYSA

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** April 6, 2020 at 7:52:46 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: Question

Does this work?

(b) (5)

(b) (5)

(b) (5)

(b) (5)

On Apr 6, 2020, at 6:43 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

For task force

Does CDRH have a list of major approved diagnostic COVID tests and what platform is used for each?

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/3/2020 11:59:15 AM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

---

**From:** Hayden, Lou <lou.hayden@lowes.com>  
**Date:** April 3, 2020 at 11:33:19 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>  
**Cc:** Russo, Joseph H. EOP/WHO (b) (6) @who.eop.gov, Tim Pataki (b) (6) @who.eop.gov  
**Subject:** A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

Drs. Hahn, Shah, and Kadlec, and Joe and Tim –

Thank you for your attention to help prioritize the expedited and thorough review for FDA approval for new Moxie-brand hand sanitizer to serve our 18 million customers a week nationwide, including first responders nationwide.

By the time the product flows into our distribution / store network, (b) (4)

Question: Since the government may have ongoing demand for essential materials, could we make a direct donation of 10,000 of the first units of hand sanitizer when they arrive (b) (4)?

(Lowe's has already made \$175 million in COVID-related contributions, including \$10 million in products to responders, \$ to the Red Cross, donating all N-95 masks, and direct cash bonuses to our working hourly employees.)

With warm regards,

Lou

**Lou Hayden**  
Head of Washington, DC Office  
Lowe's Companies  
300 New Jersey Avenue NW, Ste. 900  
Washington, DC 20001  
202-464-2780

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/3/2020 11:59:04 AM  
**To:** Hayden, Lou [lou.hayden@lowes.com]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]  
**CC:** Russo, Joseph H. EOP/WHO [Joseph.H.Russo@who.eop.gov]; Tim Pataki [Timothy.A.Pataki@who.eop.gov]  
**Subject:** Re: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

Lou

How very kind of you. I'll leave this to Bob to respond. Congratulations on your terrific work  
Steve

---

**From:** Hayden, Lou <lou.hayden@lowes.com>  
**Date:** April 3, 2020 at 11:33:19 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>  
**Cc:** Russo, Joseph H. EOP/WHO (b) (6) @who.eop.gov, Tim Pataki (b) (6) @who.eop.gov  
**Subject:** A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

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**Lou Hayden**  
Head of Washington, DC Office  
Lowe's Companies  
300 New Jersey Avenue NW, Ste. 900  
Washington, DC 20001  
202-464-2780

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**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 3/24/2020 5:23:24 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: FDA encourages use of experimental coronavirus treatment made from survivors' blood

This is really good work.

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Date:** March 24, 2020 at 5:09:53 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** FDA encourages use of experimental coronavirus treatment made from survivors' blood

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 3/16/2020 2:26:09 PM  
**To:** Debi Birx [Deborah.L.Birx@nsc.eop.gov]; kac@who.eop.gov  
**Subject:** Fwd: Blood Donation

Kellyanne and Deb,

(b) (5)

Please let me know how we can help.

Steve

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** March 16, 2020 at 2:09:01 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Blood Donation

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 5/1/2020 8:47:11 AM  
**To:** Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: Testing Centers  
**Attachments:** POCT COVID Testing\_4.24.pptx

Thought this might be of interest to you. Anand Shah from my office is following up with Dr. Brennan. Steve

---

**From:** Merlo, Larry J. <Larry.Merlo@CVSHealth.com>  
**Date:** April 30, 2020 at 9:53:26 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Brennan, Troyen A. <Troyen.Brennan@CVSHealth.com>  
**Subject:** Testing Centers

Dr. Hahn,

It was great spending a few minutes with you on Monday.

Attached is a summary of our Point of Care Testing at our large-scale sites. This data is approximately one week old, and we would now be at approximately (b) (4) individuals tested.

I am copying Dr. Troyen (Troy) Brennan, our Chief Medical Officer, to connect the two of you for additional discussion.

Best regards,

**Larry Merlo** | President & CEO, CVS Health  
p 401-770-2340  
1 CVS Drive, Mail Code 1000, Woonsocket, RI 02895



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# COVID-19 Point of Care Testing

## COVID POCT Data Summary

Karthik Thasu Krishnamoorthy

Robert Richards

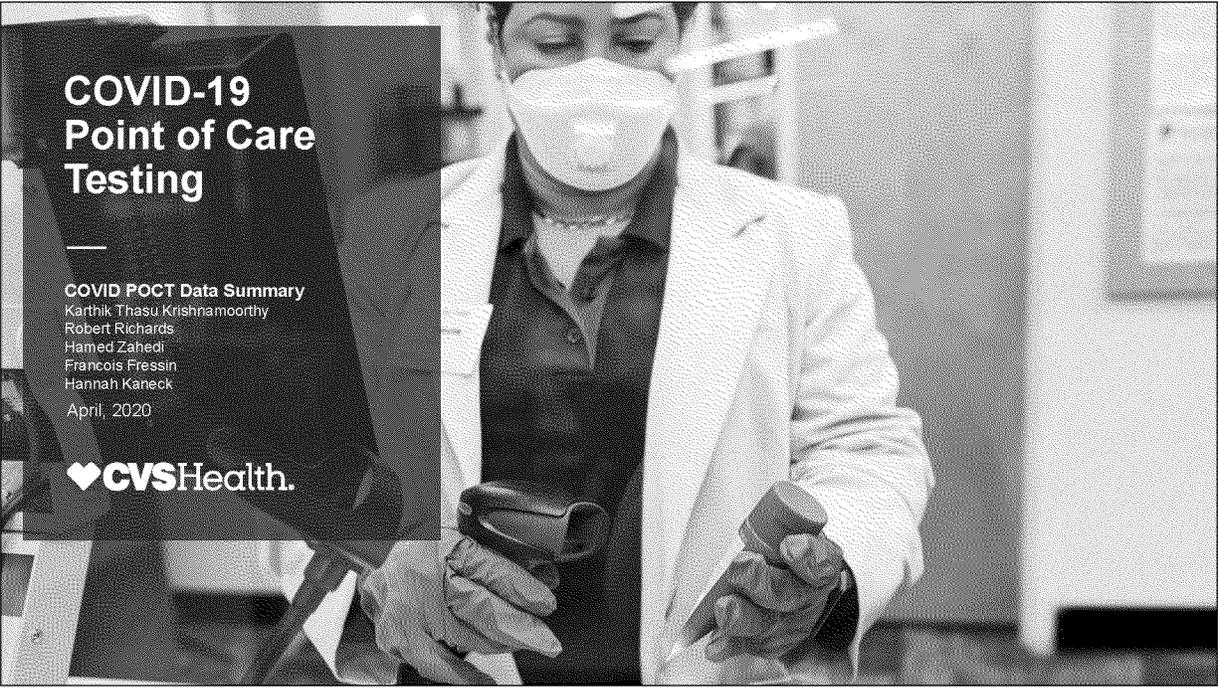
Hamed Zahedi

Francois Fressin

Hannah Kaneck

April, 2020

 **CVS**Health.



## Executive Summary

(b) (4)



(b) (4)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/21/2020 2:29:26 PM  
**To:** Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Fwd: POTUS comment for today

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**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** April 21, 2020 at 2:29:14 PM EDT  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: POTUS comment for today

Some edits. Will forward to Joe.  
S

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Date:** April 21, 2020 at 2:25:33 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: POTUS comment for today  
**Importance:** High

Suggested edits

(b) (5)

(b) (5)

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**From:** Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>

**Sent:** Tuesday, April 21, 2020 1:32 PM

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** POTUS comment for today

**Importance:** High

Guy, in the next 45 minutes, can you get me more than what I have below? For POTUS to say.

(b) (5)

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 4/21/2020 3:27:39 PM  
**To:** Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]  
**Subject:** Serology testing in Germany

FYI -- Our FDA Europe Office is still working on trying to obtain the information on serology testing in Germany from BfArM and others. No reply from BfArM yet. They did come across the following, translated from an article in German, that may be of interest:

The RKI [Robert Koch Institute] will soon start investigations on blood donors and humans in some COVID-19 outbreak areas. In the longer term, a nationwide representative study is planned. For laboratory analysis, the RKI works closely with the Institute for Virology at Charité - Universitätsmedizin Berlin, headed by Prof. Christian Drosten. The studies at a glance: Serological testing on blood donors in Germany: In cooperation with the blood donation services, blood samples from adults from all over Germany are regularly tested for antibodies. This allows conclusions to be drawn about the spread of SARS-CoV-2 in the population. Starting next week, approximately 5,000 blood samples will be tested every 14 days. First results are expected in early May 2020. Seroepidemiological studies at several particularly affected locations ("hotspots") in Germany: The aim of the localized studies is to estimate the immunity in the local population by determining antibodies against SARS-CoV-2 in representative samples of the inhabitants. The aim is also to better estimate the proportion of asymptomatic infections and risk factors for a severe course in the population. In each location, about 2,000 test persons aged 18 years and older will be examined several times. In addition, the test persons will be questioned about clinical symptoms, previous illnesses, health behaviour, living conditions and mental health. The study is scheduled to start in mid-April 2020, with initial results expected in May 2020. In planning and conducting these so-called "hotspot" studies, the RKI is cooperating with researchers around Prof. Gérard Krause from the Helmholtz Centre for Infection Research in Braunschweig. Nationwide population-representative seroepidemiological study: By determining antibodies against SARS-CoV-2 in a nationwide representative sample, the actual spread, immunity, the proportion of asymptomatic infections, the actual mortality rate and risk factors for a severe course in the German population will be better estimated. The study will involve 15,000 people aged 18 years and older at 150 study sites. The subjects will also be asked about clinical symptoms, previous illnesses, health behaviour, living conditions and mental health. The study is expected to start in mid-May 2020, and the first results are expected in June 2020.

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**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 5/26/2020 7:40:24 AM  
**To:** John Fleming (b) (6) @who.eop.gov]  
**Subject:** Zhu Chinese Ad5 Lancet 2020.pdf  
**Attachments:** Zhu Chinese Ad5 Lancet 2020.pdf

Sorry for all of the messages. Here is the report of a Phase I study of the Chinese Ad5 vaccine.  
Steve



# Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial

Feng-Cai Zhu\*, Yu-Hua Li\*, Xu-Hua Guan, Li-Hua Hou, Wen-Juan Wang, Jing-Xin Li, Shi-Po Wu, Bu-Sen Wang, Zhao Wang, Lei Wang, Si-Yue Jia, Hu-Dachuan Jiang, Ling Wang, Tao Jiang, Yi Hu, Jin-Bo Gou, Sha-Bei Xu, Jun-Jie Xu, Xue-Wen Wang, Wei Wang, Wei Chen

## Summary

**Background** A vaccine to protect against COVID-19 is urgently needed. We aimed to assess the safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 (Ad5) vectored COVID-19 vaccine expressing the spike glycoprotein of a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) strain.

**Methods** We did a dose-escalation, single-centre, open-label, non-randomised, phase 1 trial of an Ad5 vectored COVID-19 vaccine in Wuhan, China. Healthy adults aged between 18 and 60 years were sequentially enrolled and allocated to one of three dose groups ( $5 \times 10^{10}$ ,  $1 \times 10^{11}$ , and  $1.5 \times 10^{11}$  viral particles) to receive an intramuscular injection of vaccine. The primary outcome was adverse events in the 7 days post-vaccination. Safety was assessed over 28 days post-vaccination. Specific antibodies were measured with ELISA, and the neutralising antibody responses induced by vaccination were detected with SARS-CoV-2 virus neutralisation and pseudovirus neutralisation tests. T-cell responses were assessed by enzyme-linked immunospot and flow-cytometry assays. This study is registered with ClinicalTrials.gov, NCT04313127.

**Findings** Between March 16 and March 27, 2020, we screened 195 individuals for eligibility. Of them, 108 participants (51% male, 49% female; mean age 36.3 years) were recruited and received the low dose ( $n=36$ ), middle dose ( $n=36$ ), or high dose ( $n=36$ ) of the vaccine. All enrolled participants were included in the analysis. At least one adverse reaction within the first 7 days after the vaccination was reported in 30 (83%) participants in the low dose group, 30 (83%) participants in the middle dose group, and 27 (75%) participants in the high dose group. The most common injection site adverse reaction was pain, which was reported in 58 (54%) vaccine recipients, and the most commonly reported systematic adverse reactions were fever (50 [46%]), fatigue (47 [44%]), headache (42 [39%]), and muscle pain (18 [17%]). Most adverse reactions that were reported in all dose groups were mild or moderate in severity. No serious adverse event was noted within 28 days post-vaccination. ELISA antibodies and neutralising antibodies increased significantly at day 14, and peaked 28 days post-vaccination. Specific T-cell response peaked at day 14 post-vaccination.

**Interpretation** The Ad5 vectored COVID-19 vaccine is tolerable and immunogenic at 28 days post-vaccination. Humoral responses against SARS-CoV-2 peaked at day 28 post-vaccination in healthy adults, and rapid specific T-cell responses were noted from day 14 post-vaccination. Our findings suggest that the Ad5 vectored COVID-19 vaccine warrants further investigation.

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## Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first reported in January, 2020. The virus is highly transmissible between humans and has spread rapidly, causing the COVID-19 pandemic.<sup>1,2</sup> Patients infected with SARS-CoV-2, especially older patients and those with pre-existing respiratory or cardiovascular conditions are at greater risk for severe complications, including severe pneumonia, acute respiratory distress syndrome, multiple organ failure, and in some cases, death.<sup>3,4</sup> By May 20, 2020, SARS-CoV-2

had infected more than 4.7 million people across 215 countries or territories and killed more than 316 000 worldwide.<sup>5</sup>

In the absence of effective prevention measures, current management to control the epidemic is the enforcement of quarantine, isolation, and physical distancing.<sup>6,7</sup> Effective vaccines against COVID-19 are urgently needed to reduce the enormous burden of mortality and morbidity associated with SARS-CoV-2 infection.<sup>8</sup> There are more than 100 candidate vaccines in development worldwide,<sup>9</sup> among them at least eight have started or will soon

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### Research in context

#### Evidence before this study

We searched PubMed on May 8, 2020, for clinical trial reports with the terms "COVID-19" or "SARS-CoV-2", "vaccine", and "clinical trial" and no date or language restrictions; no other data from a human clinical trial of COVID-19 vaccine have been reported thus far, to our knowledge. We also searched the ClinicalTrials.gov registry for unpublished trials of COVID-19 vaccines, up to May 6, 2020. In addition to the adenovirus type-5 (Ad5) vectored COVID-19 vaccine reported here, seven candidate COVID-19 vaccines are in ongoing clinical trials, including Moderna's mRNA COVID-19 vaccine, Inovio Pharmaceuticals' DNA vaccine, Sinovac, Wuhan and Beijing Institute of Biological Products' inactivated COVID-19 vaccines, University of Oxford's chimpanzee adenovirus-vectored vaccine, and BioNTech's mRNA COVID-19 vaccine.

#### Added value of this study

This first-in-human trial showed that the Ad5 vectored COVID-19 vaccine was tolerable and immunogenic in healthy adults. One dose of the vaccine at all dose concentrations ( $5 \times 10^{10}$ ,  $1 \times 10^{11}$ , and  $1.5 \times 10^{11}$  viral particles) tested induced

both specific antibody and T-cell responses in most participants. Rapid specific T-cell responses were noted at day 14 and specific humoral responses against severe acute respiratory syndrome coronavirus 2 peaked at day 28 post-vaccination. Although we found that the high dose vaccine tended to be more immunogenic than the middle dose and low dose vaccines, it was also associated with a higher reactogenicity. Severe fever, fatigue, dyspnoea, muscle pain, and joint pain were reported in some of the recipients in the high dose group.

#### Implications of all the available evidence

Many vaccine candidates are in rapid development, including recombinant-protein based vaccines, replicating or non-replicating viral vector-based vaccines, DNA vaccines, and mRNA vaccines (which mostly have focused on the spike glycoprotein or receptor binding domain), live attenuated vaccines, and inactivated virus vaccines. All of these vaccine platforms have advantages and disadvantages, and it is too soon to predict which will be more successful. Our study suggests that there is potential for further investigation of the Ad5 vectored COVID-19 vaccine for prevention of COVID-19.

start clinical trials. These include Moderna's mRNA COVID-19 vaccine and CanSino's non-replicating adenovirus type-5 (Ad5) vectored COVID-19 vaccine, which both entered phase 1 clinical trials on March 16, 2020; Inovio Pharmaceuticals' DNA vaccine for COVID-19, which entered trials on April 3, 2020; three inactivated COVID-19 vaccines manufactured by Sinovac, Wuhan Institute of Biological Products, and Beijing Institute of Biological Products entered clinical trials in April, 2020, successively; University of Oxford's non-replicating chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19, and BioNTech's mRNA COVID-19 vaccine also started trials in recent months.

Here, we report the preliminary assessment at 28 days post-vaccination of the safety, tolerability, and immunogenicity of CanSino's non-replicating Ad5 vectored COVID-19 vaccine in healthy adults in China.

## Method

### Study design and participants

We did a single-centre, open-label, non-randomised, dose-escalation phase 1 trial of an Ad5 vectored COVID-19 vaccine candidate in a rehabilitation centre in Wuhan, Hubei province, China. Eligible participants were healthy adults aged between 18 and 60 years, who did not have SARS-CoV-2 infection, confirmed by negative results of serum specific IgM and IgG antibodies with a commercial SARS-CoV-2 rapid test kit (Jinwofu, Beijing, China), negative nucleic acid for SARS-CoV-2 in pharyngeal swabs or sputum and anal swabs detected with a nucleic acid diagnostic kit (PCR-fluorescence probing, Sansure Biotech, Changsha, China), and a clear chest CT image with no evidence of lesions in the lungs at the time of

screening. Exclusion criteria were a history of seizures or mental illness; allergy to any ingredient included in the vaccine; acute febrile disease on the day of enrolment; receipt of any blood products in the past 4 months; receipt of any research medicines or vaccine in the past month; and being unable to comply with the study schedule. Further details are outlined in the protocol.<sup>10</sup> Participants were sequentially enrolled to receive a single intramuscular injection in a dose-escalating manner: the first group of participants were allocated to receive the low dose, followed up for a minimum of 3 days before proceeding to recruit further participants to receive the middle dose, and then after safety observation for 3 days, the last group of participants were recruited and allocated to receive the high dose. The administration of higher dose injections and new enrolment were paused if any criteria for pausing dose escalation were met.

The protocol and informed consent were approved by the institutional review board of the Jiangsu Provincial Center of Disease Control and Prevention. Written informed consent from all participants was obtained before screening. This study was undertaken by Jiangsu Provincial Center for Disease Control and Prevention, Hubei Provincial Center for Disease Control and Prevention, and Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology in accordance with the Declaration of Helsinki and Good Clinical Practice.

### Procedures

The Ad5 vectored COVID-19 vaccine was developed by Beijing Institute of Biotechnology (Beijing, China) and CanSino Biologics (Tianjin, China). The vaccine is a

replication defective Ad5 vectored vaccine expressing the spike glycoprotein of SARS-CoV-2. We cloned an optimised full-length spike gene based on Wuhan-Hu-1 (GenBank accession number YP\_009724390) with the tissue plasminogen activator signal peptide gene into an E1 and E3 deleted Ad5 vector, and constructed the Ad5 vectored COVID-19 vaccine using the Admax system from Microbix Biosystem (Toronto, ON, Canada). The Ad5 vectored COVID-19 vaccine was manufactured as a liquid formulation containing  $5 \times 10^{10}$  viral particles per 0.5 mL in a vial.

A single shot was allocated intramuscularly in the arm of the participants in the low dose group, with one vial of the Ad5 vectored COVID-19 vaccine ( $5 \times 10^{10}$  viral particles per 0.5 mL). The participants in the middle dose group received one shot intramuscularly in the arm with two vials of the Ad5 vectored COVID-19 vaccine ( $1 \times 10^{11}$  viral particles per mL). Participants in the high dose group received a double-shot regimen with one vial of the Ad5 vectored COVID-19 vaccine in one arm and two vials of the Ad5 vectored COVID-19 vaccine in the other arm ( $1.5 \times 10^{11}$  viral particles per 1.5 mL).

Adverse events were self-reported by the participants, but verified by investigators daily during the first 14 days after vaccination. Subsequently, adverse events were recorded by the participants on diary cards in the following weeks. Laboratory safety tests including white blood cell count, lymphocyte count, neutrophils, platelets, haemoglobin, alanine aminotransferase, aspartate aminotransferase, total bilirubin, fasting blood glucose, and creatinine were measured on day 7 to assess any toxic effects post-vaccination. We graded adverse events and abnormal changes in laboratory tests according to the scale issued by the China State Food and Drug Administration (version 2019).<sup>11</sup>

Blood samples were taken from participants for serology tests at the scheduled site visits before the vaccination, and on days 14 and 28 after the vaccination. We assessed binding antibody responses against the receptor binding domain (RBD) and spike glycoprotein with ELISA kits manufactured by Beijing Wantai BioPharm (Beijing, China). A dilution of 1:40 was the positivity cutoff value for ELISA. We also measured the neutralising antibody responses induced by vaccination using both live SARS-CoV-2 virus neutralisation (virus strain SARS-CoV-2/human/CHN/Wuhan\_IME-BJ01/2020, GenBank number MT291831.1) and pseudovirus neutralisation tests (a vesicular stomatitis virus pseudovirus system expressing the spike glycoprotein).<sup>12</sup> Peripheral blood mononuclear cells were isolated from whole blood before the vaccination and at days 14 and 28 post-vaccination. Specific T-cell responses were quantified with an interferon (IFN)  $\gamma$  enzyme-linked immunospot (ELISpot) assay using fresh peripheral blood mononuclear cells stimulated with overlapping spike glycoprotein peptide pools for about 12–24 h before detection, and expressed as the number of spot-forming cells per 100 000 cells. All measurements

were subtracted from the unstimulated control values, and minus values were corrected to zero. The results were considered positive if there was at least a two-times increase in the number of IFN $\gamma$  secreting T cells post-vaccination. We also assessed the CD4<sup>+</sup> and CD8<sup>+</sup> T-cell responses to vaccination according to the secretion of IFN $\gamma$ , interleukin-2 (IL-2), and tumour necrosis factor  $\alpha$  (TNF $\alpha$ ), which were measured by intracellular cytokine staining assays in peripheral blood mononuclear cells after the stimulation with overlapping spike glycoprotein peptide pools for about 6 h and detected by flow cytometry. Similar methods to measure T-cell responses by intracellular cytokine staining assays have been reported previously.<sup>13,14</sup> The pre-vaccination and post-vaccination anti-Ad5 neutralising antibody titres were detected with a serum neutralisation assay.<sup>15</sup>

### Outcomes

We analysed all outcomes in the intention-to-treat cohort. The primary endpoint for safety was the occurrence of adverse reactions within 7 days after the vaccination. Any abnormal changes in laboratory measures at 7 days post-vaccination, and adverse events within 28 days across the treatment groups were also analysed as secondary safety endpoints. The specific ELISA antibody titres to RBD and the spike glycoprotein, and the neutralising antibody amounts against live SARS-CoV-2 and a pseudovirus were measured as humoral immunogenicity endpoints. We defined a positive antibody response (seroconversion) as at least a four-fold increase in post-vaccination titre from baseline. ELISpot IFN $\gamma$  and positive T-cell responses measured by intracellular cytokine staining assays were compared across the groups as endpoints for cell-mediated responses. Stratified analyses of the immune responses were done based on the pre-existing Ad5 neutralising antibody titres among the participants as low or negative ( $\leq 1:200$ ) or high ( $> 1:200$ ).

### Statistical analysis

The sample size was not determined on the basis of statistical power calculations; however, a minimum sample size of 20–30 participants for a pilot vaccine trial has been recommended by the National Medical Products Administration, China. We assessed the number and proportion of participants with adverse reactions post-vaccination and compared safety profiles across the dose groups. The antibodies against SARS-CoV-2 were presented as geometric mean titres with 95% CIs and the cellular responses were shown as a proportion of positive responders. We used the  $\chi^2$  test or Fisher's exact test to analyse categorical data, ANOVA to analyse the log transformed antibody titres, and Wilcoxon rank-sum test for data that were not normally distributed. When the overall difference across the three groups was significant, pairwise comparisons were made and the differences between groups were estimated with 95% CIs. Multi-variable analysis was used to establish the possible effects

on the immunogenicity and safety profile of the vaccine candidates. Hypothesis testing was two-sided with an  $\alpha$  value of 0.05. Statistical analyses were done by a statistician using SAS (version 9.4) or GraphPad Prism 8.0.1. SPICE (version 6.0) was used for the analysis of data from multicolour flow cytometry experiments.

An independent data and safety monitoring committee, with one independent statistician, one clinician, and one epidemiologist, was established before the start of the trial. Safety data for the first 3 days post-vaccination were assessed and reviewed by the committee to ensure that there was sufficient holding time between dose escalation. This study is registered with ClinicalTrials.gov, NCT04313127.

### Role of the funding source

The sponsors of the study participated in study design, but had no role in data collection, data analysis, data interpretation, or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

Between March 16 and March 27, 2020, we screened 195 individuals for eligibility. Of them, 108 were sequentially enrolled and assigned to receive the low dose (n=36 [33%]), middle dose (n=36 [33%]), or high dose (n=36 [33%]) of the Ad5 vectored COVID-19 vaccine (appendix p 2). All participants completed the vaccination and the scheduled visits within 28 days. Baseline

characteristics of the participants were similar across the treatment groups (table 1).

87 (81%) of 108 participants reported at least one adverse reaction within the first 7 days after the vaccination: 30 (83%) in the low dose group, 30 (83%) in the middle dose group, and 27 (75%) in the high dose group (table 2). No significant difference in the overall number of adverse reactions across the treatment groups was observed. The most common injection site adverse reaction was pain, which was reported in 58 (54%) vaccine recipients. Pain was reported in 17 (47%) participants in the low dose group, 20 (56%) participants in the middle dose group, and 21 (58%) participants in the high dose group. The most commonly reported systematic adverse reactions overall were fever (50 [46%]), fatigue (47 [44%]), headache (42 [39%]), and muscle pain (18 [17%]). Fever was reported in 15 (42%) participants in the low dose group, 15 (42%) participants in the middle dose group, and 20 (56%) participants in the high dose group. Headache was reported in 14 (39%) participants in the low dose group, 11 (31%) participants in the middle dose group, and 17 (47%) participants in the high dose group. Muscle pain was reported in seven (19%) participants in the low dose group, three (8%) participants in the middle dose group, and eight (22%) participants in the high dose group. Most adverse reactions were mild or moderate in severity. Nine participants (two [6%] in the low dose group, two [6%] in the middle dose group, and five [14%] in the high dose group) had an episode of severe fever (grade 3) with axillary temperature greater than 38.5°C. Of them, one (3%) from the high dose group reported severe fever along with severe symptoms of fatigue, dyspnoea, and muscle pain. One participant in the high dose group reported severe fatigue and joint pain (appendix p 3). These reactions occurred within 24 h post-vaccination, and persisted for no more than 48 h. We found no significant difference in the incidences of adverse reactions or overall adverse events among the dose groups. High pre-existing Ad5 immunity (titre of >1:200 vs ≤1:200) was associated with significantly fewer occurrences of fever post-vaccination (odds ratio 0.3, 95% CI 0.1–0.6; appendix p 4). No serious adverse event was reported within 28 days. At day 7 after vaccination, nine (8%) participants had mild to moderate total bilirubin increase, ten (9%) had alanine aminotransferase increase, and four (4%) had fasting hyperglycaemia (appendix p 5), but no instances were considered as clinically significant.

Rapid binding antibody responses to RBD were observed in all three dose groups from day 14 (table 3). At day 28, the recipients in the high dose group tended to have a higher binding antibody geometric mean titre of 1445.8 (95% CI 935.5–2234.5), followed by 806.0 (528.2–1229.9) in the middle dose group, and 615.8 (405.4–935.5) in the low dose group (high dose vs low dose 1611.5, 531.5–2691.5). At least a four-fold increase of anti-RBD antibodies was noted in 35 (97%) of 36 participants in the low dose group, 34 (94%) of 36 in the middle dose group, and 36 (100%) of

See Online for appendix

	Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)
Age, years			
18–29	9 (25%)	12 (33%)	10 (28%)
30–39	13 (36%)	14 (39%)	15 (42%)
40–49	8 (22%)	3 (8%)	7 (19%)
50–60	6 (17%)	7 (19%)	4 (11%)
Mean age, years	37.2 (10.7)	36.3 (11.5)	35.5 (10.1)
Sex			
Male	18 (50%)	19 (53%)	18 (50%)
Female	18 (50%)	17 (47%)	18 (50%)
Mean body-mass index, kg/m <sup>2</sup>	23.3 (2.7)	23.9 (2.7)	24.1 (3.1)
Underlying diseases*			
Yes	1 (3%)	2 (6%)	4 (11%)
No	35 (97%)	34 (94%)	32 (89%)
Pre-existing adenovirus type-5 neutralising antibody			
Mean GMT	168.9 (13.9)	149.5 (10.5)	115.0 (13.4)
≤200, titre	16 (44%)	17 (47%)	20 (56%)
>200, titre	20 (56%)	19 (53%)	16 (44%)

Data are n (%) or mean (SD). GMT=geometric mean titre. \*Seven participants had hypertension, chronic bronchitis, gout, or were a carrier of hepatitis B virus.

**Table 1: Baseline characteristics**

36 in the high dose group. Neutralising antibodies against live SARS-CoV-2 were all negative at day 0, and increased moderately at day 14, peaking at 28 days post-vaccination. Neutralising antibody titre with a geometric mean titre of 34.0 (95% CI 22.6–50.1) was noted in the high dose group, which was significantly higher compared with 16.2 (10.4–25.2) in the middle dose group and 14.5 (9.6–21.8) in the low dose group, with an estimated difference of 27.7 (1.0–54.4) between the high dose group and the middle dose group and 33.2 (6.5–59.9) between the high dose group and the low dose group at day 28. Meanwhile, 18 (50%) participants in the low dose group, 18 (50%) in the middle dose group, and 27 (75%) in the high dose group had at least a four-fold increase in neutralising antibody titres by day 28. Similar patterns of the binding antibody to spike glycoprotein and neutralising antibody titre to pseudovirus post-vaccination across the dose groups were also noted (appendix p 6). The association between the ELISA antibodies to RBD and neutralising antibody titres against live virus showed a moderate positive correlation of 0.749, and that between the ELISA antibodies to spike glycoprotein and neutralising antibody titres against live virus was 0.753, at the peak antibody response ( $p < 0.0001$ ). The neutralising antibody titres measured using a pseudovirus were also correlated well with those measured by live SARS-CoV-2 (appendix p 7).

Before vaccination, 20 (56%) participants in the low dose group, 19 (53%) participants in the middle dose group, and 16 (44%) participants in the high dose group had a high pre-existing Ad5 neutralising antibody titre ( $>1:200$ ). Only five (25%) participants of 20 in the low dose group, seven (37%) participants of 19 in the middle dose group, and ten (63%) participants of 16 in the high dose group, who had high pre-existing Ad5 immunity, had at least a four-fold increase in neutralising antibody titre at day 28 post-vaccination (appendix pp 8–10). Multivariable analysis showed that high pre-existing Ad5 neutralising antibody titres compromised the seroconversion of neutralising antibody post-vaccination, regardless of the vaccine doses, and recipients aged 45–60 years seemed to have lower seroconversion of neutralising antibody compared with the younger recipients (appendix p 11). The Ad5 neutralising antibodies were significantly boosted post-vaccination (appendix p 12).

ELISpot responses at baseline were undetectable with spot-forming cells below the level of detection of the assay in all participants, but peaked at day 14 post-vaccination. The proportions of positive responders ranged from 83–97% across the dose groups, with a mean number of spot-forming cells per 100 000 cells of 20.8 (95% CI 12.7–34.0) in the low dose group, 40.8 (27.6–60.3) in the middle dose group, and 58.0 (39.1–85.9) in the high dose group (figure 1). T-cell responses in the high dose group were significantly higher than that in the low dose group ( $p < 0.0010$ ), but not significant compared with that

	Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)	Total (N=108)
<b>All adverse reactions within 0–7 days</b>				
Any	30 (83%)	30 (83%)	27 (75%)	87 (81%)
Grade 3	2 (6%)	2 (6%)	6 (17%)	10 (9%)
<b>Injection site adverse reactions within 0–7 days</b>				
Pain	17 (47%)	20 (56%)	21 (58%)	58 (54%)
Induration	2 (6%)	1 (3%)	1 (3%)	4 (4%)
Redness	2 (6%)	1 (3%)	1 (3%)	4 (4%)
Swelling	4 (11%)	4 (11%)	0	8 (7%)
Itch	2 (6%)	3 (8%)	0	5 (5%)
Muscular weakness	0	0	1 (3%)	1 (1%)
<b>Systemic adverse reactions within 0–7 days</b>				
Fever	15 (42%)	15 (42%)	20 (56%)	50 (46%)
Grade 3 fever	2 (6%)	2 (6%)	5 (14%)	9 (8%)
Headache	14 (39%)	11 (31%)	17 (47%)	42 (39%)
Fatigue	17 (47%)	14 (39%)	16 (44%)	47 (44%)
Grade 3 fatigue	0	0	2 (6%)	2 (2%)
Vomiting	1 (3%)	0	1 (3%)	2 (2%)
Diarrhoea	3 (8%)	4 (11%)	5 (14%)	12 (11%)
Muscle pain	7 (19%)	3 (8%)	8 (22%)	18 (17%)
Grade 3 muscle pain	0	0	1 (3%)	1 (1%)
Joint pain	2 (6%)	2 (6%)	5 (14%)	9 (8%)
Grade 3 joint pain	0	0	1 (3%)	1 (1%)
Throat pain	1 (3%)	3 (8%)	4 (11%)	8 (7%)
Cough	1 (3%)	2 (6%)	3 (8%)	6 (6%)
Nausea	2 (6%)	1 (3%)	3 (8%)	6 (6%)
Functional GI disorder	1 (3%)	0	0	1 (1%)
Dyspnoea	0	0	2 (6%)	2 (2%)
Grade 3 dyspnoea	0	0	1 (3%)	1 (1%)
Appetite impaired	6 (17%)	5 (14%)	6 (17%)	17 (16%)
Dizziness	1 (3%)	0	1 (3%)	2 (2%)
Mucosal abnormality	0	0	1 (3%)	1 (1%)
Pruritus	1 (3%)	1 (3%)	1 (3%)	3 (3%)
<b>Overall adverse events within 0–28 days</b>				
Any	31 (86%)	30 (83%)	27 (75%)	88 (81%)
Grade 3	2 (6%)	2 (6%)	6 (17%)	10 (9%)

Data are n (%). Any refers to all the participants with any grade adverse reactions or events. Adverse reactions and events were graded according to the scale issued by the China State Food and Drug Administration. Grade 3=severe (ie, prevented activity). GI=gastrointestinal.

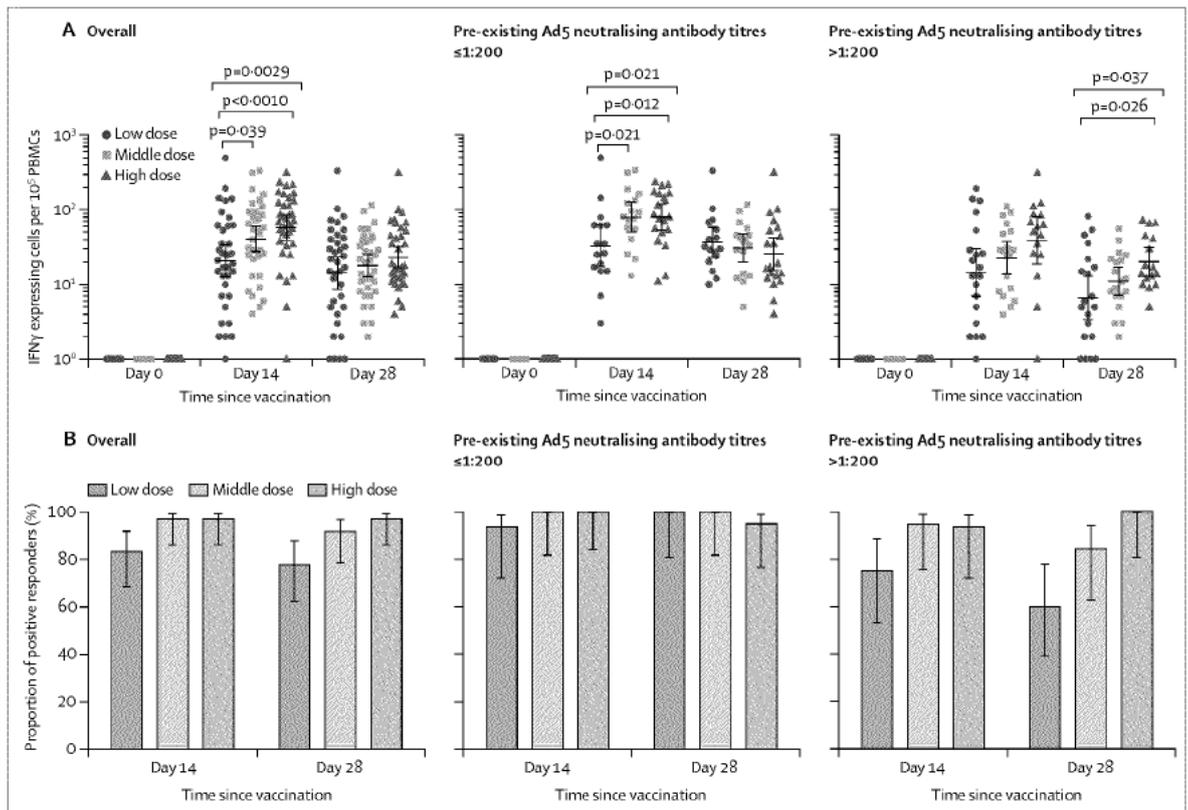
**Table 2: Adverse reactions within 7 days and overall adverse events within 28 days after vaccination**

in the middle dose group. A slight decrease of the T-cell responses across the dose groups was noted at day 28. High levels of baseline Ad5 neutralising antibody titre reduced the peak of post-vaccination T-cell responses in all the dose groups, particularly for the low dose group. Despite the effect of high pre-existing Ad5 immunity, positive responders were identified in 15 (75%) of 20 participants in the low dose group, 18 (95%) of 19 participants in the middle dose group, and 15 (94%) of 16 participants in the high dose group at day 14, and 12 (60%) of 20 participants in the low dose group, 16 (84%) of 19 participants in the middle dose group, and 16 (100%) of 16 participants in the high dose group at day 28.

	Day 14			p value	Day 28			p value
	Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)		Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)	
<b>ELISA antibodies to the receptor binding domain</b>								
GMT	76.5 (44.3-132.0)	91.2 (55.9-148.7)	132.6 (80.7-218.0)	0.29	615.8 (405.4-935.5)	806.0 (528.2-1229.9)	1445.8 (935.5-2234.5)	0.016
≥4-fold increase	16 (44%)	18 (50%)	22 (61%)	0.35	35 (97%)	34 (94%)	36 (100%)	0.77
<b>Neutralising antibodies to live SARS-CoV-2</b>								
GMT	8.2 (5.8-11.5)	9.6 (6.6-14.1)	12.7 (8.5-19.0)	0.24	14.5 (9.6-21.8)	16.2 (10.4-25.2)	34.0 (22.6-50.1)	0.0082
≥4-fold increase	10 (28%)	11 (31%)	15 (42%)	0.42	18 (50%)	18 (50%)	27 (75%)	0.046

Data are mean (95% CI) or n (%). The p values are the result of comparison across the three dose groups. If the difference was significant across the three groups, the differences between groups were estimated with 95% CIs. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. GMT=geometric mean titre.

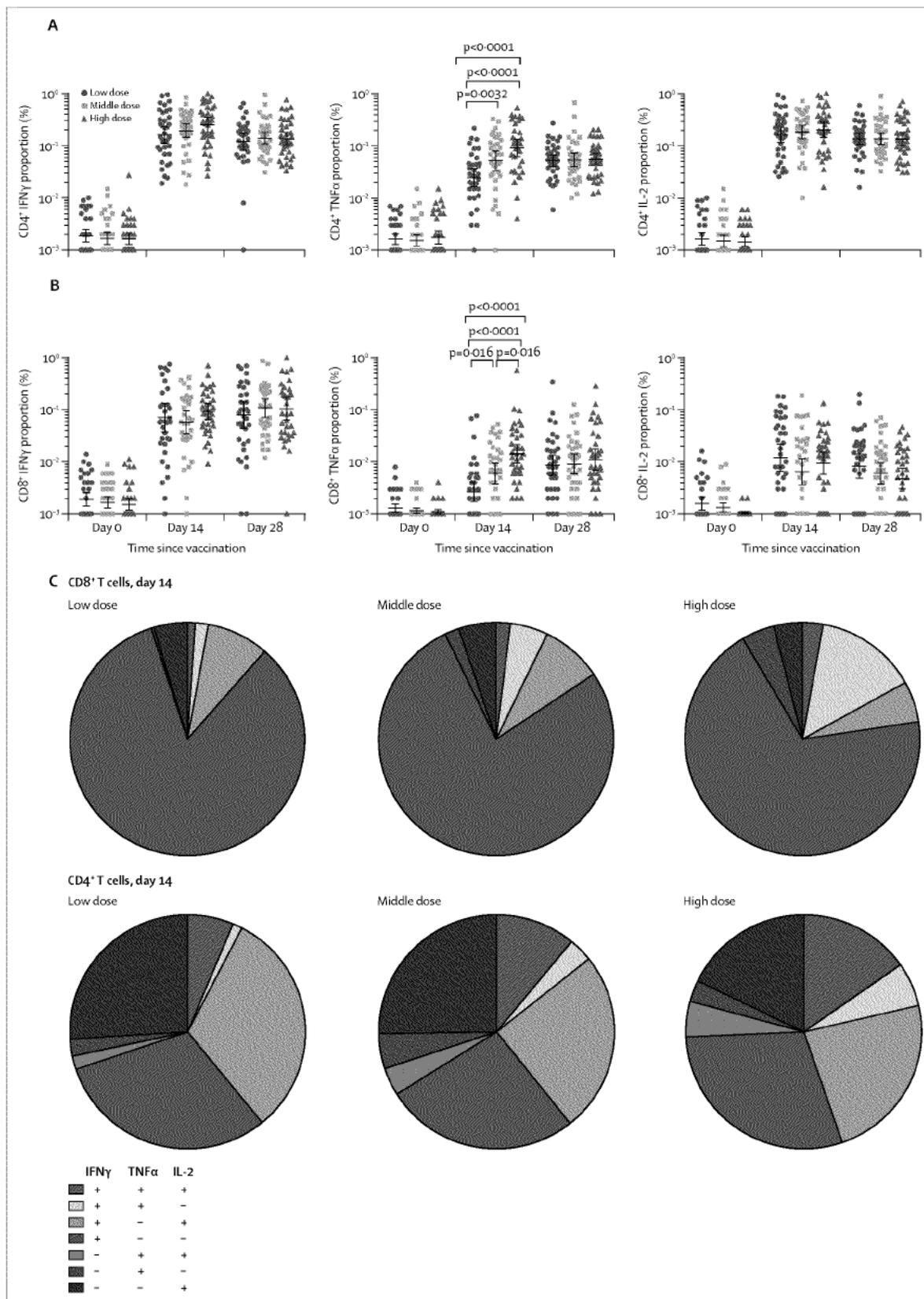
**Table 3: Specific antibody responses to the receptor binding domain, and neutralising antibodies to live SARS-CoV-2**



**Figure 1: Specific T-cell response measured by ELISpot**  
 (A) The number of specific T cells with secretion of IFN $\gamma$  at days 0, 14, and 28 in all participants, and stratified by pre-existing Ad5 neutralising antibody titres.  
 (B) The proportion of positive ELISpot responders at days 14 and 28 post-vaccination in all participants, and stratified by pre-existing Ad5 neutralising antibody titres. IFN=interferon. PBMCs=peripheral blood mononuclear cells. Ad5=adenovirus type-5. ELISpot=enzyme-linked immunospot.

IFN $\gamma$  was detected from CD4 $^+$  and CD8 $^+$  T cells after the vaccination at day 14 and 28, in all dose groups (figure 2, appendix p 13). The TNF $\alpha$  expression from CD4 $^+$  T cells tended to be significantly lower in the low dose group than that in the high dose ( $p < 0.0001$ ) and middle dose groups ( $p = 0.0032$ ), on day 14. The TNF $\alpha$  expression from CD8 $^+$  T cells showed an overall p value of less than 0.0001 across the three groups on day 14. And the TNF $\alpha$  expression

from CD8 $^+$  T cells tended to be higher in the high dose group than that in both the middle dose group ( $p = 0.016$ ) and the low dose group ( $p < 0.0001$ ). The p values are for the pairwise comparisons between groups. Amounts of IL-2 detected from CD4 $^+$  T cells were higher than that detected from CD8 $^+$  cells. The proportions of polyfunctional phenotypes detected from memory CD4 $^+$  T cells were higher than those from CD8 $^+$  T cells. Higher



**Figure 2: Flow cytometry with intracellular cytokine staining before and after vaccination**  
 (A) Percentage of cells secreting IFN $\gamma$ , TNF $\alpha$ , and IL-2 from CD4<sup>+</sup> T cells. (B) Percentage of cells secreting IFN $\gamma$ , TNF $\alpha$ , and IL-2 from CD8<sup>+</sup> T cells. (C) The proportion of CD4<sup>+</sup> T cells and CD8<sup>+</sup> T cells producing any combination of IFN $\gamma$ , TNF $\alpha$ , and IL-2. The analyses are for 108 participants, with 36 in each dose group. IFN=interferon. TNF=tumour necrosis factor. IL=interleukin.

proportions of polyfunctional phenotypes were noted with the higher vaccine doses. We also noted that pre-existing Ad5 neutralising antibody had a negative effect on the pattern of T-cell responses (appendix pp 14–16). A post-hoc analysis showed that 28 (78%) participants in the low dose group, 33 (92%) participants in the middle dose group, and 36 (100%) participants in the high dose group showed either positive T-cell responses to spike glycoprotein or seroconversion of neutralising antibody to live SARS-CoV-2, at day 28 post-vaccination (appendix p 17).

To exclude any possible SARS-CoV-2 exposure during the study period, we tested the serum antibodies to nucleocapsid protein of SARS-CoV-2 in participants at day 28 using a special IgG/IgM rapid test kit (Vazyme Biotech, number CD101, Nanjing, China), but none of the participants were positive.

## Discussion

To our knowledge, this is the first report on a first-in-human clinical trial of a novel Ad5 vectored COVID-19 vaccine. The Ad5 vectored COVID-19 vaccine was tolerated in healthy adults in all three dose groups. The most common adverse reactions were fever, fatigue, headache, and muscle pain with no significant difference in the incidence of adverse reactions across the groups. Most adverse events reported were mild or moderate in severity. We noticed a higher reactogenicity profile of the high dose at  $1.5 \times 10^{11}$  viral particles, presenting as severe fever, fatigue, muscle pain, or joint pain, which might be associated with viraemia caused by Ad5 vector infection. However, the severe adverse reactions were transient and self-limiting. Additionally, no abnormal changes in laboratory measurements were clinically significant or considered to be related to the vaccine. The profile of adverse events reported in this trial is similar to that of another Ad5 vector-based Ebola vaccine expressing glycoprotein.<sup>16</sup> To accelerate the process of clinical evaluation of the candidate COVID-19 vaccine, we selected doses for the phase 2 study mainly on the basis of the safety profile of the candidate vaccines shown in the participants within 7 days and 14 days post-vaccination. We chose the low dose ( $5 \times 10^{10}$  viral particles) and middle dose ( $1 \times 10^{11}$  viral particles) to be further assessed in a phase 2 clinical trial.

The Ad5 vectored COVID-19 vaccine was immunogenic, inducing humoral and T-cell responses rapidly in most participants. Onset of detectable immune responses was rapid, with T-cell responses peaking at day 14 after vaccination and antibodies peaking at day 28. The antibody response to the vaccine in the high dose group was slightly greater than that in the middle dose and low dose groups. A single dose of Ad5 vectored COVID-19 vaccine was able to elicit a four-fold increase in binding antibodies to RBD in 94–100% of participants, and a four-fold increase to live virus in 50–75% of participants. Despite differences in magnitudes of the antibodies measured through different methods, there was a strong

positive correlation between binding antibodies and neutralising antibody titres to the live virus. High proportions of participants with positive T-cell responses were noted across the all dose groups post-vaccination. The activation of both CD4<sup>+</sup> T cells and CD8<sup>+</sup> T cells was observed in vaccine recipients, particularly for antigen-specific CD4<sup>+</sup> T cells and CD8<sup>+</sup> T cells. However, both the specific antibody response and T-cell response induced by vaccination were partly diminished by the presence of high pre-existing anti-Ad5 immunity.

Currently, correlates of protection for a vaccine against COVID-19 are unknown, and the roles of the specific antibodies or T cells in building effective protection are not yet defined. Therefore, we are unable to predict the protection of the Ad5 vectored COVID-19 vaccine on the basis of the vaccine-elicited immune responses in this study. However, previous studies investigating SARS and Middle East respiratory syndrome (MERS) found that the increases in specific antibodies were temporary, and declined quickly in patients after recovery, whereas the specific CD4<sup>+</sup> and CD8<sup>+</sup> T-cell responses played an essential role in immunity.<sup>17,18</sup> A similar rapid decline of the specific antibody amounts in patients with COVID-19 after recovery was also noted,<sup>16,20</sup> suggesting that both specific cellular and humoral immunity are potentially important for a successful COVID-19 vaccine. Here, we only report the data within 28 days after the vaccination, but we are going to follow up the vaccine recipients for at least 6 months, so more data will be obtained.

This study was done in Wuhan, Hubei province, which was the centre of the COVID-19 epidemic in China.<sup>21</sup> People living in the city of Wuhan had a much higher risk of SARS-CoV-2 infection compared with those living in other cities outside of Hubei province, even though when we initiated this trial, the city had already begun lockdown and implemented mandatory home isolation for residents. Therefore, we did serological screening, nucleic acid testing, and chest CT to exclude participants who had been previously exposed to SARS-CoV-2 during recruitment. In addition, we arranged for all participants in our study to stay in a designated hotel for 14 days post-vaccination. This arrangement facilitated the observation of adverse events after the immunisation of the participants, and reduced the risk of SARS-CoV-2 exposure during the following 2 weeks. These measures allowed the study to be done successfully without interference by the circulation of SARS-CoV-2, which is especially important in the absence of a placebo control.

Interpretation of the results of this study is limited by the small size of the cohort, the short duration of follow-up, and the absence of a randomised control group. As it was a first-in-human study of the Ad5 vectored COVID-19 vaccine, it was not designed to measure the vaccine efficacy. However, in preclinical studies, seven out of eight ferrets were protected from having detectable virus copies when challenged by SARS-CoV-2 through nasal dripping 21 days after immunisation with the vaccine,

whereas only one out of eight ferrets in the control group was negative for virus copies (Wei C, unpublished). We aimed to evaluate the safety and tolerability of the candidate vaccine in healthy adults, with no interference by underlying diseases or medicines. However, results of our study indicated that older age could have a negative effect on the vaccine-elicited responses to SARS-CoV-2. In this trial, no participants were older than 60 years and only 16% of the participants were older than 50 years, providing limited information on the capability of generating a potent cellular and humoral response in the older population. Since age has also been identified as an independent risk factor for severe disease associated with SARS-CoV-2 infection,<sup>4,22</sup> and there is a possibility that an even lower immune response might be found in the older population, we are going to include participants who are older than 60 years in the phase 2 study considering this population as an important target population for a COVID-19 vaccine. Additionally, experience with vaccine candidates for SARS and MERS have raised concerns about the antibody-dependent enhancement in participants who are infected with a circulating SARS-CoV-2 post-vaccination.<sup>23</sup> However, this study was not statistically powered to measure any safety outcome, especially for the concerns around immunopathology and antibody-dependent enhancement events associated with the full-length spike glycoprotein vaccine antigen.<sup>24</sup> Our study found that the pre-existing Ad5 immunity could slow down the rapid immune responses to SARS-CoV-2 and also lower the peak of the responses, particularly for humoral immunity. The high pre-existing Ad5 immunity might also have a negative effect on the persistence of the vaccine-elicited immune responses. In previous studies, heterologous prime-boost combinations or homologous prime-boost regimens with Ad5 vectored vaccines were shown to be able to induce more strong and durable immunogenic responses in populations with high pre-existing Ad5 immunity.<sup>25–27</sup> Nevertheless, limited information is available for the effects of multiple doses of the candidate Ad5 vectored COVID-19 vaccine in humans, which warrants further investigation.

Over the past decade, the vaccine industry and clinical research centres have been asked to provide urgent responses to epidemics of emerging infectious diseases, such as H1N1 influenza, Ebola virus, Zika, MERS, and now SARS-CoV-2.<sup>23</sup> The risk of COVID-19 caused by SARS-CoV-2 is ongoing, making the need for effective vaccines even more urgent.<sup>28</sup> We started the development of this candidate vaccine in January, 2020, when SARS-CoV-2 was first isolated and sequenced. The full-length spike glycoprotein was selected as the vaccine antigen, mainly on the basis of previous experience with SARS and MERS vaccines. Previous findings suggested that those vaccines expressing full-length spike glycoprotein can induce good immune responses and protective efficacy.<sup>29</sup> Although the RBD comprises

the critical neutralising domains for the coronaviruses, the neutralising epitopes located outside the RBD were also identified.<sup>30,31</sup> The full-length spike was chosen in most of the viral vectored, mRNA, or DNA COVID-19 vaccines in development.<sup>9</sup> The Ad5 vector vaccine platform is highly efficient and well established as a vaccine antigen delivery system. In addition to our candidate Ad5 vectored COVID-19 vaccine, there are several other Ad5-based vaccines against COVID-19 listed in the WHO draft landscape of COVID-19 candidate vaccines, including Ad5 S (GREVAX™ platform) in the USA, and Oral Ad5 S (Stabilitech Biopharma) in the UK.<sup>9</sup> However, aside from pre-existing anti-Ad5 immunity, there is a concern about the increased risk of HIV-1 acquisition associated with Ad5 activated CD4<sup>+</sup> T cells.<sup>32</sup> Although the association between HIV-1 acquisition risk and Ad5 vectored vaccine is controversial and its mechanism is unclear, the potential risks should be taken into account in studies with this viral vector delivery platform. We plan to monitor the participants in our upcoming phase 2 and phase 3 studies to assess the indication for any such acquisition.

In conclusion, we found that the Ad5 vectored COVID-19 vaccine is tolerable and immunogenic in healthy adults. Specific humoral responses against SARS-CoV-2 peaked at day 28 post-vaccination, and rapid, specific T-cell responses were noted from day 14 after one shot of the vaccine. There is potential for further investigation of the Ad5 vectored COVID-19 vaccine for the control of the COVID-19 outbreak. An ongoing phase 2 trial in China (NCT04341389) will provide more information on the safety and immunogenicity of the Ad5 vectored COVID-19 vaccine.

#### Contributors

F-CZ and Y-HL were co-first authors. F-CZ, WW, and WC were joint corresponding authors. F-CZ is the principal investigator of this trial. X-HG and WW worked as co-principal investigators of this trial. F-CZ, WC, X-HG, L-HH, Y-HL, W-JW, J-XL, and S-YJ designed the trial and the study protocol. J-XL drafted the manuscript. WC contributed to critical review and revision of the manuscript. F-CZ, W-JW, J-XL, and S-YJ contributed to the data interpretation and revision of the manuscript. X-WW was responsible for the statistical analysis. J-JX and B-SW contributed to study supervision. WW, W-JW, ZW, LeW, S-YJ, and H-DJ led and participated in the site work, including the recruitment, follow-up, and data collection. Y-HL, TJ, YH, LiW, and S-BX were responsible for laboratory analyses. W-JW, J-XL, and S-YJ contributed to the literature search. J-BG and S-PW monitored the trial.

#### Declaration of interests

WC reports grants from the National Key R&D Program of China (2020YFC10841400), and grants from the National Science and Technology Major Project (2016ZX10004001, 2018ZX09201005). J-BG is an employee of CanSino Biologics. All other authors declare no competing interests.

#### Data sharing

We support data sharing of the individual participant data. The individual participant data that underlie the results reported in this Article, after de-identification (text, tables, figures, and appendix) will be shared. Individual participant data will be available beginning 3 months and ending 1 year after publication. Supporting clinical documents including the study protocol, statistical analysis plan, and the informed consent form will be available immediately following publication for at least 1 year. Researchers who provide a scientifically sound proposal will be

For supporting clinical documents see [http://www.jsdc.cn/jkfw/kygz/202005/t20200517\\_68894.html](http://www.jsdc.cn/jkfw/kygz/202005/t20200517_68894.html)

allowed access to the individual participant data. Proposals should be directed to jszfc@vip.sina.com or cw0226@foxmail.com. These proposals will be reviewed and approved by the sponsor, investigator, and collaborators on the basis of scientific merit. To gain access, data requesters will need to sign a data access agreement.

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**Sent:** 5/26/2020 7:35:22 AM  
**To:** John Fleming (b) (6) @who.eop.gov]  
**Subject:** Liu Conv Plasma Mt Sinai 2020 preprint.pdf  
**Attachments:** Liu Conv Plasma Mt Sinai 2020 preprint.pdf

Nice early report from Mt. Sinai regarding the efficacy of convalescent plasma. I thought you'd find it of interest, John.

thanks

Steve

# 1 **Convalescent plasma treatment of severe COVID-19: A matched control study**

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31 **Abstract**

32 *Background*

33 Since December 2019, Coronavirus Disease 2019 (COVID-19) has become a global pandemic,  
34 causing mass morbidity and mortality. Prior studies in other respiratory infections suggest that  
35 convalescent plasma transfusion may offer benefit to some patients. Here, the outcomes of  
36 thirty-nine hospitalized patients with severe to life-threatening COVID-19 who received  
37 convalescent plasma transfusion were compared against a cohort of retrospectively matched  
38 controls.

39 *Methods*

40 Plasma recipients were selected based on supplemental oxygen needs at the time of enrollment  
41 and the time elapsed since the onset of symptoms. Recipients were transfused with convalescent  
42 plasma from donors with a SARS-CoV-2 (severe acute respiratory disease coronavirus 2) anti-  
43 spike antibody titer of  $\geq 1:320$  dilution. Matched control patients were retrospectively identified  
44 within the electronic health record database. Supplemental oxygen requirements and survival  
45 were compared between plasma recipients and controls.

46 *Results*

47 Convalescent plasma recipients were more likely than control patients to remain the same or  
48 have improvements in their supplemental oxygen requirements by post-transfusion day 14, with  
49 an odds ratio of 0.86 (95% CI: 0.75~0.98;  $p=0.028$ ). Plasma recipients also demonstrated  
50 improved survival, compared to control patients (log-rank test:  $p=0.039$ ). In a covariates-adjusted  
51 Cox model, convalescent plasma transfusion improved survival for non-intubated patients  
52 (hazard ratio 0.19 (95% CI: 0.05 ~0.72);  $p=0.015$ ), but not for intubated patients (1.24 (0.33~4.67);  
53  $p=0.752$ ).

54 *Conclusions*

55 Convalescent plasma transfusion is a potentially efficacious treatment option for patients  
56 hospitalized with COVID-19; however, these data suggest that non-intubated patients may  
57 benefit more than those requiring mechanical ventilation.

58

59 **Introduction**

60 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-  
61 stranded RNA virus belonging to the family *Coronaviridae*. Humans infected with SARS-CoV-2  
62 may develop Coronavirus Disease 2019 (COVID-19), which manifests across a wide spectrum of  
63 clinical severity ranging from a mild upper respiratory tract illness to a diffuse viral pneumonia  
64 causing acute respiratory failure, with sequelae including acute lung injury, multi-organ  
65 dysfunction syndrome, and death.<sup>1-3</sup> Antibody responses to coronavirus infections typically  
66 appear 2-3 weeks after the onset of illness and are rarely observed earlier.<sup>4-6</sup>

67 Although the relationship between disease severity and antibody response has yet to be firmly  
68 established,<sup>7</sup> transfusion with convalescent plasma may provide a therapeutic option in the  
69 current treatment-limited environment.<sup>8-10</sup> Historical evidence supports the efficacy of  
70 convalescent plasma transfusions to treat a variety of infectious diseases, including influenza,  
71 Junin virus, and severe acute respiratory syndrome (SARS).<sup>11-14</sup> Initial data supporting  
72 convalescent plasma transfusions for COVID-19 include three case series from China of 5, 10, and  
73 6 patients.<sup>15-17</sup> In respiratory infections specifically, the strongest evidence suggests that the  
74 benefit of passive antibody transfer is most demonstrable in patients who were treated within  
75 days of symptom onset.<sup>12,13,18,19</sup> Therefore, we hypothesized that treatment of patients with  
76 convalescent plasma early in the disease course may reduce morbidity and mortality associated

77 with COVID-19. Presented here are preliminary outcomes for 39 patients with severe to life-  
78 threatening COVID-19 who received convalescent plasma transfusions at a single academic  
79 medical center, The Mount Sinai Hospital, in New York City.

## 80 **Methods**

### 81 *Patients*

82 Forty-five adult patients were identified as eligible for COVID-19 convalescent plasma transfusion  
83 under the criteria established for the FDA single patient emergency investigational new drug  
84 (eIND) process. FDA authorization was requested and obtained for COVID-19 convalescent  
85 plasma transfusion. Four patients improved and 2 patients withdrew consent prior to receipt of  
86 plasma, leaving 39 evaluable patients who received COVID-19 convalescent plasma. Patients  
87 were hospitalized in a single academic medical center in New York City for COVID-19 between 24  
88 March 2020 and 8 April 2020. Patients were screened by symptom duration and by severity of  
89 disease on a case-by-case basis, as assessed by oxygen supplementation requirements and  
90 laboratory parameters. Patients or their legally authorized representatives provided informed  
91 consent prior to treatment. Both treatment and research were performed with the oversight of  
92 the Icahn School of Medicine at Mount Sinai Institutional Review Board (IRB).

### 93 *Convalescent plasma transfusion*

94 Convalescent plasma donors were screened for SARS-CoV-2 antibody titers by a two-step Spike  
95 protein-directed ELISA.<sup>20,21</sup> Donors with anti-spike antibody titers  $\geq 1:320$  were referred for blood  
96 collection at the New York Blood Center, which performed the plasmapheresis and then returned  
97 convalescent plasma units to The Mount Sinai Hospital. Plasma recipients were transfused with  
98 two units of ABO-type matched convalescent plasma. Each unit, approximately 250 milliliters in

99 volume, was infused over 1 to 2 hours. Recipients were monitored every 15 minutes for signs of  
100 transfusion-related reactions and then followed post-transfusion for outcomes.

### 101 *Statistical analysis*

102 To confirm the independent effect of convalescent plasma transfusion on improvement in  
103 oxygenation and survival, we conducted a propensity score-matched analysis using The Mount  
104 Sinai Hospital's COVID-19 confirmed patient pool from the same calendar period (24 March 2020  
105 to 8 April 2020). A logistic regression was fit to predict the potential for plasma therapy based  
106 on time series data obtained at baseline upon admission, prior to transfusion, and the day of  
107 transfusion. Among the predictors, exact matching was enforced on the administration of  
108 hydroxychloroquine and azithromycin, intubation status and duration, length of hospital stay,  
109 and oxygen requirement on the day of transfusion. Other medications were administered too  
110 infrequently to enforce exact matching. Balance was well achieved between the plasma and  
111 control groups, as all predictors had a standardized mean difference less than 0.2. Details of the  
112 matching method and results are described in the Supplementary Appendix. A medical data  
113 team reviewed charts of the control patients to determine outcomes at 1, 7, and 14 days. The  
114 data team was not informed of the recipient to whom each control patient was matched. Because  
115 control patients were matched to plasma recipients by length of stay prior to transfusion, "day  
116 0" was defined as the day of transfusion for the plasma recipients and as the corresponding day  
117 in the hospitalization course of the control patients.

### 118 *Oxygen supplementation*

119 Patients were then evaluated for their supplemental oxygen requirements and survival at three  
120 time points: days 1, 7, and 14 post-transfusion. Four categories of supplemental oxygen use  
121 status were collected for both cases and controls. These include, in order of increasing severity:

122 room air without supplemental oxygen required; low-flow oxygen delivery by standard nasal  
123 cannula; high-flow oxygen delivery, including non-rebreather mask; high-flow nasal cannula or  
124 bi-level positive airway pressure (BiPAP) non-invasive ventilation; and mechanical ventilation. A  
125 patient's oxygenation status at the three time points was considered to have worsened if they  
126 changed from a lower- to a higher-severity category compared to Day 0, or if they had died prior  
127 to the time point. A generalized estimating equations (GEE) approach with a logit link for binary  
128 data was used to model the effect of plasma on the odds of oxygenation improvement on days  
129 1, 7, and 14 following transfusion, controlling for oxygen status on day 0. An independent  
130 working correlation structure was assumed for the patients within each cluster; however, the p-  
131 values were calculated based on the empirical standard errors. Since some patients were  
132 discharged with continued oxygen supplementation, the oxygen status of discharged patients  
133 was assumed to be no worse than low-flow oxygen by standard nasal cannula.

#### 134 *Survival*

135 Kaplan-Meier survival curves and the log rank test were used to depict the overall post-  
136 transfusion survival. A Cox model was fit to estimate the hazard ratio for in-hospital mortality  
137 for the plasma group, with matched clusters treated as random effects and onset of intubation  
138 as a time-varying covariate. In addition, interactions between convalescent plasma  
139 administration and intubation duration were tested to see if the plasma effects were the same  
140 in subgroups.

141 Both oxygen status and survival models were adjusted for duration of symptoms prior to  
142 admission and drugs administered, as these data were only ascertained after the matching was  
143 completed. The initial drug list consisted of COVID-19 therapies used during the time of the

144 study that included azithromycin, broad-spectrum antibiotics, hydroxychloroquine, therapeutic  
145 anticoagulants, corticosteroids, directly acting antivirals, stem cells, and interleukin 1 and  
146 interleukin 6 inhibitors. Only those that had a p-value < 0.5, however, were included in the final  
147 model for adjustment. A liberal p-value was used here to be inclusive of any potential  
148 confounders. As a sensitivity analysis, the 1:2 matching without replacement data were also  
149 analyzed, where the balance between the matched pairs was enhanced but the study power  
150 was reduced. Descriptive data are reported as number (percent), mean ( $\pm$  standard deviation)  
151 or median [min, max], as appropriate. Analysis was performed using SAS 9.4 (SAS Institute Inc.,  
152 Cary, NC). All tests were 2-sided and statistical significance was defined as a p value < 0.05,  
153 unless otherwise indicated.

## 154 **Results**

### 155 *Recipient characteristics*

156 The average age of the recipients of convalescent plasma transfusion was 55 ( $\pm$  13) years (Table  
157 1). The cohort was approximately two-thirds male and one-third female, similar to the  
158 proportions of men and women with severe disease in prior studies.<sup>1</sup> Recipients generally had  
159 few baseline co-morbidities: 54% were obese (body mass index  $\geq$ 30) and 18% had a current or  
160 former history of tobacco use. One patient had end-stage renal disease requiring peritoneal  
161 dialysis. The median duration of symptoms prior to initial presentation was 7 [0, 14] days.  
162 Inflammatory markers were elevated with median d-dimer of 1.4 [0.27, >20]  $\mu$ g/mL fibrinogen  
163 equivalent units, median ferritin 1135 [107, 7441] ng/mL, and median C-reactive protein 159 [12,  
164 319] mg/L. The median time between admission and transfusion was 4 [1, 7] days. On the day of  
165 transfusion, the majority of the recipients were requiring supplemental oxygen via a non-invasive  
166 delivery device (87%). Four plasma recipients (10%) were mechanically ventilated at the time of

167 transfusion. In addition to receiving convalescent plasma transfusion, many recipients received  
168 a variety of inpatient pharmacotherapies throughout their hospitalizations (Table 2). There were  
169 no significant differences between plasma recipients and control patients in exposures to  
170 measured pharmacotherapies, except for therapeutic anticoagulation.

### 171 *Respiratory Status*

172 Plasma recipients and control patients were 100% matched on their supplemental oxygen  
173 requirement on day 0. Of them, 69.2% were receiving high-flow oxygen and 10.3% were receiving  
174 invasive mechanical ventilation. By day 14, clinical condition had worsened in 18.0% of the  
175 plasma patients and 24.3% in the control patients ( $p=0.167$ , Cochran-Mantel-Haenszel test). The  
176 covariates-adjusted odds ratio for worsening oxygenation on day 14 was 0.86 (95% CI: 0.75~0.98;  
177  $p=0.028$ ) (Figure 1). The effect of plasma appeared to be confounded by the use of therapeutic  
178 anticoagulants (unadjusted vs. adjusted OR: 0.90 vs. 0.84), but not on other types of drugs or  
179 duration of symptoms before admission (OR remained in the range of 0.90~0.91). On days 1 and  
180 7, the plasma group also showed a reduction in the proportion of patients with worsened  
181 oxygenation status, but the group difference did not reach statistical significance.

### 182 *Survival*

183 As of 1 May 2020, 12.8% of plasma recipients and 24.4% of the 1:4 matched control patients had  
184 died (21.6% in the 1:2 matched dataset), and 71.8% and 66.7% (68.9%) had been discharged alive,  
185 respectively. The median follow-up time was 11 [1, 28] days for the plasma group and 9 [0, 31]  
186 days for the control group. Overall, we observed improved survival for the plasma group (log-  
187 rank test:  $p=0.039$ ) (Figure 2). In a covariates-adjusted Cox model, convalescent plasma  
188 transfusion was significantly associated with improved survival in non-intubated patients (hazard  
189 ratios: 0.19 (95% CI: 0.05 ~0.72);  $p=0.015$ ), but not in intubated patients (1.24 (0.33~4.67);

190  $p=0.752$ ) (P-value for the plasma and intubation interaction term was 0.050). There is no  
191 evidence that the effect of plasma depended on the duration of symptoms ( $p=0.19$  for the plasma  
192 by duration interaction). The results remain robust in the model without covariates adjustment  
193 and in the 1:2 matched sample (Figure 3).

## 194 **Discussion**

195 The COVID-19 pandemic poses an unprecedented challenge, as physicians and scientists struggle  
196 in real time to identify effective interventions against SARS-CoV-2 and its complications. This  
197 initial assessment offers evidence in support of convalescent plasma transfusion as an effective  
198 intervention in COVID-19. Preliminary data suggest a potential mortality benefit, but greater  
199 numbers are needed to draw definitive conclusions. Interestingly, these data suggest that the  
200 survival effect of convalescent plasma may begin to manifest more than 1 week after transfusion.  
201 If this observation is borne out in subsequent studies, it could indicate that convalescent plasma  
202 prevents longer-term complications, such as acute lung injury or multi-organ dysfunction  
203 syndrome; however, this speculation awaits confirmation in a larger patient cohort.

204 This study has many unique strengths. It describes the largest cohort of COVID-19 patients  
205 treated with convalescent plasma thus far worldwide. Furthermore, New York City has a large  
206 and very diverse population, and its metropolitan area was among the earliest and hardest hit by  
207 the COVID-19 pandemic in the United States. Over this study's 16-day enrollment period (24  
208 March 2020 to 8 April 2020), the Mount Sinai Health System admitted 4,152 confirmed COVID-  
209 19-positive patients. This large pool from which to draw control patients permitted an aggressive  
210 matching algorithm. Data from three different time frames -- baseline, prior to transfusion, and  
211 day of transfusion -- informed the matching of controls to cases to maximize their similarity.

212 In addition, the efficacy of passive antibody transfer relies heavily on the quality of the donor  
213 convalescent plasma. Mount Sinai rapidly developed and clinically deployed an ELISA to titrate  
214 SARS-CoV-2-specific antibodies in serum,<sup>18</sup> enabling our center to refer for blood collection only  
215 those convalescent donors with the highest peripheral serum antibody titers of  $\geq 1:320$ .<sup>22</sup> Prior  
216 smaller studies have reported on a variety of titer cutoffs,<sup>15,16</sup> and at the time of this publication  
217 some centers are bypassing donor antibody titer pre-collection completely.<sup>17</sup> Although the total  
218 quantity of anti-SARS-CoV-2 spike antibodies were assessed, it must be noted that we have not  
219 yet assessed the functionality of these antibodies in neutralizing the virus. Recent studies with  
220 SARS CoV-2 have generally found a high correlation between ELISA S protein binding activity and  
221 neutralization of SARS CoV-2.<sup>21,23</sup>

222 Although controls were retrospectively identified by propensity matching, the conclusions drawn  
223 from these data are not as robust as a prospective, randomized, placebo-controlled study.  
224 Furthermore, the convalescent plasma recipient cohort is highly heterogeneous in regards to  
225 oxygen needs at the time of transfusion and the duration of symptoms prior to admission. Other  
226 than intubated versus non-intubated patients, the small size of this cohort lacks sufficient power  
227 to permit additional subgroup analyses. We did not observe significant benefit of convalescent  
228 plasma in intubated patients, consistent with past literature demonstrating that passive antibody  
229 transfer therapies are most efficacious early in disease.<sup>12,13,18,19</sup> However, the number of  
230 intubated patients in this study is small, limiting our ability to reach any conclusions about this  
231 population. Future studies that include more mechanically ventilated patients will be needed to  
232 address this uncertainty.

233 No significant transfusion-related morbidity or mortality were observed in the convalescent  
234 plasma recipient cohort; however, potential harms are associated with plasma transfusion. There

235 is a risk of fluid volume overload, particularly in patients with end-stage renal disease or advanced  
236 heart failure. Allergic reactions to plasma are typically mild and self-limited. Plasma naturally  
237 contains procoagulants, whose additive effects are unknown in this disease, which is  
238 independently associated with hypercoagulability;<sup>24</sup> thus, pending more data, additional caution  
239 should be exercised in patients with acute thrombotic events. Convalescent plasma transfusions  
240 also have theoretical risks, such as hindering the maturation of the patient's own adaptive  
241 immune memory response and antibody-dependent enhancement. While keeping these risks in  
242 mind, additional studies are needed to confirm these findings and draw more definitive  
243 conclusions about the efficacy of convalescent plasma transfusion for the treatment of COVID-  
244 19 in different populations.

245

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274 Dr. Krammer reports that patent applications have been filed for the assay used to select  
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- 338

339 **Table 1. Demographics and clinical parameters of recipients prior to transfusion**

Characteristic*	Patients (N = 39)
<b>Demographics</b>	
Mean age $\pm$ SD – year	55 $\pm$ 13
Sex –	
Male / Female	25 (64) / 14 (36)
Mean Body-mass index $\pm$ SD †	31.7 $\pm$ 6.0
Coexisting disorder – no. (%)	
Asthma	3 (8)
Cancer¶	2 (5)
Chronic kidney disease	1 (3)
Chronic obstructive pulmonary disease	1 (3)
Current or former smoker	7 (18)
Diabetes mellitus	8 (21)
Hemorrhagic or ischemic stroke	0
Human immunodeficiency virus	0
Obesity	21(54)
Obstructive sleep apnea	2 (5)
Median duration of symptoms before admission – days	7 [0, 14]
Presenting symptoms – no. (%)	
Fever	26 (67)
Shortness of breath	26 (67)
Cough	24 (62)
Diarrhea	8 (21)
Sputum production	3 (8)

Sore throat	2 (5)
Vital signs on admission – no. (%)	
Temperature >100.4°F or 38°C	13 (33)
Heart rate >100 beats per min	22 (56)
Respiratory rate ≥ 20 breaths per min	28 (72)
Imaging – no. (%)	
Chest radiography	38 (97)
Chest computed tomography	3 (8)
<b>Clinical parameters</b>	
Laboratory data prior to transfusion	
White-cell count	
Median [range] – per mm <sup>3</sup>	7600 [3900-22600]
Distribution – no (%)	
≥10,000/mm <sup>3</sup>	10 (26)
≤4000/mm <sup>3</sup>	2 (5)
Aspartate aminotransferase >40 U/liter – no (%)	26 (67)
Alanine aminotransferase >40/liter – no (%)	18 (46)
Lactate ≥1.5 mmol/liter – no (%)	23 (59)
D-dimer, median [range] - µg/ml Fibrinogen Equivalent units	1.4 [0.27, >20]
Fibrinogen, mean (±S.D.) –no./total no. (mg/dl)	684±140
Ferritin, median [range] – ng/ml	1135 [107, 7441]
C-Reactive Protein, median [range] – mg/liter	159 [12, 319]

Interleukin-6, mean ( $\pm$ S.D.) – no./total no. (pg/ml)	178 $\pm$ 348
Length of stay prior to transfusion	
Median duration [range] – days	4 [1, 7]
Supplemental oxygen requirement prior to initiation of transfusion	
Standard nasal cannula – no. (%)	7 (18)
2 liters – no. (%)	0
3 liters – no. (%)	2 (5)
4 liters – no. (%)	2 (5)
$\geq$ 5 liters – no. (%)	3 (8)
High-flow oxygen, high-flow nasal cannula or BiPAP – no. (%)	27 (69)
Mechanical ventilation – no. (%)	4 (10)

---

340 \*Plus-minus values are mean  $\pm$ SD. Percentages may not total 100 because of rounding.

341 †The body-mass index is the weight in kilograms divided by the square of the height in meters.

342 ¶Cancer represents a patient with thyroid cancer status post resection and a patient with Gleason 6 prostate cancer.

343 ¶High-flow oxygen included venti-mask and non-rebreather mask; BiPAP = bi-level positive airway pressure.

344 \*Plus-minus values are mean  $\pm$ SD. Percentages may not total 100 because of rounding.

345 **Table 2. Recipient pharmacologic interventions**

		<b>1:4 matching</b>	<b>1:2 matching</b>
	<b>Patients</b>	<b>Controls</b>	<b>Controls</b>
<b>Pharmacologic interventions</b>	<b>(N = 39)</b>	<b>(N=156)</b>	<b>(N=74)</b>
<hr/>			
Antimicrobial agents – no. (%)			
Azithromycin	31 (79)	133 (85)	63 (85)
Broad spectrum antibiotics	29 (74)	112 (72)	57 (77)
Hydroxychloroquine	36 (92)	148 (95)	69 (93)
Investigational antivirals	1 (3)	9 (6)	4 (5)
Therapeutic anticoagulation – no. (%)	26 (67)	64 (41)	32 (43)
Anti-inflammatory agents – no. (%)			
Corticosteroids	22(56)	90 (58)	38 (51)
Interleukin-1 inhibitors	0	0	0
Interleukin-6 inhibitors	3 (8)	13 (8)	6 (8)

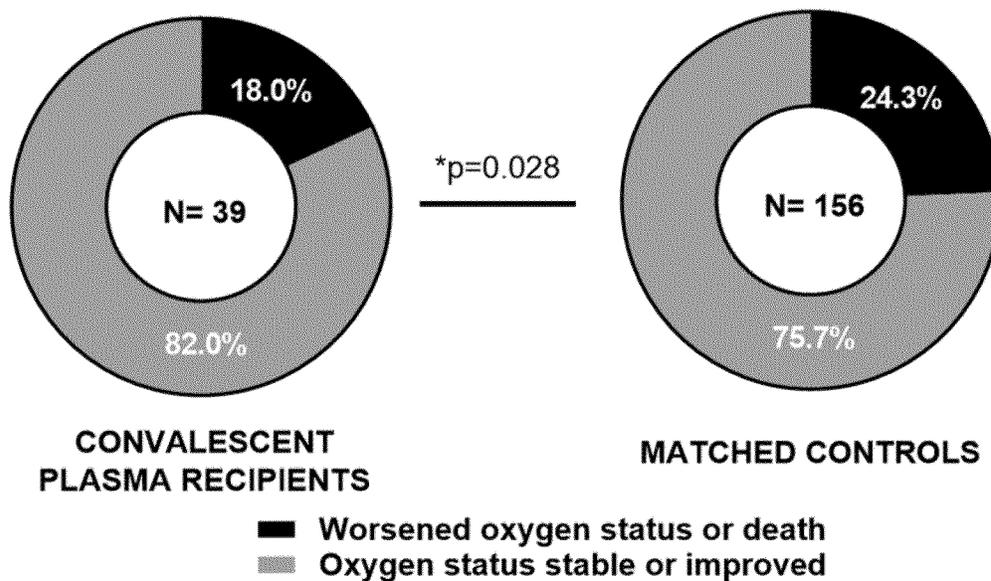
\* No significant differences were found between groups in both matched samples (p-values all >0.44), except for use of therapeutic anticoagulation (p <0.001 1:4 ratio and p=0.02 1:2 ratio).

346

347 **Figure 1. Comparison of oxygen requirements between Day 14 versus Day 0.**

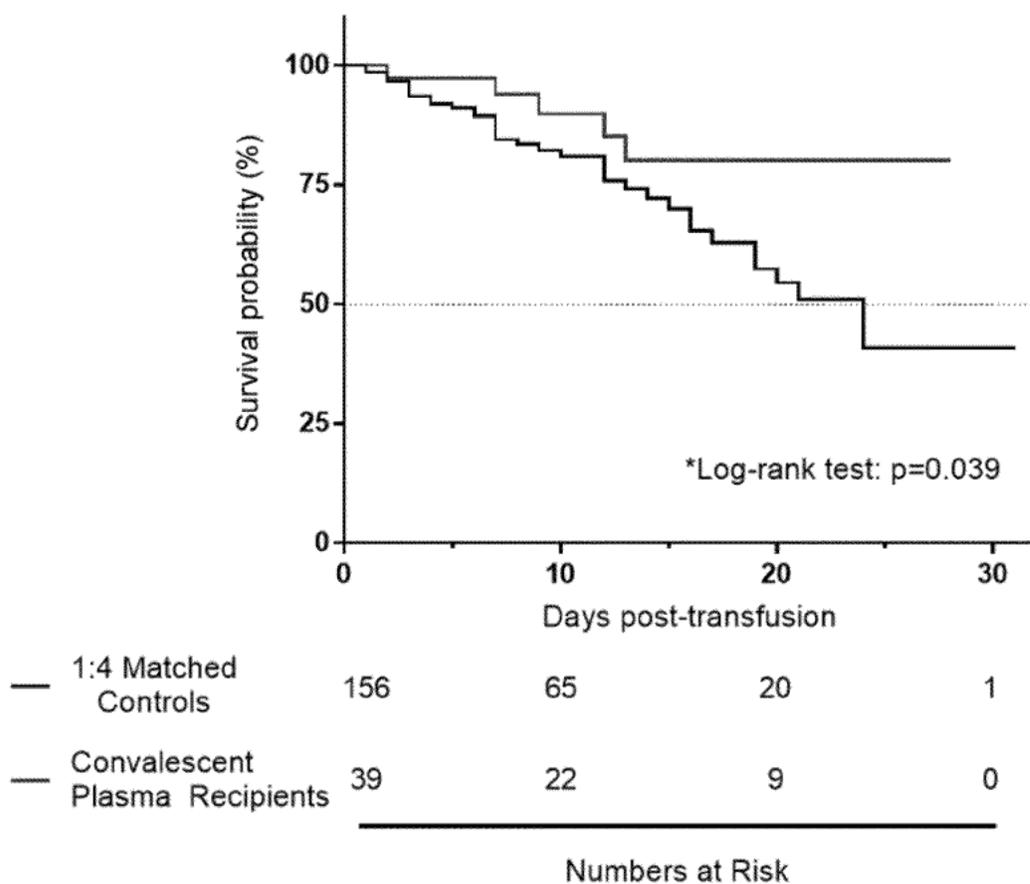
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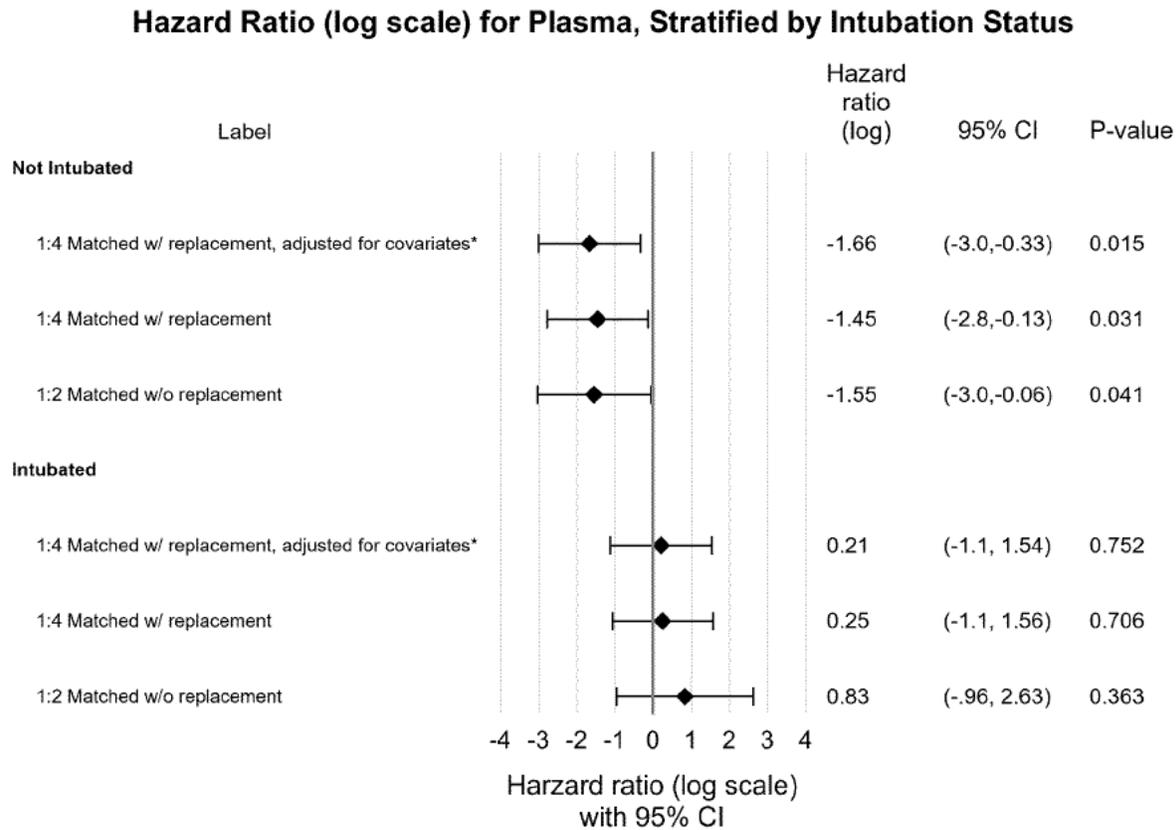
\* Covariates adjusted. No significant differences were observed at day 1 (p=0.444) or day 7 (p=0.425).

350 **Figure 2. Survival Probability**



351

352 **Figure 3. Hazard ratios for in-hospital mortality**



\* Adjustment: Duration of symptoms prior to admission, therapeutic anticoagulant, broad spectrum antibiotics, and antivirals.

353