COVID 3D TRUST: Supporting the Open Hardware Community through Intergovernmental and Public/Private Partnership

Open Source Hardware Summit 2021

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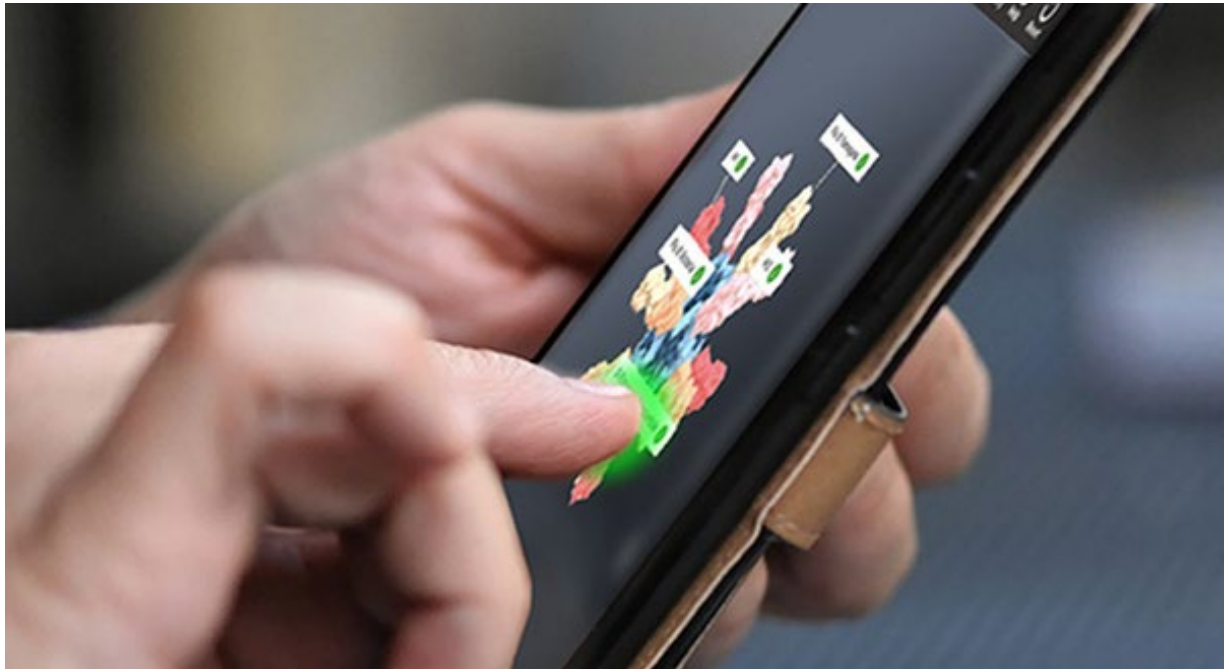
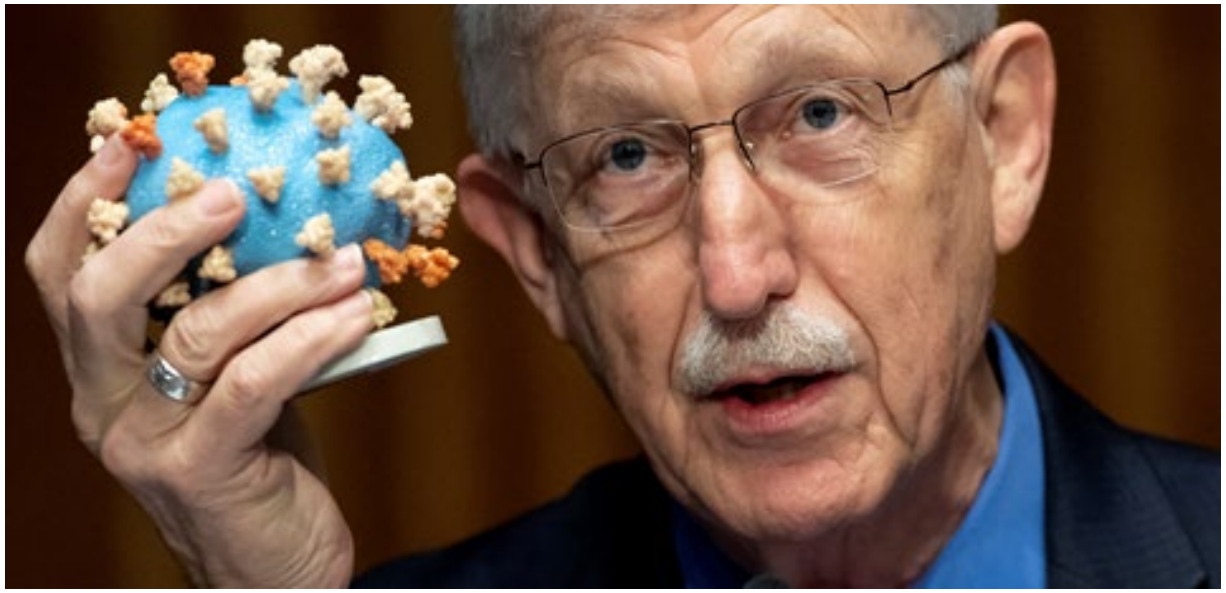
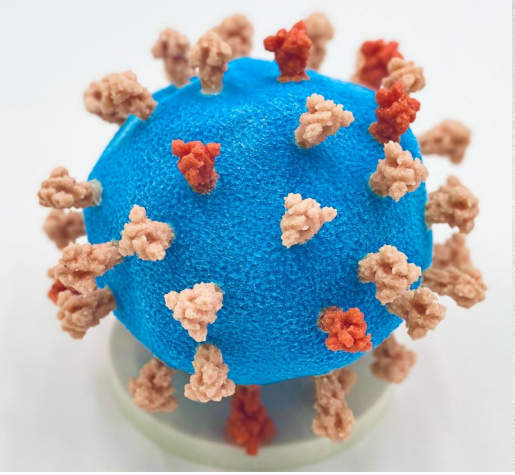
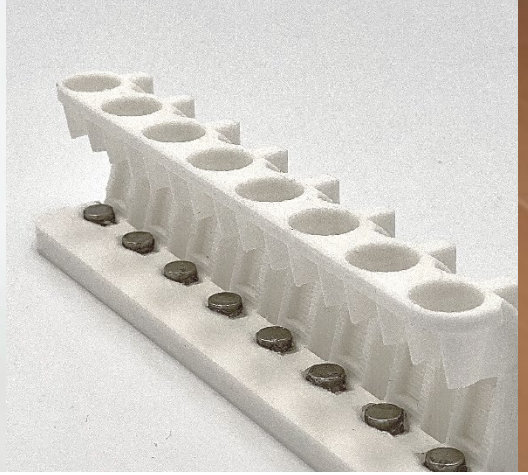
Contractor, Medical Science and Computing, Inc.

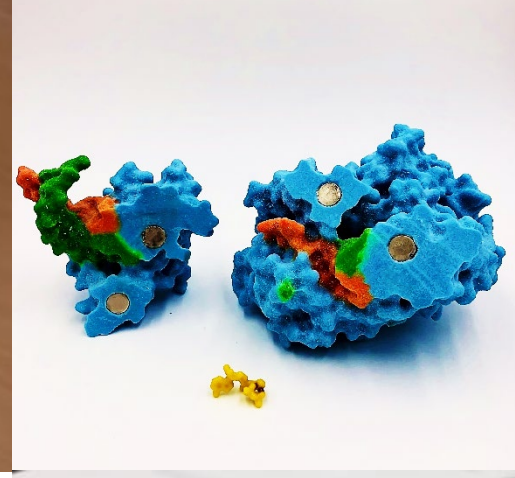
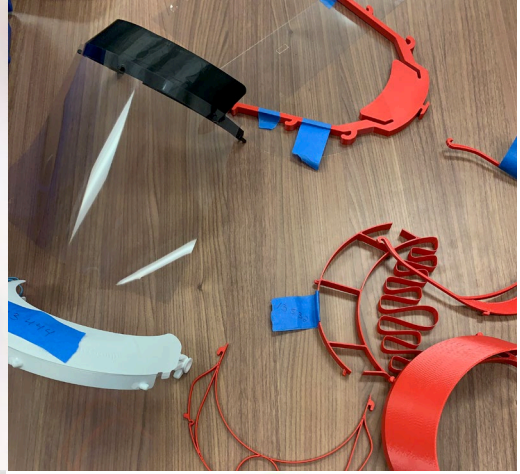
National Institute of Allergy and Infectious Diseases

This work is funded in part through NIAID BCBB Support Services Contract HHSN316201300006W/HHSN27200002





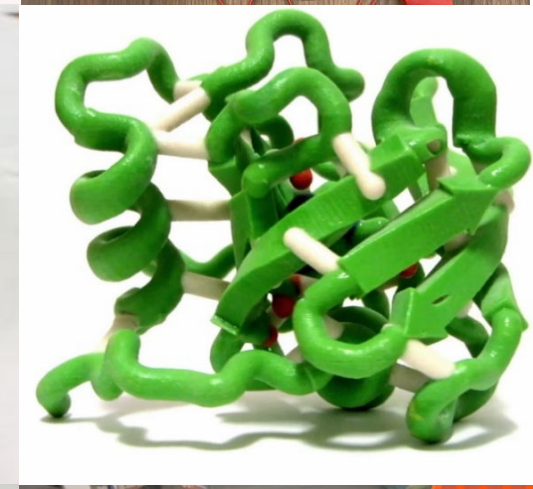
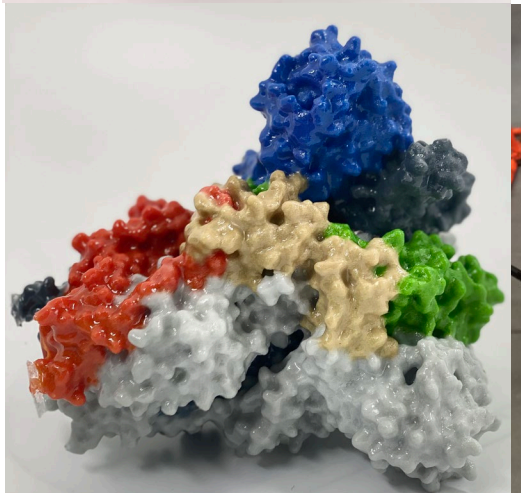
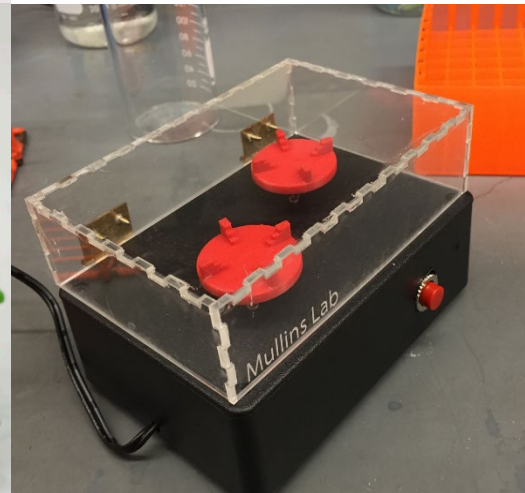



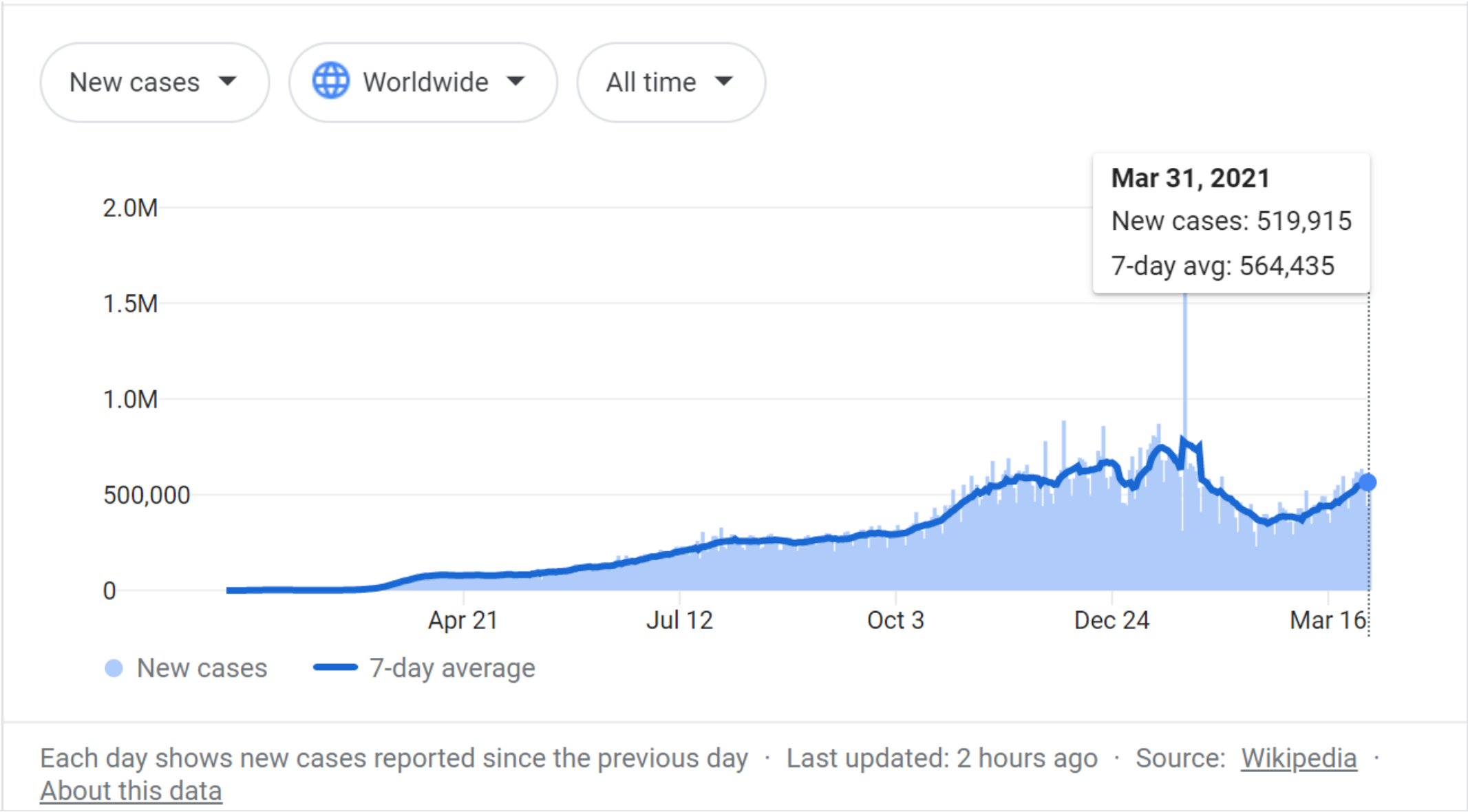
The NIH 3D Print Exchange

an open, community-driven portal to download, share, and create bioscientific and medical 3D models for 3D printing

https://3Dprint.nih.gov

Version 2: “NIH 3D” expands support for interactive 3D visualization, including virtual and augmented reality (3D.nih.gov)



Google COVID-19 Statistics. New cases per day, worldwide. Retrieved April 9, 2021, 8:30 AM EST

Why America ran out of protective masks — and what can be done about it

If the US was better prepared for pandemics, it could have avoided the shortage of masks and other protective gear.

By German Lopez | @germanrlopez | german.lopez@vox.com | Mar 27, 2020, 2:50pm EDT

Vox.com. Accessed April 9, 2021.


Pakistan
USA
Ukraine

Open Source and the COVID-19 Supply Chain Crisis

- Enthusiasm and generosity
- Open source community
- Democratized, global technology
- Agile manufacture
- Urgent need

- Less-experienced producers
- Lack of documentation and instructions
- Gray areas in standards
- Liability concerns
- REAL safety concerns – *high stakes*

FDA Efforts to Connect Manufacturers and Health Care Entities: The FDA, Department of Veterans Affairs, National Institutes of Health, and America Makes Form a COVID-19 response Public-Private Partnership

First draft of MOU – March 23rd; Signed on March 25th; published by FDA on March 27th!!!

MOU available at https://go.usa.gov/xvHSc

Image credits: Dr. Beth Ripley and Timothy Prestero.

COVID-19 ~~Supply Chain Response~~

Curated by NIH/NIAID in collaboration with the U.S. Food and Drug Administration, the Veterans Healthcare Administration, and America Makes

COVID 3D TRUST: Trusted Repository for Users and Suppliers Through Testing

3DPX-014168

Stopgap Surgical Face Mask (SFM) Revision B

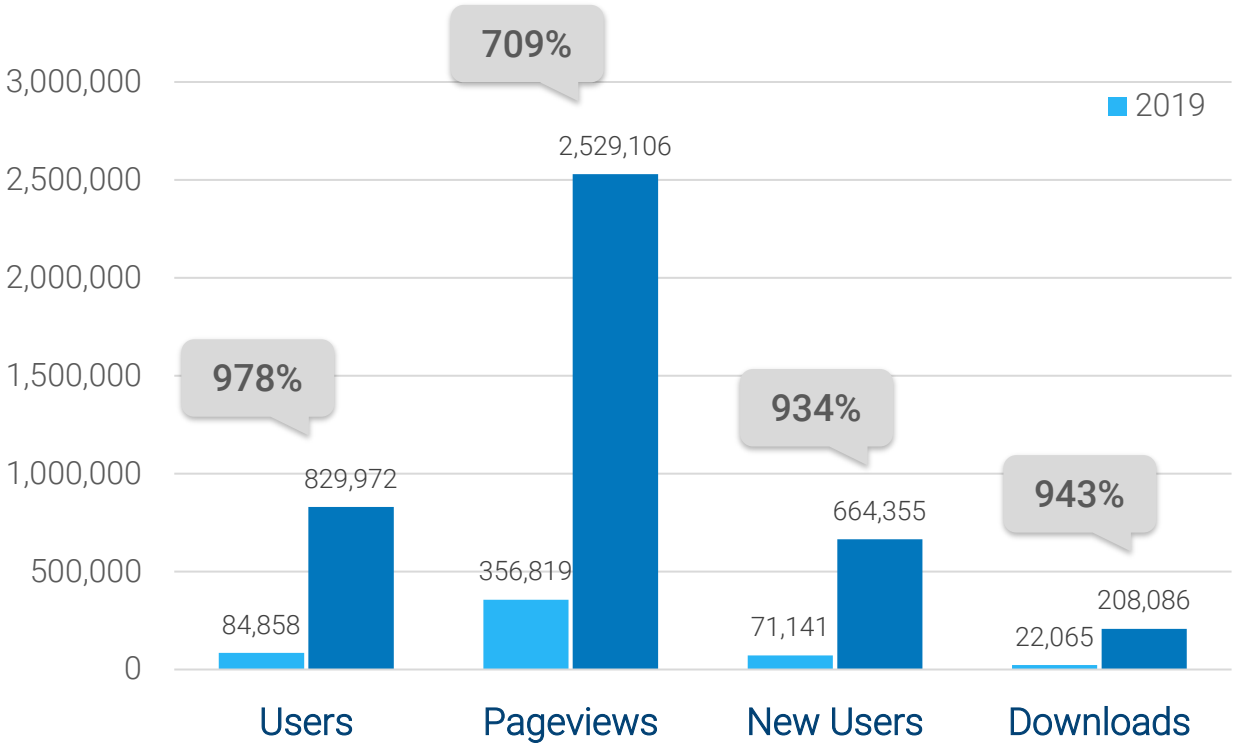
VHA Innovation ...

https://3dprint.nih.gov/discover/3dpx-014168

https://3dprint.nih.gov/discover/3dpx-013306

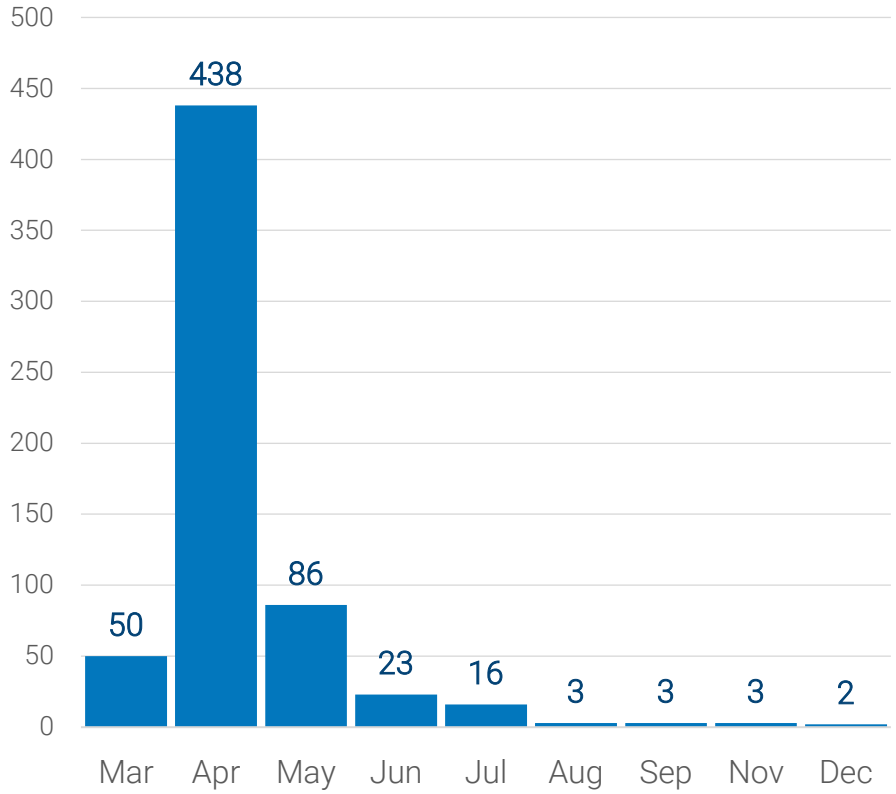
COVID 3D TRUST: NIH 3D Print Exchange Site Activity

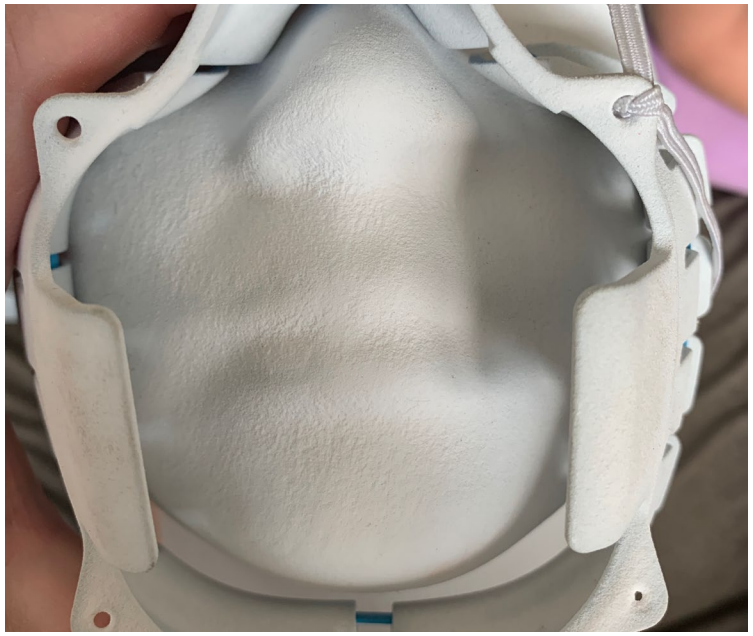
Site Activity, 2019 vs. 2020 comparison



March 29th through September 28th, respectively for each year 2019 and 2020.

New COVID 3D TRUST Designs per Month in 2020





Heroic printing and assessment process led by the VHA 3D Printing Innovation Network

Team led by Dr. Beth Ripley
Seattle Veterans Administration Hospital and
University of Washington

Warning
Potentially significant risk

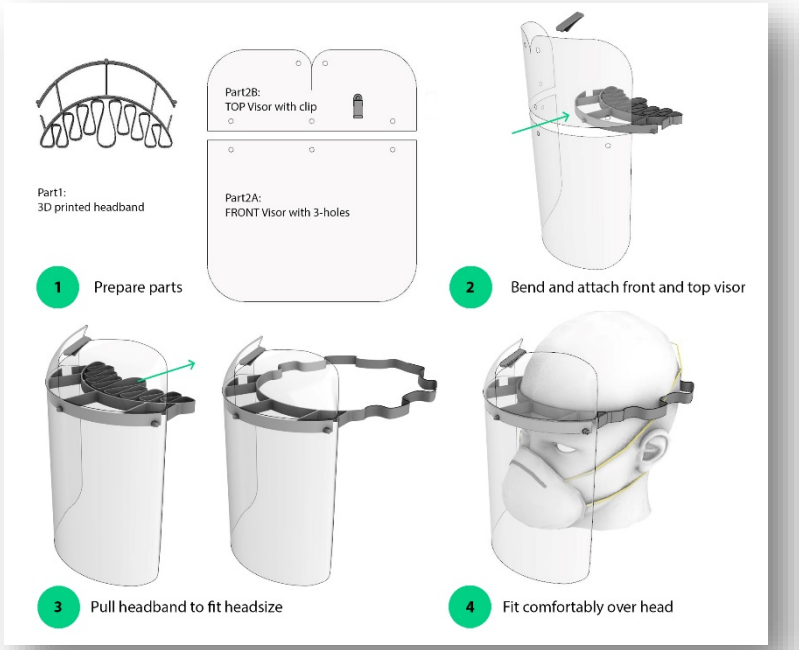
Prototype
not reviewed or not optimized;
proceed with caution

Community Use
Low risk, good instructions, not for use in a clinical setting

Clinically Reviewed
tested in a clinical setting, thoroughly documented, with IFU; must be fabricated as described, including printer type/materials

Designs are assessed by the Veterans Healthcare Administration and should not be considered as "Approved" by the FDA, NIH, VA, or America Makes

COVID 3D TRUST: Focus on Documentation



The “Scrunchie Shield” is an example of a user providing thorough documentation necessary to reproduce a design with a 3D printer, see 3DPX-013532. Designs without adequate instructions for fabrication and use can present safety risks to the wearer, including risk of SARS-CoV-2 infection.

Search by 3DPX-ID, author, title, description

Device Type

-Ear Saver
-Face Shield
-Nasal/Throat Swabs
-Face Mask
-PAPR
-Ventilator

Review Status

-Prototype
-Clinical Review
-Community Use

Search Printers

Printer Technology

Binder jetting
Direct Energy Depositio
Material Extrusion
Material Jetting
Powder Bed Fusion
Sheet Lamination
Vat Photopolymerizatio

Items per page

50 Apply

Reset

Search the COVID 3D TRUST Design Collection

Displaying 50 of 624 results. Show 50 | 100 | 150 | 200 results per page.

3DPX-015194
Face mask with filter and neoprene seal
basicrespirator

3DPX-015184
The Three Mask-eteers-Mask
ThreeMasketeers

3DPX-015115
Reusable Elastomeric Respirator
Wendy Edwards

3DPX-015110
DtM-3.1 Face Shield Remix with Flip-Up...
rcc13

3DPX-015088
Reusable Elastomeric Respirator
Wendy Edwards

3DPX-014827
Surgical Mask Tension Release Band for Ear...
jgroeli

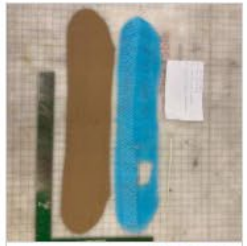
3DPX-014825
Welch Allyn Spot Vision Screener Shield (...
BCPLemanski

3DPX-014816
Brimmed heavy-duty faceshield with...
noam

3DPX-014737
Anchored Tsunami Ear Saver
JohnK

3DPX-014736
Covid Shield
JTowers

3DPX-014725
3d printed mask frame
chansenGSD



3DPX-014692
UW-DFab Shoe Cover
JeffreylLipton

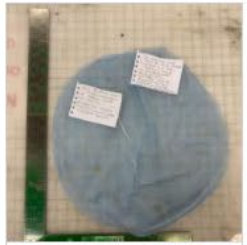
3DPX-014691
UW-DFab Boot Cover
JeffreylLipton

3DPX-014685
NES Universal Frame for Face Shield
NES

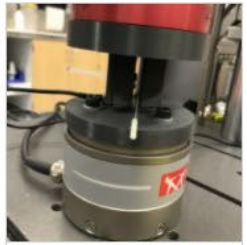
3DPX-014684
NES Universal Frame for Face Shield
NES

3DPX-014679
Transparent Face Mask with Filter
Jessica D Ventura

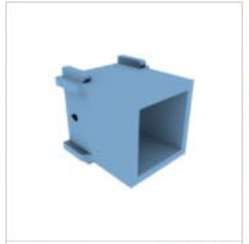
3DPX-014678
Transparent Face Mask
Jessica D Ventura



3DPX-014671
UW-DFab Bouffant Cap
JeffreylLipton



3DPX-014670
BEND TESTING PROTOCOL FOR NASAL SWABS; Rev 1...
VHA Innovation ...



3DPX-014669
ABRASION TESTING PROTOCOL FOR NASAL SWABS;...
VHA Innovation ...

3DPX-014668
'Go / No-Go Gauge' PROTOCOL FOR NASAL SWABS...
VHA Innovation ...

Trust was essential to our rapid response

NIH National Institute of Allergy and Infectious Diseases

- Extend capabilities of the website
- Respond to needs of site users
- Host informational content

FDA U.S. FOOD & DRUG ADMINISTRATION

- Inform decision-making
- Provide initial testing parameters
- Aid in development of new protocols
- Publish information and guidance

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

- Document user needs and design requirements
- Design and publish protocols
- 3D print and test designs
- Label designs as appropriate

America Makes

- Engage with government (local, state, federal)
- Organize testing and evaluation
- Host an online user/supplier matchmaking portal

Contribute 3DP/AM subject matter expertise | Identify challenges and opportunities for urgent response

Engage design, manufacturing, and end user communities to coordinate efforts

Gather information and create resources to inform decision-making

> NIH 3D Print Exchange was THE game changer in having hospitals be comfortable accepting donations of 3D printed face shields from MatterHackers Maker Response Hub and other community organizations.

- Mara Hitner, MatterHackers, Capitol Hill Maker Caucus Webinar
July 23, 2020

Designers and Makers – THANK YOU

48.3+ Million
Units of Medical Supplies Delivered

$271 Million
Worth of Supplies Manufactured

42,000+
Citizen Responders

1,878+
Individuals & Groups Tracked

86
Countries with Local Response Efforts

93%
Volunteers

DESIGN | MAKE | PROTECT – Collective Impact Report Presentation. OSMS and Nation of Makers. Online, January 28, 2021. https://opensourcemedicalsupplies.org/wp-content/uploads/2021/01/Design-Make-Protect_Presentation-Slides_21.01.28.pdf

WE LEARNED A LOT

Wilson Center & NYU Engleberg Law Center
Stitching Together a Solution: Lessons from the Open Source Hardware Response to COVID-19.

Nation of Makers & Open Source Medical Supplies
Download the “Collective Global Impact” Report
https://opensourcemedicalsupplies.org/impact/

> The NIH 3D Print Exchange is a model for government facilitation of open source design sharing.
>
> *- Collective Impact Report, OSMS & Nation of Makers, January 2021*

What does responsible design look like?

How can government support responsible open hardware design?

Making open source hardware trustworthy and “FAIR”

Improved standards for descriptive, embedded, and structured, metadata:

- Attribution, licensing
- Versioning/Provenance
- Validation
- Security
- Fabrication instructions, materials
- Facilitate data sharing and curation
- Can we incorporate digital signatures to ensure “verified” versions?

COVID 3D TRUST: Next steps

America Makes

AMCPR
Advanced Manufacturing Crisis Production Response

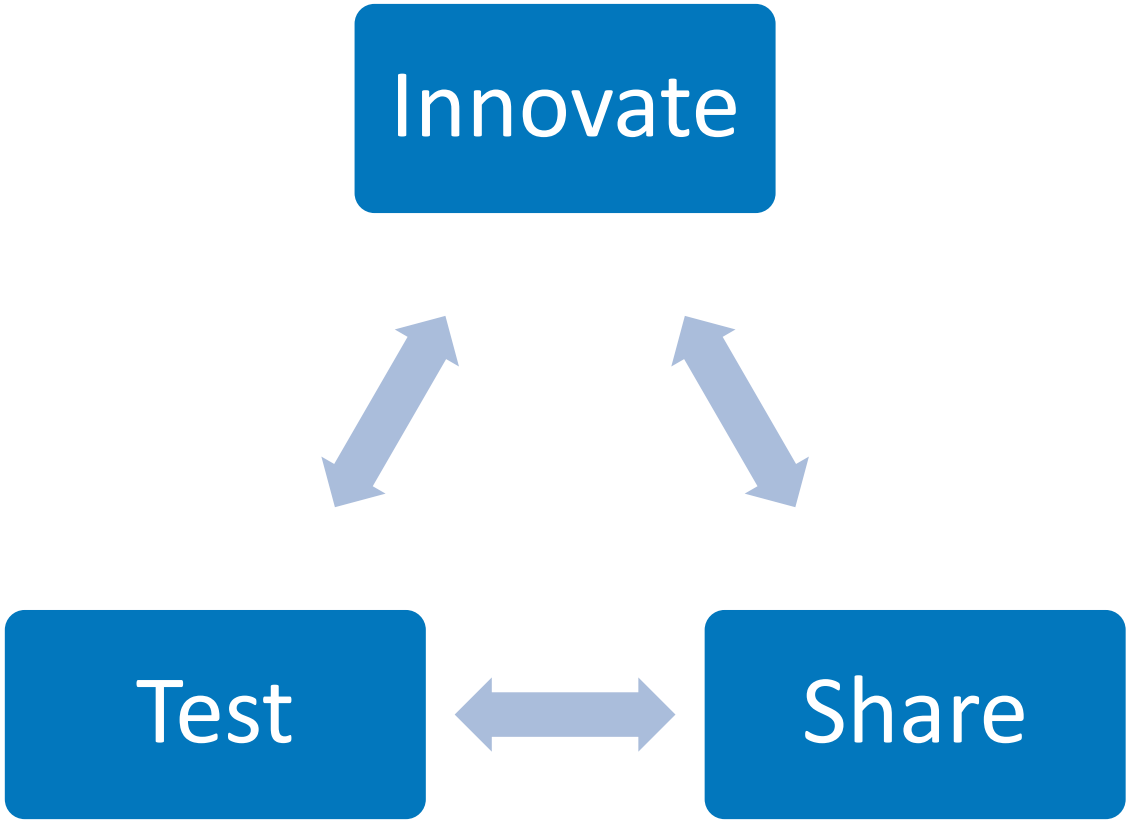
- Signed MOU in December to collaborate on API development
- Subset of NIH 3D designs will be visible through their portal, based on the tagging system for validation established during COVID 3D TRUST

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

"VHA is ready to re-establish the United States as a leader in medical device innovation to ensure Veterans, frontline staff and all Americans have superior tools to improve healthcare."

- VHA will use 3DPX/NIH 3D as the home for its design innovations
- Contribute to requirements gathering for NIH 3D and throughout the testing process
- Continue labeling system similar to COVID 3D TRUST
- VHA's testing and design tagging is critical to AMCPR

Readiness for future emergencies



NIH 3D: 2022 Release

- Extend scope beyond 3D printing
- Rebuilt from the ground up
- Improved information architecture
- More interactive 3D features
- Incorporate lessons learned from COVID 3D TRUST
- Badging with your Open Source Hardware Certification!

The Open Source Hardware Community is Important to Us!

COVID 3D TRUST Supporting Organizations

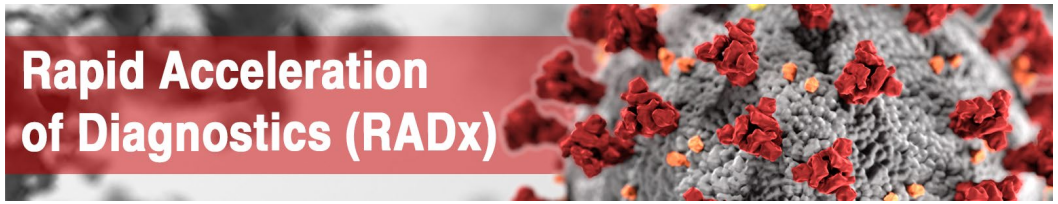
NIOSH

NIH National Institutes of Health Clinical Center

NASA

U.S.ARMY

DEVCOM CHEMICAL & BIOLOGICAL CENTER



ASME SETTING THE STANDARD

NATION OF MAKERS

RSNA®

AUTODESK.

Microsoft

OSMS Open Source Medical Supplies

COVID 3D TRUST Team

Meghan McCarthy, Ph.D.
3D Printing and Biovisualization

Phil Cruz, Ph.D.
Computational Structural Biologist

Matthew Di Prima, Ph.D.
Materials Scientist

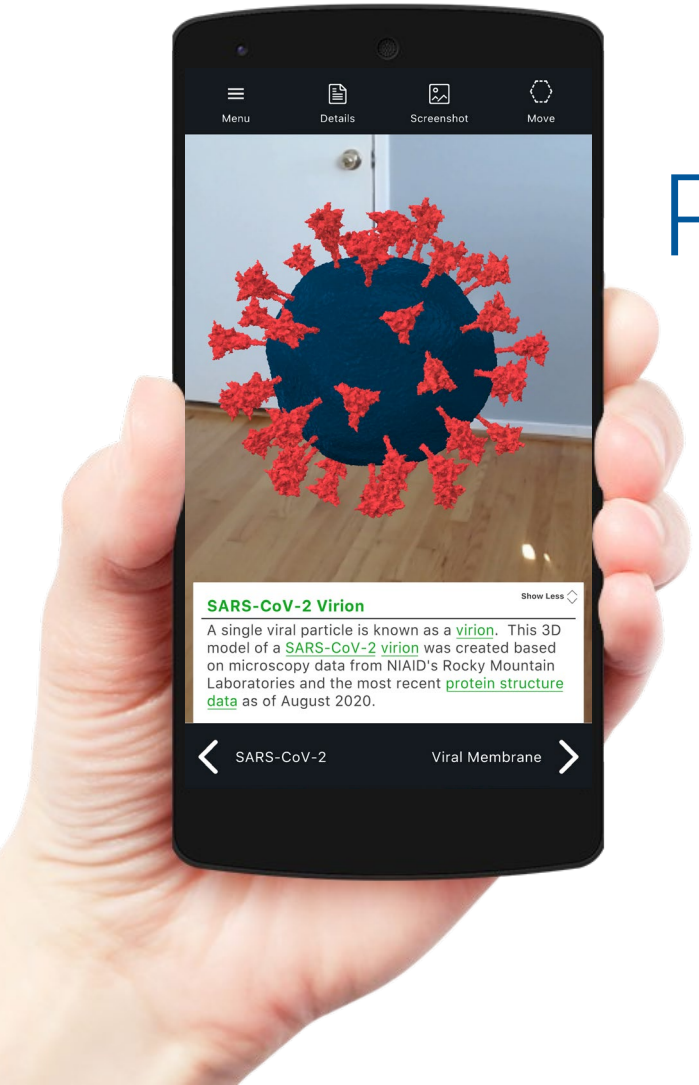
James Coburn, Ph.D.
Senior Advisor, Emerging Technologies

Beth Ripley, M.D.
Director, Innovation Ecosystem

John Wilczynski
Executive Director

Brandon Ribic, Ph.D.
Technology Director

More resources from our team

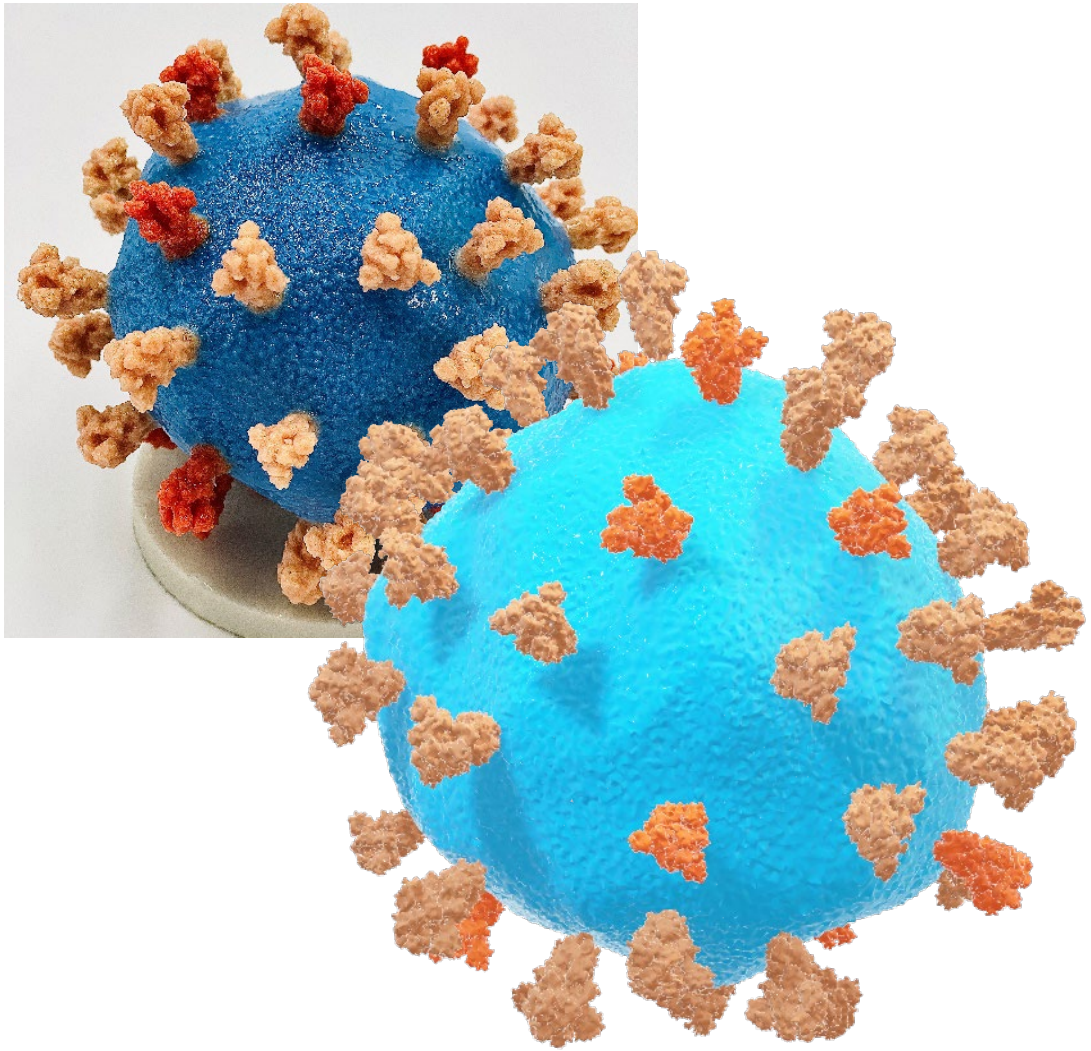


PathogenAR

Download on the App Store

GET IT ON Google Play

http://onelink.to/k6sbpv



https://3Dprint.nih.gov/niaid/sars-cov-2

SARS-CoV-2 virion modeled on cryoelectron microscopy data. A. Athman, K. Browne, and P. Cruz (NIH/NIAID) 3DPX-013323. Print by Victor Starr Kramer.

Thank you!

https://3Dprint.nih.gov

3Dprint@nih.gov

@NIH3DPrint

NIH 3D Print Exchange

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