Review of COVID-19 Capabilities and Needs Repository

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Overview

- Collaboration with the Food and Drug Administration (FDA), Department of Veterans’ Affairs (VA), and National Institutes of Health (NIH)

- Help ensure the additive manufacturing can effectively and safely meet the needs of America’s healthcare workers on the front lines of the Coronavirus crisis

- Intended for those within their organizations that have the authority within their organization to speak on behalf of the company and dedicate necessary resources
Why America Makes?

• The Department of Defense’s Manufacturing Innovation Institute (DoD MII) for additive manufacturing, part of the Manufacturing USA network

• The nation’s leading and collaborative partner in AM and 3D printing technology research, discovery, creation, and innovation

• Our mission is to drive collaboration within our industry to meet the needs of the U.S. government and manufacturing base – a mission more critical in the fight against the COVID-19 pandemic
Purpose

• The site streamlines the review process for uploaded designs, allowing manufacturers to rapidly create those items to prioritize delivery where it is needed most.

• The site will allow for reviewed 3D print designs to be available to additive manufacturers.

• The site matches industry capabilities with real-time needs of the healthcare community.

• The site positions the industry to continue to meet supply chain needs long-term.
How it works

NEEDS
Of the national health care community

DESIGNS
From a variety of sources

CAPABILITIES
Of the additive manufacturing community

NON-PROFIT ENTITY
Coordinating the capabilities of the additive community with the needs of the health care community
- Acts as “match maker”
- No responsibilities
- Resources to assist with contracting are available upon request from America Makes/NCDMM

FDA
Emergency Use Authorization

VA
Preliminary Evaluation

NIH
Housing Designs & Providing Taxonomy

Approved model repository

TEST DESIGNS
SHARE LESSONS LEARNED

Consultation

MODEL MARKED EMERGENCY AUTHORIZATION
What happens to the data?

The data collected will be used to:

• Act as a pathway for designs to be reviewed and tested for recommendation in a clinical setting.

• Connect the manufacturing community’s capability with the needs of the health care community to streamline supply chain structure
Health care providers

• We are asking that individuals coordinate needs submissions through their appropriate procurement channels

• Once your needs are submitted the system will match them with a manufacturer’s capabilities in your area

• The repository is not a marketplace, the manufacturer will be notified of your need and connect independently

• All designs, regardless of designation, will be placed on the NIH 3D Print Exchange with the appropriate label
Manufacturers

- Manufacturers capabilities will be visible by the America Makes team and government partners (FDA, NIH and VA) only.

- Critical information to include: materials, design tools, print capabilities and capacity.

- Best efforts in connecting the health care community with capable suppliers and will be notified through email.
Designers

- Designs submitted are intended to be open sourced and shared with additive manufacturers.
- Submitted designs will be fast tracked for review by FDA, VA, and NIH for recommended use in a medical setting.
- All designs, regardless of designation, will be placed on the NIH 3D Print Exchange with the appropriate label.
The Design Review Process

Submission
Designs are submitted through the America Makes repository

Review
Designs are reviewed by FDA, VA and NIH for recommended use in clinical settings

Designation and Placement
All designs are placed on the NIH 3D Print Exchange and available for use by manufacturers
The Design Review Process

All submitted designs will be labeled with 1 of 5 designations and placed as such on the NIH 3D Print Exchange

Designations

- PROTOTYPE
- DO NOT USE
- VA CLINICALLY REVIEWED Hospital Use
- VA CLINICALLY REVIEWED Community Use
- FDA EUA
For additional information

Questions
• Email us at covid19@americamakes.us

Regular updates
• Visit the repository for regular updates at www.americamakes.us/covid-19
• Join the mailing list at www.americamakes.us/join-maling-list

Media inquiries
• Email Andrew Resnick at andrew.resnick@ncdmm.org
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