America Makes

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America Makes

America Makes COVID-19 Response

Summary Brief of Phase 1 of America Makes' Advanced Manufacturing Crisis Production Response (AMCPR) Effort

November 2020

Executive Summary

Background

In March of 2020, the United States found itself embroiled in a global pandemic. In response, America Makes, the flagship Manufacturing Innovation Institute (MII), acted. As a leader in innovation for additive manufacturing, and in collaboration with an expansive network of federal agencies, private industry, academia, and state and local governments, America Makes was equipped to aid in the nation's response to COVID-19.

The rapid acceleration of the COVID-19 outbreak resulted in manufacturing disruptions and critical shortages of personal protective equipment (PPE), such as medical-grade face masks, face shields, gloves, and swabs. These shortages exposed vulnerabilities developed over the last few decades, due to the nation's reliance on globalization and the adoption of decentralized, offshore supply chains. In light of the emerging crisis, America Makes found its niche in the broader response effort and developed a response plan.

Our Approach: Convene, Coordinate, and Catalyze

America Makes established its place in the broader U.S. response to convene the manufacturing ecosystem; coordinate roles, resources, and tools; and catalyze the response mission and stakeholders to deliver results. This effort rapidly evolved into the "Advanced Manufacturing Crisis Program Response" (AMCPR) initiative, with America Makes in the lead.

America Makes looked to the DoD and its expertise around logistics and manufacturing; the VA, as the most extensive health system in the U.S.; the FDA, as an authoritative voice around regulatory requirements; and the NIH, as a leader in cutting edge research. The fast pace of the effort led the inter-agency partnership to leverage the existing technological infrastructure that supported the development of PPE design submissions and manufacturer and needs community engagement.

The healthcare community's specific needs were captured at a national scale and matched to vetted PPE design submissions. America Makes established platforms and processes focused on sensing the market and dialing in on PPE with the highest demand.

The AMCPR initiative embraced a "control tower" strategy for sensing public data, news, and social media, arming the team with the insights (e.g., PPE demand signals, regulatory updates) required to make decisions around the direction of their efforts.

Program Assessment

Through its relationships, America Makes was able to align efforts across government agencies (FDA, VA, and NIH) and build a process to prioritize and expedite the clinical review of promising open-sourced PPE designs. America Makes continues to establish itself as an authoritative voice for the additive manufacturing community and continues to drive that message across industries.

As of May 2020, the AMCPR online portal **engaged with 481 manufacturers**. The AMCPR partnership has **reviewed over 500 designs** for face shields, masks, and other PPE, with more than 31 reviewed for clinical use.

The NIH repository website has been viewed over a million times since the beginning of March 2020. The top 10 designs on the NIH repository have been **downloaded more than 70,000 times** since the start of the pandemic. Additionally, the manufacturers using the repository have reported the **printing and distribution of more than 280,000 units of PPE across the country**.

Throughout the COVID-19 crisis, additive manufacturing played a crucial role in supplying critical products to combat COVID-19, while global supply chains were interrupted. America Makes will continue articulating the value

proposition of hybrid (conventional and nonconventional) supply chains to enable a larger, more impactful response.

Crisis management involves responding to a continually evolving environment, often requiring rapid decision making and building solutions in parallel, without prior consideration or planning. The America Makes team used an agile approach to learn quickly and adapt. As processes improved, the team tracked their successes and persistent challenges, and critical lessons learned stood out to shape the next phase of the effort. These give rise to three major themes:

1. Establishing Inter-agency Partnerships:

- Identification and documentation of each institution's unique role is vital in understanding how data should be shared and communicated to various stakeholders and end-users.
- Including regulatory considerations with each design submitted helped build confidence and gain public trust in the database of designs collected by America Makes. The support of the FDA, NIH, and VA was critical in establishing America Makes as an authority in the space.

2. Engaging Member Networks:

- Many design submissions did not translate to a diverse range of solutions. Those designs suffered similar issues and were not addressing the real need from the medical community. It is key to communicate to designers fluctuating demand signals as local and regional PPE needs change, sometimes even daily.
- Vibrant, coordinated ecosystems enable rapid communication and feedback loops, resulting in higher quality design solutions. An improved demand picture helps to identify gaps and steer the community to the most critical need.

3. Operationalizing Infrastructure & Resources:

- America Makes initially leveraged its existing Customer Relationship Management (CRM) platform. While this allowed the team to mobilize quickly, it did not meet the team's need from an operational standpoint; limited compatibility with the NIH online repository required manual data migration from system to system.
- Enduring infrastructure to house critical PPE designs for the healthcare community is a necessary, proactive investment to address future nationwide crises. A system designed to address a pandemic and general crisis management requires robust functionality outside of design submission and inspection. As the central player in this effort and future efforts, America Makes recognized the value in building its infrastructure, explicitly dedicated to crisis management.
- In a rapidly changing crisis with widespread national effects, a “control tower” strategy for sensing public data, news, and social media can be important for decision making and direction of efforts.

It is clear that this crisis is not over, and there is more work to be done for the U.S. to effectively transition to the Recovery and Resiliency phase of the pandemic. America Makes will continue to promote the AMCPR’s role and value in the nationwide response. Continued support in conceptualizing, developing, and structuring new facets of this initiative is critical as America Makes expands its scope to enhance U.S. capabilities in times of crisis.

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List of Abbreviations

AMCPR	America Makes' Additive Manufacturing Crisis Production Response
CDC	Centers for Disease Control and Prevention
DoD	Department of Defense
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HHS	Health and Human Services
MOU	Memorandum of Understanding
NCDMM	Mobilized National Center for Defense Manufacturing and Machining
NIH	National Institutes for Health
NIOSH	National Institute for Occupational Safety and Health
PPE	Personal Protective Equipment
VA	Veterans Affairs
WHO	World Health Organization

Introduction

When the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic in early March 2020, countries worldwide locked down their borders and economies and braced for a surge in hospitalizations. Demand for critical goods, including personal protective equipment (PPE), medical devices, and diagnostic testing equipment, skyrocketed as consumers ranging from governments to hospital systems to even individuals attempted to stockpile supplies. This explosive demand created an immediate shortfall and left many frontline workers without the supplies they needed to stay safe and attend to patients. Shocks to global and local supply chains left manufacturers, distributors, and retailers unequipped to meet the sudden spike in demand. By the end of March 2020, the United States was among the countries with the highest infection and hospitalization rates [1]. National leadership realized the immediate need for the U.S. government and manufacturing community to act and called upon the expertise and networks of the DoD, VA, FDA, NIH, and America Makes.

In the early days of the pandemic, America Makes, as the flagship Manufacturing Innovation Institute, coordinated the federal inter-agency response and began mobilizing the additive manufacturing community to address medical equipment shortages. The Institute recognized its unique position as a government-sponsored organization with a member network of private and industrial partners and its ability to support using additive manufacturing's rapid and flexible response capability. The nationwide additive manufacturing ecosystem has continued to step up during this crisis, showcasing its ability to react quickly using distributed capacity and activate local, regional, and national supply channels to continue to fulfill points of need.

Crisis Response Approach

Through participation in a series of interactive, virtual workshops, America Makes with support from a trusted partner, Deloitte Consulting LLP (Deloitte), established three pillars that framed the space in which America Makes could operate and support the national response to COVID-19:

- **Convene** the additive manufacturing ecosystem: inter-agency partners, Institute membership, and non-member designers and makers
- **Coordinate** the tools, processes, and resources to support the response
- **Catalyze** mission and stakeholders into actionable results

The report is structured around the above-referenced approach and narrates America Makes' activities from the middle of March through Phase 1 at the end of May 2020 that aimed at addressing a crisis all Americans were facing. The pandemic presented an opportunity where America Makes could demonstrate its value and reach through its network of resources, members, and partnerships to make a real, lasting impact on a national, public scale. To build on that momentum, America Makes has continued to work on combating COVID-19 and is defining a path forward for how the organization can support nationwide responses to crises in the future.

Convene – Genesis of Effort

Grassroots Effort

As individual states began to enact Stay-at-Home orders, America Makes anticipated the impact on state and local economies and disruptions to their supply chains. America Makes engaged with its members, a

[1] Weekly Coronavirus Situation Reports 31 March 2020

diverse group of additive manufacturing ecosystem players, ranging from large multi-national corporations to interested hobbyists, to discuss the immediate and downstream impacts. Through these conversations, America Makes found members asking two primary questions:

1. How do we help make an impact?
2. Where does additive manufacturing fit into the response effort?

Concurrently, individuals were publishing designs for 3D printed PPE online in support of a national response. However, much of this effort largely ignored regulatory guidance. These designs caused manufacturers to raise further questions and concerns:

- How does one evaluate and trust designs available online?
- How does one understand the evolving regulatory landscape, and where should one go to get trusted information?
- How does one navigate IP and Legal concerns of using open-source designs?
- How does one understand demand signals for these products?

America Makes as Convener

The Executive Director of America Makes recognized the growing need for the organization to spearhead an effort to convene and catalyze the additive manufacturing community in a coordinated response to the evolving COVID-19 crisis. America Makes communicated the value in convening the additive manufacturing community in a letter to the FDA Commissioner Stephen Hahn, emphasizing the need for a collective, organized response. Within two weeks of circulating that letter, America Makes had begun orchestrating a public-private partnership. The result was a memorandum of understanding (MOU) between the VA, FDA, and NIH. This cooperation ultimately gave rise to America Makes' Additive Manufacturing Crisis Production Response (AMCPR) initiative.

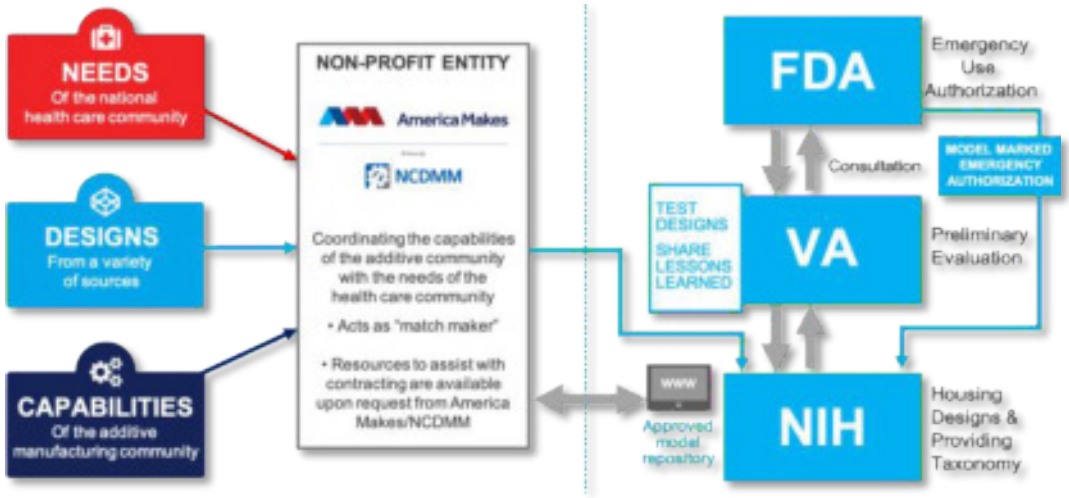


Figure 1. *Inter-agency Partnership Workflow Diagram*

Figure 1 illustrates the interconnected processes established amongst America Makes and its federal partners. America Makes took responsibility for collecting information from designers with models and drawings intended to meet PPE demand needs, manufacturers with available production capabilities, and the needs community requesting PPE supply. The needs community included hospital workers, first responders, frontline workers, and others in need of medical equipment.

America Makes worked with the NIH to confirm the designers submitting engagement forms on the America Makes portal were also directed to the NIH model database to present the design specifications. Once submitted to the NIH online database, the VA could download and print the designs for testing. If a design necessitated further consultation, the FDA would conduct a second test and provide an Emergency Use Authorization for the design's use for clinical purposes. After test completion, finalized designs were uploaded onto the NIH model repository website, where manufacturers accessed the designs to begin 3D printing.

America Makes was an integral partner in this effort. It was able to leverage its relationships with the federal government through its cooperative agreement and subsequent MOUs and the additive manufacturing community. Therefore, the Institute was well-positioned to effectively link national strategy and regulations to a commercial, local response.

Standing Up the AMCPR Initiative

In partnership with Deloitte, America Makes formally shaped its strategic, longer-term response into the Advanced Manufacturing Crisis Production Response (AMCPR) initiative. The mission quickly became apparent – leverage a distributed model to mobilize conventional and unconventional domestic supply chains to support the growing demand for medical equipment.

Key Consideration: The concept of a public-private, distributed digital advanced manufacturing supply chain was not proven or demonstrated before the inception of AMCPR. A central authority is needed to convene the ecosystem and provide de-risking and capital investment for a successful distributed model to work with small- and medium-sized manufacturers. A distributed model seeks to accelerate production while reducing regulatory, technological, and economic barriers.

At the heart of the AMCPR, America Makes positioned itself to act as a trusted voice to the additive manufacturing community, providing structure, support, and organized processes to safely create designs that enable the production of additively manufactured products. To do so, America Makes set out to establish an online portal to identify the needs of health care providers, qualify U.S. additive manufacturers' capabilities, and collect a list of clinically reviewed 3D print designs.

Key Lesson Learned: America Makes initially leveraged its existing Customer Relationship Management (CRM) platform. While this allowed the team to mobilize quickly, it did not meet the team's need from an operational standpoint; limited compatibility with the NIH online repository required manual data migration from system to system.

America Makes utilized a 'Tiger Team' approach, allowing the formation of focused teams to address a subset of challenges faced by the broad program. The Tiger Teams consisted of resources from NCDMM and Deloitte to provide balanced support and additional capacity to respond quickly and react to the evolving project requirements. The Tiger Team structure defined at the program's inception evolved throughout the course of Phase 1 to respond and adapt to the rapidly changing health landscape in the U.S. By the conclusion of Phase 1, Tiger Teams included:

- *Ecosystem Building* – Focused on bringing together a mix of Institute members, non-members, as well as media and maker networks, to support the AMCPR effort

- *Product Identification* – Focused on understanding the products needed by the extended ecosystem to mitigate shortages and other risks. This team also focused on "matchmaking," connecting the needs community with the supplier community.
- *Process and Technology* – Focused on deploying structured technology and process required to bring AMCPR to life
- *Regulatory* – Focused on understanding the regulatory environment, risks, and barriers, as it pertained to the different members of the AMCPR ecosystem

These tiger teams worked in parallel to stand up and establish the platforms, tools, and processes key in carrying out the AMCPR mission.

Coordinate – Design and Engagement Platforms and Tools

As the teaming structure of the effort was established, America Makes also turned to its inter-agency partners to determine the platforms and tools best suited to support engagement with the manufacturing ecosystem. The fast pace of the effort initially led the partnership to leverage existing technological infrastructure to shape PPE design submission and manufacturer and needs community engagement.

NIH 3D Print Exchange

The NIH 3D Print Exchange**(Figure 2)**, a public-facing website, was initially used to house a broad range of 3D printable designs. The AMCPR effort leveraged the site as a searchable repository of open-source models in formats compatible for use on a wide variety of additive manufacturing equipment. Designs were submitted and placed in a fast track review cycle for evaluation by the FDA, VA, and NIH to determine use in a health care or community setting. Upon review, the AMCPR team placed designs on the NIH 3D Print Exchange with one of the following review designations:

- *Clinical Use* – Indicates that design is appropriate for healthcare workers in contact with patients who have tested positive or show symptoms of COVID-19. Devices in this category may have different requirements and classification by the FDA. Designs with Clinical Use status have been printed by the VA Innovation Ecosystem team with the printer types and materials specified and evaluated in a clinical setting.
- *Community Use* – Indicates that design is suitable for workers in grocery stores, restaurants, law enforcement, or in general, use interacting with others. Community use designs have been tested for fit, efficiency, and reliability when the wearer is not in direct contact with a person diagnosed or suspected of having COVID-19.
- *Prototype* – All designs are automatically tagged as a Prototype upon submission. The designation means a Prototype is not reviewed. As such, the VA Innovation Ecosystem reviewers cannot recommend them for use, so users should exercise their best judgment in deciding to use these designs over others. Exceptions to this initial tagging are models that: (a) require FDA approval or emergency use authorization, or are associated with health and safety risks, (b) models that have already been submitted for FDA approval, (c) designs that already have FDA emergency use authorization.
- *Warning* – Indicates that design that requires FDA approval for use and, by the nature of their design or application, could introduce risks to health and safety. Users should proceed with caution.

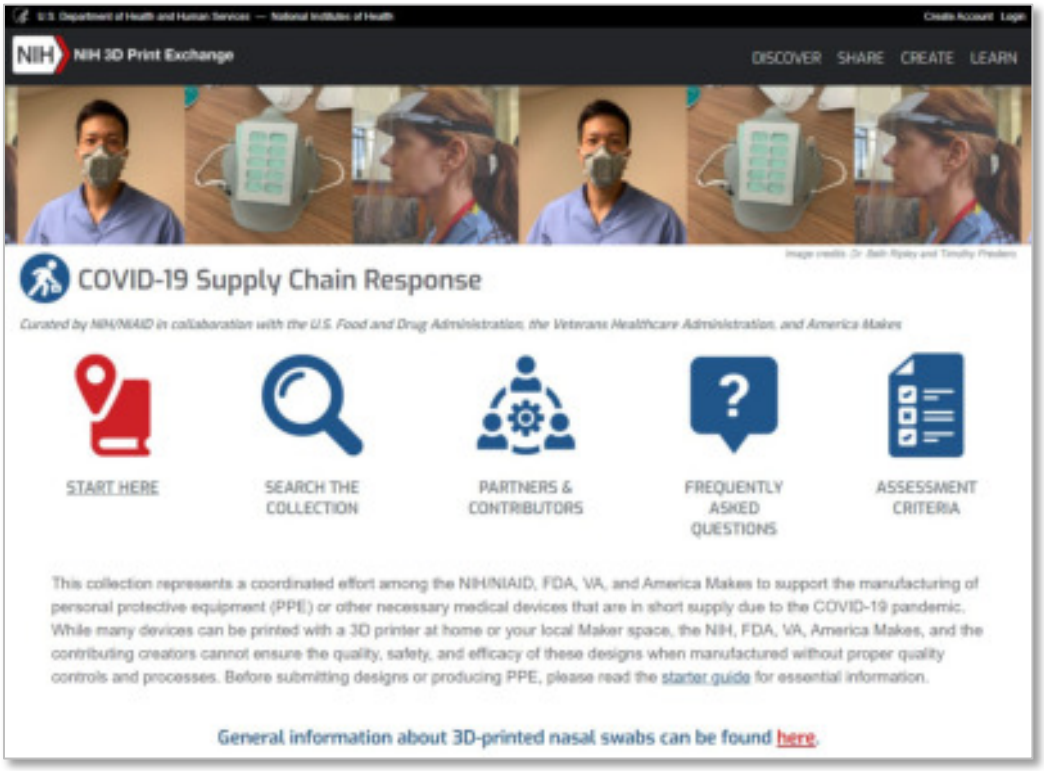


Figure 2. *NIH 3D Print Exchange Homepage*

While the repository was already in use before the COVID-19 crisis, America Makes worked with the NIH to update the site's functionality, explicitly adding design filter functionality to allow end-users to query for a specific design of review designation.

Key Lesson Learned: Enduring infrastructure to house critical PPE designs for the healthcare community is a necessary, proactive investment to address future nationwide crises. A system designed to address a pandemic and general crisis management requires robust functionality outside of design submission and inspection. As the central player in this effort and future efforts, America Makes recognized the value in building its infrastructure, explicitly dedicated to crisis management.

Product Review Matrix

The Product Review Matrix was created to organize designs and identify the best candidates for production. Only after design submission to the NIH 3D Print Exchange, testing, and deemed 'acceptable for community use' or 'acceptable for clinical use' could an item be added to the Product Review Matrix.

Table 1 lists the product information collected and tracked for those designs deemed 'acceptable for community use' and 'acceptable for clinical use':

Key Consideration: The need for the Product Review Matrix was realized after designs were submitted on the NIH 3D Print Exchange. Thus, and because America Makes did not control the NIH 3D Print Exchange, data was manually collected and tracked in the matrix.

Product Review Matrix Criteria	
Product and Design Identification	Product Matrix Number ID
	NIH Main Category
	NIH Subcategory
	America Makes Product Type
	NIH Design Name
	NIH Model ID
	NIH Model Description
	Point of Use
Manufacturing Requirements	GMP Accreditation Requirement
	Machine/Equipment Requirement
	Materials Requirement

***Table 1**. Product Review Matrix Data Inputs*

The information collected around each product was an important input into identifying the manufacturers best suited to produce PPE in demand by the needs community.

America Makes Engagement Portal and Database

In building out the submission process, America Makes developed a landing page on its website dedicated to the effort entitled "Fighting COVID-19 with 3D Printing" **(Figure 3)**. The webpage allowed parties to submit PPE needs, production capabilities, and designs and acted as a throughway for designers to submit them to the 3D Print Exchange.

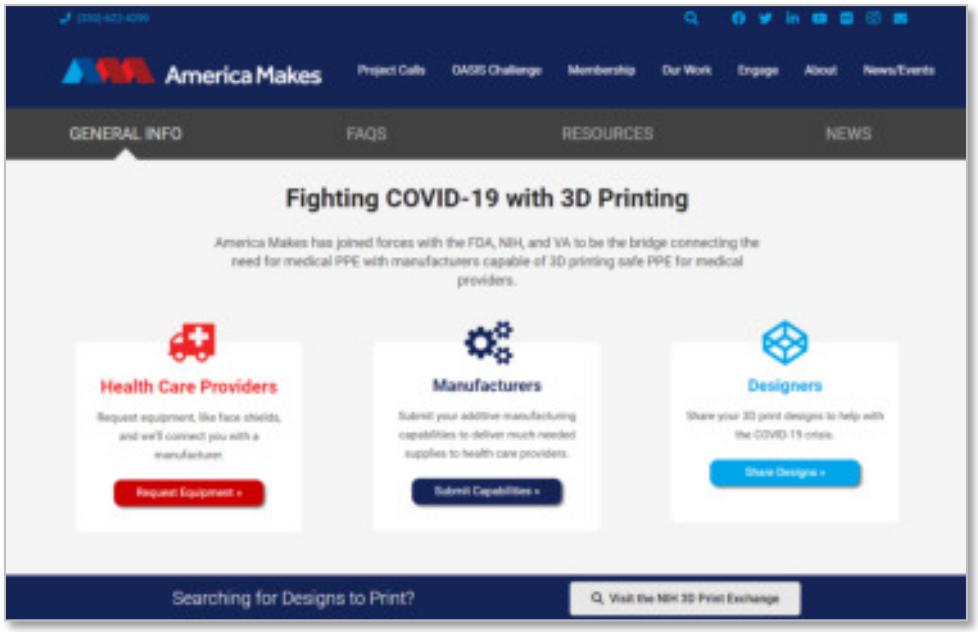


***Figure 3.** America Makes Website COVID-19 Response Portal*

The portal serviced three different groups:

- *Healthcare providers* and other members of the needs community requested PPE through a web form with built-in functionality that prompted the end-user to select directly from the NIH 3D Print Exchange catalog of designs reviewed for clinical use by the FDA. PPE inquiries were submitted from a wide range of facilities all around the nation, including hospitals, schools, long term care facilities, therapy services, surgical centers, and fire departments.

- *Manufacturers* could access a separate web form and submit their additive manufacturing capabilities and select directly from the NIH 3D Print Exchange interface the medical equipment they were equipped to make. The form also requested certification and accreditation information, design tools and engineering services, and inspection and testing conducted during production.
- The system prompted designers to follow a two-step process. Step 1 included accessing and submitting a web form providing detailed design information on the America Makes Portal. Step 2 navigated the end-user to the NIH 3D Print Exchange site, where design specifications were to be submitted for review.

Key Consideration: The America Makes Portal was not fully integrated with the NIH 3D Print Exchange site due to timing and the rigor required to build, test, and deploy such integration.

Data collected from the forms was tracked and maintained in a repository. Metrics and insights were pulled from the data within the form submissions and reported to the broader team daily. The team also created maps visualizing where PPE requests were coming from relative to where applicable manufacturers were geographically situated **(Figure 4).**

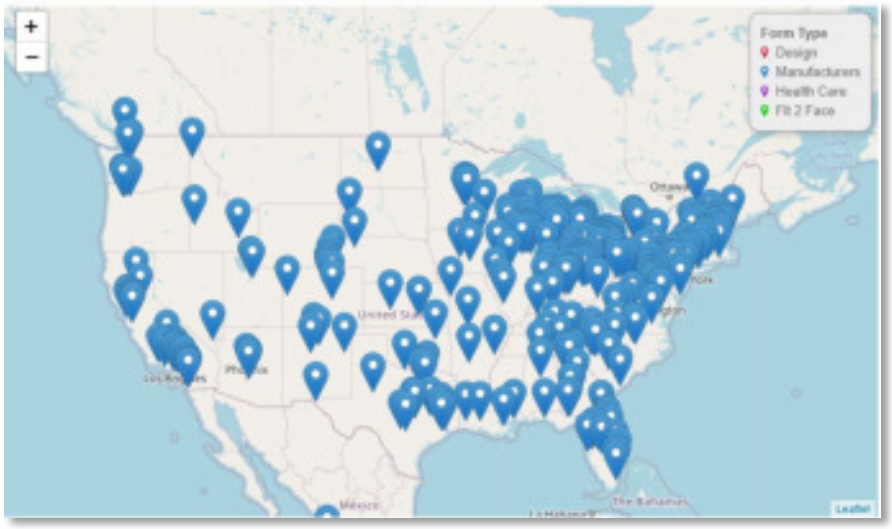


Figure 4*. The geographic location of manufacturers that engaged with the AMCPR initiative*

Coordinate – Design and Engagement Processes

Need for Process Documentation

As America Makes continued to oversee and manage the evolving design submission process, the need to further refine and codify processes and subprocesses became apparent. The team organized and mapped the end-to-end processes for design submission, review, and need identification into three discrete process areas:

1. Designer Submission Process,
2. Coordinate & Execute Test Process, and
3. Need, Manufacturing, Matchmaking Process

The process maps drilled down to unique process steps and denoted decision points, linked subprocesses, decision points, data transmitted between partners, and documentation (e.g., forms) produced. The maps

also distinguished which inter-agency partner was responsible for each activity, as observed in the excerpt from the Designer Submission Process in **Figure 5.**

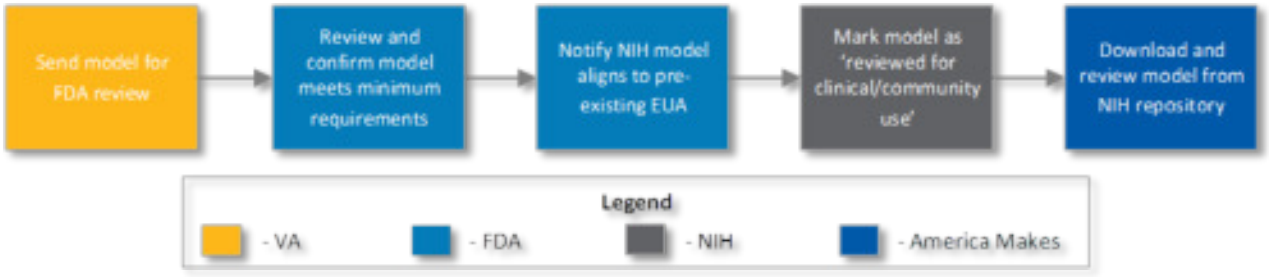


Figure 5. *Process map excerpt of PPE design submission process*

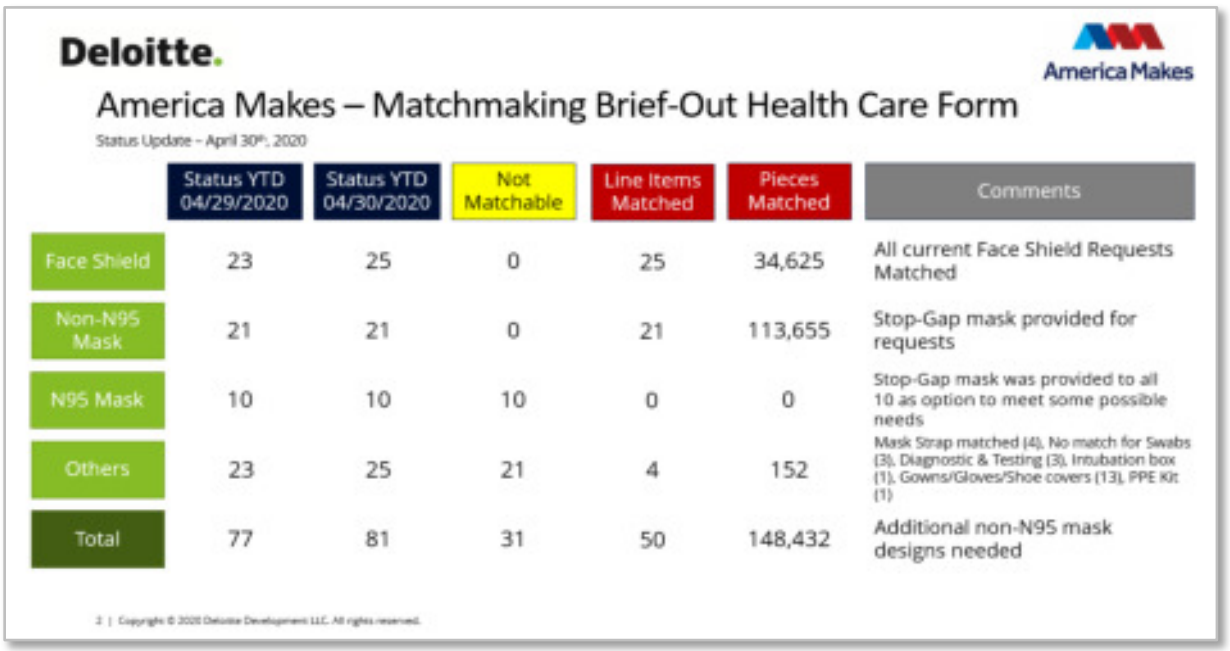
Matchmaking Evolvement

When a PPE request was submitted through the America Makes Portal, the supply network was queried to identify manufacturers fit to produce the requested equipment. The Product Review Matrix helped to define that matchmaking process by answering the following questions around the product being requested:

- Does the product require a GMP accredited manufacturer?
- What type of machine and other equipment is required to manufacture?
- What materials are needed to manufacture?

With the above product context and an understanding of the manufacturer's capacity, America Makes could facilitate pairing the needs request and the appropriate maker.

Each week the status of requests for face shields, N95 masks, and other PPE was consolidated into a report **(Figure 6)** and circulated to the internal team.



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America Makes – Matchmaking Brief-Out Health Care Form

Status Update – April 30th, 2020

	Status YTD 04/29/2020	Status YTD 04/30/2020	Not Matchable	Line Items Matched	Pieces Matched	Comments
Face Shield	23	25	0	25	34,625	All current Face Shield Requests Matched
Non-N95 Mask	21	21	0	21	113,655	Stop-Gap mask provided for requests
N95 Mask	10	10	10	0	0	Stop-Gap mask was provided to all 10 as option to meet some possible needs
Others	23	25	21	4	152	Mask Strap matched (4), No match for Swabs (3), Diagnostic & Testing (3), Intubation box (1), Gowns/Gloves/Shoe covers (13), PPE Kit (1)
Total	77	81	31	50	148,432	Additional non-N95 mask designs needed

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Figure 6. *Weekly Matchmaking Outbrief Report*

Key Consideration: The team retroactively developed an 'ideal' matchmaking process through which the effort did not end when the match was made between the need requester and the manufacturer. The ideal-state process incorporated a tracking application through which the manufacturer communicates updates on production and distribution status. The requester would formally review the build and performance of the final product. This process was not delivered up during Phase 1, given resource and technical limitations. Instead, the priority was on production turnaround to address demand.

Roles and Responsibilities

As the technology and associated processes were refined and socialized among the inter-agency partners, the need to map out each organization's discrete roles and responsibilities also became apparent. The partnership relied on each organization working closely together, sharing resources, and those interdependencies further necessitated transparent governance and role structure. Roles and their inherent responsibilities were organized around the design, needs, and manufacturing submission processes, as seen in **Table 2**.

Process	Roles	Responsibilities
Design Submission	Model Reviewer America Makes	• Reviews model, marks model as prioritized, notifying NIH
	Strategic Design & Supply Committee	• Prioritizes the designs • Assesses the design risk: demand signal, regulatory, safety, performance
	Model Reviewer NIH	• Reviews model, marks model as a warning of any deficiencies. • Notifies VA on prototype status
	VA Design Tester	• Prints the design and tests • Records and publishes results • Notifies the FDA that design is tested
	FDA Reviewer	• Review results, assess if the device falls within existing EUA's or recommends new EUA be issued.
Needs Submission	Match Maker Needs Liaison	• Reviews the need submission, requests any additional information. • Notifies Product team to Update Prioritization Matrix if applicable • Compare the need against the supplier list and interrogate mfg. criteria Geography/Capability/Capacity, and expands the search as needed • Reports out metrics on needs submissions and matches made. • Crafts email with a list of contacts and emails Need submitter with contact info for suppliers. • Tracks the quality of the match and follows up with parties 1-2 weeks after initiation.
Manufacturing Submission	Manufacturing Match Maker	• Filters and cleanses data collected from forms that are stored in SQL database • Reviews the manufacturing submission, requests any additional information. • Maintains manufacturing matrix (spreadsheets in SharePoint) • Reports out Daily Metrics on manufacturing submissions • Connecting with manufacturers when needed to assess capabilities/capacities

Table 2. *Roles and responsibilities table by submission process*

Key Lesson Learned: Identification and documentation of each institution's unique roles are vital in understanding how data should be shared and communicated to various stakeholders and end-users.

The America Makes team took the exercise a step further by developing a Reliable, Accountable, Consulted, and Informed (RACI) Matrix by assigning the America Makes tasks to specific individuals or Tiger Teams. **Figure 7** evidences a reliable (R) party and an accountable (A) party were always designated for each job. A majority of the tasks also were assigned multiple informed (I) parties, given the interdependencies of the tasks.

Process	Task	Model Reviewer (Bill Walch)	Match Maker Needs Liaison (Scott Crynock)	Manufacturing Match Maker (Ashley Tolin)	Strategic Design & Supply Committee	Strategic Communications	Regulatory/Strategic Design & Supply (Brandon Ribic)	Product Identification Team	Alexander Steeb	John Wilczynski
Design	America Makes Team member accesses NIH repository, reviews the model marks as prioritized and Notifies Product Team of new Design	R			C	I	A	I		
	Product Team updates Product Matrix	I	I	I	C		C	R	A	
	Review Product Matrix and submits request to tech team to update Needs form		R	I	I	I	I	I	A	
Needs	Daily Metrics on needs submissions are Reported out		R	I	I	I		I	A	
	Reviews the submission Compare the need against the NIH reviewed models list		R	I	I	I		I	A	
	Notify Product team to Update Prioritization Matrix if Applicable	I	R	I	I		I	I		
	Update Prioritization Matrix if Applicable	I			C		A	R	C	I
Manufacturing	Export submission data from SQL data base, filter and cleanse spreadsheet for daily metric reporting			R					A	
	Reviews the submission for completeness, request additional information if needed			A/R						
	Manufacturing Matrix (spreadsheets in SharePoint) is Updated & Daily Metrics on manufacturing submissions are Reported out			A/R	I	I	C	I		

***Figure 7**. RACI Matrix by submission process*

As the platforms, processes, and roles and responsibilities were established and further refined, America Makes was able to shift more of its focus to sensing the market and dialing in on PPE in highest demand.

Catalyze – High Priority Products and Trends

With a complete understanding of how grassroots response efforts were evolving, America Makes refined its response, ensuring all players moved in the same direction. They established the NIH 3D Print Exchange as the repository for model and design submissions resulted in a strong response from the designer and manufacturing community. Over 400 manufacturers registered through the portal, all wanting to use their unique skills to help the nation in crisis. It became clear that the team needed a way to evaluate individual designs based on objective criteria systematically.

Key Consideration: While the NIH 3D Print Exchange was not designed to evaluate designs, the team needed a platform solution that could be leveraged immediately. The lack of features, such as filtering and tagging, meant that much of this needed to be done manually on the America Makes team's back end.

Establishing Priority

To evaluate the hundreds of design submissions the AMCPR received, the America Makes team compiled a list of criteria to factor into the final product ranking. **Table 3** lists the data collected for each design submitted to the NIH 3D Print Exchange.

Product Prioritization	
General	Product category
	Appropriate for AM?
Regulatory Criteria	Classification
	Product Code
	GMP Required
	Existing EUA / Guidance
	Enforcement Discretion from COVID Guidance
	Compliance with other standards required?
Manufacturing Criteria	Part complexity
	Capacity available?
	Short-term feasibility
	Long-term Feasibility
Demand Criteria	Supply Gap

Table 3. *Product Prioritization Criteria*

Each of the inter-agency partners was assigned criteria for which they were responsible for evaluating. The design submissions were assessed, and high-ranking designs were given priority for further review and testing by the VA. The overall flow from design submission to full product testing using this evaluation system is illustrated in **Figure 8**.

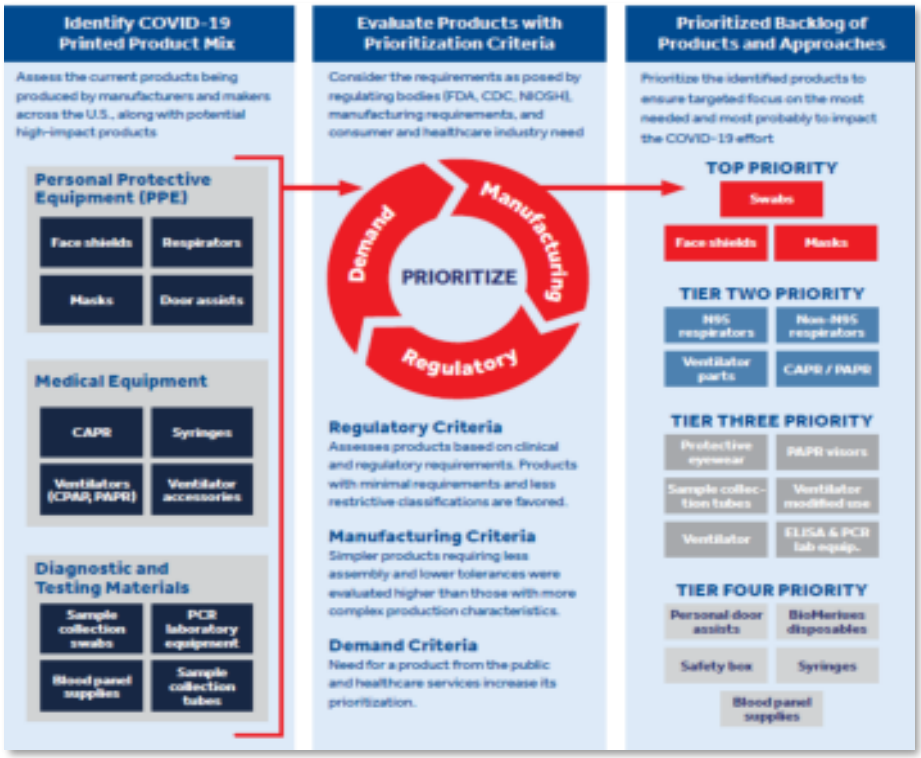

Figure 8*. Design submission and initial evaluation process flow to establish priority*

This framework enabled vital players to quickly understand product flow and how each evaluation point connected to a final priority ranking. The VA printed top-ranked design submissions and subjected them to a formal review process, during which they were designated as appropriate for either community use or clinical use (see above).

Market Sensing and Communications

The rapid pace of crisis response efforts necessitated multiple players and actions taken in parallel. Evaluation and ranking of designs, for example, required understanding of public needs and how events were unfolding across the country. To provide a meaningful approach to product prioritization and focus and pivot other efforts, the team needed to gather a broad context.

Key Lesson Learned: In a rapidly changing crisis with widespread national effects, a "control tower" strategy for sensing public data, news, and social media can be important for decision making and direction of efforts.

The evaluation criteria and ranking system were informed by continuously monitoring developments and regulations that guided manufacturing and use requirements. Web scraping tools and accelerators, brought by Deloitte, allowed for automated approaches to gathering news, infection data, and regulatory changes. Predictive social media, media sensing, and social listening platforms facilitated efficient decision making. To best organize this rapidly evolving information, the America Makes team built a dashboard, focusing on five key areas of interest: 1) news highlights, 2) matchmaker/designer information, 3) PPE demand signals, 4) manufacturer information, and 5) regulatory news. The data was refreshed daily and aggregated into biweekly Sensing Brief reports, providing digestible insights to support efficient decision making. **Figure 9** shows a Brief compiled in April from early in the response effort.

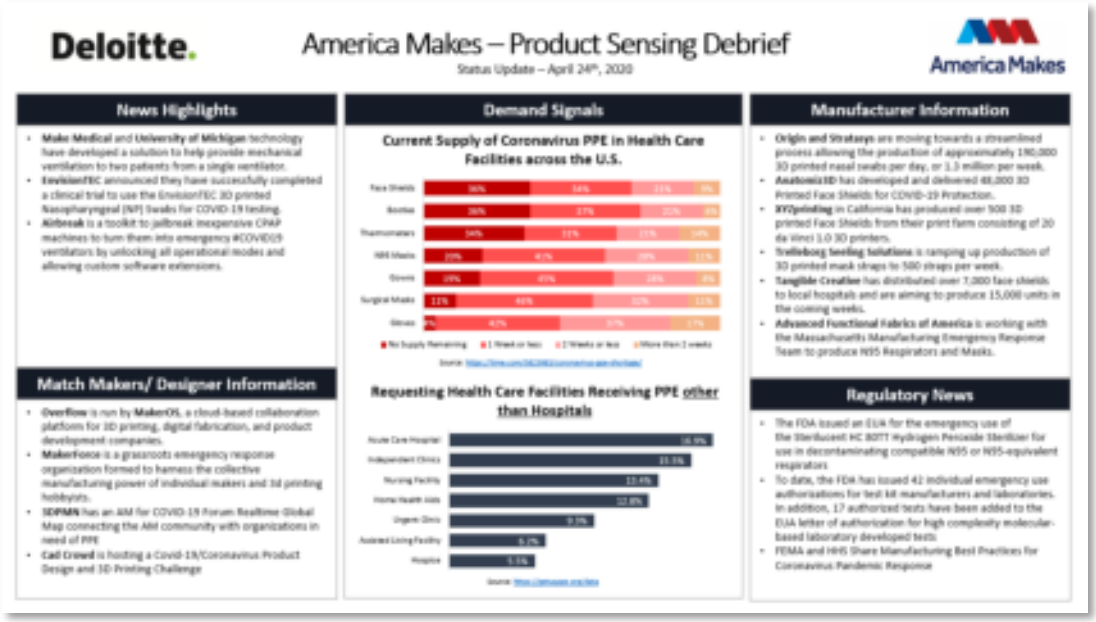

Figure 9. Sensing Brief example

Further development of the product and increased participation and engagement enabled the team to include location data and establish links between demand and regional infection spikes. Regularly updated information was critical to focusing on relevant issues and addressing the most pressing challenges.

America Makes' unique position as a public-private partnership, with a member network in the additive manufacturing community, provided valuable access to insight and relationships. Submissions through the America Makes online portal allowed the team to monitor regional demand for specific products, how that demand changed overtime, the regulations associated to those products, and how regions responded. **Figure 10** illustrates how location data can quickly uncover trends and use distributed capacity to connect with regional needs.

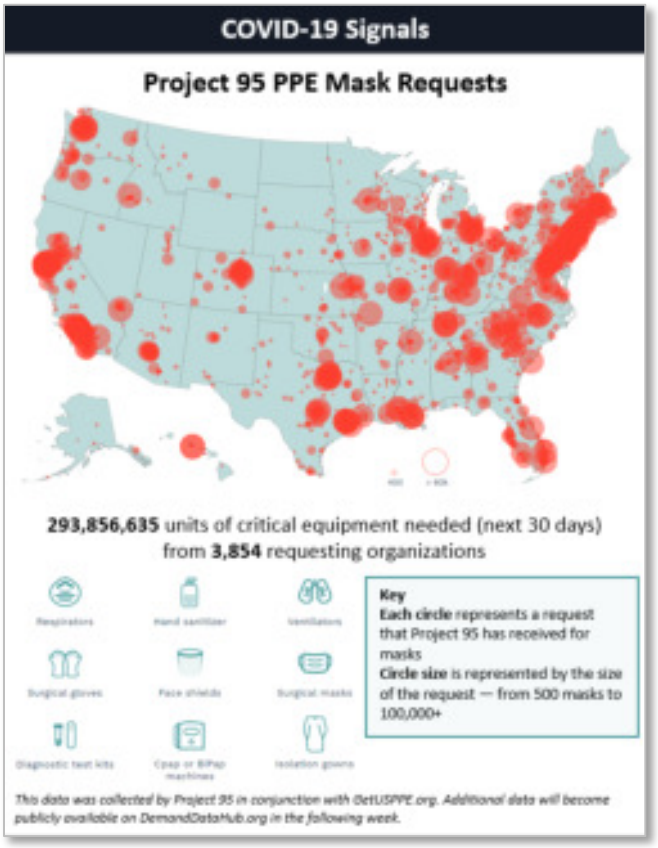

Figure 10. *Representation of regional PPE needs*

The data included in Sensing Brief reports varied slightly depending on how trends had changed. However, the format remained consistent, and routine monitoring of public data remains an essential element of America Makes' long-term crisis response plan.

Through the Sensing Briefs, the America Makes team discovered many other organizations committed to matching designers and manufacturers to PPE requesters. The analysis uncovered a matchmaking effort in nearly every state and some that were already providing this service reasonably successfully. Organizations such as Get Us PPE, driven by Google, excelled in user engagement and outreach, data visualization, and user experience. Rather than attempt to compete with these organizations and potentially convolute the space, America Makes shifted its focus. They established a primary goal of providing a trusted voice, a destination where users can find reliable, up-to-date information, and validate designs.

Key Consideration: Web scraping and media sensing highlighted an organic willingness from the public to get involved; however, leadership and coordination through targeted communication and engagement were lacking, resulting in unfocused and duplicative efforts, as well as designs that had not considered regulatory requirements.

Sensing Briefs also enabled the America Makes team to stay current with what their member networks needed most and what was still lacking from current offerings. When they started comparing their engagement database with the trends they saw in the news, there were immediate indicators that a general widespread request for designs was not effective in addressing individual needs. America Makes' design submission repository had received hundreds of designs for face shields and 27 designs for face masks. However, in the Sensing Brief reports, it became apparent that face shields were neither in high demand nor incredibly challenging to design and produce. Face Masks, however, were much more challenging, precisely due to the difficulty in fitting a mask to a wide range of individuals.

The critical function face masks served for the medical community in clinical use led to increasingly stringent regulations and rapidly growing demand. **Figure 11** evidences the additive manufacturing community's response to the PPE shortage, with an overwhelming focus on face shield production.

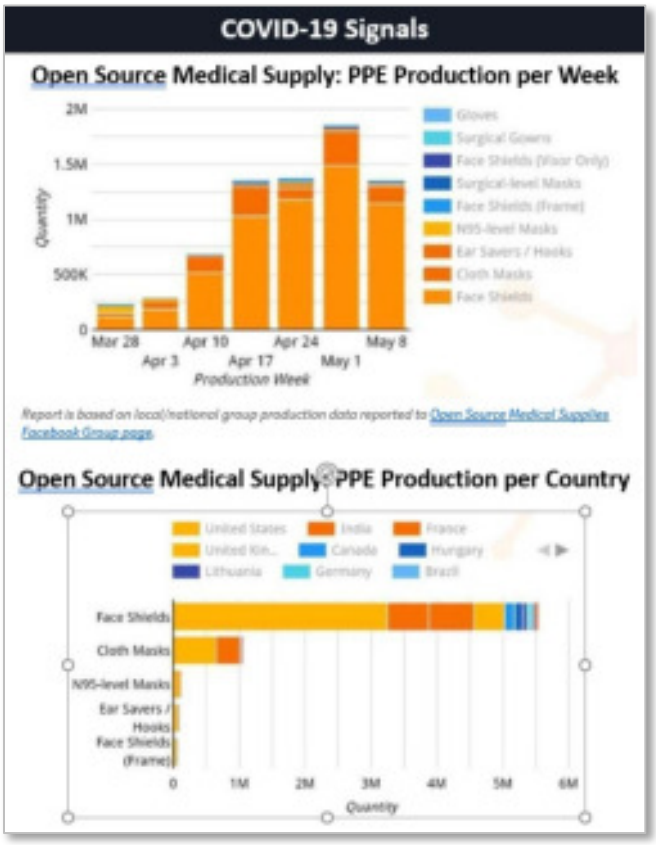

Figure 11. *PPE production by type*

The relatively low attention given to face mask design and production yielded options that were not meeting the healthcare community's needs. Many available mask designs would only work for a specific size or shape of a face or provide an adequate seal for clinical use. The shortcomings of available mask

designs inspired the America Makes team to mobilize their network by issuing a much more focused directive.

Key Lesson Learned: Many submissions did not translate to a diverse range of solutions. Many designs suffered similar problems and were not addressing the real need from the medical community. It is key to communicate to designers fluctuating demand signals as local and regional PPE needs change, sometimes even daily.

Fit to Face Mask Challenge

Once the America Makes team established a focal point for how their organization can be most effective, they decided to catalyze their member network with an intentionally narrow design challenge. The Fit to Face Challenge was modeled after similar design challenges and solicited participants to create designs that used a novel approach to address one discrete challenge. **Figure 12** shows the steps a prospective participant would take to enter the Design Challenge.

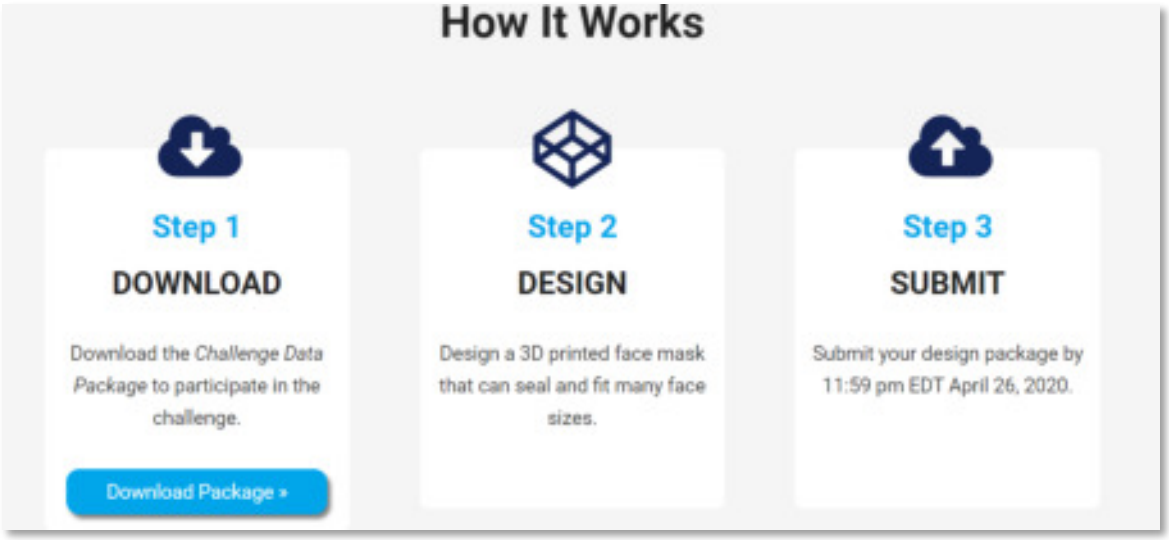

Figure 12. *The submission form for Fit to Face Challenge*

Participants submitted designs that met very narrow criteria to encourage a wide range of solutions to a specific challenge: face masks to fit diverse face sizes and shapes. NIOSH provided 3D models for head forms in five sizes for designers to work with. One week after the submission deadline, the designs were reviewed by a panel of representatives from America Makes, VA, and FDA. The top mask designers were notified that they passed the first round of review and given specific feedback. These designers were able to incorporate the feedback into their design before resubmitting. Top design winners received membership benefits, and their designs were featured on the America Makes website.

Key Consideration: The mask challenge area was selected based on analysis gathered in the Sensing Briefs, indicating that despite the variety of mask designs available to the public, many of them suffered from the same problems. Masks needed to provide an adequate seal against the skin without leaking but still enabling the user to breathe.

This challenge required coordination from the various Tiger Teams. The Product Identification Team helped promote the need for targeted design innovation around a single product. The Process & Technology Team

specifically developed a portal for the submission of Challenge designs and worked with the other teams to identify a review process. Ecosystem Building Team led the charge to communicate and broadcast the challenge and develop incentives for the leading designs.

Feedback received from participants in the challenge was mostly positive. Designers appreciated the rapid iteration and specific critique of their designs, while the medical community appreciated that the solutions met their real needs.

Key Lesson Learned: Vibrant, coordinated ecosystems enable rapid communication and feedback loops, resulting in higher quality design solutions. An improved demand picture helps to identify gaps and steer the community to the most critical need.

Regulatory and Performance Considerations

Throughout the AMCPR mobilization effort, regulations around products for clinical use were reviewed for updates and those guidelines were continually communicated to the designer and manufacturer networks. Success was achieved through routine collaboration with the FDA around what needed consideration and what language to use. Regulatory concerns included Manufacturing Considerations, such as instructions for use, labeling, and product tracking, as well as Minimum Performance Considerations, such as bio and chemical compatibility, face seal fit, compatible sterilization methods, and several others. These performance considerations were posted to the America Makes website and can be referenced in **Appendix A – 3D Printing: COVID-19 Regulatory and Performance Considerations.**

Key Lesson Learned: Including regulatory considerations with each design submitted helped build confidence and gain public trust in the database of designs collected by America Makes. The support of the FDA, NIH, and VA was critical in establishing America Makes as an authority in the space.

Lessons Learned

Crisis management involves responding to a continually evolving environment, often requiring rapid decision making and building solutions in parallel without prior consideration or planning. The America Makes team used an agile approach to learn quickly and adapt. As processes improved, the team tracked their successes and persistent challenges, and critical lessons learned stood out to shape the next phase of the effort. These lessons were bucketed to form three major themes: 1) establishing inter-agency partnerships, 2) engaging member networks, and 3) operationalizing infrastructure and resources. The consolidated key lessons learned and considerations highlighted throughout the report can be found in **Appendix B – Summary of Key Lessons Learned and Considerations.**

Establishing Inter-agency Partnerships

America Makes' ability to work directly with public and private partners uniquely positions the Institute to convene, coordinate, and catalyze COVID-19 response efforts with the NIH, FDA, and VA, as well as other agencies on the periphery, including the DoD, Health and Human Services (HHS), CDC, and NIOSH. In addition to working with government agencies, America Makes, at its core, is a collaboration of members. In times of crisis, America Makes should be poised to act at the center of a "Network of Networks," with the ability to coordinate agency collaboration while simultaneously convening and rallying its network of members to expand its reach and enable a widespread impact.

Throughout the AMCPR initiative, America Makes successfully forged strong relationships with federal agencies, as demonstrated in the swift formation of the inter-agency partnership. However, at times, the partnership was out of step with grassroots efforts at the state and local level. The misalignment is evidenced by the number of disparate portals and databases for designs at the state level and individual partnerships that were forming without any regulatory oversight. Through this initial project's successes and challenges, America Makes has recognized the value of bringing together government partners in a formal MOU to validate the effort and establish a trusted voice.

Engaging Member Networks

Before COVID-19, America Makes occupied a fixed space within the U.S. manufacturing community. However, the Institute needed to quickly coordinate across other networks to work toward its goal of crisis response. America Makes had established relationships within some of these networks, such as their current members, but others were novel to the organization, such as the health care industry.

America Makes made concerted efforts to reach out to States, Governors, Health Associations, and many others throughout the first phase of the project. Through these efforts, the team learned valuable stakeholder engagement lessons and identified six key opportunities for improvement:

1. *Product Sensing Report:* The report was used to identify product trends, manufacturers, and other matchmaking websites. This resource could have been deployed earlier to better inform America Makes on how to increase stakeholder engagement;
2. *Strategic Communications and Coordination:* Earlier membership engagement could have led to more initial buy-in from the membership, the opportunity to leverage members' engagement resources, and, higher success in state outreach and ecosystem efforts.

   Increased coordination between the internal teams focused on membership, ecosystem building, and strategic communications would have ensured concise, targeted messaging and limited duplication of efforts;
3. *Paid Digital Advertising*: The COVID-19 response highlighted the importance of supply and demand signals. The initial focus on matchmaking required America Makes to bring together the additive manufacturing supply community with the healthcare community's demand. America Makes should deploy paid digital advertising to increase awareness among the end-users (health care supply chain managers) of America Makes' value proposition as well as a targeted national public relations campaign to generate media coverage and publicity for America Makes that may include reporter roundtables, op-ed placement, SMTs, and other vehicles to drive coverage;
4. *Relationship Mapping:* Members have tremendous resources and reach into their communities. An identified need to map America Makes' members' relationships across the broader additive manufacturing community. This mapping would enhance America Makes' understanding of key stakeholders and initiate the ability to mobilize members for a targeted outcome;
5. *Defined Value Proposition:* Communicating a clear and concise value proposition for America Makes to reach a broader set of stakeholders so that they can understand not only America Makes' role in the COVID-19 crisis but also its role post-pandemic; and
6. *Targeted Outreach:* America Makes would have benefited from a targeted outreach to state and local governments earlier in the project to make the states aware of the role of America Makes as a public-private interface between the federal government efforts and the private sector.

Operationalizing Existing Infrastructure and Resources

The America Makes team reacted quickly to create a functional prototype website and model repository to help the manufacturing community submit designs, capabilities, and available capacity. Due to the rapid pace of the crisis, America Makes needed to act quickly on efforts occurring in parallel, sometimes creating additional complexities or rework downstream.

For example, America Makes decided to leverage its existing NCDMM CRM platform. While this enabled rapid development, the platform was not well suited to coordinate with the NIH online repository. This required time and effort to be spent on developing a manual data migration process. America Makes worked for several weeks with the NIH, FDA, and VA to establish a process for sharing data across the organizations.

Looking forward, an action to define process needs and objectives to understand what data needs to be collected, and how it will be accessed will help eliminate rework and streamline processes in the future. It will also help establish the roles of each inter-agency partner from the outset. Additionally, when a third party is used to augment America Makes' staff, it will be essential to identify an adequate leadership counterpart at the beginning of the project as a point of contact to help drive succinct communication and coordination channels.

While the team was assembled quickly and remained agile throughout the rapid pace of the AMCPR initiative, overall operations improved as processes were mapped and codified. Creating a detailed project roadmap from the outset will help teams understand the end goal and visualize how tasks and products fit overall project objectives.

Assigning clear ownership and timelines will drive rigor and speed in response, resulting in faster response to shortfalls, conflicting tasks, and redundancy. The Fit to Face Challenge represents a successful use case that adopted an existing tested process to meet an end goal. In this instance, the process included an external review panel evaluation and a feedback cycle for targeted innovation. To increase the design community's speed and response, it was critical to improve the demand picture (sensing, partnerships, SEO strategy) to better identify demand gaps and steer the design community to the most significant need.

Program Impact

America Makes' response to the national PPE shortage consistently evolved to adapt to the changing health landscape. As quickly as the environment was changing, the team's actions were reactive and precipitated from a detailed awareness of current events and community engagement. However, as was the goal from the outset, the products built in Phase 1 of this response effort are part of a lasting infrastructure that will enable America Makes, their partner organizations, and their member network to anticipate future needs and facilitate response to future crises.

America Makes and the AMCPR initiative demonstrate value as the U.S. responds to the COVID- 19 crisis and prepares for future, as yet unforeseen emergencies. While the initiative has evolved to best support crisis response, America Makes has defined its role as the trusted, authoritative Institute to convene, coordinate, and catalyze the additive manufacturing ecosystem to enable the production of safe and effective products. To that end, the AMCPR initiative can categorize its impact into two significant areas: 1) Trusted Voice and 2) Engagement Infrastructure.

Trusted Voice

The engagement and endorsement by federal agencies (FDA, NIH, VA, and FEMA) of the AMCPR effort provide a strong indicator of America Makes' ability to fill the role of a trusted voice. Trust was apparent during the Swab Town Halls, hosted by federal agencies, that consistently referenced America Makes.[2]

In addition to federal agencies' trust, America Makes is serving as a trusted voice for the additive manufacturing community. The *Prioritization Framework* and *Performance and Regulatory Considerations* documents demonstrate how America Makes advocates the role of additive manufacturing as a critical response capability and communicates back to the additive manufacturing ecosystem federal regulatory guidelines. Additional funding awards could also be seen as an indicator that the service America Makes is providing is valued by federal oversight agencies.

Engagement Infrastructure

America Makes and its collaborators achieved a significant accomplishment in developing the AMCPR into a lasting infrastructure capable of quickly mobilizing potentially disparate networks to respond to any crisis. The AMCPR established an online portal for designers, manufacturers, and the needs community to connect through America Makes to identify safe and effective product designs for clinical and community use.

As of May 2020, the AMCPR online portal engaged with 481 manufacturers. The AMCPR partnership has reviewed over 500 designs for face shields, masks, and other PPE, with more than 31 reviewed for clinical use.

The NIH model repository website (with specific links to product design models) has been viewed over a million times since the beginning of March 2020. The top 10 designs on the NIH model repository have been downloaded more than 70,000 times since the start of the pandemic. Additionally, the manufacturers using the repository have reported the printing and distribution of more than 280,000 units of PPE across the country.

The portal that was used in this phase was improved upon to reduce the need for manual support. A new solution is currently under construction, incorporating features and functionality that had not previously available due to timing and technical feasibility. The new portal will be created with flexibility in mind and the understanding that the next crisis may not be a medical one. Therefore, it will involve entirely different industry stakeholders and products.

Looking Forward

Through its relationships, America Makes was able to align efforts across government agencies (FDA, VA, and NIH) and build a process to prioritize and expedite the clinical review of promising open-sourced PPE designs. Through this effort, America Makes continues to establish itself as the authoritative voice for the additive manufacturing community and continues to drive that message across industries.

Throughout the COVID-19 crisis, additive manufacturing played a crucial role in supplying critical products to combat COVID-19, while global supply chains were interrupted. America Makes must continue articulating the value proposition of hybrid (conventional and nonconventional) supply chains to enable a larger, more impactful response.

[2] FDA Virtual Town Hall - 3D Printed Swabs

Over the next year, America Makes plans to develop a national strategy for 3D printing to advance U.S. competitiveness in additive manufacturing. America Makes will continue to invest in research and development in additive and advanced manufacturing capabilities.

Role of Additive Manufacturing

America Makes will continue to promote the AMCPR effort and communicate additive manufacturing's role in the COVID-19 crisis as the American economy seeks to transition into Recovery and Resiliency phases. America Makes can support this transition and promote additive manufacturing by leveraging its membership to align support and grow awareness of the effort. An improved marketing and communications strategy, including the development of infographics to describe and explain challenges and opportunities related to additive manufacturing and AMCPR (Design Challenges, Regulatory and Performance Considerations), will also be an essential element of future engagement.

Role of America Makes

Public health officials have made it clear that the crisis is not over, and there is more work to be done for the U.S. to effectively transition to the Recovery and Resiliency phase of the pandemic. America Makes will continue to play a central role in articulating additive manufacturing and the Manufacturing Innovation Institutes' value proposition. Continued support in conceptualizing, developing, and structuring new facets of this initiative is critical as America Makes expands its scope to enhance U.S. capabilities in times of crisis. Throughout the current and future phases of the AMCPR initiative, other imperatives and associated vital findings, lessons learned, and enhancements will come to light.

Appendix A – 3D Printing: COVID-19 Regulatory and Performance Considerations

3D PRINTING: COVID-19 Regulatory and Performance Considerations

The information below is provided to give manufacturers regulatory and product performance considerations related to producing clinically reviewed designs.

RELEASE DATE: July 14, 2020

For up-to-date information and resources, visit: www.AmericaMakes.us/covid-19

Manufacturing Regulatory Considerations	Product Type					
Description	**Face Shield**	**Community Use Face Mask**	**Surgical / Clinical Use Face Mask [1]**	**Mask Tension Release Bands**	**Personal Assistance Device**	**Nasopharyngeal Swabs**
IFU – Instructions for Use Manufacturers are responsible for telling the user the intended use, how to wear/use the device, storage, assembly, cleansing, and disposal information. Moreover, information on materials, warnings, performance testing, adverse reactions, and a disclaimer should be included. General Device Labeling Requirements	✔	✔	✔	✔	✔	✔
Labeling Medical devices sold in the US, from manufacturing through distribution to a patient, must be labeled. Device Labeling UDI System Link	✔		✔			✔
Product Tracking Device manufacturers must track how many devices are distributed to each customer and offer a method for receiving, recording, and tracking potential issues with devices. Medical device tracking	✔		✔			✔
GMP – Good Manufacturing Practice Manufacturers must establish and follow quality systems to help ensure their products consistently meet applicable requirements and specifications. Typically, a manufacturer following good manufacturing practice (GMP) means they maintain a relevant certification for all respective quality systems utilized in the production of devices. QS Regulation and GMP Overview of Device Regulation						✔
Unadulterated Product We recommend manufacturers use the design as presented and strictly adhere to the recommended practices outlined in the data package from the NIH 3D Print Exchange prior to printing, assembling, and shipping a part.	✔		✔			✔
Adverse Event Tracking Manufacturers must report to the FDA upon discovery of an adverse event where the device may have caused or contributed to a death or serious injury. As of 2018, certain manufacturers may be able to submit voluntary summary reports of adverse events to the FDA. How to Report Medical Device Problems Mandatory Reporting Requirements	✔		✔			✔
Registration and Listing Owners or operators of places of business (or establishments/facilities) involved in production and distribution of medical devices intended for use in the US must register annually with the FDA through a process known as establishment registration. Device Registration and Listing						✔
FDA Resources, Guidance and EUA Links. Face Mask FDA Online Resource	Face Shield EUA	FDA Guidance May 2020	FDA Guidance May 2020			FAQ on Testing for SARS-CoV-2

Much of the provided information is in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services

[1] If you are making a Surgical / Clinical Use Face Mask for community use, regulatory considerations for community use face mask apply

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3D PRINTING: COVID-19 Regulatory and Performance Considerations

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RELEASE DATE: July 14, 2020

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Minimum Performance Considerations

Description	Product Type: Face Shield	Community Use Face Mask	Surgical / Clinical Use Face Mask [1]	Mask Tension Release Bands	Personal Assistance Device	Nasopharyngeal Swabs
Chemical Compatibility Chemical characterization of devices should be conducted within the framework of a risk management process to understand what interactions and components may alter the physicochemical characteristics of the device. Use of ISO 10993-1 – Biological Evaluation	✔		✔	✔	✔	✔
Bio-compatibility Risk assessment of the device should consider chemical toxicity of the materials, the processing method, and manufacturing methods in relation to any unacceptable biological response to the device. Exposure duration of the device should be considered in evaluating biological impacts on users. *Standard: ISO 10993*		✔	✔			✔
Flammability Proper flammability standards should be adhered to based on the class of device being manufactured. For surgical masks intended for use in the operating room, Class 1 and Class 2 flammability materials are recommended by FDA. *Standard: ASTM F2100-19* Surgical Mask Guidance			✔			
Liquid Barrier The fluid resistance is the ability of the mask's material to demonstrate a liquid barrier and resist penetration of blood and bodily fluids. FDA recommends using ASTM F 1862 for surgical masks. *Standards: ASTM F1862-17; ASTM F2100-19* Surgical Mask Guidance			✔			
Face Seal Fit Face seal fit can be evaluated with a fit test, either qualitative or quantitative according to OSHA guidelines. A fit factor can also be determined as an estimated ratio of concentration of a substance in the ambient air to its concentration in the respirator when worn. *Standard: 29CFR 1910.134 App A* OSHA-Accepted Fit Test Protocols; Respiratory PPE Definitions		Loose	Loose			
Splash Resistance Splash resistance refers to protection of the facial area and associated mucous membranes from splashes, sprays, and spatters of bodily fluids. Face Shields for Infection Control	✔					
Offgassing Offgassing, or outgassing, refers to the release of volatile compounds as a gas from the materials of the device. Outgassing Wiki		✔	✔			
Cleanliness A method of cleaning the device should be established to mitigate the presence of foreign debris or contaminants which can affect testing validity or patient safety. *Standards: ASTM F3127-16* FDA Validation of Cleaning Processes						✔
Compatible Sterilization Methods Compatible sterilization methods are developing and are defined as processes to clean and disinfect soiled medical devices to render them safe for handling and to the extent necessary for subsequent processing. Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency			✔			✔

Much of the provided information is in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services

[1] If you are making a Surgical / Clinical Use Face Mask for community use, regulatory considerations for community use face mask apply

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Appendix B – Summary of Key Lessons Learned and Considerations

Key Lessons Learned

#	Major Theme	Key Lesson Learned
1	**Operationalizing Infrastructure and Resources**	America Makes initially leveraged its existing Customer Relationship Management (CRM) platform. While this allowed the team to mobilize quickly, it did not meet the team's need from an operational standpoint; limited compatibility with the NIH online repository required manual data migration from system to system.
2	**Operationalizing Infrastructure and Resources**	Enduring infrastructure to house critical PPE designs for the healthcare community is a necessary, proactive investment to address future nationwide crises. A system designed to address a pandemic and general crisis management requires robust functionality outside of design submission and inspection. As the central player in this effort and future efforts, America Makes recognized the value in building its infrastructure, explicitly dedicated to crisis management.
3	**Establishing Inter-agency Partnerships**	Identification and documentation of each institution's unique roles are vital in understanding how data should be shared and communicated to various stakeholders and end-users.
4	**Operationalizing Infrastructure and Resources**	In a rapidly changing crisis with widespread national effects, a “control tower” strategy for sensing public data, news, and social media can be important for decision making and direction of efforts.
5	**Engaging Member Networks**	Many submissions did not translate to a diverse range of solutions. Many designs suffered similar problems and were not addressing the real need from the medical community. It is key to communicate to designers fluctuating demand signals as local and regional PPE needs change, sometimes even daily.
6	**Engaging Member Networks**	Vibrant, coordinated ecosystems enable rapid communication and feedback loops, resulting in higher quality design solutions. An improved demand picture helps to identify gaps and steer the community to the most critical need.
7	**Establishing Inter-agency Partnerships**	Including regulatory considerations with each design submitted helped build confidence and gain public trust in the database of designs collected by America Makes. The support of the FDA, NIH, and VA was critical in establishing America Makes as an authority in the space.

Key Considerations

#	Topic Area	Key Consideration
1	**Approach & Methodology**	The concept of a public-private, distributed digital advanced manufacturing supply chain was not proven or demonstrated before the inception of AMCPR. A central authority is needed to convene the ecosystem and provide de-risking and capital investment for a successful distributed model to work with small- and medium-sized manufacturers. A distributed model seeks to accelerate production while reducing regulatory, technological, and economic barriers.
2	**Technology Platforms & Tools**	The need for the Product Review Matrix was realized after designs were submitted on the NIH 3D Print Exchange. Thus, and because America Makes did not control the NIH 3D Print Exchange, data was manually collected and tracked in the matrix.
3	**Technology Platforms & Tools**	The America Makes Portal was not fully integrated with the NIH 3D Print Exchange site due to timing and the rigor required to build, test, and deploy such integration.
4	**Approach & Methodology**	The team retroactively developed an 'ideal' matchmaking process through which the effort did not end when the match was made between the need requester and the manufacturer. The ideal-state process incorporated a tracking application through which the manufacturer communicates updates on production and distribution status. The requester would formally review the build and performance of the final product. This process was not delivered up during Phase 1, given resource and technical limitations. Instead, the priority was on production turnaround to address demand.
5	**Technology Platforms & Tools**	While the NIH 3D Print Exchange was not designed to evaluate designs, the team needed a platform solution that could be leveraged immediately. The lack of features, such as filtering and tagging, meant that much of this needed to be done manually on the America Makes team's back end.
6	**Market Sensing**	Web scraping and media sensing highlighted enthusiasm from the public to get involved and ample resources and creativity. What was lacking was coordination and leadership, resulting in unfocused and duplicative efforts.
7	**Market Sensing**	The mask challenge area was selected based on analysis gathered in the Sensing Briefs, indicating that despite the variety of mask designs available to the public, many of them suffered from the same problems. Masks needed to provide an adequate seal against the skin without leaking but still enabling the user to breathe.