

MA DIGITAL HEALTH COUNCIL REPORT

JULY 2019





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EXECUTIVE SUMMARY

Digital health is a rapidly growing sector at the intersection of healthcare and information technology. The sector spans a variety of technologies, including electronic health records, consumer wearable devices, care systems, payment management, big data analytics and telemedicine. When fully leveraged, a robust digital health ecosystem has the potential to improve the lives of patients while also driving economic growth in the state by creating jobs, attracting investment, and developing solutions that improve healthcare delivery and ultimately containing healthcare costs. A 2019 report by McKinsey suggests that technology driven innovation in the healthcare sector has the potential to deliver \$350B - \$410B in annual value by 2025.¹ As host to world-class healthcare and academic institutions, strong startup culture, significant venture capital investment, a dominant life sciences sector and roughly 350 existing digital health companies,² Massachusetts is ideally situated to become the leading global digital health hub.

In recognition of this potential, in 2016 the Massachusetts Digital Health Council (hereafter the "Council") was established pursuant to Executive Order #574 and updated through Executive Order #585. The Council was charged with developing a set of strategic proposals to foster and support a leading ecosystem for digital health in Massachusetts. The creation of the Council represented a continuation of efforts first initiated in 2013 by the Massachusetts Competitive Partnership (hereafter "MACP").

The Council, co-chaired by Dr. Jeffrey Leiden, M.D., Ph.D. of Vertex Pharmaceuticals and Secretary Mike Kennealy, Secretary of Housing and Economic Development, has developed a series of recommendations designed to establish Massachusetts as a leading player in the digital health industry. As detailed in this report, the initiatives recommended by the Council focus on growing, enabling and supporting the digital health ecosystem by leveraging regional strengths and expertise to deliver resources, infrastructure and access to data, as well as increasing collaboration with the world class academic and scientific leaders in Massachusetts. If fully leveraged, these recommendations have the potential to better position Massachusetts as the global leader in the digital health industry.

DIGITAL HEALTH INITIATIVE HISTORY

The Massachusetts Digital Health Initiative is a public-private partnership working to establish the state as a leading ecosystem for digital health innovation, driving economic impact and improving healthcare costs and quality.

The initiative was first launched through MACP in 2013. In January 2016, MACP announced several private industry-led initiatives focused on accelerating growth in the digital health sector, including:

- Creation of an Angel Investor Tax Credit
- Modernizing the R&D Tax Credit
- Investing in computer science education for grade K-12
- Support of immigration reform
- Harmonizing tech transfer licensing policies
- Creating a lecturer and mentorship program
- Creation of a digital health focused accelerator – PULSE@MassChallenge (now MassChallenge HealthTech)

In parallel to the efforts of MACP, public sector interest in the importance of digital health started. In June 2014, MeHI was authorized by the Legislature to expend money from the eHealth Institute Fund to support digital health development³ and digital health was identified as a key component of the Commonwealth's economic development plan signed by Governor Baker on December 23, 2015.⁴ The economic plan recognized

COUNCIL SNAPSHOT

7 Council meetings



39 Working Group and Committee meetings



>85 participants across Council, Working Group and Committees



digital health as an emerging area of interest as part of a broader goal to advance and harness key industry groups to drive job growth in the Commonwealth.

On November 22, 2016, Governor Baker signed Executive Order #574 establishing the Massachusetts Digital Healthcare Council⁵ and on October 31, 2018, Governor Baker signed Executive Order #585 to update and supersede the original order.⁶ The Council was charged with identifying a set of near-term strategic initiatives that support a three year growth plan and executing against the initiatives through public-private partnerships.

The Council has developed a set of eight near-term strategic initiatives and two longer-term recommendations.⁷ The details of the eight near-term initiatives are set forth in this report.

SUMMARY OF PRIORITIZED INITIATIVES

The Council prioritized a set of eight near-term recommendations focused on accelerating growth in the digital health sector and supporting the digital health startup community.

PILOT ENVIRONMENTS AND PRODUCT VALIDATION	ECOSYSTEMS AND CONNECTIVITY	DISTRIBUTED DATA NETWORK
<ol style="list-style-type: none"> 1. Create Sandbox environments (Home and Hospital) to accelerate product development and enable startups to test their products in secure environments 2. Create a Hacker Hospital to serve as a resource for product development, security and privacy, event simulation 3. Establish a cybersecurity group of experts to develop a training toolkit and resources for startups 	<ol style="list-style-type: none"> 4. Establish a pre-eminent conference around digital health in MA 5. Support the growth and continued success of MassChallenge HealthTech 6. Provide a centralized web portal for digital health resources 	<ol style="list-style-type: none"> 7. Create a Distributed Data Network to facilitate the flow of key health information within the Commonwealth 8. Develop uniform Data Use Agreements as part of the Distributed Data Network

As detailed in this report, with the exception of the Distributed Data Network the above recommendations have been planned and are currently being implemented.⁸

1. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/the-era-of-exponential-improvement-in-health-care?utm_source=STAT+Newsletters&utm_campaign=54377e9650-health_tech_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-54377e9650-151487801
 2. <https://www.massdigitalhealth.org/why-massachusetts>
 3. Section 38 of <https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter287>
 4. <https://www.mass.gov/files/documents/2016/12/pt/edplan2015.pdf>
 5. <https://www.mass.gov/executive-orders/no-574-establishing-the-massachusetts-digital-healthcare-council>
 6. <https://www.mass.gov/executive-orders/no-585-reaffirming-and-restructuring-the-massachusetts-digital-healthcare-council>
 7. The 2 longer term recommendations include the creation of a Massachusetts IRB Network to simplify review processes and the creation of a Digital Health Innovation Accelerator funding vehicle. Both of the longer-term recommendations will require further consideration by the State before any further action is taken.
 8. As noted in the Pilot Environments and Product Validation section, the ISC structure will enable the establishment of a Hacker Hospital. The DHC recommends establishing a full featured Hacker Hospital in 2019.



PILOT ENVIRONMENTS & PRODUCT VALIDATIONS

SANDBOX ENVIRONMENTS PILOT PROGRAM⁸

OBJECTIVE	Establish a pilot program to facilitate access to sandbox environments that allows digital health companies to test their solutions in a realistic, safe setting and deliver validated, secure products to patients sooner.
RATIONALE	Entrepreneurs and startup companies often need to compete for sandbox resources in hospital settings. Facilitating sandbox access to run the testing and validation work and offsetting the cost of sandbox utilization can streamline the process and create broader access to these resources.

To determine the utility of sandbox environments in supporting the digital health ecosystem, the Council recommended the development of a pilot program to test the value proposition and establish a governance mechanism and funding framework that can later be expanded to support additional sandboxes.

Specifically, the pilot program will:

- Focus on the **creation of two sandbox environment types** to address current needs:
 - an environment that mimics a home; and
 - an environment that mimics a hospital inpatient setting (OR, inpatient room, ICU).
- Provide for at least one sandbox environment that can **support cybersecurity research** (see Hacker Hospital proposal)
- Match digital health companies, startups and entrepreneurs with sandbox environments **based on need and capabilities**
- Provide a funding mechanism to **defray the utilization costs** for startups

In addition, sandboxes in the pilot program will include access to technical infrastructure to run production software and provide access to clinical focus groups and champions, synthetic data, and training support for entrepreneurs. As such, these sandbox environments will enable digital health companies to develop their value proposition, validate workflow for new technologies and ensure that their solutions are secure and offer adequate privacy protections.

Independent Steering Committee and Pilot Administration

In February 2019, the Council established an Independent Steering Committee (hereafter the "ISC") to advise on execution of the pilot program. ISC members include representatives from hospitals, payers, startup accelerators, startup and entrepreneurs and academia. ISC membership can be found in [Appendix E](#). The ISC's responsibility for the pilot program includes:

- Advising on development, execution and evaluation of sandbox pilot program;
- Advising on application process and approve selection criteria;
- Reviewing applications and making recommendations for sandbox matching and funding;
- Evaluating the pilot program using the pre-agreed measures of success, which can be found in [Appendix G](#); and
- Making recommendations on ways to improve and scale the program

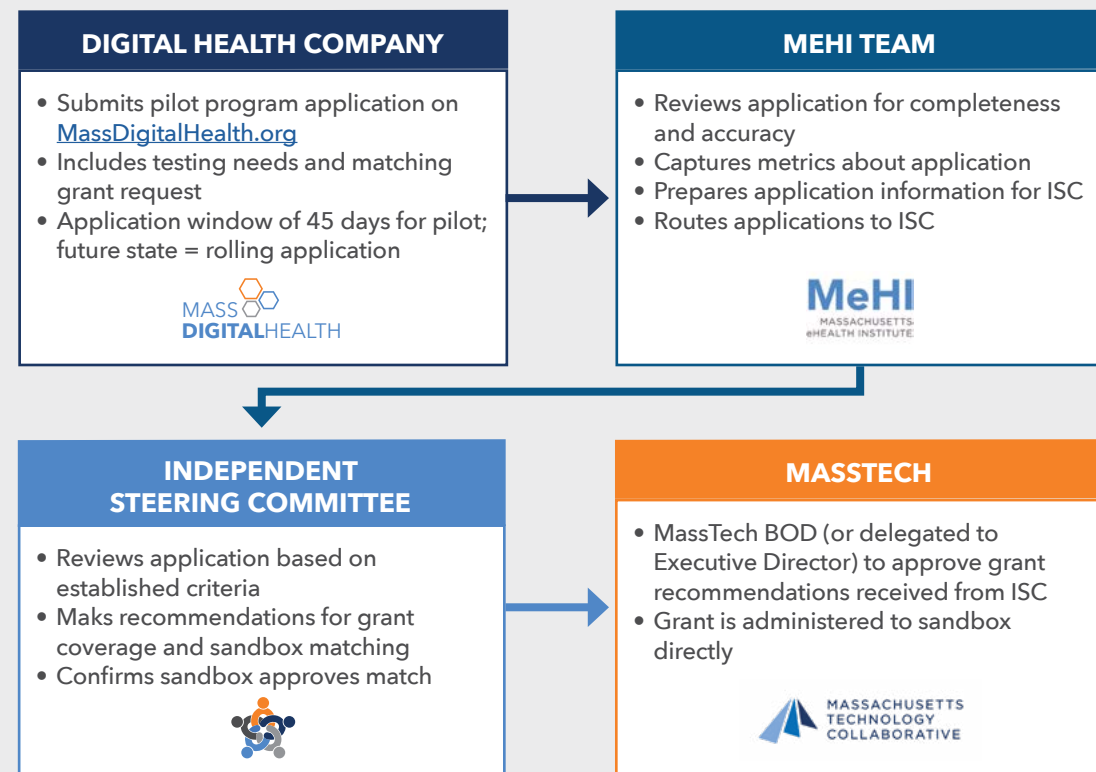
8. <https://www.massdigitalhealth.org/mass-digital-health-programs/digital-health-sandbox-grant-program>

PILOT SNAPSHOT

CREATE 2 sandbox environment types	
AT LEAST 1 can support cybersecurity research	
MATCH applicants with the sandboxes	
PROVIDE funding mechanism	

ADMINISTRATION & COORDINATION

The Council recommended that MassTech/MeHI be responsible for the administration and coordination of program logistics, including initial application review, routing funding requests to the ISC and grants administration. The overall coordination of application information during the pilot is depicted below:



Funding

The cost of accessing sandbox services may be prohibitive for small digital health companies. To facilitate greater access for startups, the Council proposed that MassTech establish an initial \$500,000 grant pool for the two years of the pilot program in order to defray the user fees for digital health companies. Digital health companies with a presence in Massachusetts can apply for grants to offset the cost of using a sandbox through an application process administered by MeHI.⁹ Grants will be awarded to offset user fees based on need. The ISC developed a selection matrix to evaluate grant applications including an assessment of the following:

- The maturity of the company and/or idea
- Whether the proposed use of the sandbox supports a high-value opportunity
- Whether the proposed use of the sandbox technically viable
- Whether engagement with the sandbox positively influence the trajectory of the product/solution

The detailed selection criteria can be found in [Appendix I](#).

Selection of Sandbox Environments

A working group of the Council, including members of the ISC, conducted an in-depth review of 20 existing environments in Massachusetts and evaluated each based on a number of factors including, geographic

diversity, availability or self-funding, ability to grow and support expanded use and willingness to participate in the pilot and share learnings.

Based on this review, a sub-committee of the Council determined that several existing sandbox environments met the defined criteria and could be leveraged for participation in the pilot program. After careful consideration, a sub-committee of the Council recommended PracticePoint at Worcester Polytechnic Institute (hereafter "PracticePoint") as the first sandbox to participate in the pilot program with the goal of adding at least one additional sandbox environment in 2019 based on demand.

In the initial phase of the pilot program, PracticePoint will provide pilot participants with access to their newly-opened residential and rehabilitative care suites for home health and consumer product development and testing and to their controlled care and surgical imaging suites. PracticePoint is a new facility, funded through a \$5M MassTech matching grant along with initial funding of \$9M from WPI and \$2.5M from GE. PracticePoint was built to serve as both a home and hospital sandbox environment. This facility brings together a community of research institutions, healthcare providers, and companies to work collaboratively on new technologies and incorporate them quickly into commercially viable products. Additional details on PracticePoint can be found in [Appendix H](#).

In April 2019, the Council launched the pilot program to coincide with the PracticePoint Phase I opening. Simultaneously, the Council launched a survey to assess interest and understand capabilities of additional Massachusetts sandboxes. As of finalization of this report, five additional sandboxes have expressed interest in participating in the program. The ISC plans to release a formal application for additional sandboxes in summer 2019. Applications by these sandboxes will be reviewed by the Independent Steering Committee in the coming months.

HACKER HOSPITAL SANDBOX ENVIRONMENT

OBJECTIVE	Provide access to a sandbox environment that supports the ability to stress-test new devices, software and systems against cybersecurity threats in a realistic hospital setting (a "Hacker Hospital").
RATIONALE	Hacker Hospitals provide a safe environment to simulate cyber defensive systems and hacker approaches, run hackathons, scenario plan for future attacks and enable an environment to help support more secure health apps and devices. These services will also help to safeguard Massachusetts institutions (providers, entrepreneurs, companies) against cyber threats and enable healthcare delivery systems to identify cyber vulnerabilities prior to an attack.

The Council recommends adding an additional sandbox environment in 2019 that can support cybersecurity testing. The initial sandbox pilot site at WPI includes some cybersecurity capabilities. Additionally the ISC, in conjunction with the Cybersecurity Group of Experts (discussed below), will support the recruitment and evaluation of Hacker Hospital sandbox environments. Once a Hacker Hospital sandbox environment is selected by the ISC, the Cybersecurity Group of Experts will continue to provide additional resources to complement the services of that environment (e.g., training events, updated resource guides, Hackathons).

⁹. Launched April 24, 2019 <https://www.masstech.org/digital-health-sandbox-program-solicitation>

CYBERSECURITY TOOLKIT AND GROUP OF EXPERTS

OBJECTIVE	Establish a Cybersecurity Group of Experts to advise on cybersecurity threats and develop a cybersecurity toolkit comprising a suite of educational resources and guidelines to help healthcare entrepreneurs and organizations prepare for and respond to cyber threats.
RATIONALE	Cybersecurity risks represent a growing concern for digital health companies. According to a recent report by Carbon Black, cyber criminals appear to be shifting focus away from retail and banks to health care, and the average health organization experiences two attacks per week. A recent report from Radware estimates an average healthcare organization spends approximately \$1.4M to recover from a cyberattack. A cybersecurity toolkit will assist digital health companies and startups prepare for and respond to cybersecurity threats.



Cybersecurity Group of Experts

In February 2019, the Council launched the Cybersecurity Group of Experts (hereafter the “CGE”) to facilitate the creation of a cybersecurity toolkit and embed cybersecurity expertise across the digital health initiatives (e.g., sandbox program and Hacker Hospital). The CGE, chaired by MITRE, is composed of 11 industry experts from hospitals, industries including software, security and medical devices, academia and government. Membership can be found in [Appendix L](#). The CGE will support the growth of the digital health ecosystem by enhancing access to security and validation information needed to support commercialization of products and working with the Massachusetts Cyber Center,¹⁰ as well as supporting future Hacker Hospital sandbox environments. The CGE will also offer ongoing hackathon events, development training workshops around cybersecurity, HIPAA and other relevant topics.

The Cybersecurity Toolkit

A primary deliverable for the Cybersecurity Group of Experts is the creation of a cybersecurity toolkit for digital health entrepreneurs and startups. The toolkit will enable faster clinical adoption of new digital health products, software and solutions by enhancing access to security needs and requirements and will address:

- Cybersecurity needs for digital health companies
- Medical device and software solutions
- Best practices
- Available state and national resources and tools

This toolkit will be made available through the digital health web portal (described below) and will serve as an educational resource for digital health companies at all stages of growth on both the fundamentals and best practices for cybersecurity and privacy protection. Designed to be an online and interactive resource, the toolkit will enable healthcare organizations to share experiences and guidance with each other, helping our ecosystem increase its cyber resiliency and fostering collaboration between providers and entrepreneurs in addressing cybersecurity challenges.

In addition to serving as a resource guide, the toolkit will also contain a Massachusetts common security checklist, created by MassChallenge HealthTech in collaboration with the CGE and with funding support from MeHI. This checklist provides a standard set of questions asked by a hospital prior to deployment of a new device or software in a clinical setting. The checklist is designed to provide startups an upfront guide to the key security and standardization requirements they will need to meet for any hospital engagement.

Version 1.0 of the toolkit was launched virtually at www.massdigitalhealth.org in July 2019. In the coming months, the toolkit will be upgraded to include additional content and video components.

10. <https://www.masscybercenter.org/about-masscybercenter>



ECOSYSTEMS AND CONNECTIVITY

ESTABLISHING A DIGITAL HEALTH CONFERENCE IN MASSACHUSETTS¹¹

OBJECTIVE	Establish a pre-eminent digital health conference in Massachusetts to convene digital health leaders and increase recognition of Massachusetts' digital health leadership.
RATIONALE	There are numerous major conferences that touch on digital health but no major Massachusetts-based conferences that are focused primarily on digital health. Hosting a digital health conference in Massachusetts would not only increase global recognition of Massachusetts' digital health leadership and create a forum for digital health leaders to convene, but would also drive economic development for the Commonwealth.

HLTH

The Council conducted an evaluation of existing conferences, including existing local conferences that could be leveraged to support this goal. After a careful review, the HLTH conference was identified as a top-tier digital health conference and one of the premier conferences for healthcare innovation. Launched in 2018, the conference convened over 3,500 attendees in its first year with a goal to scale to 10,000 attendees within the first 5 years. HLTH attracts attendees across the ecosystem, including providers, vendors, investors and VCs, startups and public companies. Additional details about the HLTH conference can be found in [Appendix N](#).

Following extensive discussions with Council co-chair, Dr. Jeffrey Leiden, additional Council members, and BCEC, HLTH executed a contract to move the conference to Boston initially for 2021. HLTH is currently in discussions with the Boston Convention and Exhibition Center regarding bringing the conference back to Boston in 2023, with a goal of cycling the conference between Boston and Las Vegas every other year.

SUPPORTING MASSCHALLENGE HEALTHTECH GROWTH




OBJECTIVE	Elevate MassChallenge HealthTech to a globally pre-eminent digital health accelerator by establishing a Steering Committee of healthcare and technology executives to oversee the strategic goals of the program, enable financial sustainability and provide strategic guidance and mentorship to companies in the program.
RATIONALE	Supporting the strategic growth of MCHT will enable the program to become the premier digital health accelerator, increasing the number and quality of companies being started in Massachusetts, creating more jobs and improving the odds of success for companies growing and scaling in the state.

About MassChallenge HealthTech

MassChallenge HealthTech (MCHT) is a cutting edge digital health innovation program launched in 2016 with the support of the business community, MACP, the Commonwealth of Massachusetts, and City of Boston. MCHT provides invaluable mentorship, training, and access to the Massachusetts digital healthcare ecosystem to help entrepreneurs address key challenges. The model leverages "reverse pitches" from established partners to promote challenges in high-impact areas of the healthcare industry for entrepreneurs to address.

Since the program launched, there have been a total of 88 participating startup companies, some of whom

PROGRAM SNAPSHOT

88 participating startup companies	
\$378M funding raised \$52M total revenue	
1,207 direct jobs created 7,000 indirect jobs created	

¹¹ Based on increasing national and global recognition of Massachusetts as a leader in digital health, two additional events recently announced plans to move to Boston, including TedMed in March 2020 and the STAT Healthcare Summit in November 2019. The trend of healthcare innovation/technology conferences moving to Boston is further evidence of Massachusetts' position as a leader in digital health.

participated in more than one cycle, for a total of 93 selected companies across 3 cohorts. The total funding raised by companies by MCHT graduates is over \$378 million, and total revenue is over \$52 million. It is estimated that approximately 1,207 direct jobs were created by these companies and over 7,000 indirect jobs were created.

Executive Steering Committee

MCHT runs under the MassChallenge umbrella of programs. The MCHT program is currently run by a Managing Director with an Advisory Board. To elevate MCHT and provide greater strategic guidance, the Council recommended that MCHT modify the structure of the program by creating an Executive Steering Committee. In addition to helping develop and support the strategic vision for the program, the Executive Steering Committee would also create a network of mentors for the MCHT companies. The establishment of this structure is consistent with the approach taken by the MassChallenge FinTech program, which was launched after the initial creation of MCHT.

The Executive Steering Committee will comprise of 3-5 C-suite executives representing a variety of stakeholders in the digital health community and will be responsible for:

- Providing strategic leadership to support MCHT's vision, focusing on program growth and sustainability
- Evaluating and advising MassChallenge on startup selection
- Setting strategic goals to enable MCHT companies to develop into growth stage companies in Massachusetts
- Providing mentorship to digital health startups with highest potential

The Executive Steering Committee will further advise the MassChallenge executive team and will oversee the Advisory Board. A diagram of this proposed organizational structure chart is provided below:



The detailed scope of responsibilities and criteria for potential members of the new Executive Steering Committee can be found in [Appendix O](#).

WEB PORTAL AND HUB FOR DIGITAL HEALTH RESOURCES

OBJECTIVE

Create an interactive web portal that will become the centralized 'hub' for digital health assets, resources, and community engagement. The portal will include digital health resources, a jobs board and educational tools, as well as news, events, and ways for people to connect and interact with each other.

RATIONALE

There are currently a variety of disparate sources for digital health resources, programs, events and news which are decentralized and difficult to navigate. Providing a centralized source for digital health-related information will make it easier for startups and entrepreneurs to access relevant resources and will enable the community to better connect and interact.

www.MassDigitalHealth.org

In 2016, www.massdigitalhealth.org, managed by MeHI and MassTech, was launched as the landing page for the Digital Health Initiative. The Council recommended capitalizing on this existing webportal, but improving and enhancing resources found on the portal, including:

- Improving the landing page
- Enabling easier navigation to resources on the portal
- Developing landing pages for the work of the Digital Health Council
- Creating a Massachusetts Digital Health Jobs Board
- Refreshing the content to share up-to-date news, events and content

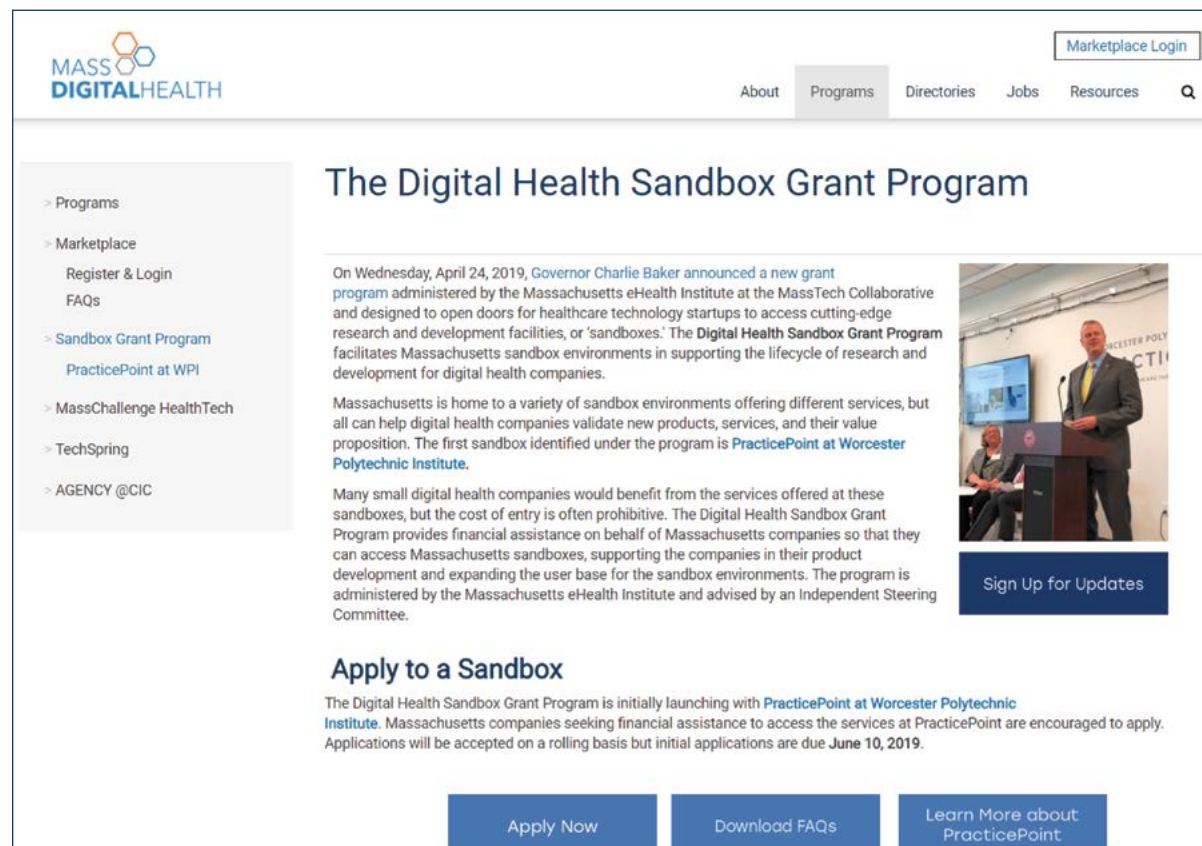
The Council further recommended the creation of a communications group to develop content and engage with the digital health companies to better understand the resource needs of the community.



Web Portal Content and Navigation

To further understand the gaps in content and navigation challenges, the MeHI and MassTech teams hosted two focus groups with startup companies in early 2019. Based on the feedback, initial changes were made to the portal to better surface the available resources, including a re-design on the home page which was completed in April 2019. In addition, over 100 resources have been developed and launched on the web portal. During the second half of 2019, recommendations for further upgrades to the web portal will be completed.

Further, as the Council's other recommended initiatives are adopted and implemented, landing pages and resources for each of the programs have been launched on the web portal. An example includes the Sandbox Pilot Program as seen below:



Jobs Board

As a key component of the enhancements to the web portal, the Council recommended creating a Massachusetts digital health jobs board to support growth of the digital health ecosystem. An initial jobs board was launched in June 2018. This version 1.0 required labor-intensive manual curation resulting in out-of-date postings. In February 2019, version 2.0 of the jobs board launched, which programmatically aggregates digital health jobs across over 300 companies in Massachusetts. Notably, as far as we can tell, this is one of the first comprehensive regional digital health jobs board to exist in the country. Since launch, the jobs board has listed 1,800 - 2,000 open positions on any given day. The jobs board was promoted to over 100 college and university career centers after launch.

JOB BOARD SNAPSHOT

- 300 MA companies with digital health jobs are posted automatically
- 1,800–2,000 open positions listed per day since launch
- 900 unique visitors and 8,200+ page views since February 2019

Communications Strategy

To increase awareness of the available resources, the Council recommended creating a communications group to enable collaboration across the ecosystem, sharing of news and events and curating content for the web portal.¹² The Communications Working Group launched in January 2019, and chaired by MeHI, includes 20 members of the digital health community and meets quarterly. Membership of the Communications Working Group can be found in [Appendix P](#).

The Communications team also worked with MCHT and MassTech to partner with STAT News, an online-only publication of the Boston Globe, as the exclusive sponsor of a new Digital Health weekly newsletter. STAT HealthTech is an international digital newsletter, delivered to 7,000 subscribers at the time of this report every Wednesday. The newsletter content highlights stories on how technology is transforming health care and the life sciences. As a result of the sponsorship, MassDigitalHealth will receive a weekly feature over the course of the year (May 2019 - June 2020) to highlight the Massachusetts digital health ecosystem and will also be prominently featured on the top panel of the newsletter as seen below:



12. <https://massdigitalhealth.org/events>



DISTRIBUTED DATA NETWORK

OBJECTIVE	Create “public good” infrastructure for robust healthcare data exchange in Massachusetts that can be used to more fluidly provide patients access to their own data and also enhance care coordination to improve care delivery, outcomes and population health.
RATIONALE	<p>The creation of a Distributed Data Network (hereafter “the DDN”) will enable Massachusetts to develop a leading program to fuel innovation through real time aggregation of healthcare data. The DDN will enable the ability to supplement EMR and hospital system data and change the discussion between patients and physicians to focus less on capturing information and more on providing care. While healthcare information exchange in the Commonwealth is currently in place, it is not universally adopted or consistently understood. The DDN provides an opportunity to bring all of the disparate information exchange approaches and efforts together.</p> <p>The February 11, 2019 CMS and ONC notice of proposed rulemaking imposes penalties for information blocking. The DDN will help providers ensure compliance once the rules are finalized.</p> <p>The DDN will serve the dual purpose of enabling patients to better access and control their healthcare information under a trusted framework and improving care coordination.</p>

NETWORK OVERVIEW

The Council recommends the creation of a DDN to allow for the sharing of key electronic health records across the Commonwealth. The DDN would serve the primary purpose of enabling providers’ real time access to historical records and diagnoses to improve care and facilitate patients’ access to their healthcare data.

Leveraging federal initiatives and standards, the DDN would serve to address existing gaps and create a framework for data exchange for the limited purposes of care coordination and patient access.¹³ Through the establishment of a uniform certification process, as well as an oversight mechanism, the DDN has the potential to both reduce risk and improve access to data. A working group of the Council was formed and has issued the recommendations discussed below as to how to implement the DDN. The Working Group membership can be found in [Appendix B](#).

Key features of the DDN:

<p>FLEXIBLE INFRASTRUCTURE</p> <p>The DDN will fuel innovation through the aggregation of healthcare data without requiring new government infrastructure or mandating the use of a particular technology. Indeed, the construct of the DDN allows for the evolution of technology as the industry progresses. The initial implementation of the DDN could leverage existing Direct Messaging or MLLP/VPN technologies but provide flexibility to adopt APIs as they become more widespread.</p>	<p>DATA STEWARDS</p> <p>The Commonwealth would certify and audit certain entities that would be authorized to use statewide health data for limited purposes (discussed below) and to provide this data to authorized care providers or patients. These entities would be referred to as Data Stewards.</p>
<p>DATA SHARING</p> <p>Healthcare entities would be required to share prescribed datasets with certified Data Stewards. Data producers would publish data based on the formats and processes defined for the network and authorized data stewards would subscribe to these feeds and could package and combine multiple feeds for different purposes. Initially providers would be required to contribute ADTs and the proposed v1.0 USCDI dataset, with the exception of clinical notes, to the DDN. Additional data could be added to the requirement at a later time.</p>	<p>REGULATED USE-CASES</p> <p>Data Stewards would be permitted to use data only to perform certain activities. As an initial matter, Stewards would only be able to use data to facilitate care coordination and provide patients with access to their data. Within these use cases, Stewards would be able to provide a range of services (e.g., data aggregation, notification services, analytics). Additional uses cases could be added at a later time.</p>

13. Including ONC and CMS updated proposed rules to advance interoperability, Commonwell, Carequality national networks, the ONC NPRM, the CMS MyHealthData initiative, Argonaut FHIR project. See Appendix for additional details.

Governing Authority

The Council recognized that the creation of a robust DDN that meets the objectives listed above would require a state mandate for participation. Through a government mandate, the state should require uniform participation of data producers; however, as detailed below, such required participation would be limited in scope.¹⁴

To facilitate the implementation and oversight of the DDN, the Council explored three potential governance structures, including: 1) the creation of a new quasi-public authority, 2) leveraging an existing quasi-public authority and 3) amending existing statute to broaden EOHHS's authority over health information exchange activities to include oversight of the DDN and a provider participation mandate. The high-level benefits and risks of each governance model are listed below. Additional details can be found in [Appendix X](#).

OPTION	1. New Quasi-Public Authority	2. Existing Quasi-Public Authority	3. Updating Chapter 118I
PROS	Creating a new quasi-public authority for the DDN would have the advantage of a tailor-made governance structure	Quasi-public authorities with various useful capabilities already exist (examples: MeHI and CHIA)	<ul style="list-style-type: none"> The shortest, fastest path to creating a DDN Requires minor amendments to MGL Chapter 118I: <ul style="list-style-type: none"> Already reflects a clear legislative determination that EOHHS should be the Commonwealth's lead agency for promoting health information exchange Not specific to the Mass HIWay (e.g. this change would not impact the HIWay) Includes a provider mandate and a mature mechanism for addressing patient consent issues Amend composition of HIT Council to serve as public-private advisory body to the DDN and HIE more broadly.
CONS	<ul style="list-style-type: none"> Longest timeline of all options Requires significant legislative input Following legislature buy-in, requires lengthy process to select governing board members, selecting Executive Director and hiring staff to run the program and manage procurements and contracts 	<p>Existing quasi-public organizations are not particularly well-suited to serve as the overall GA</p> <ul style="list-style-type: none"> MeHI, although an important participant in EOHHS' health information exchange, is within EOHED domain and does not currently have regulatory experience or authority CHIA, although it has many of the technical skills needed by the DDN GA, is a regulatory authority with no history of promoting health information exchange 	<ul style="list-style-type: none"> Potential resource impact

With regard to Option 3 (amendments to Chapter 118I), the Council recommended that implementation should include either revamping the Health Information Council (hereafter the "HIT Council") that was established to oversee the MassHIway to include relevant stakeholders and provide oversight to the newly-formed DDN or the creation of a separate advisory board to oversee the DDN.

Leveraging any of the oversight models above, the DDN governing body would be responsible for implementing the DDN and ensuring its success, including developing and managing a formal application and selection process for Data Stewards and providing ongoing oversight and regulation of Data Stewards, including compliance with restricted use cases and establishing minimum obligations.¹⁵ As noted above, implementation of the DDN would require statutory and regulatory changes to mandate provider participation and set the terms of their participation.¹⁶

The governing authority would rely on the advice of private-sector experts and, where practical, leverage national standards, the MassHIway infrastructure and existing technological capabilities to minimize effort and cost required from participating providers.¹⁷ However, the Council recommended a modest assessment on Data Stewards seeking certification to fund DDN operating costs.

Legal framework

The DDN will require a legal framework that standardizes policies and processes for protected health information exchange. Foley Hoag was engaged by MassTech to advise on how best to implement the DDN under today's laws and regulations. A number of potential structures could be leveraged to implement the DDN. In summary, the legal options for implementation are as follows:

OPTION A	OPTION B	OPTION C
<p>Leveraging existing business associate agreement structure, an "Operational Virtual Entity" would be created and would contract with each covered entity ("CE") in the Commonwealth.</p> <p>The entity would be deemed a business associate of each CE to facilitate data flow in to the entity.</p> <p>The entity would then contract with Stewards to enable outbound data flow.</p>	<p>A separate entity would be created to serve as a health care clearinghouse under HIPAA.</p> <p>The mandate would require CEs to push data to the clearinghouse, which would then provide data to stewards.</p> <p>Note: Clearinghouse is a virtual entity and not a physical data clearinghouse.</p>	<p>All covered entities in the Commonwealth and certified stewards would form an "organized healthcare arrangement" allowing them to transfer data between each other with few legal constraints.</p>

An additional consideration for the legal model was the creation of a uniform data use agreement to significantly increase efficiency, reduce the time and expense of individual contracting for every engagement and offer standardization of such agreements across Massachusetts (discussed in greater detail below). Each of the legal options outlined above would leverage a uniform data use agreement.

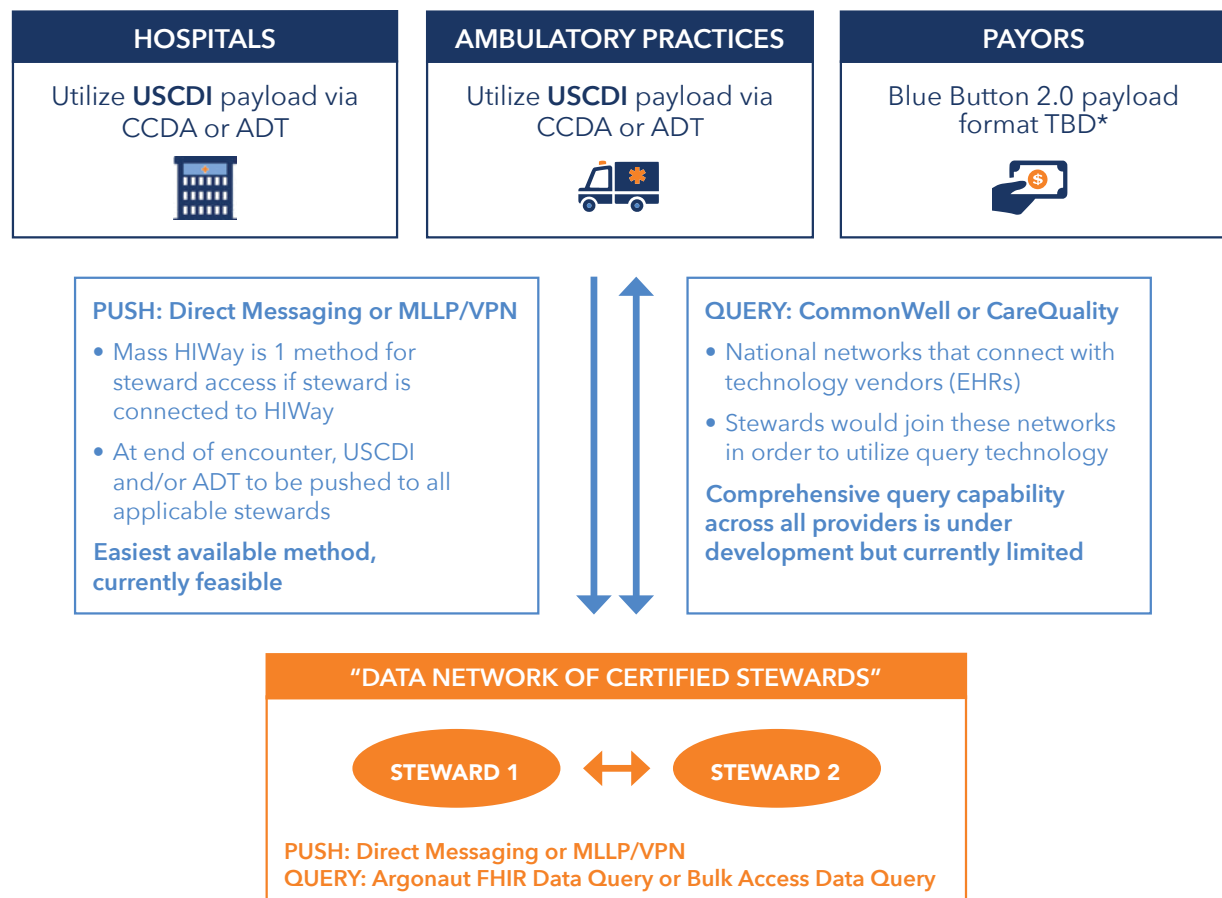
Dataset

The Council recommended that providers would make available an initial data set to all certified data stewards based on the two initial use cases. The proposed initial data set includes ADTs and the proposed v1.0 USCDI dataset, with the exception of clinical notes. It is anticipated that new data elements maybe added to the DDN common data set over time with oversight from the governing body. A detailed listing of the required data set is provided in [Appendix Y](#).

14. Alternatively, a state mandate could require providers to join the national data exchange networks such as Commonwell or Carequality as facilitators of data exchange to data stewards.
15. Selecting and overseeing Data Stewards is a relatively straightforward regulatory function, similar to what CMS does for the Qualified Entity program.
16. Setting requirements for provider participation in the DDN is a relatively straightforward regulatory function, identical to what EOHHS currently does to implement the EHR and HIE mandates in MGL Chapter 118I.
17. Creating specifications for datasets and data transport methodologies is a relatively straightforward regulatory function, similar to what CHIA does in collecting data from 1,500 private-sector data submitters.

Technical Requirements

In the initial implementation, the Council recommended that providers push the minimum data set to all certified stewards through Direct Messaging or MLLP/VPN.¹⁸ At end of a patient encounter, the USCDI (via CCDA) and/or ADT would be pushed from the provider to all applicable stewards in the network. A high-level diagram of the technical components for the DDN is provided below.

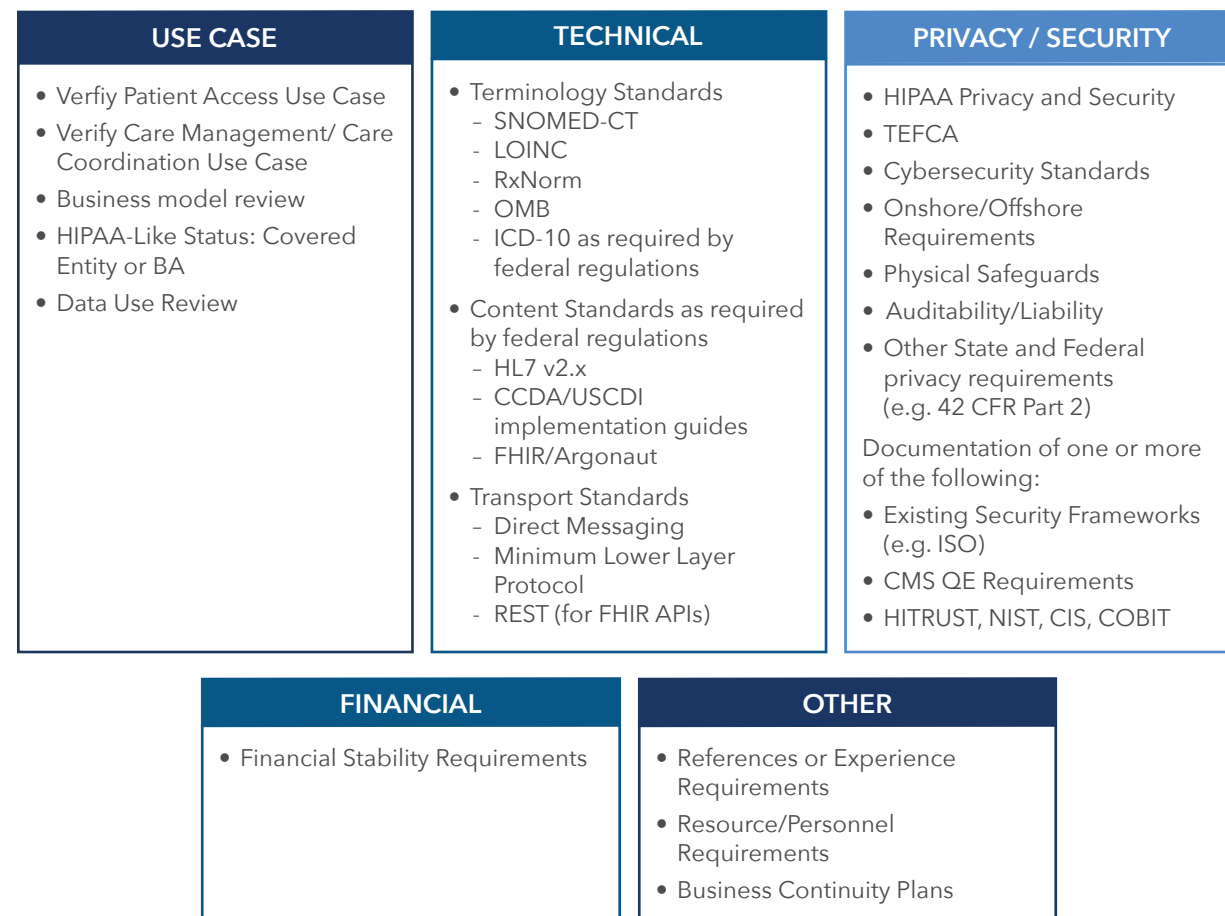


Data Steward Model and Certification

The Council anticipates that certified data stewards could provide a variety of functions including aggregation, transformation and curation of data, data analytics, notification and alert services and reporting mechanisms. However, the proposed framework for the DDN does not prescribe exact functions a data steward could perform. Instead, the DDN creates a framework to support data steward innovation for a limited purpose and with a stringent oversight model.

A key component of the DDN will be the establishment of a robust certification process for Data Stewards that will require compliance with specified security, audit, insurance and liability requirements. The proposed criteria for Data Steward certification is listed on the next page and discussed in greater detail in [Appendix AA](#).

*Payors are out of scope for initial implementation but could be added over time with oversight from governing body



Use Case Summary

As noted earlier, the initial use cases of the DDN will be limited to the following:

PATIENT ACCESS TO THEIR DATA

- Enabling patients access for integrated medical records
- Integrate patient medical records with patient reported outcomes, patient wearables, registry data, external sources (e.g. CDC for flu outbreaks) to enable patients to better manage their health and enhance the availability of data to providers in making treatment decisions.

CARE COORDINATION

- Improving direct patient care with a complete health record view across all points of care including emergency situations, and solving for current gaps in the system (e.g. an out of network patient presents in clinic or ED, the provider will not have any access to the patient's medical record).
- Enabling improved access to patient data for ACOs

The Council anticipates that additional use cases could be added over time, with appropriate oversight by the governing authority. An example patient access use case can be seen on the following page. Additional use cases for the DDN are provided in [Appendix Z](#).

18. APIs will likely replace the Direct Messaging mechanism as providers adopt the capability. The DDN governing authority would monitor the technical maturity of API to replace CCDA push as a measurable goal and work to drive accelerated adoption of FHIR API in Massachusetts. Patient facing APIs require each individual patient log-in credentials for data access; there is no way to modify the API to support steward query without the consent of the patient. National networks (such as CommonWell/Carequality) can support data pull methods but utilize XDS.b and not FHIR API; query capability is also document-based and not data-centered. The DDN GA would monitor provider membership to national networks as an alternative method for transferring data from providers to stewards.

USE CASE: PATIENT ACCESS

USE CASE: Patient access to consolidated medical record via steward with single point of access

GOAL: Patients in MA should be able to have a consolidated medical record, accessed from a single sign-on (as compared to multiple portals) that combines data elements from all providers that the patient sees in MA. This record should be longitudinal, easy-to-read and consolidate similar data types as compared to raw data dump.

DATA SOURCES: All applicable providers the patient sees in MA

DATA CLASSES: USCDI Version 1.0

STORY:

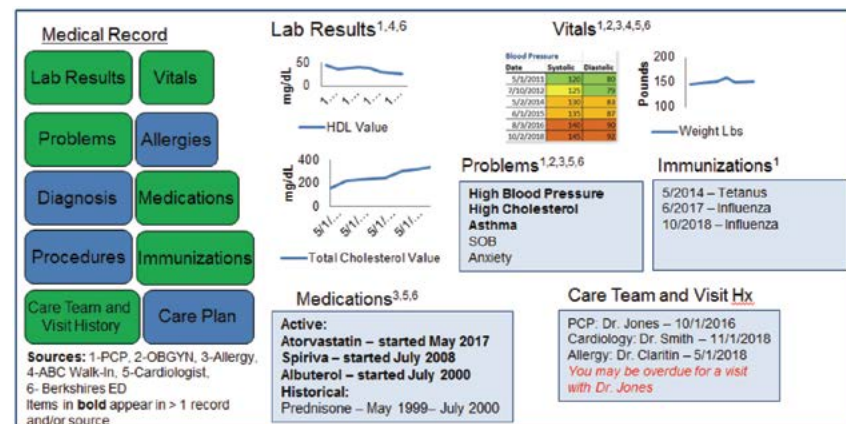
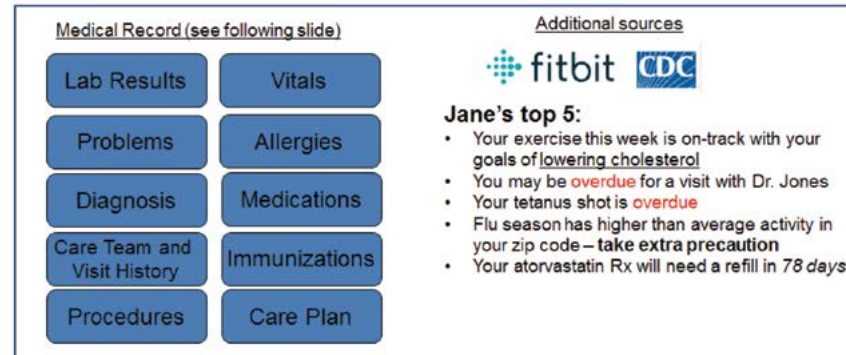
Jane is a 58 year old patient living in Massachusetts. Jane currently sees a primary care physician, gynecologist and allergist for routine care. Recently, Jane has experienced increased shortness of breath along with steadily increasing cholesterol, so she has been referred to a cardiologist. Jane often visits her local urgent care facility for minor issues and has been to the nearest ED based on her recent symptoms. She also spends time every summer in the Berkshires and has had some treatment there.

Jane has a hard time tracking down results from her appointments across the various portals. She does not have the ability to monitor her health results over time or to see her results across visits in order to better prepare herself for visits.

Jane would like to have a method of reviewing her medical information from all of her providers in a single location, with the information collated by relevant field.

SOLUTION:

Jane accesses MAHealthNow*, a service provided by a data steward in MA and is able to pull her consolidated health record from a single log-in. In addition, MAHealthNow enables Jane to link her Fitbit as method of monitoring her health in between visits.



* Fictional service, mock up for illustrative purposes only

DDN Proposal Summary

The Council has determined that DDN can be accomplished without new infrastructure but can leverage existing private and public sector services for pushing and pulling standardized data in support of patient care coordination. The DDN framework governing data sharing and steward participation could be implemented by EOHHS and a reconfigured HIT council. Such a framework would include a mandate for data producers to provide a standardized datasets to certified data stewards. A regulatory “clearinghouse” could mitigate risks for participants by placing all data exchange partners under one legal framework. In order to participate in the DDN, data stewards would need to meet the certification criteria and would be subject to audits and other requirements defined by the governing authority. The Council has developed a complete proposal of recommendations for implementation as detailed in this report and will submit this report with supporting Appendices to the Governor for consideration.

UNIFORM DATA USE AGREEMENTS

OBJECTIVE

Create a uniform data use agreement that all healthcare organizations can use in Massachusetts to address a significant and recurring challenge that digital health companies face: negotiating new data use agreements every time they work with a new healthcare entity (either for initial validation of their solution, or as part of the sale of an existing solution) to get access to healthcare data sets.

RATIONALE

Uniform data use agreements will help to reduce the burden, both monetary and in elapsed time, on digital health entrepreneurs and allow digital health companies to develop and deploy solutions more rapidly. In addition, uniform data use agreements will increase consumer trust in collaborations due to transparency of the agreements.

As noted above, the Council recommended establishing a uniform data use agreement for healthcare organizations in Massachusetts as a component of the DDN. As considered by the Council, all of the proposed legal options would have the benefit of establishing a uniform contracting mechanism to enable access to healthcare data sets by certified data stewards and reduce time, expense and inconsistency created by individual contracting for each engagement. The Council recommended that any implementation of the DDN should also require the use of uniform data use agreements.

CONCLUSION

The Council and working group members have dedicated countless hours towards the development and launch of the initiatives detailed in this report. The community support and engagement during this process is further evidence of the unique, collaborative and innovative environment in Massachusetts that will foster growth of the Digital Health industry. The Council initiatives focus on building the digital healthcare sector for the future by enabling the next generation of companies to grow in Massachusetts. These initiatives establish new infrastructure and resources to reduce technical barriers for startups and build a community of mentors, experts, and community resources and events to support growth.

The DDN proposal outlined in this report highlights options for implementing an innovative healthcare exchange framework that would allow Massachusetts to become a national leader in health information sharing, allow for easier access to healthcare data for digital health startups and companies, and to enable faster development of products to enhance patient well-being and the provision of healthcare in Massachusetts. The DDN would also reduce healthcare information access barriers for providers and patients, ultimately improving patient care.

Going forward, the Commonwealth will play an important leadership role and the Council recommends that the Massachusetts eHealth Institute continue working with private industry to administer the initiatives associated with pilot environments and product validation and ecosystems and connectivity. Investments, resources and engagement from the Commonwealth and private sector will be important for maintaining the momentum and success of these initiatives moving forward.

These initiatives position Massachusetts as a leader in the global digital health economy and will continue to build the digital health sector as a core economic and intellectual strength of the Commonwealth.





APPENDIX

Note: Appendix contains representative working products of Council subcommittees. The Council's final recommendations contained in the body of the Final Report may differ in significant respects.

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APPENDIX A: Digital Health Council Membership

The Digital Health Council convened from November 2016 to July 2019. The membership list below includes members as of July 2019.

Mike Kennealy, Co-Chair, Secretary of Housing and Economic Development
Dr. Jeff Leiden, Co-Chair, Chairman, President and CEO, Vertex

(In alphabetical order)

Dianne Anderson,
President and CEO, Lawrence General Hospital

Scott Bailey,
Chief Growth Officer, MassChallenge

Jeff Bussgang,
General Partner, Flybridge Capital Partners

Carl Byers,
Executive Partner, F-Prime Capital Partners

Damon Cox,
Assistant Secretary of Innovation, Technology and Entrepreneurship, Commonwealth of Massachusetts

Dr. Piali De,
CEO, Sencio Systems

Andrew Dreyfus,
President and CEO, Blue Cross Blue Shield of MA

Sandra Fenwick, CEO,
Boston Children's Hospital

Dr. Alan Garber, Provost, Harvard

Dr. Atul Gawande,
Executive Director, Ariadne Labs at Brigham and Women's Hospital and Harvard T.H. Chan School of Public Health

Michael Greeley,
General Partner, Flare Capital

Louis Gutierrez,
Executive Director, Massachusetts Health Connector

Dr. John Halamka,
CIO, Beth Israel Deaconess Medical Center

Dr. Kerry Healey,
President, Babson College

Colin Hill,
CEO and Co-founder, GNS Healthcare

Keith Hovan,
President & CEO, Southcoast Health System

Dr. Erin Jospe,
Chief Medical Officer, Kyruus

Stephen Kraus,
Partner, Bessemer Venture Partners

Laurie Leshin,
President, Worcester Polytechnic Institute

Travis McCready,
President and CEO,
MA Life Sciences Center

Dr. Elizabeth Nabel,
President, Brigham and Women's Health Care

Ed Park,
Co-founder and CEO, Devoted Health

Lora Pellegrini,
President & CEO, Massachusetts Association
of Health Plans

Larry Renfro,
Vice Chairman, UnitedHealth Group and CEO,
Optum

Marty Schmidt,
Provost, MIT

Peter Sherlock,
Special Advisor to the CEO, MITRE Corporation

Justin Steinman,
Vice President and Head of Product Management,
Aetna

Dr. Steve Strongwater,
President and CEO, Atrius Health

Laurance Stuntz,
Director, Massachusetts eHealth Institute at MassTech

Marylou Sudders,
Secretary, Executive Office of Health and
Human Services

Steve Tello,
Vice Provost for Innovation and Workforce
Development, UMass Lowell

APPENDIX A: Digital Health Council Membership

Dr. David Torchiana,
President and CEO, Partners Healthcare

Joel Vengco,
SVP & CIO, Baystate Health

Sudip Verma,
Director of Sales Strategy and Operations,
Alegeus Technologies

Kate Walsh,
President and CEO, Boston Medical Center

Dr. Rick Weisblatt,
Chief of Innovation and Strategy, Harvard Pilgrim

The Digital Health Council initiatives were supported by the following additional staff members not otherwise named in Appendices A-C: Taylor Uttley, Project Manager for DHC (Vertex Pharmaceuticals), Jamie Arterton (Vertex Pharmaceuticals), Aman Bhandari (Vertex Pharmaceuticals), Paige Goodwin (Vertex Pharmaceuticals), Stacia Reidy MacNaught (Vertex Pharmaceuticals), Juliet Domb (Optum), Brian Noyes (MassTech), Katherine Green (MeHI), Maeghan Welford (MITRE)

APPENDIX B: Working Group Membership

Working Group convened from August 2018 - July 2019 to begin execution on proposals and complete planning phase for DDN.

Dr. Jeff Leiden, Chairman, President and CEO, Vertex, co-chair of Working Group
AG Breitenstein, Partner, Optum Ventures, co-chair of Working Group

Dr. John Halamka,
CIO, Beth Israel Deaconess Medical Center, Project Lead for Distributed Data Network

Dr. Adam Landman,
CIO, Brigham and Women's Hospital, Project Lead Pilot Environments and Product Validation

Scott Bailey,
Chief Growth Officer, MassChallenge, Project Lead Ecosystems and Connectivity

Jay Ash,
CEO, Massachusetts Competitive Partnership

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Executive Director, Massachusetts Health Connector

Bryan Jamele,
COO, Massachusetts Competitive Partnership

Nell Meosky Luo,
Founder and CEO, Folia Health

Mike Kaneb,
Deputy Chief Legal Counsel, Governor's Office

Mike Kennealy,
Secretary of Housing and Economic Development

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CEO, Partners Healthcare

Stephen Kraus,
Partner, Bessemer Venture Partners

Dr. Shawn Murphy,
Chief Research Information Officer, Partners Healthcare

Dr. Dan Nigrin,
SVP, Chief Information Officer, Boston Children's Hospital

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Co-founder and CEO, Devoted Health

Lauren Peters,
Undersecretary for Health Policy, Executive Office of Health and Human Services

Anthony Philippakis,
Chief Data Officer at Broad Institute

Peter Sherlock,
SVP and Chief Operating Officer, The MITRE Corporation

David Sontag,
Associate Professor, MIT and Chief Health Strategist, ASAPP

Laurance Stuntz,
Director, Massachusetts eHealth Institute at MassTech

Titles and membership valid as of February 2019.

APPENDIX C: Planning Phase Committee Membership

Committees convened from January - May 2018 to create detailed plans for execution.

DISTRIBUTED DATA NETWORK

A.G. Breitenstein Co-Chair, General Partner, Optum Ventures
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Dr. John Halamka, Co-Chair, CIO, Beth Israel Deaconess Medical Center

Mary Beckman,
Chief, Health Care and Fair Competition Bureau, MA Attorney General's Office

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VP Data Sciences, Vertex Pharmaceuticals

Carl Byers,
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Raymond Campbell,
Executive Director of Center for Health Information and Analysis (CHIA)

Alan Garber,
Provost, Harvard

Patrick Gilligan,
EVP - Sales, Marketing and Product, BCBSMA

Paige Goodwin,
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Louis Gutierrez,
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Jason Johnson,
Chief Information Officer, Dana Farber

Mike Kaneb,
Deputy Chief Legal Counselor, Governor's Office

Kat Kuzmeskas,
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Dr. Adam Landman,
Chief Information Officer and Vice President, Information Systems | Brigham Health

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Senior VP & Chief Information Officer, Boston Children's Hospital

Ed Park,
Co-founder and CEO, Devoted Health

Anthony Philippakis,
Chief Data Officer, Broad Institute

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Director Government Affairs, athenahealth

APPENDIX C: Planning Phase Committee Membership

Committees convened from January - May 2018 to create detailed plans for execution.

PILOT ENVIRONMENTS AND PRODUCT VALIDATION

Adam Landman, Co-Chair, Chief Information Officer and Vice President, Information Systems | Brigham Health

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Scott Bailey,
Executive Director, MassChallenge Boston

John Brownstein,
Chief Innovation Officer, Children's Hospital

Chris Coburn,
Chief Innovation Officer, Partners

Louis Gutierrez,
Executive Director, MA Health Connector

Bryan Jamele,
COO, Massachusetts Competitive Partnership

Titles and membership valid as of January 2018.

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Partner, Bessemer Venture Partners

Jason Robart,
Chief Strategy Officer, BCBSMA and President
& CEO at Zaffre Investments

Rick Weisblatt,
Chief of Innovation & Strategy, Harvard Pilgrim
Health Care

APPENDIX D: MassTech Summaries of Ecosystem

MASSACHUSETTS

The Top Digital Health Destination for Growth, Expansion, and Partnerships

OUR STRATEGY

Through the Mass Digital Health Initiative, public and private leaders are coming together to build the world's leading digital health ecosystem. We have resources, programs, and strategic support to help digital health innovations succeed quickly. We are building a stronger and more transparent digital health marketplace for entrepreneurs and customers, helping startups grow and scale, harnessing the big data opportunity, and helping all our residents and organizations use digital health for better care delivery and cost outcomes.

Mass Digital Health Offers:

- Home to 380 Digital Health companies
- Top healthcare delivery, life sciences, and technology clusters
- #1 in U.S. health reform
- Smart, innovative, and startup-friendly
- #1 Innovation State (Milken, Bloomberg, and WalletHub)
- 114+ academic and R&D partners producing top talent
- #2 Digital Health investment destination



**Massachusetts has everything
you need to succeed, grow, and scale.**

Join us in the world's leading digital health ecosystem!






APPENDIX D: MassTech Summaries of Ecosystem




Why Massachusetts?

Talent. Innovation. Investment. Collaboration.

<p>Talent:</p> <ul style="list-style-type: none"> 114 Colleges/Universities: over 400,000 students, over 118,000 graduates in 2015. #1 in STEM degree density 47% of adults have Bachelor's degrees, highest percentage of any US state 	<p>Investment:</p> <ul style="list-style-type: none"> Strong private equity and grant environment, currently #2 venture capital destination in the U.S. Top destination for US federal funding Best-in-class support network of programs and resources #2 in overall R&D investment in the country
<p>Innovation:</p> <ul style="list-style-type: none"> 10+ Digital Health innovation programs and accelerators, including the the digital health innovation hubs MassChallenge HealthTech and TechSpring #1 Innovation State (Milken, Bloomberg, and WalletHub) High-quality and innovative payers 79 academic, specialty, & community hospitals 	<p>Collaboration:</p> <ul style="list-style-type: none"> World-leading life sciences ecosystem Strong and growing medical device, cybersecurity, robotics, big data, software, and healthcare sectors A coordinated public-private partnership through Mass Digital Health to support and accelerate growth

HERE TO HELP

Visit www.MassDigitalHealth.org to learn more about the many public and private programs and resources available to support company growth and accelerate the pace of innovation.

THE MASS DIGITAL HEALTH ECOSYSTEM



APPENDIX E: Summary of Timeline of Work and Process

Sub-committees of the Council met over 10 times between May and June 2017 in order to generate the initial proposal concepts

Committees convened from January 2018 to May 2018 to create detail plans for execution:

Ecosystems and Connectivity: 1/26, 2/28, 3/13, 3/22, 5/2

DDN: 1/4, 1/18, 1/31, 2/2, 2/5, 2/8, 2/21, 2/23, 2/26, 3/5, 3/9, 3/19, 3/23, 4/13, 4/24

Pilot Environments and Product Validation: 1/23, 1/31, 2/1, 2/14, 2/15, 2/26, 3/1, 3/21, 3/22, 4/19, 4/26

2016

- **Digital Health Council (DHC) Kickoff** Meeting November 22nd, 2016

2017

- **DHC Meetings:** April 6th, 2017, July 13th, 2017 and November 14th, 2017
- **Final recommendations** for proposal ideas were submitted to Governor Baker in September 2017

2018

- **DHC Meetings:** March 27th, 2018 and October 2nd, 2018
- **Working Group Meetings:** August 8th, 2018, September 26th, 2018, October 25th, 2018 and November 28th, 2018 (sub-group only)

2018

- **DHC Meetings:** July 16th, 2019
- **Working Group Meetings:** January 31st, 2019, March 27th, 2019 and July 10th, 2019

APPENDIX F: Independent Steering Committee Membership

Dr. Adam Landman, Chair of ISC, CIO, Brigham and Women's Hospital

Scott Bailey, Chief Growth Officer, MassChallenge

Nell Meosky Luo, Founder and CEO, Folia Health

Ed Park, Co-founder and CEO, Devoted Health

Peter Sherlock, Special Advisor to the CEO, MITRE Corporation

David Sontag, Associate Professor, MIT and Chief Health Strategist, ASAPP

Rick Weisblatt, Chief of Innovation & Strategy, Harvard Pilgrim Health Care

APPENDIX G: Measures of Success

The ISC developed measures of success in order to evaluate the progress and outcome of the pilot program including:

- The number of applicants into the pilot program
- Testing/validation needs for applicants as compared to the ability of each sandbox in the pilot program
- Estimated cost, time and effort to test and validate with the sandbox compared to independent process
- Staffing resources required to conduct the pilot program by MeHI/ISC
- Final outcomes of pilot program (e.g. lessons learned, # of products/solutions run through pilot, etc.)

APPENDIX H: PracticePoint Details

PracticePoint is a new facility, funded through a \$5M MasTech matching grant along with initial funding of \$9M WPI and \$2.5M from GE. PracticePoint is located at 50 Prescott St. in Worcester Polytechnic Institute's Gateway Park. PracticePoint was built to serve as both a home and hospital sandbox environment. This facility brings together a community of research institutions, healthcare providers, and companies to work collaboratively on new technologies and incorporate them quickly into commercially viable products. In April 2019, PracticePoint opened Phase I: residential and rehabilitative care suites for home health and consumer product development and testing. In Summer 2019, PracticePoint anticipates opening Phase II: the controlled care and surgical imaging suites.



Rehabilitative Care Suite

- Interactive development space
- Assess and optimize device performance
- Innovate wearables, assistive and rehabilitative robotics and devices



Surgical Imaging Suite

- Robotic surgery and implantation
- Image-guided, cyber-physical-aided interventions



Controlled Care Suite

- Multiple care settings
- Administration of "companion diagnostics"
- Automated systems such as robotic lifts and transfers



Residential Suite

- Home health technology
- Telepresence, personal healthcare monitoring, and assisted living technology

Companies partnering with PracticePoint will have access to state of the art equipment, clinical partners within WPI's ecosystem, and WPI researchers and experts and additional benefits like:

- Access to existing IRB for user studies and focus groups;
- Ability to conduct cybersecurity development and testing at device, networking and data storage levels;
- Collaborative research opportunities with WPI faculty experts in areas;
- Clinical partners within the WPI ecosystem, including hospital administrators, doctors, surgeons, and nursing care staff; and
- Multi-modality cross-validation of new designs with industry standards

PracticePoint is a membership-based research, development, and commercialization alliance founded to advance healthcare technologies. An annual membership for a startup includes 25 days of space use at PracticePoint and is \$50,000 annually (can be a mix of in-kind and cash contribution). Digital health startups can apply to the sandbox pilot program matching grant to help offset this cost.

PracticePoint was selected for the pilot program based on the ability to support home, hospital and cybersecurity/hacker hospital requirements. In addition, the PracticePoint membership structure, the ability and desire to partner with startups for projects and willingness to participate in the pilot program as expressed by the PracticePoint leadership were all positive factors in selecting PracticePoint for the pilot.

Opened in February, the Rehabilitation and Assistive Care Suite will enable development and testing of new exoskeletons, prosthetics, rehabilitative robots, and sensors in a high-end motion capture facility. Alongside this, a Residential Care Suite will offer highly instrumented setting to further develop and evaluate devices related to healthcare IOT, assistive and home care, aging in place, sleep, and telehealth. Combined with

APPENDIX H: PracticePoint Details

diverse 3D printing capabilities, companies will be able to prototype new technologies and analyze their effect on gait and full-body motion or evaluate their performance in a realistic home environment.

EQUIPMENT IN THE REHABILITATION SUITE INCLUDES:

- 10 Camera VICON Vantage motion capture system with Lock+ 64 channel ADC and VICON Vue for color video overlay
- Gait analysis track with 2 integrated AMTI OPT400600 force plates
- Delsys Trigno Wireless system with 8 Avanti EMG sensors containing integrated IMU, Bluetooth compatibility, and SDK/API support
- Ceiling gantry for subject safety and support
- Configurable exercise equipment and obstacles such as doors and stairs
- Instrumented residential setting for testing of smart-home technologies
- Markforged Metal X, Markforged MarkTwo, and Formlabs Form 2 printers for prototyping plastic, metal, and fiber reinforced parts
- AVA telepresence robot for video collaboration and smart-home applications

Completing the build out by summer 2019, the addition of a hybrid operating room, MRI imaging suite, Clinical care suite, RF electronics test suite, collaboration areas, dedicated corporate pods, machine shop, and microelectronics fabrication area will enable a host of medically related research and development. PracticePoint members can evaluate technologies in a reconfigurable ICU/ER/patient care space, test integration of new devices into an operating room environment, evaluate how MRI compatible robots perform inside an MRI bore, and evaluate image-guided therapies in phantom studies—all of this while quickly iterating designs with on-site mechanical and electrical fabrication facilities.

- Medical imaging suite with GE 3T Signa Premiere MRI scanner
- Hybrid imaging operating room with C-arm fluoroscope and CT reconstruction
- Clinical care suite (modular ICU) with patient monitoring, beds, and lifts
- Mechanical fabrication and prototyping with CNC mill, CNC lathe, ProtoMAX small format waterjet cutter, and Epilog Helix24 75W laser cutter
- RF electronics suite with mixed signal oscilloscopes, function generators, and spectrum analyzers
- General purpose soldering stations and nano-rework station
- Circuit board assembly with BGA rework system, pick and place machine, and reflow oven

APPENDIX H: PracticePoint Details

Membership Tiers

Platinum	50 days (equivalence) of space use at PracticePoint <ul style="list-style-type: none"> • 1 research assistant in PracticePoint • 2 student projects • 1 branded pod • 1 board seat 	\$250,000 annually (mix of in-kind and cash contributions) <ul style="list-style-type: none"> • 3-year commitment • Max of 4 members at this level
Gold	25 days (equivalence) of space use at PracticePoint <ul style="list-style-type: none"> • 1 student project • Use of unbranded pod • 1 board seat 	\$100,000 annually (mix of in-kind and cash contributions) <ul style="list-style-type: none"> • 3-year commitment • Max of 10 members at this level
Silver	1 student project <ul style="list-style-type: none"> • Discount on space rental 	\$25,000 annually (mix of in-kind and cash contributions) <ul style="list-style-type: none"> • 1-year commitment • No max number of members at this level
Startup	25 days (equivalence) of space use at PracticePoint <ul style="list-style-type: none"> • 1 student project • Use of unbranded pod 	\$50,000 annually (mix of in-kind and cash contributions) <ul style="list-style-type: none"> • 1-year commitment • Max of 10 members at this level

APPENDIX I: Sandbox Evaluation Criteria

The following evaluation criteria will be used to review Applicants for the Sandbox Grant Program. The ISC will review applications on a project-by-project basis. The ISC will review projects for technical merit and economic impact potential of each individual proposal with a goal to identify and support the highest-value opportunities to strengthen and expand the state's economy, with a focus on existing or new digital health products/solutions. Evaluation considerations for this goal will include:

- Is the proposed use of the sandbox technically viable?
- Is the funding for the proposed use of sandbox economically viable?
- Can intervention/engagement with sandbox positively influence the trajectory of the project?
- Does the product sufficiently demonstrate the potential of the proposed project to feasibly result in new (or materially enhanced) products, processes or applications which will build upon the digital health ecosystem?
- Is there a critical mass of firms within the sector/cluster already in the state?
- Priority will be given to projects that include high-impact activities, with direct, immediate interaction with industry that demonstrably enhances competitiveness and sector dominance.

A scoring matrix was developed to include the follow:

- Feasibility of the proposed project:
 - Technical merit
 - Economic viability
 - Uniqueness of company or product in the digital health ecosystem
- Potential impact of the project, including:
 - Impact of the project on the company
 - Impact of the project on expanding and strengthening the state's economy
 - Impact of the project on patients' lives
- Projects addressing the following areas will receive preference:
 - Cost or access challenges identified by the Health Policy Commission or other public bodies
 - Cybersecurity and privacy issues
- Does project specifically support cybersecurity research and help digital health companies develop features to ensure that their solutions are validated to be secure and protect privacy?
- Does the project enable the ability to stress-test new devices, software and systems against cyber threats?
 - Workflow for new technologies in home or hospital settings (e.g. wearables or consumer apps)
- Does project help to validate a workflow for new technologies in the hospital and home setting, such as wearables and consumer apps.
- Does the project utilize synthetic data to simulate a realistic hospital setting?
 - Collaboration with academic researchers to increase the evidence base for digital health solutions
- Does the project support collaboration with academic researchers to help increase the evidence base for digital health solutions and/or help digital health companies develop their value proposition?

APPENDIX J: Final Application for Startups / RFP



GRANT SOLICITATION

Sandbox Pilot Program
Solicitation No. 2019-MeHI-02

Massachusetts Technology Collaborative
75 North Drive
Westborough, MA 01581-3340
<http://www.masstech.org>

Solicitation Issued: 4/24/2019
Team Leader: Katherine Green
Applications Due: 6/10/2019

1. INTRODUCTION

The Massachusetts eHealth Institute ("MeHI"), a non-divisible component of the Massachusetts Technology Collaborative ("Mass Tech Collaborative"), is offering grants to fund projects to support companies looking to test and validate new products and services in a sandbox environment. MassTech Collaborative anticipates awarding grants in the range of \$25,000 to \$60,000.

Mass Tech Collaborative acts as the contracting entity on behalf of Massachusetts eHealth Institute and will enter into an agreement with selected Applicants containing certain standard provisions (the "Agreement") (See the Mass Tech Collaborative site for the template Agreement). The funding for this Program is sourced from MeHI - Digital Health.

Mass Tech Collaborative reserves the right to amend the Agreement at any time. Applicants should review the Grant Agreement and Statement of Work located [HERE](#) as they are required to specify any exceptions to the Agreement and to make any suggested counterproposal in their Application. **A failure to specify exceptions and/or counterproposals will be deemed an acceptance of the Agreement's general terms and conditions, and no subsequent negotiation of such provisions shall be permitted.** Although Mass Tech Collaborative will be the contracting counter-party with the Applicant, for purposes of this Solicitation (and except where the specific context warrants otherwise), Massachusetts eHealth Institute and the Mass Tech Collaborative are collectively referred to as Massachusetts eHealth Institute or MeHI.

2. GRANT OVERVIEW

2.1 Background

In 2016, Governor Baker launched the Digital Health Initiative (the "Initiative") to position Massachusetts as a leading ecosystem for digital health innovation. Executive Order #574 established the Digital Health

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Council (the "Council") to advise the Governor and develop a growth plan to achieve the goals of the Initiative. The Council is co-chaired by the Secretary of the Executive Office of Housing and Economic Development and Dr. Jeffrey Leiden, Chairman, President, and CEO of Vertex, and is supported by the Massachusetts eHealth Institute. In 2017, the Council recommended focusing on three priority areas: creating a distributed data network; improving the Commonwealth's digital health ecosystem and connectivity; and supporting pilot environments and product validation. Under the last priority area, the Council recommended supporting sandbox environments with a "hacker hospital" to support the lifecycle of research and development for digital health companies. To help achieve that goal, the Council and MeHI established a Sandbox Grant Program and formed an Independent Steering Committee ("ISC") to oversee the program. The ISC advised MeHI and the Council on the development of the program and the criteria for evaluating applicants. The ISC will review applications and make funding recommendations to MeHI.

2.2 Grant Requirements & Guidance

In conjunction with the Council, MeHI is releasing this solicitation for applications from Massachusetts based digital health companies seeking support to test and validate their products or services in a sandbox environment. This is a rolling solicitation and any responses submitted after the initial deadline will be reviewed on a periodic basis pursuant to the evaluation criteria set forth in this solicitation.

The ISC and MeHI will select Massachusetts based sandbox environments to participate in the program. Information on the participating sandboxes and their capabilities will be kept up-to-date on www.massdigitalhealth.org. Sandboxes will be periodically added as they are approved by MeHI and the ISC. Applicants should carefully review the information to determine which sandbox can support their testing needs and they are strongly encouraged to engage in conversations with the sandboxes before applying.

Applicants must complete Attachment A, the "MA Digital Health Sandbox Pilot Application". The application should indicate the sandbox they would like to work with and clearly describe the applicant's organization, their proposed use of the sandbox, any equipment needs, and expected outcomes during the project period. If selected, in addition to contracting with MeHI, applicants may be required to execute agreements with their selected sandbox. MeHI anticipates directing any awarded funds directly to a selected applicant's sandbox environment. At the end of their project, selected applicants will be required to submit a final report summarizing their project, outcomes, barriers to completing the project, and plans for next steps, including the ability to move into a clinical environment post-testing.

Selected applicants are eligible for grant awards expected to range from \$25,000 to \$60,000. The ISC will recommend award amounts based on the cost of the applicant's proposed project, the applicant's annual revenue, the amount of funding the applicant has raised, and other criteria determined by the ISC.

3. EVALUATION PROCESS AND CRITERIA

MeHI will collect and prepare the applications for the ISC to review. The ISC will make funding recommendations to MeHI based on its review.

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The ISC will include the following evaluation criteria in its review:

- Feasibility of the proposed project, including:
 - Technical merit
 - Economic viability
 - Uniqueness of company or product in the digital health ecosystem
- Potential impact of the project, including:
 - Impact of the project on the company
 - Impact of the project on expanding and strengthening the state's economy
 - Impact of the project on patients' lives
- Projects addressing the following areas will receive preference:
 - Cybersecurity and privacy issues
 - Cost or access challenges identified by HPC or other public bodies
 - Value proposition for digital health solutions
 - Workflow for new technologies in home or hospital settings (e.g. wearables or consumer apps)
 - Collaboration with academic researchers to increase the evidence base for digital health solutions

All applicants will be notified of final decisions via e-mail to the identified Project Director. We anticipate that funding decisions for the first round of applications will be made by July 15, 2019.

4. APPLICATION PROCESS

4.1 Application and Submission Instructions

Applicants are cautioned to read this Solicitation carefully and to conform to its requirements. Failure to comply with the requirements of this Solicitation may serve as grounds for rejection of an Application.

- a. Applications **must** be delivered electronically to: proposals@masstech.org (please include the solicitation number in the subject heading).
- b. A statement indicating compliance with the terms, conditions and specifications contained in this Solicitation must be included in the Application. Submission of the signed Authorized Applicant's Signature and Acceptance Form (Attachment B) shall satisfy this requirement.
- c. Any and all responses, Applications, data, materials, information and documentation submitted to Mass Tech Collaborative in response to this Solicitation shall become Mass Tech Collaborative's property and shall be subject to public disclosure. As a public entity, the Mass Tech Collaborative is subject to the Massachusetts Public Records Law (set forth at Massachusetts General Laws Chapter 66). There are very limited and narrow exceptions to disclosure under the Public Records Law. If an Applicant wishes to have the Mass Tech Collaborative treat certain information or documentation as confidential, the Applicant must submit a written request to the Mass Tech Collaborative's General Counsel's office no later than 5:00 p.m. fourteen (14) business days prior to the required date of Application submission set forth in Section 4.2 below. The request must precisely identify the information and/or documentation that is the subject of the request and provide a detailed explanation supporting the application of the statutory exemption(s) from the public records cited by the Applicant. The General Counsel will issue a written determination within ten (10) business days of receipt of the written request. If the General Counsel approves the request, the Applicant shall clearly label the relevant information and/or documentation as "**CONFIDENTIAL**" in the Application and

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shall submit a hard copy of the Application with the confidential material to:

General Counsel
Massachusetts Technology Collaborative
75 North Drive
Westborough, MA 02108

No confidential material should be included in the electronic copy of the Application. Any statements in an Application reserving any confidentiality or privacy rights that is inconsistent with these requirements and procedures will be disregarded.

Applicants please note: By executing the Authorized Applicant's Signature and Acceptance Form and submitting an Application in response to this Solicitation, Applicant certifies that it (1) acknowledges and understands the policies and procedures for handling materials submitted to Mass Tech Collaborative, as described in this Solicitation, (2) agrees to be bound by those policies and procedures, (3) acknowledges that the statutory exemptions from the Massachusetts public records law are very limited; and (4) agrees that Mass Tech Collaborative shall not be liable under any circumstances for any disclosure of materials submitted in connection with this Solicitation that is required by law.

4.2 Application Timeframe

The application process will proceed according to the following schedule. The target dates are subject to change. Therefore, Applicants are encouraged to check Mass Tech Collaborative's website frequently for updates to the schedule.

Solicitation Released	4/24/2019
Questions Due	5/10/2019 @ 5 PM EST
Question and Answer File Posted	5/17/2019 @ 5 PM EST
Applications Due	6/10/2019 @ 3 PM EST
Notification of Award	7/15/2019

4.3 Questions

Questions regarding this Solicitation must be submitted by electronic mail to proposals@masstech.org with the following Subject Line: "Questions - Solicitation No. 2019-MeHI-02". All questions must be received by 5:00 p.m. EST on May 10, 2019. Responses to all questions received will be posted on or before 5:00 p.m. on May 17, 2019 to the Mass Tech Collaborative and Comm-Buys website(s).

4.4 Application Guidelines

Applications must include the items listed below.

- MA Digital Health Sandbox Pilot Application (Attachment A)
- Authorized Application Signature and Acceptance Form (Attachment B). **By executing the Authorized Applicant's Signature and Acceptance Form and submitting a response to this**

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solicitation, Applicants certify that they (1) acknowledge and understand the procedures for handling materials submitted to the Mass Tech Collaborative as set forth herein, (2) agree to be bound by those procedures, and (3) agree that the Mass Tech Collaborative shall not be liable under any circumstances for the disclosure of any materials submitted to the Mass Tech Collaborative pursuant to this solicitation or upon the applicant's selection as a grantee.

- Exceptions to the Grant Agreement and Statement of Work located HERE, if any.

5.0 GENERAL CONDITIONS

5.1 General Information

- If an Application fails to meet any material terms, conditions, requirements or procedures, it may be deemed unresponsive and disqualified. The Mass Tech Collaborative reserves the right to waive omissions or irregularities that it determines to be not material.
- This Solicitation, as may be amended from time to time by Mass Tech Collaborative, does not commit Mass Tech Collaborative to select any firm(s), pay any costs incurred in preparing an Application or in connection with the award of any contracts. Mass Tech Collaborative reserves the right, in its sole discretion, to make no awards through this Solicitation, to withdraw the Solicitation, to engage in preliminary discussions with prospective Applicants, to accept or reject any or all Applications received, to request supplemental or clarifying information, to negotiate with any or all qualified Applicants, and to request modifications to Applications in accordance with negotiations, all to the same extent as if this were a Request for Information.
- Unless otherwise specified in this Solicitation, all communications, responses, and documentation must be in English, and all cost Applications or figures in U.S. currency. All Applications must be submitted in accordance with the specific terms of this Solicitation.
- On matters related to this Solicitation that arise prior to an award decision by the Mass Tech Collaborative, Applicants shall limit communications with the Mass Tech Collaborative to the Procurement Team Leader and such other individuals as the Mass Tech Collaborative may designate from time to time. No other Mass Tech Collaborative employee or representative is authorized to provide any information or respond to any questions or inquiries concerning this Solicitation. Applicants may contact the Procurement Team Leader for this Solicitation in the event this Solicitation is incomplete.
- The Mass Tech Collaborative may provide reasonable accommodations, including the provision of materials in an alternative format, for Applicants with disabilities or other hardships. Applicants requiring accommodations shall submit requests in writing, with supporting documentation justifying the accommodations, to the Procurement Team Leader. The Mass Tech Collaborative reserves the right to grant or reject any request for accommodations.
- Applicant's Application shall be treated by the Mass Tech Collaborative as an accurate statement of Applicant's capabilities and experience. Should any statement asserted by Applicant prove to be inaccurate or inconsistent with the foregoing, such inaccuracy or inconsistency shall constitute sufficient cause for Mass Tech Collaborative in its sole discretion to reject the Application and/or terminate of any resulting Agreement.

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5.2 Posting of Modifications/Addenda to Solicitation

This Solicitation has been distributed electronically using the Mass Tech Collaborative, Mass Digital Health, and COMMBUYS websites. If the Mass Tech Collaborative determines that it is necessary to revise any part of this Solicitation, or if additional data is necessary to clarify any of its provisions, an addendum will be posted to the websites. It is the responsibility of each potential Applicant to check the Mass Tech Collaborative, Mass Digital Health, and COMMBUYS websites for any addenda or modifications to the Solicitation. The Mass Tech Collaborative accepts no liability and will provide no accommodation to Applicants who submit a response based on an out-of-date Solicitation.

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Attachment A MA Digital Health Sandbox Pilot Application

Name of Applicant Organization		Applicant Website	
Mailing Address		City/Town/Zip Code	Telephone
Applicant legal status and state of jurisdiction <i>(e.g., a Massachusetts corporation, a Delaware Limited Liability Company, a Connecticut limited partnership, etc).</i>			Applicant Taxpayer ID#
Applicant Organization FTE Count	Applicant Organization Revenue Range (past 12 months)	Applicant Organization Total Equity Financing Range	
	<input type="checkbox"/> Less than \$1M <input type="checkbox"/> Between \$1M - \$3M <input type="checkbox"/> Between \$3M - \$10M <input type="checkbox"/> More than \$10M	<input type="checkbox"/> Less than \$1M <input type="checkbox"/> Between \$1M - \$3M <input type="checkbox"/> Between \$3M - \$10M <input type="checkbox"/> More than \$10M	
Name of Primary Contact	Primary Contact Title	Contact e-mail	Contact Telephone

Indicate which Sandbox you are applying for:

Provide a brief description of your company

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Describe your proposed use of the sandbox, including testing and validation needs, estimated length of project, timeline when project needs to commence, etc.

Describe specific equipment needed to conduct project, including any hardware, software and/or networking requirements, etc.

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Describe your expected outcomes. What do you hope you hope to achieve? How will you measure success? What are the potential impacts of your project – both on your company and the digital health ecosystem?

Budget

Complete the budget template below:

Use of Sandbox (e.g. membership level; proposed services)	Rate or Fee	Period of Use (if applicable)	Total
Total			
Matching funds			
Total MassTech Share			

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Attachment B

Massachusetts Technology Collaborative

Authorized Applicant's Signature and Acceptance Form

The undersigned is a duly authorized representative of the Applicant listed below. The Applicant has read and understands the Solicitation requirements. The Applicant acknowledges that all of the terms and conditions of the Solicitation are mandatory, and that Applicant's response is compliant with such requirements. The Applicant specifically acknowledges the application of the procedures regarding disclosure of sensitive information as set forth in Section 4.1 (d) of the Solicitation, and specifically agrees that it shall be bound by those procedures.

The Applicant understands that, if selected by the Mass Tech Collaborative, the Applicant and the Mass Tech Collaborative will execute written agreements specifying the mutual requirements of participation. The undersigned has either (*please check one*):

- specified exceptions and counter-proposals to the terms and conditions of the Grant Agreement and Statement of Work; or
- agrees to the terms and conditions set forth therein;

The undersigned acknowledges and agrees that the failure to submit exceptions and counter-proposals with this response shall be deemed a waiver, and the Agreement shall not be subject to further negotiation.

Applicant agrees that the entire bid response will remain valid for sixty (60) days from receipt by the Mass Tech Collaborative.

I certify that Applicant is in compliance with all corporate filing requirements and State tax laws.

I further certify that the statements made in this response to the Solicitation, including all attachments and exhibits, are true and correct to the best of my knowledge.

Applicant: _____
(Printed Name of Applicant)

By: _____
(Signature of Authorized Representative)

Name: _____

Title: _____

Date: _____

APPENDIX K: Listing of Existing MA Sandboxes

Application and Process for Adding New Sandboxes to Pilot Program

DEFINITION OF A MASSACHUSETTS SANDBOX:

Approved Massachusetts Digital Health Sandboxes provide an environment to test and validate digital health products or services. Approved sandboxes must be based in Massachusetts and have the staffing, space, and expertise to work with external digital health companies. The sandboxes must have an established fee structure and user agreement for engaging with external users. Additionally, sandboxes must be able to describe their methodology for supporting external users.

Information to Gather from Sandboxes:

- Type of testing environment available:
 - User experience
 - Infrastructure
 - Data Repository
 - Cybersecurity
- Services Offered
 - Research support capabilities (IRB access, study design, etc.) offered
 - Settings available (home; hospital; Hacker Hospital; post-acute care; outpatient facility; dental facility, etc.)
- Access to data:
 - Real
 - Synthetic
 - De-identified
- Access to healthcare professionals (delineate what kinds, including doctors, nurses, other clinical staff and non-clinical staff such as IT, finance, supply chain, operations, compliance, information security, etc)
- Experience and methodology for engaging with external users
- Ability to support digital health companies
- Fee structure
- Sample user agreement

Evaluation Criteria:

- Uniqueness of testing environment or services offered
- Ability to support MA digital health companies in validating products, services, and their value proposition.
- Identified staff with expertise and ability to connect with external users, manage relationships and guide validation projects

APPENDIX K: Listing of Existing MA Sandboxes

FACILITY	WEBSITE	GENERAL
PracticePoint at WPI	https://www.wpi.edu/research/partnerships/medical-cyber-physical-systems	Research, Development and Commercialization Alliance to build advanced healthcare technologies and launch new medical cyber-physical systems.
Goldstein Simulation Center	http://www.northeastern.edu/bouve/about/simulation-center/	Healthcare simulation laboratory at Northeastern University
Carl J. Shapiro Simulation and Skills Center	http://www.bidmc.org/Medical-Education/Shapiro-Simulation-and-Skills-Center.aspx	Surgical simulation center at Beth Israel Deaconess Medical Center
Harvard Center for Medical Simulation	https://harvardmedsim.org/	Simulation training at CMS gives healthcare providers a new and enlightening perspective on how to handle real medical situations. Through high-fidelity scenarios that simulate genuine crisis management situations, the CMS experience can open new chapters in the level of healthcare quality that participants provide. Medical device usability testing is available.
NERVE Center at UMass Lowell	http://nerve.uml.edu/	The New England Robotics Validation and Experimentation (NERVE) Center at the University of Massachusetts Lowell is a dedicated research, testing, and training facility. The mission of the NERVE Center is to improve the development of robotic systems by both academic researchers and corporations by facilitating evaluation throughout the design cycle. It offers testing and prototyping services.
MassRobotics	https://www.massrobotics.org/	An independent, non-profit organization serving as the innovation hub for robotics and connected devices. Through programming and events, they help bring together innovative startups and existing technology organizations to nurture the next generation of talent, and promote economic growth and innovation. Offers product development support, shared infrastructure, and space.
MIT Age Lab	http://agelab.mit.edu/	The MIT AgeLab is a multidisciplinary research program that works with business, government, and NGOs to improve the quality of life of older people and those who care for them.
MedRC	http://medrc.mit.edu/	The Medical Electronic Device Research Center at MIT establishes a partnership among the microelectronics industry, the medical devices industry, medical professionals, and MIT. Working together, MEDRC seeks improvements in the cost and performance of medical electronic devices similar to those that have occurred in personal computers, communication devices and consumer electronics.

APPENDIX K: Listing of Existing MA Sandboxes

FACILITY	WEBSITE	GENERAL
Partners Medical Device Plug-and-Play Interoperability Lab	http://www.mdnp.org/lab.php	The Medical Device Plug-and-Play Interoperability Lab at Massachusetts General Hospital / Partners HealthCare/ CIMIT is designed as a collaborative lab space. It provides an environment of computing and medical device resources to support projects, testing, and prototyping work by the MD PnP team and collaborators. The facility has been outfitted with a high-speed virtual medical network by Partners HealthCare Information Systems
WPI HDI Living Lab	https://www.wpi.edu/research/areas/centers/healthcare-delivery-institute/living-lab	With strategic relationships with the University of Massachusetts Medical School and the Visiting Nurse Associations of New England, HDI has collaborated with over 10 healthcare provider organizations across the continuum of care. The result is a living learning lab for healthcare innovation in central Massachusetts centered at HDI at WPI, healthcare graduate programs, thought leadership programs such as symposia and innovation forums, and workforce talent.
STRATUS Center for Medical Simulation	http://www.brighamandwomens.org/Departments_and_Services/emergencymedicine/STRATUS/default.aspx	The Neil and Elise Wallace STRATUS Center for Medical Simulation is one of the most comprehensive and technologically-advanced medical training centers in the world, backed by the world-class experience of Brigham and Women's Hospital, a major teaching affiliate of Harvard Medical School. Beyond its clinical applications, simulation can also be a valuable tool for industry, especially sales staff and product developers. We work with medical device and pharmaceutical companies to set up simulated environments to inform the process of bringing new technologies from the bench to the bedside.
BWH iHUB	https://www.bwhihub.org	Brigham Innovation Hub (iHub) launched in September 2013 as a resource center for innovators at Brigham and Women's Hospital to advance their ideas for improving care. Since then iHub has evolved into a broader digital health consulting team, supporting internal innovation and also bringing in leading-edge digital solutions to create the hospital of the future.
Natick Soldiers	https://www.army.mil/info/organization/natick	Natick Soldiers focuses on the following: <ul style="list-style-type: none"> • Develop new technology. • Invest in the continuous development and provide quality of life for our workforce. • Advance, assess and apply emerging technology. • Create a collaborative environment between government, academia and industry on behalf of the Soldie
Stanley Healthcare - Waltham	https://www.stanleyhealthcare.com/company/visit-us/experience-center	Located in Waltham, Massachusetts at STANLEY Healthcare's headquarters, the 6,500 square foot center offers a hands-on environment for you to evaluate, design and fine-tune our comprehensive portfolio of safety, security and operational efficiency solutions, products and services. The Experience Center enables current and prospective customers to interact first hand with our full suite of solutions in our state-of-the-art simulated healthcare settings, which include a nursing station, emergency department/PACU, OR/Cath lab, labor, delivery & recovery, senior living and home health, medical-surgical ICU/ critical care, supply storage area and security station.

APPENDIX K: Listing of Existing MA Sandboxes

FACILITY	WEBSITE	GENERAL
IBM Cyber Range	https://www.ibm.com/industries/federal/cyber-security/cyber-range	<p>Evolve your critical cybersecurity-related crisis leadership skills in a safe "live fire" environment where participants can experience the effects of live malware, DDoS, and other traditional and more advanced attacks. The IBM Cyber Range, based in Cambridge Massachusetts, uses live malware, ransomware and other real-world hacker tools culled from the dark web to deliver realistic cyberattack scenarios.</p> <p>During this immersive experience, your team will have an opportunity to practice security-related crisis leadership skills in a safe, collaborative environment. You will operate real tools, investigate active infections and respond to internal and external cyber security events, as well as respond to real world situations. These exercises will help train and prepare agencies to take the necessary steps required to respond quickly in the wake of an incident.</p> <p>Sign your cyber analysts/specialists up today to visit the IBM Cyber Range.</p>
Baystate Health	https://www.baystatehealth.org/education-research/education/simulation-center	Our 4,000 square foot training facility houses the Baystate Simulation Center and the Goldberg Surgical Skills Laboratory.
TechSpring	http://www.techspringhealth.org/living_lab	<p>Our process for guiding experienced product developers at any stage (from ideation through solution success) includes everything from governance, project roles, team structure, stage/gate iterative fast/fail process, compliance, information security, contracts (MSA, SOW), and more.</p> <p>We're not new to this. We've skillfully tuned our process over the last 3 years, putting the parts that can be standardized "on rails" - in place and ready to go. As for the myriad of complexity and variables, we know from experience how to tackle those aspects with the right blend of structure and flexibility.</p> <p>We guide and coach healthcare professionals and product innovators through all stages:</p> <ul style="list-style-type: none"> • Inquiry, discovery, strategy, and team selection; • Iterative testing, learning, pivoting, and refining; • Navigating and nailing the 14 layers of compliance instances. • Identifying and capturing value.
Harvard Innovation Labs	https://innovationlabs.harvard.edu/	<p>We are a three-lab ecosystem that exists to support Harvard students and select alumni in their quest to explore the world of innovation and entrepreneurship.</p> <p>Whether you're here to solve a problem by creating a business, or simply interested in learning about innovation more broadly, we'll help you get there further, faster.</p> <p>Our ecosystem encompasses three distinct spaces:</p> <ul style="list-style-type: none"> • the i-lab for current Harvard students interested in innovation and entrepreneurship, • the Launch Lab for eligible Harvard alumni leading promising early-stage startup ventures, and the • the Pagliuca Harvard Life Lab for Harvard students, faculty, and alumni working on high-potential life sciences and biotech startups.

APPENDIX K: Listing of Existing MA Sandboxes

FACILITY	WEBSITE	GENERAL
Boston Children's Hospital - Innovation and Digital Health Accelerator	http://accelerator.childrenshospital.org/	<p>Through the creation of the Innovation and Digital Health Accelerator, Boston Children's reinforces a commitment to, and investment in pediatric innovation. We are combining our data, clinical expertise, and health care technology development experience, with leading worldwide industry partners - including start-ups - to transform health care. We work to surface, support and accelerate Boston Children's innovations for the purpose of improving pediatric care Until Every Child is Well. Today, there is a new level of investment and urgency behind accelerating innovations and expanding our reach globally.</p> <p>Our cross-functional team with expertise in software development, data analytics, clinical care and lean startup practices, work together to accelerate innovations and technologies from concept to global deployment.</p>

APPENDIX L: Cybersecurity Group of Experts Membership

Margie Zuk, Co-Chair, Principal Cybersecurity Engineer, MITRE
Maeghan Welford, Co-Chair, Director of Integration and Plans, MITRE

Josh Corman, Chief Security Officer, PTC

Jen Ellis, VP of Community and Public Affairs, Rapid 7

Ron Ford, Regional Cybersecurity Advisor New England, Department of Homeland Security, Office of Cybersecurity and Communications

Julian Goldman, MD, Director of Biomedical Engineering for Partners HealthCare, anesthesiologist at MGH and Director of Program on Medical Device Interoperability research program.

Stephanie Helm, Director, MassCyberCenter

Christina Mazzone, Chief Information Security Officer, BWH

Michael McNeil, Head of Global Product and Security, Phillips

Paul Schieb, Chief Information Security Officer, Boston Children's

Daniel Weitzner, Director, MIT Internet Policy Research Initiative and Research Scientist at CSAIL

Additional members may be added as expertise is needed

APPENDIX M: Cybersecurity Toolkit for Digital Health Entrepreneurs

Organizational Cybersecurity Best Practices:

- US-CERT SMB: Toolkit Includes section dedicated for startups. Toolkit to assist SMBs and startups with securing their organization. Includes roadmap for critical infrastructure requirements for small and midsize businesses (<https://www.us-cert.gov/sites/default/files/c3vp/smb/DHS-SMB-Road-Map.pdf>)
- FCC Small Biz Cyber Planner Helps businesses create and save a custom cyber security plan quickly to address specific business needs and concerns.
- FTC Small Business Fact Sheet Covers cybersecurity basics and best practices including the NIST cybersecurity framework for SMBs, and covers security threats (e.g. phishing, ransomware, email spoofing, and tech support scams, etc.)
- NIST Framework - <https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf>
- DHS Entrepreneurs Tip Card: Provides simple cybersecurity tips and resources for entrepreneurs.
- HHS Quick Response Checklist for HIPAA Covered Entity or Business Associate: Provides HIPAA-related organizations brief guidance on responding to cyber incidents. "My entity just experienced a cyber-attack! What do we do now?"
- HIPAA Security Rule and NIST Crosswalk: Identifies "mappings" between the Cybersecurity Framework and the HIPAA Security Rule. This crosswalk maps each administrative, physical and technical safeguard standard and implementation specification1 in the HIPAA Security Rule to a relevant NIST Cybersecurity Framework Subcategory.
- ISO2700: <https://www.iso.org/standard/73906.html> and <https://www.iso.org/isoiec-27001-information-security.html>
- CIS Top Controls: <https://www.cisecurity.org/controls/cis-controls-list/>

Health Sector Joint Cybersecurity Resources:

- Report on Improving Cybersecurity in the Healthcare Industry: <https://healthsectorcouncil.org/health-care-industry-cybersecurity-task-force/>
- Voluntary Cybersecurity Practices for the Healthcare Industry - compiled with feedback from over 150 industry representatives - released on an annual basis: <https://healthsectorcouncil.org/hhs-and-hscc-release-voluntary-cybersecurity-practices-for-the-health-industry/>
- Medical Technology Joint Security Plan includes medical devices and EHRs. Includes a maturity model for manufacturers for improved security in medical device design: <https://healthsectorcouncil.org/hscc-releases-the-medical-device-and-health-it-joint-security-plan/>

Cybersecurity Practices and Guidance for Medical Devices:

- FDA Medical Device Cybersecurity Page - includes premarket and post market management of medical devices: <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm>
- Fact Sheet: the FDA's Role in Medical Device Cybersecurity - includes an overview of FDA: <https://www.fda.gov/downloads/medicaldevices/digitalhealth/ucm544684.pdf>
- Hippocratic Oath for Connected Medical Devices: <https://www.iamthecavalry.org/domains/medical/oath/>

APPENDIX M: Cybersecurity Toolkit for Digital Health Entrepreneurs

- MDS2 - Consists of the MDS2 form and instructions for completing it. Assists professionals responsible for security-risk assessment in the management of medical device security issues. The information on the MDS2 form is not intended, and may be inappropriate, for other purposes. <http://www.nema.org/Standards/Pages/Manufacturer-Disclosure-Statement-for-Medical-Device-Security.aspx>
- AAMITIR57

Secure by Design Best Practices:

- FOWASP Secure Medical Device Deployment Standard: https://www.owasp.org/index.php/OWASP_Secure_Medical_Device_Deployment_Standard
- OWASP Top Ten for Security: https://www.owasp.org/images/7/72/OWASP_Top_10-2017_%28en%29.pdf.pdf
- UK Code of Practice for IOT: <https://www.gov.uk/government/publications/secure-by-design/code-of-practice-for-consumer-iot-security>
- Workshop - Building code for medical devices: <http://www.landwehr.org/2015-01-landwehr-gw-cspri.pdf>
- Secure coding course: <http://opensecuritytraining.info/IntroSecureCoding.html>
- CWE/SANS Top 25 Most Dangerous Software Errors: <https://www.sans.org/top25-software-errors>

Vulnerability Disclosure Best Practices:

- https://www.ntia.doc.gov/files/ntia/publications/ntia_vuln_disclosure_early_stage_template.pdf
- ISO29147: <https://www.iso.org/standard/72311.html>
- ISO30001: <https://www.iso.org/standard/53231.html>
- <https://www.iamthecavalry.org/resources/disclosure-programs/>
- US Cert

Applicable Regulations:

- A Startup's Guide to HIPAA - Rock Health guide to HIPAA Read More
- Architecting Your Healthcare Application for HIPAA Compliance - Medium post from AWS on privacy in digital health product development Read More
- HIPAA Compliance for Startups - Rock Health startup support video - Read More
- Ten Steps Towards Achieving HIPAA Compliance - A list with advice for achieving HIPAA compliance - Read More
- FDA Digital Health Innovation Plan - How does the FDA define digital health? Read More
- GDPR

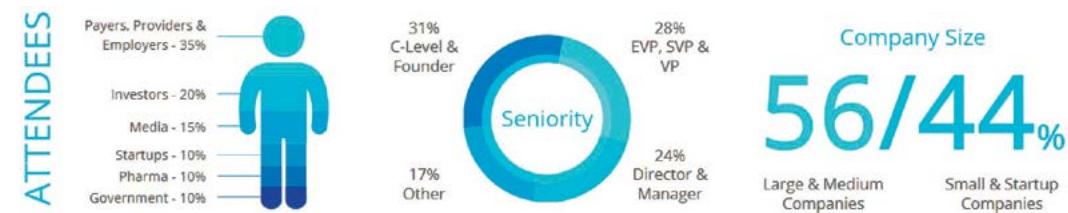
APPENDIX N: Digital Health Conference

HLTH 2018

HLTH (pronounced “health”) is a one-of-a-kind ecosystem event for the health industry, and we’re on a mission to bring together 5,000+ senior leaders to solve the most pressing problems facing healthcare today and actualize the most promising opportunities to improve health.

At a time when improvements of the quality of health care may be uncertain, we bring together senior leaders from across payers, providers, employers, investors, fast-growing startups, pharma, policymakers and innovation centers to ask one question: how do we create the future of health?.

Attendee distribution of HLTH 2018, the first year of the conference, can be seen below:



HLTH 2018 includes numerous opportunities for interacting across the ecosystem, including 17 content tracks, a 36-hr hackathon with over 300 participants, a forum for company-focused announcements with over 100 individual company updates provided, peer group dinners, “speed-dating” for startups and investors/ VCs, and a hosted buyer program to pair over 140 buyers with startup companies to pitch products and solutions. It has the potential to rival JPM as a leading industry conference solely focused on digital health.

HLTH 2019 is planned for October 2019 and expects over 5,000 attendees including over 850 CEOs and Founders, over 200 media and analyst attendees, and over 100 content sessions across 20 tracks,

Additional details can be found here: <https://hlth.com/>

APPENDIX O: MassChallenge HealthTech

Executive Steering Committee Details

RESPONSIBILITIES

The Executive Steering Committee will:

- Set and maintain MCHT’s vision, purpose and values
- Select, manage and support leadership for further growth and sustainability
- Provide strategic leadership and mentorship to support digital health startups and entrepreneurs
- Appoint senior team member to join MassChallenge HealthTech Board of Advisors and entrepreneurs

MASSCHALLENGE HEALTHTECH EXECUTIVE STEERING COMMITTEE & BOARD OF ADVISORS CHARTER

Draft Charter Document - to be ratified by Executive Steering Committee once in place

I. Purpose

The MassChallenge HealthTech Executive Steering Committee shall evaluate and advise MassChallenge on the sustainable growth of MassChallenge HealthTech. We will continue to seek startups and institutions that will address the greatest opportunities and challenges in healthcare, improving individual lives, increasing shareholder value, and leading to a better world. Our work will dramatically accelerate innovation in the healthcare industry by making it easier for startups and established businesses, institutions and organizations to work together.

II. Structure and Operations

Composition and Qualifications

EXECUTIVE STEERING COMMITTEE

The Executive Steering Committee shall be comprised of three to five members to include CEO’s from Diamond Partners from leading healthcare organizations in the Greater Boston Community, MACP, and MassChallenge.

BOARD OF ADVISORS

The Board of Advisors (“BoA”) shall be comprised of up to 15 members including representatives from Executive Steering Committee organizations, Diamond partners, distinguished leaders, and the MassChallenge HealthTech Managing Director. The ESC and BoA can nominate potential BoA members for approval by MassChallenge leadership.

Appointment and Removal

The members of the Executive Steering Committee shall be designated annually, with each Diamond Partner naming one representative. Each representative shall serve until their successors shall be duly designated or until such member’s earlier resignation or removal. Unless a Chair is designated by

APPENDIX O: MassChallenge HealthTech

the full BoA, the members of the BoA shall designate a Chair by majority vote of the full BoA membership. The Chair will lead all regular sessions of the BoA and set agendas and dates for BoA meetings in close consultation with other BoA members.

Delegation to Subcommittees

In fulfilling its responsibilities, Executive Steering Committee members shall be entitled by majority agreement to delegate any or all of its responsibilities to a subcommittee. Subcommittees are to be comprised of members from the Board of Advisors, which may or may not be composed of members of the Executive Steering Committee, employees from Diamond Partners, and possibly other individuals through nomination of the Board or MassChallenge. Subcommittee members will be appointed by nomination of the Executive Steering Committee.

III. Time Commitment

EXECUTIVE STEERING COMMITTEE

In fulfilling its responsibilities, Executive Steering Committee members shall be entitled by majority agreement to delegate any or all of its responsibilities to a subcommittee. Subcommittees are to be comprised of members from the Board of Advisors, which may or may not be composed of members of the Executive Steering Committee, employees from Diamond Partners, and possibly other individuals through nomination of the Board or MassChallenge. Subcommittee members will be appointed by nomination of the Executive Steering Committee.

BOARD OF ADVISORS

The Board of Advisors shall ordinarily meet at least four times annually usually between two to four hours, or more frequently as circumstances dictate. In addition to quarterly meetings and to discharge their responsibilities, Board members are requested to:

- Participate in Board sub-committees and working groups on an ad hoc basis as appropriate
- Support the Managing Director and staff team on an ad hoc basis between meetings in their area(s) of specialization
- Promote MassChallenge HealthTech as appropriate to their professional networks and contacts
- Attend key MassChallenge HealthTech events and functions where possible, and occasionally accompany staff to meetings with funders or potential partners.

Additionally,

- The Board also may invite to its meetings any member of management of the Diamond Partners and such other persons as it deems appropriate to carry out its responsibilities

APPENDIX O: MassChallenge HealthTech

IV. Responsibilities and Duties

EXECUTIVE STEERING COMMITTEE

To fulfill its responsibilities and duties, the Executive Steering Committee shall collaborate with the MassChallenge Executive team to:

- Set and maintain MassChallenge HealthTech vision, purpose and values
- Develop a strategy to consider both growth and sustainability of the program
- Establish and monitor policies consistent with MassChallenge
- Ensure compliance with governing document
- Appoint senior team member to join MassChallenge HealthTech Board of Advisors
- Review opportunities developed by Board of Advisors to strengthen the program
- Support and approve partner strategy to prioritize and maximize program goals
- Support the Managing Director
- Promote MassChallenge HealthTech

BOARD OF ADVISORS

To fulfill its responsibilities and duties, the Board shall collaborate with the MassChallenge HealthTech Team and Managing Director to:

- Ensure the program is producing results aligned to goals and objectives
- Support best in class challenge creation to attract entrepreneurs to MCHT program
- Collaborate across advisors to increase value to partners participating in the program
- Support the Managing Director
- Identify key opportunities to strengthen the MCHT program
- Recommend key events, activities, and initiatives that should be supported within the Digital Health Initiative broadly

EXECUTIVE STEERING COMMITTEE MEETINGS

- To be determined based on availability of Members

APPENDIX P: Communication Group Membership

FIRST NAME	LAST NAME	TITLE	ORGANIZATION	TYPE
Leila	Amerling	Program Manager, Innovation and Digital Health Accelerator	Boston Children's Hospital	Health System
Colleen	Arons	Director of Communications	Executive Office of Housing & Economic Development (EOHED)	Community Activator/Investor
Kristi	Bond	Vice President of Marketing	IBM	Technology
Brett	Campbell	Communications Manager	Massachusetts Technology Collaborative	Government
Natalie	Cantave	Marketing Coordinator, HealthTech	MassChallenge	Community Activator
Juliet	Domb	Senior Client Executive	Optum	Technology
Nick	Dougherty	Managing Director, HealthTech	MassChallenge	Community Activator
Cameron	Eckenrode	Sr. Associate	Optum Ventures	Investor
Jessica	Emond	External and Internal Communications	IBM	Technology
Christine	Galligan	Operations and Marketing Manager	Philips	Technology
Madeleine	Halle	Marketing and Events Coordinator	Innovation at Partners Healthcare	Health System
Valerie	Hart	VP for Administration & Communications	Mass. Competitive Partnership	Community Activator/Investor
Dawn	Irish	Head of Digital Experience and Brand	Shire	Pharma
Cassandra	Lee	Marketing Specialist	Brigham Digital Innovation Hub	Health System
Midori	Morikawa	Director of Business Strategy	City of Boston	Government
Brian	Mullen	Innovation Strategy Manager	Brigham Digital Innovation Hub	Health System
Mike	Murphy	Strategic Communications	MITRE	R&D/Community Activator
Brian	Noyes	Director of Research and Communications	Massachusetts Technology Collaborative	Government
Garrett	Quinn	Marketing Manager	Massachusetts eHealth Institute (MeHI)	Government
Sara	Quist	Director of Community Engagement	Cigna	Insurance
Brian	Rosnov	Clinical Innovation Partnerships & Business Development Leader, Americas	Philips	Technology
Kara	Shemin	Communications Director	TechSpring, Bay State Health	Community Activator
Carla	Small	Sr. Director, Innovation and Digital Health Accelerator	Boston Children's Hospital	Health System
Emma	Smith	Vice President of Marketing	Kyruus	Startup/Technology
Taylor	Uttley	Associate Director, Office of the CEO	Vertex	Pharma
Sarah	Wiley	Senior External Communications	UMass Medical	Health System
Austin	Williams	Economic Development Office Mayor	City of Boston	Government

APPENDIX Q: Web Portal Audience Grid

The audience grid was developed to ensure the key messages of the Digital Health Initiative were clear for each consumer type of the Web Portal. The audience segments were categorized as Digital Health Professionals, the Business Community, which includes start-ups, entrepreneurs, and investors and lastly, the Media. The audience grid includes a value proposition and proof points for each segment type and will support future content development for target audiences of the web portal.

Core Message	<p>Massachusetts' leadership in digital health—the intersection of health care and technology—is built around our state's unique mix of world-class healthcare institutions, top universities, unrivaled talent pool, and dynamic start-up ecosystem.</p> <p>Massachusetts welcomes and nurtures professionals from around the world who, through clinical research and validation, develop life-changing technologies, drive cutting-edge research, and advance emerging solutions that have a direct impact on people. These innovations enable them to better track, manage, and improve individual and family health, and live better, more productive lives, which benefits society overall.</p>							
Proof Points	<ul style="list-style-type: none"> Public / Private initiative with more than 350 digital health companies and 150 academic, R&D and public sector partners collaborating to grow the sector Digital Health solutions built in Massachusetts are backed by clinical research and solve real problems experienced by the healthcare sector today Our top health care leaders work with and can leverage Massachusetts internationally-leading complementary industry sectors, including artificial intelligence, biotech, cybersecurity, robotics, and virtual reality Massachusetts has been working on and implementing health reform for longer than everyone else in the country 							
Target Audiences	Digital Health Professionals		Business Community				Media	
Audience Segment	Job Seekers	Community	Smaller Companies / Entrepreneurs	Larger Companies / Institutions	Non-MA Companies / Institutions	Investors	MA/Regional	National
Key Insights / Pain Points	Actively looking at jobs, lack of visibility across the DH - MA ecosystem	Employers are spread out – strong desire to meet colleagues in the field, build community	Looking for capital, work/lab space, talent; trying to connect with investors / larger companies	Competing for talent, looking for opportunities to develop employees & partner with R&D centers	Competing for talent, limited ecosystem in current state, may consider relocation, may not be aware of DH – MA ecosystem	Ensuring success of current investments, prospecting for new ones	Limited understanding of DH, except for a few reporters with dedicated beats	Lack of awareness of DH and MA's prominence
Target Audiences	Digital Health Professionals							
Audience Segment	Job Seekers				Community			
Key Insights / Pain Points	Actively looking at jobs, lack of visibility across the DH - MA ecosystem				Employers are spread out – strong desire to meet colleagues in the field, build community			
Value Proposition	The MassDigitalHealth ecosystem offers unlimited job opportunities for a wide variety of skill levels at companies that are not only profitable but improving lives around the world.				The MassDigitalHealth ecosystem offers unlimited job opportunities for a wide variety of skill levels at companies that are not only profitable but improving lives around the world.			
Proof Points	<p>The MDH jobs board, the only one of its kind dedicated solely to digital health jobs in Massachusetts, hosts nearly 2000 postings from more than 337 companies</p> <p>Plug into a strong network of over 330,000 health information technology professionals</p> <p>Our educational infrastructure leads the country: Superior K-12 education combined with world class institutions</p> <p>Massachusetts is more affordable than California and New York when it comes to cost of living and taxes.</p>				<p>Find events and networking opportunities on the MDH.org events board.</p> <p>Identify ways to partner with like-minded innovators in the community.</p> <p>Become a Mentor startup entrepreneurs through programs like MassChallenge HealthTech and TechSpring.</p> <p>Plug into a strong network of over 330,000 health information technology professionals.</p> <p>Work with partners from world-class higher-education and healthcare research institutions.</p>			

APPENDIX Q: Web Portal Audience Grid

Target Audiences	Business Community			
Audience Segment	Smaller Companies / Entrepreneurs	Larger Companies / Institutions	Non-MA Companies/ Institutions	Investors
Key Insights / Pain Points	Looking for capital, work/lab space, talent; trying to connect with investors / larger companies	Competing for talent, looking for opportunities to develop employees & partner with R&D centers	Competing for talent, limited ecosystem in current state, may consider relocation, may not be aware of DH – MA ecosystem	Ensuring success of current investments, prospecting for new ones
Value Proposition	Massachusetts offers entrepreneurs and small businesses the ability to drive innovation with an unmatched mix of talent, healthcare leaders, tech firms, investors, and healthcare partners.	Massachusetts is <i>the place</i> to supercharge your Research & Development, while tapping into a vibrant ecosystem of partners.	Through the MDH Initiative, public and private sector partners have come together to solidify the Commonwealth's <i>Global Leadership</i> in digital health, driving workforce development, innovative R&D labs, and partnership opportunities.	Collaborative ecosystem, working on game changing research, backed by top accelerators & incubators producing top digital health entrepreneurs.
Proof Points	<p>Over 350-plus Digital Health companies, major hospitals, and healthcare-focused companies.</p> <p>#2 Digital Health investment destination in the U.S., driving growth of Massachusetts companies.</p> <p>New Digital Health 'sandboxes' offer cutting-edge innovation spaces to develop products in real-world settings.</p> <p>Business support programs aim to connect your business to prospective customers both inside and outside of Massachusetts.</p>	<p>The highest educated STEM workforce in the United States.</p> <p>Top-tier public and private R&D centers unmatched anywhere in the world.</p> <p>New Digital Health 'sandboxes' offer cutting-edge innovation spaces to develop products in real-world settings.</p> <p>Over 350-plus digital health companies, top-tier research centers, and world-class hospitals.</p>	<p>The MDH initiative is a public/private partnership that brings together to plan events, boost startups, and promote the vibrant ecosystem that exists here.</p> <p>Nearly 400 total organizations listed in the directory of companies, investors, & startup support entities that are driving digital health in Massachusetts?</p> <p>The highest educated STEM workforce in the United States.</p>	<p>Over 350-plus Digital Health companies, major hospitals, and healthcare-focused companies.</p> <p>The highest educated STEM workforce in the United States.</p> <p>#2 Digital Health investment destination in the U.S., driving growth of Massachusetts companies.</p> <p>New Digital Health 'sandboxes' offer cutting-edge innovation spaces to develop products in real-world settings.</p>

Target Audiences	Media	
Audience Segment	MA/Regional	National
Key Insights / Pain Points	Limited understanding of DH, except for a few reporters with dedicated beats	Lack of awareness of DH and MA's prominence
Value Proposition	In addition to biotech/life sciences, Massachusetts also features an unmatched roster of companies, organizations, and researchers working at the intersection of healthcare and technology.	Massachusetts offers an unmatched collaborative ecosystem of hospitals, tech firms, VCs, and trained workers, all focused on tackling the top challenges in global healthcare.
Proof Points	<ul style="list-style-type: none"> The Massachusetts Digital Health ecosystem includes nearly 400 companies, investors, and startup support organizations, providing unmatched access to some of the top minds in healthcare, tech, and R&D. Engaged public & private sectors partners, with the Governor's Digital Health Council providing leadership and guidance. #2 Digital Health investment destination in the U.S., driving continued growth of companies and creation of new startups. Over 110 academic and R&D partners that are turning out the top talent of anywhere in the country. 	<ul style="list-style-type: none"> The highest educated STEM workforce in the United States. Over 350-plus digital health companies, top-tier research centers, and world-class hospitals. Top-tier public and private R&D centers unmatched anywhere in the world. New Digital Health 'sandboxes' offer cutting-edge innovation spaces to develop products in real-world settings. #2 Digital Health investment destination in the U.S., driving growth of Massachusetts companies.

APPENDIX R: Communications Group Content Calendar

The Communications Group has established a Digital Health Editorial Calendar, which will be used to track collaboration on content with MCHT / STAT News as well as develop new content to highlight on www.massdigitalhealth.org. The content calendar will be managed by MeHI/MassTech teams and will be reviewed with the Communications Working Group at each meeting.

APPENDIX S: Marketplace Resources

CATEGORY	TITLE	LINK
Clinical Innovation Programs	Boston Children's Hospital Innovation and Digital Health Accelerator	http://www.childrenshospital.org/accelerator
	Brigham and Women's Digital Innovation Hub	https://www.bwhihub.org/
	Gosnold Innovation Center	https://gosnold.org/
	MGH Healthcare Transformation Lab	http://healthcaretransformation.org/
	Partners Center for Connected Health	http://connectedhealth.partners.org/
	Robert and Rene Belfer Office for Dana-Farber Innovation	http://www.dana-farber.org/Research/Technology-Transfer.aspx
	Company/Product Development	Boston Children's Hospital Innovator's Roadmap
BU Center for Mobile Communication Studies		http://sites.bu.edu/cmcs/
CIMIT		http://www.cimit.org/
CIMIT Accelerator		http://cimit.org/accelerator
Designing a Digital Health Company		https://www.youtube.com/watch?v=iF5sxbC8Q&index=4&list=PL706EB8B0816474FD
Harvard Business School Health Care Initiative		http://www.hbs.edu/healthcare/initiative/Pages/default.aspx
M2D2 at UMass Lowell		https://www.uml.edu/Research/M2D2/
MassTech Business Assistance Program		http://www.masstech.org/masstech/programs/business-assistance
Minimum Viable Product Presentation, by Zen Chu		https://www.slideshare.net/MedicalVentures/digital-health-minimum-viable-products-mithealthcareventures2015
MIT Hacking Medicine Product Development Toolkits		http://hackingmedicine.mit.edu/toolkits/
MIT Innovation Initiative Healthcare Resources		https://innovation.mit.edu/resources/?who=alumni-friends&topics=life-sciences-health-tech
MIT Sloan Initiative for Health Systems Innovation		https://hsi.mit.edu/
More Disruption Please		http://www.athenahealth.com/more-disruption-please/more-disruption
ONC Certification Guide - The Office of the National Coordinator for Health Information Technology		https://www.healthit.gov/sites/default/files/PUBLICHealthITCertificationProgramOverview_v1.1.pdf
Payment Models: MassHealth - Executive Office of Health and Human Services (EOHHS)		http://www.mass.gov/eohhs/gov/laws-regs/masshealth/provider-library/masshealth-companion-guides.html
Payment Models: Medicare Bundles - The Centers for Medicare and Medicaid Services (CMS)		https://innovation.cms.gov/initiatives/bundled-payments/
Payment Models: Value-Based Contracting - The Centers for Medicare and Medicaid Services (CMS)		https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html
PULSE@MassChallenge		http://boston.masschallenge.org/pulse
Rock Health Digital Health Startup Handbook		https://rockhealth.com/digital-health-startup-handbook/

APPENDIX S: Marketplace Resources

CATEGORY	TITLE	LINK
Company/Product Development	TechSpring Insights Program	http://www.techspringhealth.org/our_programs
	The Engine	http://www.engine.xyz/
	UMass Center for mHealth and Social Media	http://www.umassmed.edu/mhealth/
	Who are the payers and what do they need? - AstraZeneca	http://medcommsnetworking.com/presentations/lawson_031213.pdf
	WPI Healthcare Delivery Institute	www.wpi.edu/+hdi
	FDA Digital Health Innovation Plan	https://www.fda.gov/medicaldevices/digitalhealth/
	Federal Trade Commission (FTC) Mobile Health Apps Interactive Tool	https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool
	CVS Health Innovation Lab	https://cvshhealth.com/newsroom/press-releases/cvs-health-opens-digital-innovation-lab-boston
	Eli Lilly Innovation Center	https://careers.lilly.com/Cambridge-Innovation-Center
	Johnson & Johnson Innovation Center	https://www.jnjinnovation.com
	Health IT Vendor Directory	http://mehi.masstech.org/education/vendor-directory
	TechSpring Insights Program	http://www.techspringhealth.org/our_programs
	TechStars Boston Program	http://www.techstars.com/programs/boston-program/
	Harvard i-Lab	https://i-lab.harvard.edu/
	TechStars Boston Program	http://www.techstars.com/programs/boston-program/
	Valley Venture Mentors	http://www.valleyventurementors.org
	Venture Development Center at UMass Boston	https://www.umb.edu/vdc
Competition/Challenge	Health Hackathon Database	http://hackingmedicine.mit.edu/health-hackathon-database/
	HealthXL Challenges	https://healthxl.co/challenges/
	MIT Hacking Medicine	http://hackingmedicine.mit.edu/
	Northeastern Nurse Hackathon	http://www.northeastern.edu/nurseinnovation/
	Partners Connected Health Innovation Challenge	http://www.partnerschic.org/
	SOLVE at MIT (Cure)	https://solve.mit.edu/
Data Resource	Google BigQuery Healthcare and Population Data	https://healthxl.co/challenges/
	HPC DataPoints	https://cloud.google.com/blog/big-data/2017/05/new-healthcare-and-population-datasets-now-available-in-google-bigquery
	All-Payer Claims Database (APCD)	http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/hpc-datapoints.html
	Audited Financial Information (Hospitals)	http://www.chiamass.gov/ma-apcd/
	Case Mix (Hospital Discharge) Database	http://www.chiamass.gov/public-records-request/
	Chapter 55 Data Linkage	http://www.chiamass.gov/case-mix-data/
	Health Policy Commission Cost Trends Reports	http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/

APPENDIX S: Marketplace Resources

CATEGORY	TITLE	LINK
Data Resource	Health Policy Commission Registered Provider Organization Program	http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/material-change-notices-cost-and-market-impact-reviews/registration-of-provider-organizations/
	Mass HIWay Directory	http://mehi.masstech.org/education/mass-hiway-directory
	Massachusetts eHealth Collaborative Quality Data Center	https://maehc.org/services/quality-data-center-services
	MeHI Consumer and Provider Health IT Research Study	http://mehi.masstech.org/education/resources-tools/ehealth-reports/2014-mehi-provider-and-consumer-health-it-research-study
	MeHI Digital Health Caregiver Survey	http://mehi.masstech.org/education/resources-tools/ehealth-reports/2017-caregivers-and-digital-health-report
	MIMIC	https://mimic.physionet.org/
	MITRE Synthetic Mass	https://syntheticmass.mitre.org/about.html
	Provider Cost Reports (Various)	http://www.chiamass.gov/public-records-request/
	Standard Statistics	http://www.chiamass.gov chia-standard-statistics/
	TechSpring Analytics	http://www.techspringhealth.org/our_programs
Events / Networking	Mass Digital Health Events Calendar	http://www.massdigitalhealth.org/events
	Medtech Boston Events Calendar	https://medtechboston.medstro.com/events-calendar/
	PULSE@Checks	https://www.eventbrite.com/d/ma--boston/pulse%40masschallenge/
	Tap Into TechSpring	http://www.techspringhealth.org/events
Funding Resource	Massachusetts Digital Health Venture Capital Firm List	http://www.massdigitalhealth.org/directory?title=&field_connected_community_tid=All&field_cluster_category_tid=1626&field_investment_activities_tid=All&field_focus_area_tid=All&nid=
	MassTAG Program	http://www.masslifesciences.com/programs/masstag/
	MassVentures	http://www.mass-ventures.com/
	MIT Hacking Medicine Funding Resource List	http://hackingmedicine.mit.edu/funding/
	SBIR/STTR Health-Related Funding Opportunities	https://www.sbir.gov/thinking-beyond-nih-for-health-related-sbir-sttr-funding
	8 Things You Need to Know About Raising Venture Capital	https://alexiskold.net/2015/07/14/8-things-you-need-to-know-about-raising-venture-capital/
Interoperability / Integration	athenahealth Marketplace	https://www.athenahealth.com/marketplace/marketplace-overview
	How to integrate with Epic (or any EHR) - Datica	https://datca.com/academy/how-to-integrate-with-epic-or-any-ehr/
	Sample Business Associates Agreement	https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html
	The Mass HIWay	http://www.masshiway.net/
	What is FHIR?	https://healthitanalytics.com/news/4-basics-to-know-about-the-role-of-fhir-in-interoperability
	Why do I need an Business Associates Agreement?	https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html
	Why do I need an SLA? - CIO	https://www.cio.com/article/2438284/outsourcing/outsourcing-sla-definitions-and-solutions.html

APPENDIX S: Marketplace Resources

CATEGORY	TITLE	LINK
IP / Commercialization	Intro to Patent Law	https://www.youtube.com/watch?v=qpn53WS8maQ&index=18&list=PL706EB8B0816474FD
	Standardized Digital Health Technology Transfer Agreements	http://www.massdigitalhealth.org/industry/agreement-templates
	Massachusetts Technology Transfer Center (MTTC)	http://www.mttc.org/
Piloting / Validation	Moving Past A Digital Health Pilot - Path	https://www.path.org/publications/files/TS_dhs_journey_to_scale.pdf
	Seven Tips For Conducting Pilots - MobiHealth	http://www.mobihealthnews.com/33192/seven-tips-for-healthcare-startups-doing-pilots
	TechSpring Insights Program	http://www.techspringhealth.org/our_programs
	TechSpring Projects Program	http://www.techspringhealth.org/our_programs#projects
	A Startup's Guide to HIPAA	https://rockhealth.com/a-startups-guide-to-hipaa/
	Architecting Your Healthcare Application for HIPAA Compliance	https://medium.com/aws-activate-startup-blog/architecting-your-healthcare-application-for-hipaa-compliance-part-1-f3bd11bd64d
	Five Security Steps Digital Health Startups Should Take - MobiHealth	http://www.mobihealthnews.com/33146/5-steps-for-digital-health-companies-that-need-to-protect-health-information
Sales	HIPAA Compliance for Startups	https://www.youtube.com/watch?v=rCPsN9d3eUc&index=19&list=PL706EB8B0816474FD
	How to Sell to Hospitals (Like a Boss)	https://www.youtube.com/watch?v=2JusSbbSrY&list=PL706EB8B0816474FD&index=3
	Selling to Doctors	https://www.youtube.com/watch?v=lfznluvz94&index=8&list=PL706EB8B0816474FD
Simulation / Labs	Understanding Hospital Budgets - Mass Medical Society	http://www.massmed.org/Continuing-Education-and-Events/Conference-Proceeding-Archive/Finance-101-for-Physicians-and-Practice-Administrators-Webinar-Presentation-(pdf)/
	Carl J. Shapiro Simulation and Skills Center	http://www.bidmc.org/Medical-Education/Shapiro-Simulation-and-Skills-Center.aspx
	Goldstein Simulation Center	http://www.northeastern.edu/bouve/about/simulation-center/
	Harvard Center for Medical Simulation	https://harvardmedsim.org/
	MassRobotics	https://www.massrobotics.org/
	MedRC	http://medrc.mit.edu/
	MIT Age Lab	http://agelab.mit.edu/
	NERVE Center at UMass Lowell	http://nerve.uml.edu/
	Partners Medical Device Plug-and-Play Interoperability Lab	http://www.mdppn.org/lab.php
	PracticePoint at WPI	https://www.wpi.edu/research/partnerships/medical-cyber-physical-systems
STRATUS Center for Medical Simulation	STRATUS Center for Medical Simulation	http://www.brighamandwomens.org/Departments_and_Services/emergencymedicine/STRATUS/default.aspx
	WPI HDI Living Lab	https://www.wpi.edu/research/areas/centers/healthcare-delivery-institute/living-lab

APPENDIX S: Marketplace Resources

CATEGORY	TITLE	LINK
Space	List of Available Co-Working Spaces in MA	http://masstech.org/massachusetts-collaborative-work-spaces
	MassEcon Location Search Support	http://massecon.com/services/location-services/
Talent	MassTech Intern Partnership	http://www.masstech.org/intern
	TechGen	https://www.thetechgen.org/

APPENDIX T: Focus Group Participation and Feedback

Focus groups including startups and entrepreneurs were conducted to collect feedback on content and usability of the www.massdigitalhealth.org web portal. The following goals and objectives were established prior to the conduct of the focus groups.

WEB PORTAL GOALS

- Create a pleasant and informative customer experience for Mass Digital Health visitors and Marketplace Program participants
- Provide the right content for visitors and Marketplace Program participants to use this online tool as their go-to resource

FOCUS GROUP OBJECTIVE

- Gather feedback from a subset of Mass Digital Health ecosystem participants to create a Phase II website enhancement plan focused on Marketplace participant registration and overall web portal visitor engagement

2019 SUCCESS CHECK

- Increase Mass Digital Health web portal visitors and Marketplace registrations
- Encourage and promote partnerships and connections for startups and customers

Participants

Focus groups were conducted on January 16th and March 26th for two hour lunch sessions. Focus group participants represented different types of companies in the digital health ecosystem.

- **Folia Health** provides a patient and caregiver app that allows them to report in on their chronic conditions. Currently, it is available for the cystic fibrosis patient population.
- **Medumo** provides an app that enable patients to better follow through with a care plan, test, or procedure. Over 500K patients have used the app and they have initiatives with Boston Children's Hospital, Brigham's and others.
- **PathAI** is evolving pathology using machine learning and deep learning techniques to drive faster more accurate diagnosis of disease.
- **Vertex** is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious and life-threatening diseases. In addition to clinical development programs in Cystic Fibrosis, Vertex has more than a dozen ongoing research programs focused on the underlying mechanisms of other serious diseases. **SIGNUM** – The description is not available for this company. The attendee had a background in web site design and digital health. She received an invitation from Mass Challenge.
- **Radial Analytics** technology delivers data-driven insights that help care teams make better decisions for patients in real time in particular around care transitions.
- **Pixm** provides next generation spear-phishing protection using cutting-edge computer vision technology to stop phishing attacks at the point of click.

APPENDIX T: Focus Group Participation and Feedback

Discussion Questions

The following open-ended questions were posed to the focus group participants to spur conversation.

- What do you like and dislike about the web portal navigation and overall experience?
- If a startup goes to the web portal for the first time, what message and content will make them come back?
- If a healthcare system, payer, or life sciences organization goes to the web portal for the first time, what message and content will make them come back?
- What will it take to accelerate participation and activity in the Marketplace?
- What will it take from a promotion perspective to make this web portal and Marketplace the go-to resource for startups and for those seeking digital health innovations in Massachusetts?
- How clear is our “What We Do”?

Key Messaging Feedback from combined Focus Groups

- The text should be less prose - more facts, figures, and graphics.
- Check our terminology and nomenclature. Does the visitor know the language?
- Explain and help visitor understand ecosystem players and roles.
- Consistently communicate the top level message on all landing pages if visitors land without hitting the front page first.
- Attendees had no idea what the “Marketplace” is. Provide clear, upfront definition of what it does.
- FAQ section is a graveyard. Do a better job with messaging throughout for visitor.
- Need to add an international message - come play and work here!
- The highest value items should be front and center - Jobs, Resources, “Opportunities to find Leads or Funding”, and the Sandbox.
- Term resources implies different things. Be more direct in language. Rename.

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APPENDIX T: Focus Group Participation and Feedback

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- Term resources implies different things. Be more direct in language. Rename.

Key Navigation Feedback from combined focus groups:

- Consider directing the visitor from home page based on who they are such as start-up, organization, job seeker, etc.
- Too hard to get to what the visitor needs most - jobs, resources, funding.
- Don't make the visitor define themselves - not relevant. Though Mass Challenge participants understood this but unnecessary.
- Duplication of resources is confusing.
- Use the landing page - don't make visitor keep going to left navigation bar. Use the landing pages for graphics and clear messaging of where to go next and describe links on the left.
- Get high-value parts front and center - jobs, resources, funding, and sandbox.
- Home page “Start Here” drives people away from the portal.
- Consider how MassBio organizes their content.

Based on feedback collated during focus groups, a web portal redesign plan was developed by MassTech teams. Please see [Appendix Q](#) for plan.

APPENDIX U: User Traffic Metrics 2016 – 2019

MassDigitalHealth.org:

Date Range	March 11, 2016 - June 17, 2019
Page Views	136,603
Unique Page Views	100,083
Users	33,750
Best Month	November 2018 - 2,973 users

Jobs Board 2.0 – metrics are tracked separately from MassDigitalHealth.org:

Date Range	February 26, 2019 - June 14, 2019
Unique Users	900
Unique Page Views	8,233
Clicks on Jobs	1,374
Current as of June 18, 2019	1,776 open jobs on portal

APPENDIX V: Catalog of Existing Data Exchanges

NETWORK	DESCRIPTION	STORES DATA	FREQUENCY	PROTOCOL FORMATS AND DATA TYPE(S)	COLLECTS FROM	FUNCTION	LIMITATIONS
Mass Hlway	Peer to peer interface. Direct protocol.	NO	Real Time. On as needed basis	CCDA / CCDA	Hospitals Physicians	Transport	Cannot perform analysis/data aggregation; Uses direct protocol - does not have an API Participation agreement is required (opt-out) Not all providers are sending data via the MassHlway Clinical data exchange (not administrative)
CHIA	CHIA-developed application software, which handles data and file validation, hashing and stripping of demographics and secure transmission more info at: http://www.chiamass.gov/assets/Uploads/data-apps/Government-APCD-Application.pdf	YES	Quarterly/ Annually. Multiple filing requirements, mostly quarterly and annually	CHIA's own protocols / Aggregated data in proprietary formats	Hospitals Physicians Payors	Quasi-Steward	Analyses is done on system level vs. individual level; trends (i.e. not all purpose)
NEHEN	Admin data exchange: benefits/ eligibility, referrals/ auth, claims More info at http://www.nehen.org/	NO	Real Time	X12/ <ul style="list-style-type: none"> • Member Eligibility • Claim Submission and Tracking • Claim Status Inquiry • Remittance • Referral/ Authorization • Referral Inquiry 	Hospitals Physicians Payors	Transport	Cannot perform analysis/data aggregation Administrative data exchange (not clinical)
MAeHC	Data warehouse, quality metrics for government reporting; coordinates ADT feed exchange. More info at https://maehc.org/	YES	Real Time	CCDA/ADT Encounter-level clinical data (CCDA) ADT feeds	Hospitals Physicians	Steward	

APPENDIX V: Catalog of Existing Data Exchanges

NETWORK	DESCRIPTION	STORES DATA	FREQUENCY	PROTOCOL FORMATS AND DATA TYPE(S)	COLLECTS FROM	FUNCTION	LIMITATIONS
PDMP	Scheduled drugs data from pharmacies, labs - no standard format . Secure FTP, web portal, manual entry Universal Claims Form. More info at http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/pmp/	YES	Real Time	NCPDP Universal Claims forms	Pharmacies		
CommonWell	Summary of top 10 CCD fields Record locator service more info at http://www.commonwellalliance.org/	YES	Real time on demand	CCDA / CCDA	Hospitals Physicians		
Sequoia/ Carequality	Query-based document exchange. Legal and governance framework, technical specifications, and participant directory	NO	Real Time	CCDA / CCDA	Hospitals Physicians		
DPH	Bio surveillance and Immunization repository more info at http://www.mass.gov/eohhs/docs/dph/emergency-prep/hpp-phep-training-and-plan.pdf	YES	Real Time	HL7 2.51 Immunizations, Reportable labs; Syndromic surveillance	Hospitals		

APPENDIX W: Background on Federal Initiatives and Other State Background

Objective

Overview of national HIE networks, Federal regulations related to interoperability and information exchange, and review of several state HIEs.

Objective is to understand the basic landscape of information sharing efforts, and to review various governance and technical models, participation rates, existing and future services offered (use cases), and long term goals.

Contents

1. CommonWell Health Alliance
2. Carequality / The Sequoia Project
3. Microsoft/Amazon/Google/IBM/Oracle/Salesforce recent announcement
4. HIPAA
5. HITECH
6. MACRA
7. CURES Act
8. TECFA
9. CMS BlueButton
10. MyHealthEData
11. State HIEs:
 - a. New York
 - b. California
 - c. Connecticut
 - d. Michigan
 - e. Vermont
 - f. Maine

National Networks

COMMONWELL HEALTH ALLIANCE

- NFP trade association dedicated to achieving cross-vendor interoperability
- Offers services embedded in vendor software to support exchange of health data - services enable patient identity management, patient linking, record locator, data query/retrieval
- Change Healthcare is core service provider
- Founding Members: Allscripts, athenahealth, Cerner, Change Healthcare, Evident, Greenway Health

APPENDIX W: Background on Federal Initiatives and Other State Background

Today, the following [use cases] scenarios have been made possible by CommonWell, solving widespread interoperability problems:

- As a health care provider, I can discover where my patient has been seen across remote settings of care
- As a patient, I can affirm that I have been treated at specific remote points of care in order to make more of my care history available to all of my provider(s)
- As a health care provider, I can review the available clinical artifacts and select those that best improve my ability to provide care from all of my patient's available historical content
- As a patient, I can find and review documents via a connected Portal web application
- As a health care provider, I can retrieve and view the selected clinical data
- As an HIT system, I can make my data available for consumption by other CommonWell-connected systems.

CAREQUALITY

- Carequality is a public-private initiative that enables widespread, operational connectivity between and among existing health IT data exchange programs and platforms
- Carequality is not a data sharing network. It is a framework of legally binding business, policy, and technical requirements that allow the members of existing data sharing networks to communicate with the members of other networks
- Carequality Framework, which was developed and is maintained through a broad-stakeholder, consensus-based approach that brings together a diverse group of representatives from the private sector and government
- Carequality connects "Implementers" (HIEs, EHR vendors, payers, clearinghouses, or other types of organizations) to enable data access from many different sources
- Implementers (not comprehensive): athenahealth, Cognizant, CommonWell Health Alliance, eClinicalWorks, Epic, GE Healthcare, Inovalon

Golden Spike: In December 2016, CommonWell Health Alliance and Carequality announced connectivity and collaboration efforts with the aim to provide additional health data sharing options for stakeholders. Specifically, CommonWell, per the agreement, would become a Carequality implementer on behalf of its members and their clients, enabling CommonWell subscribers to engage in health information exchange through directed queries with any Carequality participant. Carequality will work with CommonWell to make a Carequality-compliant version of the CommonWell record locator service available to any provider organization participating in Carequality.

Initial connectivity began 8/2018 – live, bi-directional data sharing with an initial set of CommonWell members and Carequality implementers.

APPENDIX W: Background on Federal Initiatives and Other State Background

Microsoft/Amazon/Google/IBM/Oracle/Salesforce (led by Josh Mandel)

AUGUST 2018 JOINT STATEMENT

We are jointly committed to removing barriers for the adoption of technologies for healthcare interoperability, particularly those that are enabled through the cloud and AI. We share the common quest to unlock the potential in healthcare data, to deliver better outcomes at lower costs.

In engaging in this dialogue, we start from these foundational assumptions:

- The frictionless exchange of healthcare data, with appropriate permissions and controls, will lead to better patient care, higher user satisfaction, and lower costs across the entire health ecosystem.
- Healthcare data interoperability, to be successful, must account for the needs of all global stakeholders, empowering patients, healthcare providers, payers, app developers, device and pharmaceutical manufacturers, employers, researchers, citizen scientists, and many others who will develop, test, refine, and scale the deployment of new tools and services.
- Open standards, open specifications, and open source tools are essential to facilitate frictionless data exchange. This requires a variety of technical strategies and ongoing collaboration for the industry to converge and embrace emerging standards for healthcare data interoperability, such as HL7 FHIR and the Argonaut Project.
- We understand that achieving frictionless health data exchange is an ongoing process, and we commit to actively engaging among open source and open standards communities for the development of healthcare standards, and conformity assessment to foster agility to account for the accelerated pace of innovation.

Together, we believe that a robust industry dialogue about healthcare interoperability needs will advance this cause, and hence are pleased to issue this joint statement.

Federal Regulations

HIPAA: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT 1996

- Health information privacy and security standards
- Applies to **Covered Entities:** health plans, clearinghouses, and providers
- **Business Associates** are entities that contract with Covered Entities to perform functions. Covered Entities are still bound by HIPAA if functions are performed by third party Business Associates.
- CE - BA contracts (**BAAs**) clarify and limit use of PHI, and contain minimum elements (description of permitted PHI uses, agreement that PHI will not be disclose outside stated use, BA must use safeguards to prevent use or disclosure of PHI in a way that is not outlined by BAA)
- HIN/HIEs are one type of BA and have agreements with participants

APPENDIX W: Background on Federal Initiatives and Other State Background

HITECH: Health Information Technology for Clinical Health Act of 2009

- Adoption and exchange of electronic health information through EHRs
- Established Office of the National Coordinator for Health IT (ONC) as an organization within HHS charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

MACRA: Medicare Access and CHIP Reauthorization Act 2015

- Providers who receive quality/merit-based incentive payments must attest to support information exchange not intentionally block information exchange, implement technologies that enable patient access, bi-directional exchange with other providers and IT vendors, respond timely and in good faith

Meaningful Use

- With introduction of MACRA, the medicare EHR incentive program (meaningful use) became one of the 4 components of the new merit-based incentive payment system (MIPS), which is a part of MACRA

CURES ACT: 21st Century Cures Act 2016

- Defined interoperability and prohibits information blocking.
- Title IV - Delivery includes assisting doctors on improving quality of care, transparent reporting, interoperability, information blocking, leveraging electronic records to improve care, enabling patients access to their HER information
- Amends HITECH act
- No data-blocking or inhibiting of appropriate exchange and access to electronic health information
- Enablement of secure data exchange without special effort on part of the user
- Allows for complete access under applicable state and federal law
- USCDI (US Core Data for Interoperability) is the common set of data classes required for interoperable exchange - ONC is responsible for outlining those data classes (which will be updated and expanded through regular process)
 - Builds on 2015 Common Clinical Data Set (CCDS), which itself built on the 2012 MU common data set. The 2015 CCDS included API certification criteria, but no specific standards, and at the same time (~2014) the independent Argonaut Project began to develop FHIR specifications (data formats and elements and an API for exchange, created by the HL7 standards organization) that could be used to meet 2015 CCDs criteria
- TEFCA: Congress directed ONC to develop or support a trusted exchange framework as part of 21st century cures, including a common agreement among health information networks nationally. A common set of principles for exchange was published 1/2018 (TEFCA draft), to bridge the gap between providers and patients information systems. Framework will include:
 - A common method for authenticating trusted health information network participants;
 - A common set of rules for trusted exchange;
 - Organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and
 - A process for filing and adjudicating noncompliance with the terms of the common agreement.

APPENDIX W: Background on Federal Initiatives and Other State Background

- TEFCA aligns with HIPPA, but recognizes that **some end users will not be CEs or BAs, and TEFCA will need to enable those entities to access health information**
- Goal is not to create a single national HIE - but to create a single "on-ramp" that provides common policy, procedure, technical standards that bridge existing HINs together
- Will require a Recognized Coordinating Entity (RCE) that will be selected by ONC to enter into agreements with HINs that qualify and elect to become qualified HINs in order to impose, at a minimum, the requirements of the common agreement.
 - A QHIN (qualified health information network) is a network of organizations working together to share data. QHINs will connect directly to each other.
 - Connectivity broker is a service provided by a QHIN to provide following functions: Master Patient Index, Record Locator Service, Broadcast and Directed Queries, eHI returns.
 - REC will act as governance body that will operationalize the TEFCA framework by incorporating it into a single, all encompassing Common Agreement, which qualified HINs will agree to abide. Will monitor HINs.
- Use cases (broadly)
 - Treatment, Payment, Operations (TPO)
 - Individual Access (patients)
 - Public Health
 - Benefits Determination
 - Provider Access for those they treat
 - Population level data for risk bearing organizations
 - APIs to encourage entrepreneurial/innovation to make information accessible and usable

Outcomes of TEFCA:

- 1) providers can access health information about their patients, regardless of where the patient received care;
- 2) patients can access their health information electronically without any special effort;
- 3) providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals without having to access one record at a time (Population Level Data),¹⁷ which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives; and
- 4) the health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability

TEFCA PRINCIPLES FOR TRUSTED EXCHANGE – PART A

Principle 1 - Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures.

- Example: Adoption of ONC IT Certification standards (2015 is latest), ISA (Interoperability Standards Advisory; Use ONC C-CDA (Clinical Data Architecture) scorecard; Pilot FHIR APIs to test quality of data exchange

APPENDIX W: Background on Federal Initiatives and Other State Background

Principle 2 - Transparency: Conduct all exchange openly and transparently.

Principle 3 - Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange Electronic Health Information, even when a stakeholder may be a business competitor.

Principle 4 - Privacy, Security, and Patient Safety: Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity.

Principle 5 - Access: Ensure that Individuals and their authorized caregivers have easy access to their Electronic Health Information.

Principle 6 - Data-driven Accountability: Exchange multiple records for a cohort of patients at one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.

TEFCA PART B - MINIMUM REQUIRED TERMS AND CONDITIONS FOR TRUSTED EXCHANGE

- Minimum set of terms and conditions for purpose of ensuring common practices are in place and required of all participants who participate in Trusted Exchange:
 - Common authentication process of network participants
 - Common set of rules for trusted exchange
 - Minimum core set of organizational and operational policies to enable exchange of data among networks

BlueButton 2.0

- All Medicare beneficiaries can use CMS-approved BlueButton applications, and can access and allow apps to access 5-years of longitudinal claims data
- Patient control over use and third party with access management at [MyMedicare.gov](https://www.medicare.gov)
- Uses HL7 FHIR standards for data
- CMS is seeking developers, and already has an estimated 600, interested in building consumer-friendly applications for Medicare beneficiaries to connect their claims data to the applications, services and research programs they trust

MyHealthEData 2018

- CMS will act as a convener for APIs across the digital system that also connects to patients' claims data. As part of the MyHealthEData initiative, CMS is leveraging HL7s (FHIR) standard and OAuth 2.0 security profiles so that Medicare beneficiaries will be able to access and share their claims data in a universal digital format

CMS Qualified Entity Program

- Authority: CMS
- Organizations that are approved can receive Medicare claims data to evaluate provider performance
- Organizations can sell analyses or combined data sets to certain authorized users
- There are 20 QEs today; it takes approximately 2 years and \$2M to become a QE
- Not all requirements can apply to DDN model (for example, CMS QEs must have access to claims data from other sources to combine with Medicare data)

APPENDIX W: Background on Federal Initiatives and Other State Background

HITRUST

- A not-for-profit organization champion for programs that safeguard sensitive information and manage information risk for organizations across all industries and throughout the third-party supply chain.
- Develops, maintains and provides broad access to its widely adopted common risk and compliance management and de-identification frameworks; related assessment and assurance methodologies; and initiatives advancing cyber sharing, analysis and resilience.
- CSF: common framework for nationally and internationally accepted standards including ISO, NIST, PCI, HIPAA, and COBIT to ensure a comprehensive set of baseline security controls.

Existing State Requirements and Programs

MassHlway

- All Providers will connect to Mass Hlway
- Opt-in / Opt-out: Hlway users can implement local opt-in or opt-out processes, but all must provide patients with written notice of use of Hlway. Hlway administers centralized opt out system. Providers can implement their own local opt in or out systems, but not required.
- Providers are in compliance with requirements if they are sending provider to provider messages for at least one use case.
- Providers must send ADTs or equivalent messages about ED visits and admissions and discharges
- EOHHS may audit providers periodically to confirm compliance

CHIA

- Massachusetts General Laws, Chapter 12C section 10, provides broad authority for CHIA to collect information from private and public health care payers, including third-party administrators.
- Data is collected monthly through CHIA-INET, a web-based transaction service. Data submitters register to submit data to CHIA by completing a Business Partner Security Agreement Form and a User Agreement for Insurance Carriers.
- Mostly all payer claims data, does include acute hospital case mix and hospital financial performance data

Chapter 55

(Key observation - specific use case driving a step change in data integration)

- Charged the Secretary of Health and Human Services, with examining "the prescribing and treatment history, including court-ordered treatment or treatment within the criminal justice system, of persons in the Commonwealth who suffered fatal opiate overdoses in C&2014
- Led by the Department of Public Health, the Chapter 55 analysis involved 10 datasets from five different government agencies. In total, 29 groups from government, higher education, and the private sector provided information and expertise.

APPENDIX W: Background on Federal Initiatives and Other State Background

- Permits the analysis of different government datasets to guide policy decisions and to better understand the opioid epidemic

MeHI

- Designated state agency for promoting Health IT innovation, technology and competitiveness to improve the safety, quality and efficiency of health care across the Commonwealth of Massachusetts
- Assists healthcare providers and organizations throughout the Commonwealth of Massachusetts in the adoption and effective use of Health IT and other electronic Health technologies.

State HIE Stories

New York

- SHIN-NY allows the electronic exchange of clinical information and connects healthcare professionals statewide
- NYeC developed and manages the technology platform that connects the 8 Qualified Entities (QEs) and enables the sharing of data statewide; ensuring that the SHIN-NY provides access to a patient's electronic medical records wherever and whenever they need it.
- The NYeC SHIN-NY Policy Committee is tasked with updating and drafting proposed SHIN-NY policy measures to protect personal health information while expanding the State's ability to share electronic health records between healthcare providers, consumers, and other community resources.
- The SHIN-NY Policy Committee is comprised of individuals from across the state with expertise in policy: public officials, healthcare providers, attorneys, public advocates, QEs, hospital leadership, and other policy specialists.
- Vision for future: SHIN-NY could provide the data needed to enable market-based solutions that could also raise additional non-governmental revenue to support the system within applicable and potentially modernized data governance rules.

California

(lack of use case creates issues with sharing)

- Merger of two State HIEs (Cal Index and Inland Empire)
- Structured as a non-profit health network
- Available data includes patient encounters and procedures, hospital admission and discharge information, care team, diagnoses, lab results, imaging reports, medications and allergies
- APIs deliver information into existing clinical workflows
- Central organization merges, matches, de-dupes data and makes a longitudinal record available to providers
- Key HIE use cases:
 - **Notification:** update clinicians on discharges or ED visits
 - **Information Access:** longitudinal health records available for records, population health, care coordination, risk management
 - **Analysis:** vision to provide population health tools (dashboards and metrics reporting)
 - **Future Data Access:** APIs and HL7 feeds that providers can pipe to existing platforms and tools

APPENDIX W: Background on Federal Initiatives and Other State Background

Connecticut

(transparency issues/duplicative efforts)

- The CT Health IT Advisory Council was established to advise the Health Information Technology Officer
- A recent article explained that CT's State Health IT Advisory Council, which was charged with creating and HIE, just found out that the CT Dept. of Social Services was continuing to construct notification services, provider registry, master person index, and clinical measure services within the department
- DSS had previously led CT's efforts to build an HIE, which terminated in 2016. DSS did not transition all activities to the Health Info Tech Officer of the State, and continued to build the services outlined above
- While the Council was not aware of DSS efforts, the State IT Coordinator was aware and knew that DSS activities were funded and approved by CMS

Michigan

(use case focus is important)

- Public-private nonprofit health information network; supports the state HIE
- Began December 2010 to administer technical and business ops of Michigan's HIE - created by Office of Health IT
- Notifications for physicians/care managers on transitions of care
- Quality measurement
- Common gateway for information sharing
- "Common key service"
- Simulators for testing new use cases
- Statewide Consumer Directory
- MiHIN's first data-sharing "use case" in production, created in partnership with the Michigan Department of Health and Human Services (MDHHS), allowed electronic submission of immunization information to the state's immunization information system - the Michigan Care Improvement Registry.
- From there, Michigan's suite of public health data-sharing use cases has grown to include a broad suite of capabilities including:
 - Cancer Notifications
 - Disease Surveillance
 - Immunizations
 - Newborn Screening
 - Syndromic Surveillance
- Use Case Factory: <https://mihin.org/use-case-factory/>
- Member of CommonWell Alliance since June 2015

APPENDIX W: Background on Federal Initiatives and Other State Background

Vermont

(use cases lead to success)

- Vermont Information Technology Leaders, Inc. is a nonprofit organization that advances health care reform efforts in Vermont through the use of health information technology, and is the legislatively designated operator of the Vermont Health Information Exchange (VHIE).
- The VHIE is a secure, statewide data network which gives health care providers in Vermont the ability to electronically exchange and access patient data.
- Services: connectivity services, provider portal for clinical data access, point to point messaging, notification through PatientPing, secure provider text through OhMD
- Client services to assist organizations with data requirements, meaningful use, security risk assessment, and EHR implementation/optimization

Maine

(use cases lead to success)

- Independent nonprofit, began 2009, contains records for nearly all Maine residents, opt-out consent process for general medical info, opt-in for certain behavioral/HIV info
- In addition to HIE, HealthInfoNet also provides a number of value added services including assisting providers with meaningful use attestation, single sign on to the state prescription monitoring program, public health reporting, event of care notifications, and population analytics and reporting services.
- HealthInfoNet also provides tools to support the needs of Accountable Care Organizations such as member aggregation services and predictive modeling solutions. Connected to all hospitals in Maine, over 450 ambulatory care locations and the Veterans Administration.
- Carequality implementer
- Website contains several "use case reports," for example: *In 2018, Penobscot Community Health Care (PCHC), a Federally Qualified Health Center and The Hope House Health and Living Center in Bangor began a unique collaboration between health care and homelessness services utilizing HealthInfoNet's Analytics and Reporting Platform (HARP). This tool identifies patients at high-risk for readmissions and connecting them to appropriate community and health services to prevent readmission*

APPENDIX X: Governance Model Options

This discussion document explores governance issues raised by the Distributed Data Network (DDN) proposal being developed by the Governor's Digital Health Council.

Need for a public-sector governing authority. The foundational question is whether the DDN is a private, voluntary effort or whether there will be some form of mandate for providers to participate. If there is a mandate, it will need to have a statutory basis and ultimate authority over its implementation will need to reside with a secretariat, agency, or quasi-public authority. The DDN governing organization can rely on an advisory group of private-sector experts, but final decision-making authority must be vested in one public-sector entity or another.

Before listing options for a DDN governing authority (GA), the following paragraphs describe the major functions a GA will be need to perform in order to operationalize the DDN.

Requirements for Data Stewards. The GA will need to develop and manage a formal application and selection process for Data Stewards, and also provide ongoing oversight of Data Stewards and their compliance with DDN program rules. Among other restrictions, the GA will initially require Data Stewards to use DDN data solely for care coordination and patient access services, but additional use cases could be added in the future. Selecting and overseeing Data Stewards is a relatively straightforward regulatory function, similar to what CMS does for the Qualified Entity program.

Requirements for Participating Providers. The GA will need to promulgate regulations implementing the provider participation mandate. The GA will need to define with particularity the provider organizations that are subject to the mandate, set the terms of their participation, establish penalties for non-compliance, and provide ongoing oversight and enforcement. Setting requirements for provider participation in the DDN is a relatively straightforward regulatory function, identical to what EOHHS currently does to implement the EHR and HIE mandates in MGL Chapter 118I.

Requirements for Datasets and Data Sharing. The GA will need to promulgate regulations providing specifics about both the data that participating providers must share and the methods they must use for sharing it with Data Stewards. The GA will rely on the advice of private-sector experts to leverage national standards and existing capabilities so as to minimize the level of effort and cost required from participating providers. Creating specifications for datasets and data transport methodologies is a relatively straightforward regulatory function, similar to what CHIA does in collecting data from 1,500 private-sector data submitters.

Other Governing Authority Duties. In addition to these specific duties, the GA will be responsible for the overall success of the DDN as a publicly-sponsored program. The GA will determine which of the foregoing governance functions could be delegated to a state agency and which should be outsourced to a vendor. The GA will convene an advisory body of private-sector experts to provide technical guidance and feedback, and will also administer any funds associated with the program.

Funding and sustainability. While the foregoing governance functions are not free, they are not particularly expensive. A relatively modest assessment on Data Stewards would be a simple, direct way to fund the DDN.

APPENDIX X: Governance Model Options

GOVERNANCE OPTIONS

There are three primary options for a public-sector Governing Authority: a new quasi-public authority, an existing quasi-public authority, or an existing secretariat/agency.

Option 1 - New Quasi-Public Authority

Creating a new quasi-public authority for the DDN would have the advantage of a tailor-made governance structure, but there are substantial disadvantages. In particular, creating a new quasi would take far more time than any other option and would necessarily involve far more legislative input. Assuming the legislature can be persuaded, members of a governing board would need to be solicited, subject to background checks, and then seated. The governing board would need to conduct a selection process for an Executive Director. Once the ED is chosen, staff would need to be hired to run program activities or to manage procurements and vendor contracts.

Option 2 - Existing Quasi-Public Authority

Another approach would be to use an existing quasi-public authority. While there are various useful capabilities at MEHI and CHIA, neither of these organizations is particularly well-suited to serve as the overall GA for the DDN. MEHI, although an important participant in EOHHS's health information exchange efforts, is within the EOHED domain, and CHIA, although it has many of the technical skills needed by the DDN GA, is a regulatory authority with no history of promoting health information exchange.

Option 3 - Updating Chapter 118I

The shortest, fastest path to creating a DDN GA would be to seek minor amendments to MGL Chapter 118I, which already reflects a clear legislative determination that EOHHS should be the Commonwealth's lead agency for promoting health information exchange. Chapter 118I is not specific to the Mass HIway project, which is never mentioned in the statute, and it has many useful features, such as the provider mandate and a mature mechanism for addressing patient consent issues. Relatively minor amendments to Chapter 118I could retain the mandate that providers adopt interoperable EHRs, but give EOHHS the flexibility to establish different HIE requirements as needs and capabilities evolve. As written, Chapter 118I makes the unspoken assumption that exchanging health information is solely about "connecting" to a single, unitary HIE. Instead, EOHHS should oversee multiple HIE mandates, such as requiring providers to: use Direct messaging for certain use cases; send ADT data to certain ENS vendor(s) certified by the state; send specified data to Data Stewards certified by the state; and so on as HIE evolves in the marketplace. The HIT Council could either be revamped to include more life science perspectives or EOHHS could form a special advisory group for the DDN that is not limited to members of the HIT Council.

APPENDIX Y: Dataset

The initial dataset to be utilized by the DDN will include the USCDI version 1.0. Proposed fields can be seen below:

1. Patient Name
2. Sex (birth sex)
3. Date of Birth
4. Preferred Language
5. Race
6. Ethnicity
7. Smoking Status
8. Laboratory Tests
9. Laboratory Values/Results
10. Vital Signs
11. Problems
12. Medications
13. Medication Allergies
14. Health Concerns
15. Care Team Members
16. Assessment and Plan of Treatment
17. Immunizations
18. Procedures
19. Unique Device Identifiers(s) for a Patient's Implantable Device(s)
20. Goals
21. Provenance
22. Clinical Notes

All data classes in draft USCDI v1 can be supported by commonly used standards, including the Health Level Seven (HL7®) Consolidated Clinical Data Architecture (C-CDA) Version 2.1 and the Fast Healthcare Interoperability Resources (FHIR®) standards.

* The addition of Provenance and Clinical Notes to the list of required data classes is currently under discussion by USCDI; clinical notes is likely to be out of scope for the Distributed Data Network v1.0

APPENDIX Z: Use Cases

The initial use cases to be permitted by the Distributed Data Network include:

- Improving direct patient care with a complete health record view across all points of care including emergency situations, and solving for current gaps in the system (e.g. an out of network patient presents in clinic or ED, the provider will not have any access to the patient's medical record).
- Enabling patients access for integrated medical records
- Integrate patient medical records with patient reported outcomes, patient wearables, registry data, external sources (e.g. CDC for flu outbreaks) to enable patients to better manage their health and enhance the availability of data to providers in making treatment decisions.
- Enabling improved access to patient data for ACOs

Future use cases for the DDN could include:

- A source of synthetic data created off of the real time feeds could be made available to startups interested in early validation of their products
- A quality reporting feed could be created off of providers' real time encounter data and sent to various registries
- Enabling the existing Center for Health Information Analysis feeds from health plans to transition to this model; provides the dual purpose of government reporting and reporting to ACOs about the claims incurred by patients
- A public health research feed created by combining and de-identifying providers' data from across the Commonwealth
- The potential for a steward to provide providers with a consolidated view of a patient's medical record into a provider-facing dashboard with the ability to apply analytics/alerts/reporting from that data is an unmet need that can be met with today's technology. While there are existing services that providers can contract to provide interfaces, it is unlikely that those services are currently obtaining access to all data for all patients and providers in Massachusetts. Second, as additional services are added in future use cases (population health, quality reporting, risk management tools, decision support tools, etc.), it will only continue to add value to providers.

APPENDIX Z: Use Cases

Use Case: Patient Access

USE CASE:

Patient access to consolidated medical record via data steward with single point of access

GOAL:

Patients in MA should be able to have a consolidated medical record, accessed from a single sign on (as compared to multiple portals) that combines data elements from all providers that the patient sees in MA. This record should be longitudinal, easy to read and consolidate similar data types as compared to a raw data dump.

DATA SOURCES:

All applicable providers the patient sees in MA

DATA CLASSES:

USCDI Version 1.0

STORY:

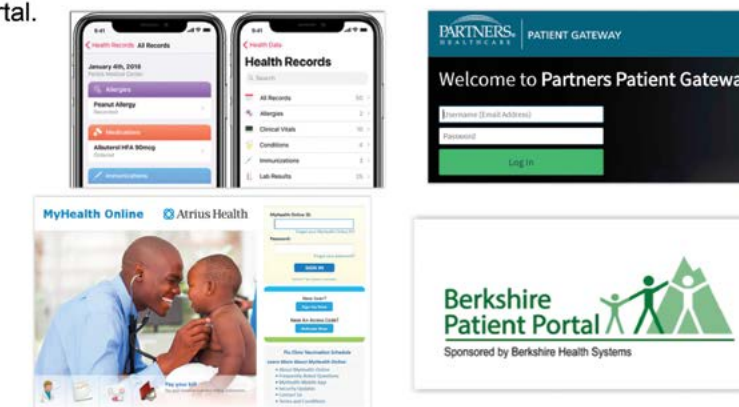
Jane is a 58 year old patient living in Massachusetts. Jane currently sees a primary care physician, gynecologist and allergist for routine care. Recently, Jane has experienced increased shortness of breath along with steadily increasing cholesterol, so she has been referred to a cardiologist. Jane often visits her local urgent care facility for minor issues and has been to the nearest ED based on her recent symptoms. She also spends time every Summer in the Berkshires and has had some treatment there.

Jane has a hard time tracking down results from her appointments across the various portals. She does not have the ability to monitor her health results over time or to see her results across visits in order to better prepare herself for visits.

Jane would like to have a method of reviewing her medical information from all of her providers in a single location, with the information collated by relevant field.

Use Case: Patient Access - Current State

Jane has to log-in to **separate portals** for all of her current health providers and she is **unable to review her results over time** due to the segmentation of information. Her walk-in clinic also **does not have a web portal**. Some of her data is available in AppleHealth, but it overlaps with the data also in the provider portal.



APPENDIX Z: Use Cases


Use Case: Patient Access – Future State

Jane accesses MAHealthNow*, a service provided by a data steward in MA and is able to pull her consolidated health record from a single log-in. In addition, MAHealthNow enables Jane to link her Fitbit as method of monitoring her health in between visits.

Medical Record (see following slide)

- Lab Results
- Problems
- Diagnosis
- Care Team and Visit History
- Procedures

Additional sources



Jane's top 5:

- Your exercise this week is on-track with your goals of **lowering cholesterol**
- You may be **overdue** for a visit with Dr. Jones
- Your tetanus shot is **overdue**
- Flu season has higher than average activity in your zip code – **take extra precaution**
- Your atorvastatin Rx will need a refill in **78 days**

*fictional service, mock up for illustrative purposes only

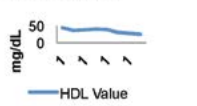
Use Case: Patient Access – Future State

Jane accesses MAHealthNow*, a service provided by a data steward in MA and is able to pull her consolidated health record from a single log-in:

Medical Record

- Lab Results
- Problems
- Diagnosis
- Procedures
- Care Team and Visit History

Lab Results^{1,4,6}



— HDL Value

Vitals^{1,2,3,4,5,6}

Date	Systolic	Diastolic
5/1/2011	130	85
7/10/2012	125	75
5/1/2014	130	83
6/1/2015	135	87
8/1/2016	140	90
10/1/2018	145	95

— Weight Lbs

Problems^{1,2,3,5,6}

- High Blood Pressure
- High Cholesterol
- Asthma
- SOB
- Anxiety

Immunizations¹

- 5/2014 – Tetanus
- 6/2017 – Influenza
- 10/2018 – Influenza

Medications^{3,5,6}

Active:
Atorvastatin – started May 2017
Spiriva – started July 2008
Albuterol – started July 2000

Historical:
Prednisone – May 1999– July 2000

Care Team and Visit Hx

PCP: Dr. Jones – 10/1/2016
Cardiology: Dr. Smith – 11/1/2018
Allergy: Dr. Claritin – 5/1/2018
You may be overdue for a visit with Dr. Jones

*fictional service, mock up for illustrative purposes only

APPENDIX Z: Use Cases

Use Case: Physician Access, Non Emergency

USE CASE:

Provider access to consolidated medical record for a given patient via data steward

GOAL:

Providers in MA should be able to access a consolidated medical record for their patients in a simple method that does not require multiple methods of access. This record should combine data elements from all providers that the patient sees in MA. This record should be longitudinal, easy to read and consolidate similar data types as compared to a raw data dump.

DATA SOURCES:

All applicable providers the patient sees in MA

DATA CLASSES:

USCDI Version 1.0

STORY:

Henry is a 75 year old patient living in Massachusetts. Henry currently sees a primary care physician and cardiologist for routine care. Recently, Henry has started to notice he is having some problems with his memory and also trouble sleeping, so he scheduled an appointment with a neurologist (who is in a different health network). Henry also had a recent ED visit due to chest pain. Henry sometimes forgets what medications he is on and also does not remember components of his medical history when he attends medical visits.

Dr. Smith is Henry's new neurologist and has trouble obtaining Henry's medical information during the appointment. Henry's primary care physician did not send over any of his medical history prior to the visit.

Dr. Smith cannot access any of Henry's recent lab work, so he orders a new set (despite Henry having had blood work 1 week prior during his ED visit).

Use Case: Physician Access, Non Emergency

Dr. Smith accesses DoctorsHelper*, a service provided by a data steward in MA and is able to pull Henry's consolidated health record. He notices Henry had blood work last week and is able to review the results instead of ordering another test. Dr. Smith also notices that Henry had an EKG last month and is able to request the results from his cardiologist.

Lab Results¹

Recent results available

Test	Value	Normal
Total Protein	7.7	6.0 - 8.5
Albumin	4.5	3.5 - 5.0
Bilirubin, Total	0.5	1 - 1.5
AST	80	0-48
ALT	51	0-52
Cholesterol	238	140-200
HDL	26	40-75
WBC	12	3.8 - 10.8
RBC	4.2	4.2 - 5.8
Platelets	176	140-400

Sources: 1-PCP, 2-Cardiologist, 3-University ED
Items in **bold** appear in > 1 record and/or source

Problems^{1,2,3}

Click on problem to pull raw data that supports problem (e.g. lab results, medications, etc.)

- High Blood Pressure
- High Cholesterol
- Coronary Artery Disease
- Memory Loss
- Chest Pain
- Shortness of Breath
- Heartburn

Allergies¹

- Shellfish

Medications^{1,2,3}

- Atorvastatin, Plavix, Lisinopril, omeprazole

Procedures²

- Angiogram – 2014
- Angioplasty – 2016
- Stent placement – 2016
- MRI – September 2018
- Chest x-ray – October 2018
- EKG – October 2018

Care Team

- Dr. Jones – PCP
- Last visit: September 2018
- Dr. Miller – Cardiologist
- Last visit: October 2018
- University ED – Attending
- Last Visit: October 2018

*fictional service, mock up for illustrative purposes only

APPENDIX Z: Use Cases

Use Case: Physician Access, Emergency

USE CASE:

Provider access to consolidated medical record for a given patient via data steward

GOAL:

Providers in MA should be able to access a consolidated medical record for their patients in a simple method that does not require multiple methods of access. This record should combine data elements from all providers that the patient sees in MA. This record should be longitudinal, easy to read and consolidate similar data types as compared to a raw data dump.

DATA SOURCES:

All applicable providers the patient sees in MA

DATA CLASSES:

USCDI Version 1.0




STORY:

Jack is a 40 year old patient living in Massachusetts. Jack is in a serious car accident and presents in the ED unconscious.

Jack has epilepsy and diabetes and requires several medications for management of these diseases; however, Jack is unable to provide any of this information as he is unconscious. The ED is also not immediately able to reach any of his emergency contacts.

Use Case: Physician Access, Emergency

The ED staff is able to access EmergenSee*, a service provided to ED staff by a MA data steward. The ED staff is quickly able to see Jack's medical history and required medications, avoiding any further complications or safety issues while he is being treated for his car accident.

Problems^{1,2,3}  Warning: Patient problem list may require urgent attention Diabetes – Type 1 Epilepsy	Medications^{1,2,3}  Warning: Patient requires daily medication Insulin, Lorazepam, Gabapentin	Procedures² N/A
	Allergies¹  Warning: Patient has allergy – please use caution Amoxicillian	Care Team Dr. Jones – PCP Last visit: September 2018 Dr. Miller – Endocrinologist Last visit: August 2017 Neurologist Last Visit: October 2018

Sources: 1-PCP, 2-Endocrinologist, 3-Neurologist

*fictional service, mock up for illustrative purposes only

APPENDIX Z: Use Cases

Use Case: ACO

USE CASE:

ACOs should be able to track patient visits to coordinate care and reduce total medical expenses

GOAL:

ACOs in MA should be able to easily track their patient visits in a simple method that does not require multiple methods of access and is inclusive of visits that take place at all providers that the patient sees in MA. This would allow for real-time sharing of patient data and enable coordination of care transitions.

DATA SOURCES:

All applicable providers the patient sees in MA

DATA CLASSES:

ADT (HL7 v3.0 standards) + USCDI v1.0

STORY:

MA ACO is an ACO located in Massachusetts, focused on delivering connected care for 100,000 patients across 15 medical practices.

MA ACO has methodology in place for sharing patient data across the member practices and select hospitals, as well as receiving alerts for patient visits across the member practices, but does not have the capability to track patient visits outside of the ACO members or easily pull patient medical information from non-members.

By gaining access to patient medical information from non-members and being aware of patient visits outside of the ACO network, MA ACO could continue to better manage costs and care quality for their patients.

APPENDIX AA: Data Steward Certification Criteria

Use Cases

It is anticipated that certified data stewards could provide one or more of the following functions in the Distributed Data Network (some of the functions below will not be rolled out until later phases of the network):

- **Aggregation, transformation and curation** – stewards may aggregate and unify the data from multiple providers sources in order to develop a single, enhanced format
- **Analytics** – stewards may leverage data to provide value added services, such as decision support tools, consolidated user interfaces for patients and providers
- **Notifications** – stewards may leverage data to provide alert services to enable transparency in how patients move across the healthcare system, access the system and adherence to appointment regimens, medication compliance, etc.
- **Reporting** – stewards may leverage the data to develop robust reporting mechanisms for patients, providers, ACOs, payers, etc.

There may be circumstances in which data stewards provide complementary functions. For example, one data steward might aggregate and unify data from multiple sources into a single enhanced format. Another data steward providing decision support might base its services on the curated data from this data steward. It is understandable that providers might want more control over the way their data is used between data stewards so we will provide a means for providers to opt out of such transfers between stewards.

Patients can also direct the use of data by steward for certain purposes. For example, if a patient utilizes an app developed by a steward in the Distributed Data Network to consolidate their medical records, the patient can then provide additional consent to that steward to use the data for any other purpose (e.g. donate data to research project, population health, disease registries, etc). Stewards would still be subject to applicable laws in obtaining such consent.

The DDN would create a robust process to certify these Data Stewards that will require compliance with specified security, audit, insurance and liability requirements. Data Stewards will be able to determine the best way to use the data to facilitate treatment and provide patients with access to their healthcare data. By allowing the market to determine how best to use the available data, our hope is that a robust and innovative digital health ecosystem will develop to support healthcare in the Commonwealth.

Federal Health Interoperability standards and regulations should form a consistent base for certification, including common language, common architecture, and common privacy and security frameworks. Individual states or organizations can mandate and accelerate federal and industry frameworks. States can also accelerate progress through defined use cases/business models and in doing so, foster innovation and economic development.

APPENDIX AA: Data Steward Certification Criteria

Use Case Certification

USE CASE | BUSINESS MODEL

DDN Governance body will only approve Data Stewards with a product or service that aligns with an approved patient access or care management and coordination use case.

As part of this certification, DDN will review the Data Stewards' business model and business case. The business model will confirm some key points:

- Under HIPAA standards, is the Steward more similar to a Covered Entity (health plan, provider, clearing house) or a Business Associate (third party functions for Covered Entities)?
- Will the Steward be using identifiable or identified data?
- Who are the end users of the product or service (patient, caregiver, provider, etc.)
- What subcontractors or vendors will the Steward work with, and will they have access to identifiable data?
- Will the adolescent population or other sensitive demographics be served by the Data Steward?
- Will your product/service leverage any non-traditional data sets (social determinants, patient reported data)?
- Do you request any exception to standard DDN data use terms?

PRIVACY & SECURITY CERTIFICATION	
HIPAA (Privacy)	Compliance with HIPAA Privacy Required: Privacy is defined as the right of an individual to keep his/her individual health information from being disclosed. This is typically achieved through policy and procedure. Privacy encompasses controlling who is authorized to access patient information; and under what conditions patient information may be accessed, used and/or disclosed to a third party. The HIPAA Privacy Rule applies to all protected health information.
HIPAA (Security)	Compliance with HIPAA Security Required: Security is defined as the mechanism in place to protect the privacy of health information. This includes the ability to control access to patient information, as well as to safeguard patient information from unauthorized disclosure, alteration, loss or destruction. Security is typically accomplished through operational and technical controls within a covered entity. Since so much PHI is now stored and/or transmitted by computer systems, the HIPAA Security Rule was created to specifically address electronic protected health information.
Security Frameworks	<p>ISO</p> <p>Information security standards published jointly by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Certification enables organizations of any size and in any industry to prove that they meet critical legislative and regulatory requirements related to information security. It demonstrates that the organization has a framework for securing and protecting confidential, personal and sensitive data.</p> <p>Provides best practice recommendations on information security management within the context of an overall Information security management system (ISMS).</p> <p>The series is deliberately broad in scope, covering more than just privacy, confidentiality and IT/technical/cybersecurity issues. All organizations are encouraged to assess their information risks, then treat them (typically using information security controls) according to their needs, using the guidance and suggestions where relevant. Given the dynamic nature of information risk and security, the ISMS concept incorporates continuous feedback and improvement activities to respond to changes in the threats, vulnerabilities or impacts of incidents.</p>

APPENDIX AA: Data Steward Certification Criteria

PRIVACY & SECURITY CERTIFICATION		
Security Frameworks (CONTINUED)	COBIT	Control Objectives for Information and Related Technologies) is a good-practice framework created by international professional association ISACA for information technology (IT) management and IT governance. COBIT provides an implementable "set of controls over information technology and organizes them around a logical framework of IT-related processes and enablers."
	HITRUST	Not-for-profit organization champion for programs that safeguard sensitive information and manage information risk for organizations across all industries and throughout the third-party supply chain. Develops, maintains and provides broad access to its widely adopted common risk and compliance management and de-identification frameworks; related assessment and assurance methodologies; and initiatives advancing cyber sharing, analysis and resilience.
	NIST	In collaboration with ONC, NIST is developing the necessary functional and conformance testing requirements, test cases, and test tools in support of the health IT certification program. NIST is responsible for leading the development of the core health IT testing infrastructure that will provide a scalable, multi-partner, automated, remote capability for current and future testing needs. The objective of the Health IT Testing Infrastructure Project is to harmonize the efforts of healthcare standards test development and delivery to meet the demands for conformance and interoperability within the healthcare domain. This is accomplished by working in collaboration with health IT stakeholders such as vendors, implementers, standards organizations and certification bodies to establish a testing infrastructure that will: <ul style="list-style-type: none"> • Provide a variety of testing services: The testing infrastructure will define a set of services including healthcare application test agents and reference implementations, tools to validate standards, tools to generate test materials, and registries and repositories to support testing. • Support a broad range of test environments: The testing infrastructure will support multiple testing environments including instance testing, isolated system testing, and peer-to-peer system testing - in addition to onsite and remote testing. • Support numerous health data standards: The testing infrastructure will support conformance and interoperability testing for numerous healthcare messaging and document data exchange standards. • Provide a component-based user interface: The testing infrastructure will include multiple components that will enable different stakeholders to use the infrastructure in different ways. • Enable user customization: The testing infrastructure will allow different stakeholders to build their own instances of the testing services to support their individual needs. • Support changing user requirements: The testing infrastructure will provide a framework that is modular, flexible, and expandable to meet changing stakeholder demands. • Leverage existing testing initiatives: The testing infrastructure will collaborate and harmonize with other tooling efforts and integrate existing toolsets when appropriate. • Provide a feedback loop to enhance the health standards: The testing infrastructure will provide a mechanism to enable valuable feedback about health data standards and specifications to be collected. • Roll out tools and resources incrementally: The testing infrastructure tools and resources will be incrementally
	CIS	CIS (Center for Internet Security, Inc.) is a non-profit entity that harnesses the power of a global IT community to safeguard private and public organizations against cyber threats. CIS employs a closed crowdsourcing model to identify and refine effective security measures, with individuals developing recommendations that are shared with the community for evaluation through a consensus decision-making process. At the national and international level, CIS plays an important role in forming security policies and decisions by maintaining the CIS Controls and CIS Benchmarks, and hosting the Multi-State Information Sharing and Analysis Center (MS-ISAC).

APPENDIX AA: Data Steward Certification Criteria

PRIVACY & SECURITY CERTIFICATION	
TEFCA	<p>Congress directed ONC to develop or support a trusted exchange framework, including a common agreement among health information networks nationally. A common set of principles for exchange was published 1/2018 (TEFCA draft), to bridge the gap between providers and patients information systems. Framework will include:</p> <ul style="list-style-type: none"> • A common method for authenticating trusted health information network participants; • A common set of rules for trusted exchange; • Organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and • A process for filing and adjudicating noncompliance with the terms of the common agreement. <p>TEFCA aligns with HIPPA, but recognizes that some end users will not be CEs or BAs, and TEFCA will need to enable those entities to access health information</p> <p>Goal is not to create a single national HIE - but to create a single "on-ramp" that provides common policy, procedure, technical standards that bridge existing HINs together</p>

TECHNICAL CERTIFICATION		
Standards	HL7	HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world.
	CDA	CDA is a base standard which provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents. CDA defines the structure of building blocks which can be used to contain a multitude of healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats. CDA DOES NOT specify how documents are transported, simply how critical data elements should be encoded for exchange and interoperability.
	USCDI	USCDI (US Core Data for Interoperability) is the common set of data classes required for interoperable exchange - ONC is responsible for outlining those data classes (which will be updated and expanded through regular process) Builds on 2015 Common Clinical Data Set (CCDS), which itself built on the 2012 MU common data set. The 2015 CCDS included API certification criteria, but no specific standards, and at the same time (~2014) the independent Argonaut Project began to develop FHIR specifications (data formats and elements and an API for exchange, created by the HL7 standards organization) that could be used to meet 2015 CCDs criteria.
Transport	API	In 2015, ONC recognized the potential for APIs to revolutionize health care data sharing, as it has already revolutionized data sharing in other industries. ONC issued a regulation that included certification criteria for APIs.
	Direct	Direct is a national encryption standard for securely exchanging clinical healthcare data via the Internet. It is also known as the Direct Project, Direct Exchange and Direct Secure Messaging. It specifies the secure, scalable and standards-based method for the exchange of Protected Health Information (PHI).

APPENDIX AA: Data Steward Certification Criteria

FINANCIAL CERTIFICATION	
Financial Stability Requirements	Ability to pay required DNN fees and certification
Auditability Requirements	Agreement to data access/use audit
Insurance/Liability Requirements	<ul style="list-style-type: none"> Data breach, cybersecurity liability Medical malpractice impact Fiduciary obligations for all apps that deliver any kind of recommendation or guidance to be in the best financial and health interest of a patient

OTHER

Resource/Personnel Requirements

- Privacy/Security staff
- Compliance
- Require healthcare informatics /data science

MASSACHUSETTS INFO

1. Executive Order No. 504: Order regarding the security and confidentiality of personal information (9/19/2008)
2. M.G.L. C. 66A and MGL ch. 93H and M.G.

APPENDIX BB: Distributed Data Network FAQ

1. What is the current state of healthcare information exchange in the Commonwealth?

Healthcare information exchange in the Commonwealth is currently in place; however, it is not universally adopted or consistently understood. For example, this is what is happening today:

- With NEHEN we can exchange administrative transactions (benefits/eligibility, referral/authorization. Claims/remittance) between most payers and providers.
- With MassHiway we can push clinical data summaries between most providers.
- With MAeHC and companies like Patient Ping we can send notifications among most providers, but this is done on a case-by-case/contract-by-contract basis.
- With efforts such as Commonwell, Carequality, and Epic's CareEverywhere we can pull records from some providers.
- With emerging technologies such as FHIR APIs and recently introduced apps, a limited subset of patients can pull their records from a small number providers.

Given the advances in technology, we have the opportunity to bring all of the disparate information exchange approaches and efforts together.

2. What is the problem we need to solve?

We want every provider to pull a common data set for care coordination (the 'Treatment' part of HIPAA) on demand using a streamlined process and every patient to be able to access their own data in an efficient manner. We propose a process to solve health data exchange problems with a safe and innovative approach, without creating another silo.

3. What is the urgency to do this?

The 21st Century Cures Act requires every provider to make a common data set available to every patient via APIs. The TEFCA guideline recently issued by ONC explains the policies and technologies that should be used to make this happen. In 1996 when the HIPAA administrative simplification regulations became effective, all stakeholders in the Commonwealth decided that it would be easier to meet these requirements together via a single project and NEHEN was born for administrative data exchange.

Today, the proposed Distributed Data Network takes this one step further by bringing together a limited set of healthcare data from all data providers to enable patient access and improve care coordination.

4. How will we do this?

Every organization producing data for treatment will provide a common data set for every patient encounter. This functionality might be created by EHR vendors, through use of direct messaging, third party companies, or healthcare organizations themselves. It will use widely available national standards (e.g., those required for Meaningful Use). It will not require substantial new investment or replacement of existing EHRs

We will create a process to certify "data stewards" who will be enabled to access all of the data. Data stewards will perform a range of functions. For example:

- Providing consolidated medical records to providers for care coordination;

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- Providing patients with direct access to their data; or
- Providing decision support analytics to providers.

Importantly, certified data stewards cannot be blocked from the data, ensuring that patients and providers can assemble data from every treatment site for the purpose of care coordination and patient access of their own data.

5. Can data stewards exchange data with each other?

There may be circumstances in which data stewards provide complementary functions. For example, one data steward might aggregate and unify data from multiple sources into a single enhanced format. Another data steward providing decision support might base its services on the curated data from this data steward. It is understandable that providers might want more control over the way their data is used between data stewards so we will provide a means for providers to opt out of such transfers between stewards.

6. What are the phases of the Distributed Data Network?

The initial roll out of the Distributed Data Network will focus on two primary use cases: patient access and care coordination. For Phase 1, the intent will be to enable a specified number of data stewards to complete the certification process to enable solutions for the two use cases.

After the initial roll out, it is anticipated that the appropriate governing body will consider new use cases, revisions to the minimal data set, additional data stewards and improvements to the technical architecture as emerging technologies are realized. The implementation team will determine the priority and timing of future phase roll out.

7. What are the functions of data stewards?

It is anticipated that certified data stewards may provide one or more of the following functions in the Distributed Data Network (some of the functions below will not be rolled out until later phases of the network):

- **Aggregation, transformation and curation** – stewards may aggregate and unify the data from multiple providers sources in order to develop a single, enhanced format
- **Analytics** – stewards may leverage data to provide value added services, such as decision support tools, consolidated user interfaces for patients and providers
- **Notifications** – stewards may leverage data to provide alert services to enable transparency in how patients move across the healthcare system, access the system and adherence to appointment regimens, medication compliance, etc.
- **Reporting** – stewards may leverage the data to develop robust reporting mechanisms for patients, providers, ACOs, payers, etc.

8. Will data flow through stewards or will it move between providers?

Data will continue to move between providers as it happens today (e.g. fax machine, MassHIWay, etc.). The Distributed Data Network is additional functionality, not replacement for existing processes that are required by regulation and workflows today. Within the Distributed Data Network, data will flow from providers to data stewards, who will then utilize the data to provide services to patients, providers and ACOs (and payers or researchers in later phases). Data can flow between data stewards. Data will flow back to providers via a

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service provided by a steward.

9. Do the politics of the DDN require patients are provided with free aggregated access to their own health records?

A component of the certification process will require data stewards to provide use cases and business model for utilizing the data within the network. Ideally, for data stewards who provide patient facing services, the steward would aggregate and expose the patient's health records for free; however, we anticipate that steward could charge patients for advanced analytics, integration with non-medical record data (e.g. wearables, home sensors, external data sources), and other add-ons. It is worth considering if a requirement of the initial certification in Phase 1 would require patient facing stewards to provide a minimum service for free or alternatively, provide incentives to those stewards that provide free services to patients.

10. What is the common data set? What is meant by data producers will provide minimum data elements required to enable the network?

Providers will expose at least the agreed standard data set to all data steward participants in the network; if a provider wants to provide additional data, it will not be restricted. The initial data set that will be utilized in Phase 1 mirrors the proposed v1.0 USCDI elements, with the exception of clinical notes. It is anticipated that new data elements will be added to the common data set in a phased approach (see paragraph [6] above). For example, claims data may be addressed in a later phase of the network as it has a different set of standards and workflows and claims data exchange standards are not yet developed.

11. Do stewards have any rights to access data being exposed to the network? Or is steward access to data based on contracts with providers?

Data steward access to the data does not require a contract with a provider. Access for stewards will be provided for as part of the network. Services provided back to the provider from the steward would be contracted for on a case-by-case basis. These relationships would not be managed by the DDN, but rather would be left to the parties. A centralized list of stewards would be maintained so providers could readily ascertain which services were available and contract with stewards (who will have access to data from all providers in MA (as compared to other non-network stewards who are unlikely to have coverage for all patients and providers in MA)).

Patients can also direct the use of data by steward for certain purposes. For example, if a patient utilizes an app developed by a steward in the Distributed Data Network to consolidate their medical records, the patient can then provide additional consent to that steward to use the data for any other purpose (e.g. donate data to research project, population health, disease registries, etc). Stewards would still be subject to applicable laws in obtaining such consent.

12. Will stewards be able to "sell data" to other stewards or recoup a profit for value they have added to the data set in some way?

Yes; however these transactions would need to be traceable and compliant with the standard participation agreement of the network / HIPAA BAA requirements.

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13. What market exists for value-added services by data stewards given that patient's access is required and for care coordination there are other methods for how providers disclose medical records to other providers?

For patient access, despite federal interoperability requirements for patient access, it is still challenging for patients to get access to their records. For example, a recent cross-sectional study of 83 US hospitals revealed that there was noncompliance with federal regulations for formats of release and state regulations for request processing times. In addition, there was discordance between information provided on medical records release authorization forms and that obtained directly from medical records departments regarding the medical records request process (<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850> and https://khn.org/news/in-days-of-data-galore-patients-have-trouble-getting-own-medical-records/amp/?_twitter_impression=true).

In addition, many providers offer patient portals for access which are often not user friendly and do not provide a consolidated record for patients who have providers in different networks. In fact, 63% of patients report not using their portal and 60% report not being offered access. (<https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05117>)

Further, services like Apple Health enable patients to pull records from select providers who have connected via FHIR interfaces.

The potential for a steward to consolidate medical records into a single-service dashboard for patients is an unmet need. Further, stewards who then integrate medical records with patient reported outcomes, wearables, registry data, external sources (e.g. CDC for flu outbreaks) will enable patients and enhance the availability of data to providers in making treatment decisions.

For provider access, there are methods for providers to disclose medical records to other providers, although this is often done on a case by case basis utilizing fax or direct messaging protocols. Providers utilizing EPIC or Cerner which are connected to Commonwell can share documents across providers, but this is not currently available for all providers.

The potential for a steward to provide providers with a consolidated view of a patient's medical record into a provider-facing dashboard with the ability to apply analytics/alerts/reporting from that data is an unmet need. While there are existing services that providers can contract to provide interfaces, it is unlikely that those services are currently obtaining access to all data for all patients and providers in MA. Second, as additional services are added in future use cases (population health, quality reporting, risk management tools, decision support tools, etc.), it will only continue to add value to providers.

14. Why would large providers contract with a steward in the network to pull a consolidated health record with a "fancy front end"?

Even large providers cannot currently pull a consolidated health record for their patients who are sometimes seen out of network. Additionally, for emergency situations, if an out of network patient presents in clinic or ED, the provider will not have any access to the patient's medical record.

15. What data will stewards receive and why?

Initial minimum data set (developed in alignment with Argonaut project):

- USCDI v1.0 elements
- ADTs

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Out of scope for version 1.0 (but will be on roadmap for future implementation):

- Claims data
- Clinical notes

We need to demonstrate proof of concept for data steward model and start with a confined, manageable and non-controversial data set

16. What is the technical mechanism for stewards to obtain data?

In Phase 1, providers will push the minimum data set to all certified stewards Direct Messaging or MLLP/VPN. The Mass HIWay is 1 method for steward access if steward is connected to HIWay. At end of a patient encounter, the USCDI (via CCDA) and/or ADT will be pushed from the provider to all applicable stewards in the network.

FUTURE STATE:

- APIs will likely replace the Direct Messaging mechanism as providers adopt the capability
- The DDN oversight body will monitor the technical maturity of API to replace CCDA push as a measurable goal
- The oversight body will also work to drive accelerated adoption of FHIR API in MA

17. Why not APIs?

- Patient facing APIs require each individual patient log-in credentials for data access; there is no way to modify the API to support steward query without the consent of the patient
- Events will trigger the data needed by a steward; if rely on pull mechanism, how would a steward know what to pull?
- National networks (such as CommonWell/Carequality) can support data pull methods but utilize XDS.b and not FHIR API; query capability is also document-based and not data-centered

18. Are payers included as a data provider in the initial implementation?

No

WHY?

We need to start small with care coordination use cases for patients, providers and ACOs. EOHHS and the advisory board will work to integrate payer use case



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