VEDP | Virginia Economic Development Partnership

November 1, 2018

The Honorable Ralph S. Northam
Governor of the Commonwealth of Virginia
Patrick Henry Building, 3rd Floor
1111 East Broad Street
Richmond, Virginia 23219

The Honorable Thomas K. Norment, Jr.
Co-Chair, Senate Committee on Finance
14th Floor, Pocahontas Building
900 East Main Street
Richmond, Virginia 23219

The Honorable Emmett W. Hanger, Jr.
Co-Chair, Senate Committee on Finance
14th Floor, Pocahontas Building
900 East Main Street
Richmond, Virginia 23219

The Honorable S. Chris Jones
Chair, House Committee on Appropriations
13th Floor, Pocahontas Building
900 East Main Street
Richmond, Virginia 23218

Re: Virginia Biosciences Health Research Corporation
Fiscal Year 2018 Annual Report

Dear Governor Northam, Senator Norment, Senator Hanger, and Delegate Jones:

Chapter 836, Item 106:I of the 2017 Acts of Assembly includes funding for the Virginia Biosciences Health Research Corporation (VBHRC), a 501(c)(3) non-stock corporation, to serve as a catalyst to accelerate and focus life science research momentum at Virginia's universities. VBHRC uses the name "Virginia Catalyst."

Chapter 836, Item 106:I.6 requires that you be provided by, November 1 of each year, a written report summarizing the activities of the consortium, including, but not limited to, a summary of how any funds disbursed to the consortium during the previous fiscal year were spent, and the consortium's progress during the fiscal year in expanding upon existing research opportunities and stimulating new research opportunities in the Commonwealth.

In conjunction with the staff of Virginia Catalyst, VEDP is pleased to provide you with a comprehensive report detailing the mission, funding, initiatives and progress of Virginia Catalyst in Fiscal Year 2018.

VEDP thanks you for your continued support of these important and innovative efforts to transform Virginia's economy. As always, please do not hesitate to contact Mike Grisham, the Chief Executive

VEDP | Virginia Economic Development Partnership

The Honorable Ralph S. Northam
The Honorable Thomas K. Norment, Jr.
The Honorable Emmett W. Hanger, Jr.
The Honorable S. Chris Jones
November 1, 2018

Officer of Virginia Catalyst, or me, if you would like any additional information.

Very truly yours,

Sandra Jones McNinch
General Counsel

Enclosure

cc: The Honorable R. Brian Ball, Secretary of Commerce & Trade
Mr. Mike Grisham, Chief Executive Office, Virginia Biosciences Health Research Corporation

Virginia Biosciences Health Research Corporation

also known as the Virginia Catalyst

"achieving competitive critical mass through collaboration"

Annual Report for Fiscal Year 2018 to the General Assembly of Virginia

Submitted November 1, 2018

VBHRC
VA CATALYST

Forward

The 2017 Virginia Acts of Assembly, Chapter 836, Item 106:I includes funding for the Virginia Biosciences Health Research Corporation (VBHRC), a 501(c)(3) non-stock corporation, to serve as a research consortium and catalyst to accelerate and focus life science research momentum at Virginia's universities.

This item also includes the requirement that you are provided, by November 1 of each year, a written report from the Virginia Economic Development Partnership Authority (VEDP) summarizing the activities of the VBHRC consortium. The report is to include a summary of how any funds disbursed to the consortium during the previous fiscal year were spent, and the consortium's progress during the fiscal year in expanding upon existing research opportunities and stimulating new research opportunities in the Commonwealth.

VEDP is pleased to submit to you the following report to detail progress made on core objectives, with a focus on the results achieved during Fiscal Year 2018. Please note, as with our prior annual reports, we are continuing our practice of including details of ongoing efforts into the current fiscal year.

Statement from Mike Grisham, CEO

"On behalf of VBHRC Virginia Catalyst and its Board of Directors, we thank you for your continued support of these important and innovative efforts to advance commercialization of Virginia's life science innovations and create high-paying jobs in Virginia. This is achieved through collaborations with our research universities, health systems, and industry.

As always, if you have any questions or requests, or if we can be of any assistance, please do not hesitate to contact us!"

Mike Grisham
President and CEO
mgrisham@VirginiaCatalyst.org
804-543-5200

Suzanne Taylor, PhD, MBA
Vice President of Operations
staylor@VirginiaCatalyst.org
804-937-3919

Virginia Biosciences Health Research Corporation
Annual Report for Fiscal Year 2018 to the General Assembly of Virginia

Overview of Virginia Biosciences Health Research Corporation

Established in 2013 as Virginia's research consortium[1] the Virginia Biosciences Health Research Corporation (VBHRC) was founded through the vision and joint efforts of the Commonwealth of Virginia and the five (5) founding members consisting of Virginia's premiere research institutions: Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Virginia Tech, and the University of Virginia. In 2014, Old Dominion University became the sixth member institution; and in October 2016, William & Mary joined as the seventh member institution of this consortium.

The overarching purpose and focus of VBHRC is to stimulate and cultivate collaborations and partnerships among Virginia's research universities, major health systems, and industry to produce a positive economic impact within the Commonwealth. This is measured by tracking job creation and follow-on funding for commercializing Virginia's innovations. VBHRC's strategic initiatives increase corporate-sponsored, federal, industry, and philanthropic research funds brought into Virginia; resulting in commercialization of new technologies, formation of new companies, creation of jobs, and expansion of bioscience companies in Virginia.

VBHRC is governed by a Board of Directors (BOD)[2] with primary duties that include:

- Reviewing and approving the annual budget
- Reviewing annual and periodic financial statements and information
- Reviewing Chief Executive Officer's performance annually, establishing salary
- Reviewing and approving all program grant projects
- Reviewing and approving all supplier contracts over $25,000
- Reviewing and approving all non-budgeted expenditures over $10,000
- Reviewing and advising staff on internal controls and accounting policies and procedures
- Annually contracting for an audit of the VBHRC, and meeting at least annually with the external auditor to review the results of the audit.

The BOD is comprised of a maximum of fifteen directors, nine of whom are ex-officio directors as follows:

- Secretary of Commerce and Trade of Virginia
- President and Chief Executive Officer, Virginia Economic Development Partnership Authority
- President of each of the (seven) member institutions

[1] Appendix A provides details regarding the history of VBHRC
[2] Appendix B lists members of VBHRC Board of Directors, Project Management Oversight Panel, and Management

Each of the nine ex-officio directors may designate an employee of his or her agency or institution to act in his or her stead. The remaining six directors represent the United States Department of Veterans Affairs, health care system providers in Virginia, life sciences companies, venture capital firms, and the biosciences industry in Virginia.

The 2017 Virginia Acts of Assembly, Chapter 836, Item 106:I includes funding of VBHRC for Fiscal Years 2017 and 2018 in order to achieve established core objectives. In addition, the President of each member university agreed to commit a cash contribution of $50,000 each year. As stated in the aforementioned Acts of Assembly, along with supporting the administrative, promotional and legal costs of establishing and administering the consortium, funding may be used to develop or maintain investments in research infrastructure tools to facilitate bioscience research (Item 106:I.2), and to capture and perform research in the biosciences (Item 106:I.3).[3]

In Fiscal Year 2017, VBHRC was funded $2,500,000 by the Commonwealth of Virginia and $350,000 through the member institutions ($50,000 per each year of the seven (7) member institutions), bringing the total funding for Fiscal Year 2017 to $2,850,000.

In Fiscal Year 2018, VBHRC was funded $3,750,000 by the Commonwealth of Virginia and $350,000 through the member institutions ($50,000 per each year of the seven (7) member institutions), bringing the total funding for Fiscal Year 2018 to $4,100,000.

Core Objectives

Also stated in the aforementioned Acts of Assembly are core objectives stating that VBHRC, a research consortium, will contract with private entities, foundations and other governmental sources to:

- capture and perform research in the biosciences,
- promote the development of bioscience infrastructure tools which can be used to facilitate additional research activities, and
- develop or maintain investments in research infrastructure tools to facilitate bioscience research.

The overarching purpose of these core objectives and efforts is to have a positive economic impact to the Commonwealth by increasing corporate-sponsored research resulting in commercialization of new technologies, formation of new companies, creation of jobs, and expansion of bioscience companies in Virginia.

[3] Appendix C provides details of VBHRC funding and disbursements.

In accordance with the core objectives, VBHRC has several strategically designed initiatives that focus on:

- stimulating collaborations and partnerships with and among our research universities, industry, and the five major medical centers: Sentara, Inova, UVA Health System, VCU Health, and Carilion,
- creating infrastructures that remove barriers and promote collaborations,
- actively pursuing opportunities to bring outside sources of research funding into Virginia's research institutions, and
- leveraging collaborations to develop a competitive critical mass of expertise and resources to commercialize Virginia's innovations.

Strategic Initiatives

Our strategically designed initiatives, each detailed further in this report, include:

- Grant Funding Rounds
- Virginia Neuroscience Initiative
- Virginia Catalyst Clinical Trials Network
- Virginia Catalyst Addiction Initiative

These initiatives continue to result in positive economic impacts to the Commonwealth of Virginia including:

- increased corporate-sponsored, federal, industry, and philanthropic research funds brought into Virginia,
- increased commercialization of new technologies,
- increased patents and resulting royalties for those respective Virginia universities
- formation of new companies based in Virginia,
- expanded involvement of bioscience companies in Virginia.

VBHRC, also known as the *Virginia Catalyst*

VBHRC VA CATALYST

As VBHRC expanded its work and initiatives of collaborations broadly across Virginia, and then began pursuing funding from corporate-sponsored, federal and industry outside of Virginia, the need for, and benefits of, effective branding and marketing became apparent. In June 2017 the Commonwealth of Virginia, State Corporation Commission recognized VBHRC doing-business-as the *Virginia Catalyst*.

Progress on Core Objectives

Grant Funding Rounds

Overview and Objectives

Each fiscal year, the Virginia Catalyst conducts formalized, competitive Grant Funding Rounds to:

- Encourage collaborative partnerships between two or more Virginia research universities and an industry partner,
- Fund the development and commercialization of life science projects that address major unmet needs for improving human health,
- Accelerate commercialization of Virginia research university inventions and discoveries,
- Increase Virginia's national and global competitiveness in the life sciences by creating critical mass through collaborations between and among Virginia's research universities, health systems, and industry partners,
- Create jobs and economic growth in Virginia.

The eligibility requirements for obtaining funding through the Virginia Catalyst Grant Rounds are:

- Substantive collaboration between investigators from at least two (2) Virginia research universities and an industry partner,
- matching funds of at least 1:1 for the project. The match must be a cash dollar-for-dollar match, not in-kind services or a waiver of indirect overhead charges. Matching funds are verified by the Virginia Catalyst.

Awards range from $200,000 to $800,000 per project and are non-dilutive. All Virginia Catalyst funding is disbursed over the project period based upon verified completion of objective and measurable milestones. The Virginia Catalyst disburses the funds directly to the Prime University, not the industry partner. The Prime University then disburses funds to the Partner University and the Industry Partner.

Project Management and Oversight Panel

The Project Management and Oversight Panel[3], the CEO, and the Board of Directors developed and approved criteria and standardized processes which govern the Virginia Catalyst Grant Rounds including:

- Project solicitation from institutions and companies
- Determination that eligibility requirements have been satisfied
- Project review for scientific rigor and impact on unmet needs for improving health

- Project review for abilities of commercialization, obtaining follow-on funding, and job creation
- Progress reporting by the project team including progress towards milestones and continuation of the project
- Related project management issues and decisions.

Fiscal Year 2018 Awarded Projects[4]

Virginia Catalyst conducted two (2) Grants Rounds in Fiscal Year 2018. Please see Appendix D.1 for a summary of all awarded projects to date.

Grant Rounds 7

In July 2017, VBHRC funded three (3) projects for a total amount of $1.4 million.

These projects[5] brought a total of $1.8 million in matching funds and involved:

- Five (5) Virginia research universities, and
- Three (3) industry partners

As of June 30, 2018 all of these projects were still open and progressing towards milestones as per their respective award agreements. One of these projects has secured $12 million in follow-on funding and created 8 new jobs in Virginia.

Grant Rounds 8

In May 2018, VBHRC funded six (6) projects for a total amount of $2.71 million.

These projects[6] brought a total of $5.69 million in matching funds and involved:

- Six (6) Virginia research universities, and
- Six (6) industry partners

As of June 30, 2018 all of these projects were open and progressing towards milestones as per their respective award agreements.

Economic Returns[7]

The Virginia Catalyst awarded its first Grant Rounds in December 2013, and as of June 30, 2018 we have conducted eight cycles of Grant Rounds. Please see Appendix D.4 for details on economic returns to date.

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[4] Appendix D.1 provides a summary of all awarded projects to date
[5] Appendix D.2 Press Release Round 7 awarded projects
[6] Appendix D.3 Press Release Round 8 awarded projects
[7] Appendix D.4 provides details on economic returns to date

Cumulatively through Grant Round 8

The Virginia Catalyst funded a total of $13.8 million to 27 collaborative projects.

Together these projects brought a total of $31.2 million in matching funds and involved:

- ***Six (6) Virginia research universities, and***
- ***Twenty-three (23) industry partners***

And resulted in a total of:

- ***$137.88 million in follow-on funding***
- ***145 new jobs created in Virginia***

Virginia Neuroscience Initiative

Overview and Objectives

Virginia Catalyst established the Virginia Neuroscience Initiative (VNI) in 2016. The VNI is an innovative, statewide collaborative approach that brings together experienced scientists, medical providers, and industry partners to increase Virginia's competitiveness in the neurosciences.

VA NEUROSCIENCE INITIATIVE

Infrastructure

In July 2017, the seven research universities and member institutions of the Virginia Catalyst signed a memorandum of understanding (MOU)[8] to share core facilities and resources in an effort to advance life sciences and other areas of research in the Commonwealth. The University of Virginia, Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Old Dominion University, Virginia Tech, and William & Mary have all agreed to provide reciprocal access to shared research and development resources.

[8] Appendix E: Memorandum of Understanding on Shared Core Facilities

Interest Groups

In Fiscal Year 2018 the Virginia Catalyst established Neuroscience Interest Groups to encourage collaborations among scientists, medical providers and industry. The interest groups are:

Interest Group	# Members	Chair(s), (Institution)
Alzheimer's Disease	78	Daniel Cohen, MD (Sentara) Carol Manning, PhD (UVA)
Anxiety	81	Anita Kablinger, MD (Carilion)
Astrocytes	25	Raymond Colello, PhD (VCU) Uri Kahanovitch, PhD (VT)
Blood-Brain Barrier	21	Shayn Peirce-Cotter, PhD (UVA)
Brain-Computer Interface	41	Dean Krusienski, PhD (VCU)
Depression	43	Susan Kornstein, MD (VCUHS)
Epilepsy	56	Alberto Musto, MD, PhD (EVMS)
Microglia	19	Tajie Harris, PhD (UVA)
Movement Disorders	52	Claudia Testa, MD, PhD (VCUHS)
Neuroanatomy	19	Ted Dumas, PhD (GMU)
Neurochemistry	29	Jill Venton, PhD (UVA)
Neuroimaging	139	Jason Druzgal, MD (UVAHS) Biraj Patel, MD (Carilion)
Neuroimmunology	78	Myla Goldman, MD (UVAHS)
Neurons	38	Nancy Xu, PhD (ODU)
Neuro-Oncology	107	William Broaddus, MD, PhD (VCUHS) Mark Malkin, MD (VCUHS) Ben Purrow, MD (UVAHS)
Neurophysiology	27	Rory McQuiston, PhD (VCU)
Neurotrauma	135	Dong Sun, MD, PhD (VCU)
Oligodendrocytes	15	Sarah C. Kucenas, PhD (UVA)
Opioid Addiction	33	Robert Lipsky, PhD (Inova) Gerry Moeller, MD (VCUHS)
PTSD	23	Scott McDonald (RVAMC)
Sensory Systems	93	Michael A. Fox, PhD (VT)
Stroke	44	Bradford Worrall, MD (UVAHS)

Virginia Catalyst Clinical Trials Network

Overview and Objectives

The Virginia Catalyst Clinical Trials Network is a collaboration among research universities and major medical centers in Virginia, designed to:

- Provide Virginia's scientists and investigators an expanded platform that accelerates their ability to conduct clinical research and strengthens abilities to win grant awards
- Attract pharmaceutical companies and clinical research organizations to conduct more funded clinical trials in Virginia

Institutions participating in the Clinical Trials Network include:

Carilion Medical Center, Virginia Tech, University of Virginia, UVA Health System Inova Health System Services, George Mason University, Virginia Commonwealth University, VCU Health, William and Mary, Old Dominion University, Sentara Healthcare, and Eastern Virginia Medical School

Virginia Catalyst Addiction Initiative

Background

The Commonwealth of Virginia is experiencing an addiction crisis that each year results in thousands of lives lost, negative impacts on health and safety, and costs of millions in health care services and public safety. In November 2016, Dr. Marisssa Levine, (former Virginia State Health Commissioner) declared a Public Health Emergency for Virginia[9] as a result of the opioid addiction epidemic, encouraging collaborative work to address the complex issues involved. Unfortunately, the crisis continued with over 1,200 deaths from opioid overdoses, and over 10,000 emergency room visits for opioid and heroin overdose treatments in 2017.[10]

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[9] Source: Virginia Department of Health http://www.vdh.virginia.gov/blog/2017/06/01/state-health-commissioner-comments-on-opioid-addiction-declaration/

[10] Source: Virginia Department of Health, Data, Opioid Addiction http://www.vdh.virginia.gov/data/opioid-overdose/

In February 2018, Governor Ralph Northam announced that Virginia was selected to participate in the National Governor's Association Project to combat the opioid crisis. As Governor Northam explained[11] *"the opioid epidemic continues to take a devastating toll on Virginia's communities… we must approach it from every angle."* The most recent report from the Joint Legislative Audit and Review Commission[12] (JLARC) on the costs of untreated substance abuse, estimated the costs of untreated substance abuse in Virginia at $613 million in public safety and health care services alone.

The Virginia Catalyst recognizes the growing crisis of addiction in Virginia and understands the need of a coordinated and collaborative response to this crisis. Using its unique and innovative structure, which focuses on cultivating collaborations and partnerships, the Virginia Catalyst has assembled a team that includes experienced researchers, leaders in health delivery systems, government leaders, industry partners and community-based organizations. The holistic approach of this team is to address addiction through prevention, treatment, and recovery, by conducting neuroscience and behavioral science research, facilitating changes in health care delivery and treatment of addiction, commercializing innovative and new pharmaceuticals, and collaborating at the community-level for services, programs, and interventions. The team is working with Deloitte Consulting,[13] a global health care consulting firm engaged by the Virginia Catalyst to prepare a blueprint and strategy for collectively making an impact on addiction.

Submitting for Federal Funding

In July 2018, VBHRC Virginia Catalyst submitted a response[14] to the National Institute on Drug Abuse (NIDA) and Substance Abuse and Mental Health Services Administration (SAMHSA) Request for Information (RFI), Notice Number: NOT-DA-18-023: The HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis.

This collaborative response, entitled "VOICE" (Virginia Opioid Integrated Crisis Enterprise), was developed by the following Virginia Catalyst team members:

[11] Source: Commonwealth of Virginia: News Releases https://www.governor.virginia.gov/newsroom/all-releases/2018/february/headline-822715-en.html
[12] Source: JLARC 2008 Report http://jlarc.virginia.gov/pdfs/reports/Rpt372.pdf
[13] Appendix F.1 Deloitte Consulting overview, deliverables, and options for business plan development
[14] Appendix F.2 Virginia Catalyst's collaborative submission to NIDA in response to RFA

- Michael Friedlander, Ph.D. – Vice President Health Sciences and Technology, Virginia Tech and Executive Director for Virginia Tech Carilion Research Institute
- F. Gerard Moeller, MD – Division Chair for Addiction Psychiatry; Director of the Institute for Drug and Alcohol Studies; Professor of Psychiatry, Pharmacology and Toxicology, and Neurology, Virginia Commonwealth University
- Jaideep Kapur – Professor of Neuroscience, University of Virginia and Director of the UVA Brain Institute
- Warren K. Bickel, Ph.D. – Virginia Tech Carilion Professor of Behavioral Health Research; Director of the Addiction Recovery Research Center; Co-Director of the Center for Transformative Research on Health Behaviors
- James L. Olds Ph.D. – University Professor of Neuroscience and Public Policy, Schar School, George Mason University
- William A. Hazel, Jr. M.D. – Senior Advisor for Strategic Initiatives and Policy for Office of the Provost, George Mason University and former Secretary of Virginia Health and Human Resources
- David L. Driscoll, Ph.D. – Director Research Development, University of Virginia
- Robert H. Lipsky, Ph.D. – Director, Translational Research, Inova Neuroscience Institute
- Doug Culling, DO, MS, CPE – Corporate Vice President, Sentara Healthcare / President, Sentara Medical Group
- Michael Grisham – Executive Director/CEO of the Virginia Catalyst

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Appendix A: History of the Virginia Biosciences Health Research Corporation

The founding members of VBHRC were Virginia's premiere research institutions: Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Virginia Polytechnic Institute and State University and the University of Virginia. Old Dominion University became the sixth member of the consortium effective in 2014, and effective in Fiscal Year 2017, the College of William & Mary became the seventh member of the consortium.

The Commonwealth of Virginia committed funding for Fiscal Years 2013 and 2014 to establish the core objectives of the consortium. In addition to this funding, the President of each member university agreed to commit a cash contribution to participate. The Commonwealth's commitment during those two fiscal years totaled $5 million, supplemented by a $100,000 contribution from each member university, distributed as $50,000 each year.

Funds from Fiscal Years 2013 and 2014 carried over to Fiscal Year 2015. Therefore there was not additional funding from the Commonwealth in Fiscal Year 2015.

For Fiscal Year 2016, VBHRC received $2,500,000 in funding from the Commonwealth and a total of $300,000 ($50,000 each) from its member universities.

In Fiscal Year 2017, VBHRC was funded $2,500,000 by the Commonwealth of Virginia and $350,000 through the member institutions ($50,000 per each year of the seven (7) member institutions), bringing the total funding for Fiscal Year 2017 to $2,850,000.

In Fiscal Year 2018, VBHRC was funded $3,750,000 by the Commonwealth of Virginia and $350,000 through the member institutions ($50,000 per each year of the seven (7) member institutions), bringing the total funding for Fiscal Year 2018 to $4,100,000.

Appendix B: Governance Overview

Non-government related positions on the Board of Directors, as well as the Project Management and Oversight Panel, are filled on a pro bono basis by qualified individuals who hold important bioscience-related expertise, value the public service nature of this position, and possess a sincere interest in helping to advance Virginia's bioscience community. VBHRC Virginia Catalyst and VEDP are deeply grateful for their voluntary contributions to the Commonwealth.

B.1 Members of Board of Directors

As per the Articles of Incorporation of VBHRC, as amended March 7, 2017, VBHRC shall be managed by a board of directors consisting of a maximum of fifteen directors, nine of whom shall be ex-officio directors designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. With respect to the remaining six directors, one (1) shall be a representative of the United States Department of Veterans Affairs, two (2) shall be representatives of statewide health care system providers in Virginia, and the board of directors shall designate an additional three directors representing life sciences company, venture capital firm that regularly invests in life science companies, and statewide representative of the biosciences industry in Virginia.

The current members of the VBHRC Virginia Catalyst Board of Directors are as follows:

Designated Board Seat	Current Board Member
1. Secretary of Commerce and Trade of Virginia or his/her designee	**Robby Demeria** Deputy Secretary for Technology
2. President and Chief Executive Officer of the Virginia Economic Development Partnership Authority or his/her designee	**Vince Barnett** Vice President, Business Investment
3. President of the University of Virginia or his/her designee	**Melur K. Ramasubramanian, Ph.D.** Interim Vice President for Research
4. President of the Virginia Polytechnic Institute and State University or his/her designee	**Michael Friedlander, Ph.D.** Founding Executive Director, Virginia Tech Carilion Research Institute, and Associate Provost for Health Sciences
5. President of George Mason University or his/her designee	**Deborah Crawford, Ph.D.** Vice President for Research

6. President of Virginia Commonwealth University or his/her designee	**Francis L. Macrina, Ph.D.** Vice President for Research
7. President of Eastern Virginia Medical School or his/her designee	**Jerry L. Nadler, M.D.** Vice Dean for Research
8. President of Old Dominion University or his/her designee	**Morris Foster, Ph.D.** Vice President for Research
9. President of College of William and Mary or his/her designee	**Dennis Manos, Ph.D.** Vice Provost for Research and Graduate/Professional Studies
10. Representative of the United States Department of Veteran Affairs	**David X. Cifu, M.D.** National Director for PM&R Services
11. Representative of statewide health care system provider in Virginia	**Howard P. Kern** President and CEO, Sentara Healthcare
12. Representative of statewide health care system provider in Virginia	To be filled at January 2019 BOD Meeting
13. Representative of a life sciences company	**Jeff Conroy** Founder and CEO Embody LLC
14. Representative of a venture capital firm that regularly invests in life sciences companies	**Thomas D. Roberts, III** General Partner Harbert Management Corporation
15. Statewide representative of the biosciences industry in Virginia	**Jeffrey M. Gallagher** CEO Virginia Bio

B.2 Members of Project Management and Oversight Panel

As per the Articles of Incorporation of VBHRC, as amended March 7, 2017, the Board of Directors shall establish a Project Management and Oversight Panel with eleven members, which include six (6) scientists, one of which will be a medical doctor or clinical practitioner; three (3) shall be representative of life science companies; and two (2) shall be representative of venture capital firms that actively invest in life science companies.

The current members of the VBHRC Virginia Catalyst Project Management and Oversight Committee are as follows:

Designated Panel Seat	Current Panel Member
1. Science and Clinical	**Ali Andalibi, Ph.D.** Associate Dean of Research George Mason University
2. Science and Clinical	**O. John Semmes, Ph.D.** Director, Leroy Canoles Jr. Cancer Research Center Eastern Virginia Medical School
3. Science and Clinical	**George S. Bloom, Ph.D.** Professor of Biology, Cell Biology and Neuroscience Director, Neuroscience Undergraduate Program, University of Virginia
4. Science and Clinical	To be filled at January 2019 BOD Meeting
5. Science and Clinical	To be filled at January 2019 BOD Meeting
6. Science and Clinical	To be filled at January 2019 BOD Meeting
7. Life Science Company	**Rony Thomas** President and CEO LifeNet Health, Inc.
8. Life Science Company	**Gerard Eldering** President Innovate Tech Ventures
9. Life Science Company	**James C. Powers** Chairman and CEO Hemoshear, LLC
10. Venture Capital Firm	**Bob Creeden** Managing Director UVA Seed Fund and New Ventures
11. Venture Capital Firm	**Scott Meza** Shareholder and Attorney at Law Greenberg Trauig

B.3 Members of Management

As per the Articles of Incorporation of VBHRC, as amended March 7, 2017, the officers of VBHRC shall consist of a President, and such other officers and assistant officers and agents as may be deemed necessary by the Board of Directors. The President shall be the chief executive officer, shall have active executive management of the operations of VBHRC subject to the control of the Board of Directors.

Mike Grisham, MBA
President and CEO

Mike Grisham has served as President and CEO of VBHRC Virginia Catalyst since 2014. Prior to this he was the Founder, Managing Member, and CEO of GPB Scientific LLC since 2002. He has over 21 years of experience in biosciences, building diagnostic and healthcare companies. Mr. Grisham founded and served as CEO of Celective DX (acquired by On-Q-ity); Verinata Health Inc. (acquired by Illumina); and Paradigm Health Corporation (acquired by Alere). Grisham holds a BA from University of California, Berkeley and an MBA from Stanford Graduate School of Business.

Suzanne Taylor, PhD, MBA
Vice President of Operations

In July 2018, Dr. Taylor joined VBHRC Virginia Catalyst as Vice President of Operations. Prior to this, Dr. Taylor worked for VBHRC to develop a marketing portfolio and provide support for the Virginia Neuroscience Initiative. Previously a member of Virginia Commonwealth University's Department of Physical Medicine and Rehabilitation, her clinical practice, instruction, research, and nationwide presentations led to recognition as a leader and expert in oncology rehabilitation. Taylor also has extensive healthcare management experience including serving as a Regional Director of Operations for American Retirement Corporation and Brookdale Senior Living. Along with being a licensed occupational therapist and having a Master of Business Administration in Healthcare Management degree, Taylor obtained a Doctor of Philosophy degree in Health Related Sciences from Virginia Commonwealth University.

Appendix C: Financial Statements and Independent Auditor's Reports

C.1 Fiscal Year 2018

(attached)

C.2 Fiscal Year 2019 Budget

(attached)

MitchellWiggins

CERTIFIED PUBLIC ACCOUNTANTS

Virginia Biosciences Health Research Corporation

Financial Statements

June 30, 2018

Virginia Biosciences Health Research Corporation

Table of Contents

Mitchell Wiggins

Certified Public Accountants

Independent Auditor's Report

Board of Directors
Virginia Biosciences Health Research Corporation
Richmond, Virginia

Report on the Financial Statements

We have audited the accompanying financial statements of Virginia Biosciences Health Research Corporation, which comprise the statement of financial position as of June 30, 2018, the related statements of activities, functional expenses, and cash flows for the year then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Virginia Biosciences Health Research Corporation as of June 30, 2018, and the changes in its net assets and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Mitchell Wiggins

Richmond, Virginia
October 29, 2018

Virginia Biosciences Health Research Corporation

Statement of Financial Position
June 30, 2018

Assets		
Current Assets		
Cash and cash equivalents	$	4,337,007
Pledges receivable, net, current portion		
Commonwealth of Virginia		3,750,000
Member universities		200,000
Total current assets		8,287,007
Long-Term Assets		
Pledges receivable, net, less current portion		
Commonwealth of Virginia		3,750,000
Total assets	$	12,037,007
Liabilities and Net Assets		
Current Liabilities		
Accounts payable	$	388,459
Net Assets		
Unrestricted		4,148,548
Temporarily restricted		7,500,000
Total net assets		11,648,548
Total liabilities and equity	$	12,037,007

See Notes to Financial Statements

Virginia Biosciences Health Research Corporation

Statement of Activities
Year Ended June 30, 2018

	Unrestricted	Temporarily Restricted	Totals
Revenue			
Contributions, Virginia General Assembly			
Program support	$ -	$ 6,500,000	$ 6,500,000
General and administrative support	-	1,000,000	1,000,000
Contributions, Member Universities			
College of William & Mary	50,000	-	50,000
Eastern Virginia Medical School	50,000	-	50,000
George Mason University	50,000	-	50,000
Old Dominion University	50,000	-	50,000
University of Virginia	50,000	-	50,000
Virginia Commonwealth University	50,000	-	50,000
Virginia Polytechnic Institute and State University	50,000	-	50,000
Other income	78,910	-	78,910
Interest income	5,196	-	5,196
	434,106	7,500,000	7,934,106
Net Assets Released from Restrictions			
Satisfaction of time restrictions	3,300,000	(3,300,000)	-
Total support and revenues	3,734,106	4,200,000	7,934,106
Expenses			
Program services	2,611,882	-	2,611,882
Management and general	81,889	-	81,889
Total expenses	2,693,771	-	2,693,771
Change in net assets	1,040,335	4,200,000	5,240,335
Net assets, beginning	3,108,213	3,300,000	6,408,213
Net assets, ending	$ 4,148,548	$ 7,500,000	$ 11,648,548

See Notes to Financial Statements

Virginia Biosciences Health Research Corporation

Statement of Functional Expenses
Year Ended June 30, 2018

	Program Services	Management and General	Total
Accounting services	$ -	$ 28,834	$ 28,834
Conferences	7,380	-	7,380
Grant expenses	2,371,884	-	2,371,884
Legal expenses	-	27,979	27,979
Marketing and promotion	5,100	-	5,100
Meals and entertainment	1,383	-	1,383
Memberships and sponsorships	18,393	-	18,393
Miscellaneous	8,219	409	8,628
Office expenses	-	291	291
Parking	-	1,880	1,880
Payroll taxes	9,755	1,084	10,839
Salaries and wages	180,000	20,000	200,000
Telephone	-	1,412	1,412
Travel and lodging	9,768	-	9,768
	$ 2,611,882	$ 81,889	$ 2,693,771

See Notes to Financial Statements

Virginia Biosciences Health Research Corporation

Statement of Cash Flows
Year ended June 30, 2018

Cash Flows from Operating Activities	
Change in net assets	**$ 5,240,335**
Adjustments to reconcile change in net assets to net cash and cash equivalents provided by (used in) operating activities	
Changes in operating assets	
Pledges receivables	**(4,400,000)**
Changes in operating liabilities	
Accounts payable	**356,900**
Net cash and cash equivalents provided by operating activities	**1,197,235**
Cash and cash equivalents, beginning	**3,139,772**
Cash and cash equivalents, ending	**$ 4,337,007**

See Notes to Financial Statements

Note 1. Nature of Organization and Summary of Significant Accounting Policies

Nature of organization

Virginia Biosciences Health Research Corporation (the Corporation) was organized as a not-for-profit corporation in 2013 and is operated for educational and research purposes. The mission of the Corporation is to foster life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities. The five founding institutions are Eastern Virginia Medical School, George Mason University, University of Virginia, Virginia Commonwealth University, and Virginia Polytechnic Institute and State University. Old Dominion University was admitted in December 2013 and College of William & Mary was admitted in October 2016. Research is to be centered in three focus areas: bioinformatics and medical informatics, point of care diagnostics, and drug discovery and delivery.

A summary of the Corporation's significant accounting policies follows:

Basis of accounting

The financial statements are presented on the accrual basis of accounting.

Financial statement presentation

Under current accounting standards, the Corporation is required to report information regarding its financial position and activities according to three classes of assets: unrestricted net assets, temporarily restricted net assets, and permanently restricted net assets. The net asset classes are summarized as follows:

Unrestricted net assets include board designated and other unrestricted funds. The unrestricted funds include revenue and expenses used currently for the general operations of the Corporation. Contributions that are restricted by the donor are reported as increases in unrestricted net assets if the donor restrictions expire in the fiscal year in which the contributions are recognized.

Temporarily restricted net assets include contributions restricted by donor designation or time restrictions and are reported as increases in temporarily restricted net assets. When a restriction expires either with the passage of time or by actions of the Corporation, temporarily restricted net assets are released and reclassified to unrestricted net assets. Temporarily restricted net assets consist of pledged contributions due in future years.

Permanently restricted net assets include contributions restricted by donor designation that they be maintained permanently by the Corporation. The Corporation currently does not have any permanently restricted net assets.

Note 1. Nature of Organization and Summary of Significant Accounting Policies (continued)

Cash and cash equivalents
The Corporation considers all highly liquid investments with an initial maturity of three months or less to be cash equivalents.

Pledges receivable
Pledges are recognized when the donor makes a promise to give to the Corporation that is, in substance, unconditional. Contributions that are restricted by the donor are reported as increases in temporarily restricted net assets. When a restriction expires, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statement of activities as net assets released from restrictions.

Revenue recognition
The Corporation recognizes revenue in the year it is earned.

Use of estimates
The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Income taxes
The Corporation is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code and is not classified as a Private Foundation.

The Financial Accounting Standards Board issued guidance on accounting for uncertainty in income taxes. Management evaluated the Corporation's tax positions and concluded that the Corporation had taken no uncertain tax positions that require adjustment to the financial statements to comply with the provisions of this guidance. Currently, the Corporation's tax years for the years ending from 2015 through 2017 are open and subject to income tax examinations by the taxing authorities.

The Corporation includes penalties and interest assessed by income taxing authorities in management and general expenses. The Corporation did not have penalties and interest relating to income taxes for the year ended June 30, 2018.

Note 2. Concentration of Credit Risk

The Corporation maintains its cash balances in one financial institution. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. At June 30, 2018, the Corporation's uninsured cash balances total approximately $4,289,000.

Note 3. Concentration of Revenue

The Corporation receives the majority of its funding from appropriations approved by the General Assembly of the Commonwealth of Virginia. Funding is typically granted for a two-year period as stipulated in the budget of the Commonwealth. These funds are temporarily restricted and will be released in time through June 30, 2020. The funding is to be used to support the mission of the Corporation to capture and perform research in biosciences, as well as promote the development of bioscience infrastructure tools which can be used to facilitate additional research activities.

Note 4. Pledged Contributions Receivable

The Corporation's policy is to record only written pledged contributions receivable. Management estimates that no allowance for doubtful accounts is required.

The pledged contributions receivable as of June 30, 2018, are as follows:

Commonwealth of Virginia	$ 7,500,000
College of William & Mary	50,000
University of Virginia	50,000
Virginia Commonwealth University	50,000
Virginia Polytechnic Insitute and State University	50,000
	$ 7,700,000
Amounts expected to be received in:	
Less than one year	$ 3,950,000
One to five years	3,750,000
	$ 7,700,000

Note 5. Subsequent Events

Management has evaluated subsequent events through October 29, 2018, the date which the financial statements were available for issue.

Virginia Biosciences Health Research Corporation
Profit & Loss Budget Overview FY 2019
July 2018 through June 2019

	Jul '18 - Jun ...
Ordinary Income/Expense	
Income	
4000 · Virginia General Assembly	
4005 · Program support	3,250,000.00
4010 · General & admin. support	500,000.00
4000 · Virginia General Assembly - Other	0.00
Total 4000 · Virginia General Assembly	3,750,000.00
4100 · Member University Contributions	
4132 · William & Mary	50,000.00
4110 · Eastern Va Medical School	50,000.00
4125 · George Mason University	50,000.00
4131 · Old Dominion University	50,000.00
4130 · University of Virginia	50,000.00
4120 · Virginia Commonwealth	50,000.00
4105 · Virginia Tech	50,000.00
Total 4100 · Member University Contributions	350,000.00
Total Income	4,100,000.00
Gross Profit	4,100,000.00
Expense	
5100 · Program Expenses	
5120 · Collaborative Grant Program	2,400,000.00
5200 · Virginia Neuroscience Initiativ	
5210 · University & Med Ctr Payments	0.00
5290 · VNI Project Management	
5220 · VNI Project Manager	97,200.00
5240 · Administrative Support Salary	122,100.00
5230 · Marketing	15,000.00
5250 · Travel	15,000.00
Total 5290 · VNI Project Management	249,300.00
Total 5200 · Virginia Neuroscience Initiativ	249,300.00
5400 · Infrastructure-Neuro Addiction	
5410 · Consulting Services	650,000.00
Total 5400 · Infrastructure-Neuro Addiction	650,000.00
5300 · CRO Clinical Trial Effort Prog	
5310 · Duirector of Program Developmnt	0.00
5320 · Travel	0.00
Total 5300 · CRO Clinical Trial Effort Prog	0.00

Virginia Biosciences Health Research Corporation
Profit & Loss Budget Overview FY 2019
July 2018 through June 2019

	Jul '18 - Jun ...
6000 · Support and development	
6200 · Salaries and Benefits	
6210 · Salaries and Wages	132,960.00
6215 · Payroll Taxes	10,800.00
Total 6200 · Salaries and Benefits	143,760.00
6400 · Program development	
6405 · Advertising	5,000.00
6415 · Conferences	7,500.00
6420 · Meals and Entertainment	2,400.00
6430 · Memberships and sponsorships	7,250.00
6425 · Travel and lodging	13,800.00
6499 · Other program development exp.	800.00
Total 6400 · Program development	36,750.00
Total 6000 · Support and development	180,510.00
Total 5100 · Program Expenses	3,479,810.00
6005 · General and administrative	
6008 · Salaries and wages 20%	33,240.00
6006 · Administrative assistant	20,400.00
6007 · Payroll taxes	4,200.00
6010 · Accounting services	21,000.00
6020 · Audit and tax returns	10,000.00
6030 · Board of Directors Expense	1,000.00
6431 · Memberships/Sponsorships G&A	7,250.00
5330 · Exhibit Booth	10,000.00
5255 · Conferences	10,000.00
6445 · Web Site	400.00
6440 · Database	2,600.00
6050 · Legal Expenses	30,000.00
6055 · Office and Computer Supplies	3,400.00
6060 · Office Rent	3,600.00
6065 · Parking	2,600.00
6070 · Postage	800.00
6080 · Telephone	2,150.00
Total 6005 · General and administrative	162,640.00
Total Expense	3,642,450.00
Net Ordinary Income	457,550.00
Net Income	**457,550.00**

Appendix D: Grant Funding Rounds

D.1 Summary of Awarded Projects to Date

Grant Round 1 – December 2013

Virginia Polytechnic Institute and State University
Virginia Commonwealth University

BioTherapeutics, Inc. **Company status: active**
Blacksburg, VA
https://www.biotherapeuticsinc.com/

Development of novel anti-inflammatory drugs

University of Virginia
George Mason University

HemoShear Therapeutics, LLC **Company status: active**
Charlottesville, VA
https://www.hemoshear.com/

Commercialization of a human tumor microenvironment system for pharmaceutical cancer drug discovery and development

Virginia Polytechnic Institute and State University
University of Virginia

FirstString Research, Inc. **Company status: active**
Roanoke, VA and Mt. Pleasant, SC
https://firststringresearch.com/

Novel regenerative drug

University of Virginia
Virginia Commonwealth University

Cavion (formerly Tau Therapeutics) **Company status: active**
Charlottesville, VA and Cambridge, MA
https://cavionpharma.com/

Determining the optimal dosing schedule for the commercialization of mibefradil in front-line glioblastoma

Grant Round 2 – March 2014

University of Virginia
Virginia Commonwealth University

Neoantigenics, Inc. **Company status: inactive**
Charlottesville, VA
https://www.linkedin.com/company/neoantigenics-inc./

UVA-VCU partnership to develop radioimmunotherapeutic and imaging agents to a unique cell-surface target relevant for multiple human cancers

Virginia Commonwealth University
University of Virginia

Gencia, LLC **Company status: active**
Charlottesville, VA
http://genciabiotech.com/

Reversing bioenergetic deficits and improving cognitive function in Alzheimer's Disease

Virginia Polytechnic Institute and State University
University of Virginia
SphynKx Therapeutics, LLC **Company status: inactive**
Charlottesville, VA
https://www.linkedin.com/company/sphynkx-therapeutics/

Lead optimization of a SphK2 inhibitor for the treatment of CKD

Eastern Virginia Medical School
University of Virginia

LifeNet Health **Company status: active**
Global Headquarters: Virginia Beach, VA
United States offices: Jacksonville, FL; Pensacola, FL; Renton, WA
Austria office: Vienna
https://www.lifenethealth.org/

Enhancement of healing in diabetic wounds using a decellularized dermal matrix

Grant Round 3 – August 2014

Virginia Commonwealth University
Old Dominion University

Ultrasonic Probe, LLC **Company status: inactive**
Glen Allen, VA

Ultrasonographic probe

Virginia Polytechnic Institute and State University
University of Virginia

PhenoCHIP Technologies, LLC **Company status: inactive**
(formerly Proteo Biosciences)
Blacksburg, VA
https://govtribe.com/vendor/phenochip-technologies-llc-blacksburg-va

PhenoCHIP-phenotype-based cell hierarchy and isolation platform

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Old Dominion University
Eastern Virginia Medical School

OncoSec Medical, Inc **Company status: active**
San Diego, CA and Pennington, NJ
https://oncosec.com/

Biomarker-driven optimization of IL-12 gene electrotransfer for the treatment of melanoma

Grant Round 4 – August 2015

Virginia Polytechnic Institute and State University
University of Virginia

FirstString Research, Inc. **Company status: active**
Roanoke, VA and Mt. Pleasant, SC
https://firststringresearch.com/

Clinical trial of new drug in dogs to treat brain cancer in humans

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Old Dominion University
Eastern Virginia Medical School
Embody, LLC **Company status: active**
Vienna, VA
https://govtribe.com/vendor/embody-llc-vienna-va

Nanofabrication of tissue scaffolds

Virginia Polytechnic Institute and State University
Virginia Commonwealth University

BioTherapeutics, Inc. **Company status: active**
Blacksburg, VA
https://www.biotherapeuticsinc.com/

Optimizing oral delivery of BT-11 as a clinical candidate for treating inflammatory bowel disease

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Virginia Commonwealth University
University of Virginia

BrightSpec **Company status: active**
Charlottesville, VA
http://brightspec.com/

Three wave mixing technique for chiral analysis in continuous process manufacturing

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George Mason University
Virginia Polytechnic Institute and State University

Ceres Nanosciences, Inc. **Company status: active**
Manassas, VA
http://www.ceresnano.com/

Nanotrap® tick-panel test development

Grant Round 5 – December 2015

University of Virginia
George Mason University
Yale University

Cavion **Company status: active**
Charlottesville, VA and Cambridge, MA
https://cavionpharma.com/

Development of a biomarker assay and protocol for the commercialization of mibefradil dihydrochloride as a first-line treatment for glioblastoma

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Virginia Polytechnic Institute and State University
University of Virginia

VoltMed, Inc. **Company status: active**
Blacksburg, VA
https://www.linkedin.com/company/voltmed-inc./

INSPIRE to fight brain cancer

Grant Round 6 – October 2016

Virginia Polytechnic Institute and State University
University of Virginia
VoltMed, Inc. **Company status: active**
Blacksburg, VA
https://www.linkedin.com/company/voltmed-inc./

Commercialization of INSPIRE brain cancer treatment

Virginia Polytechnic Institute and State University
Virginia Commonwealth University

BioTherapeutics, Inc. **Company status: active**
Blacksburg, VA
https://www.biotherapeuticsinc.com/

Development of BT-11: First-in-class oral therapeutic for Inflammatory Bowel Disease

George Mason University
Virginia Commonwealth University

Serpin Parma, LLC **Company status: active**
Manassas, VA
http://www.serpinpharma.com/

Novel and potent anti-inflammatory drug with cardio-protective effects to treat myocardial injury and prevent heart failure

Eastern Virginia Medical School
George Mason University

Sanyal Biotechnology, LLC **Company status: active**
Virginia Beach, VA
https://www.sanyalbio.com/

Accelerating the commercialization of the Diamond™ mouse model of Nonalcoholic Steatohepatitis

Old Dominion University
Eastern Virginia Medical School

Pulse Biosciences, Inc. **Company status: active**
Hayward, CA
http://pulsebiosciences.com/

Translational research with nanosecond pulsed electric fields for immuno-oncology applications

Virginia Commonwealth University
University of Virginia

Propagenix, Inc. **Company status: active**
Rockville, MD
http://www.propagenix.com/

Bioengineering for the therapeutic delivery of massively expanded islet-derived human beta-cells

Grant Round 7 – July 2017

Virginia Commonwealth University,
Virginia Polytechnic Institute and State University
Inova
George Mason University

Indivior, PLC **Company status: active**
Richmond, VA
http://indivior.com/

Novel Preventive Treatment Paradigm to Change the Standard of Care for Those Who Recover from Opioid Overdose

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Virginia Polytechnic Institute and State University
University of Virginia
Carilion

BRAINBox Solutions **Company status: active**
(Parent company: ImmunArray)
Richmond, VA
http://www.immunarray.com/brain-box/

Virginia Brain Injury Diagnosis and Monitoring Initiative

Eastern Virginia Medical School
Virginia Commonwealth University

ReAlta Life Sciences, LLC **Company status: active**
Norfolk, VA
https://www.sbir.gov/sbirsearch/detail/1430737

Development of peptide inhibitor of complement C1 as treatment for neonatal hypoxic-ischemic encephalopathy

Grant Round 8 – May 2018

Old Dominion University
University of Virginia

Embody, LLC **Company status: active**
Vienna, VA
https://govtribe.com/vendor/embody-llc-vienna-va

Biofabrication of Regenerative Musculoskeletal Therapeutics

Virginia Polytechnic Institute and State University
University of Virginia

Continuum Biosciences, Inc. **Company status: active**
Blacksburg, VA
https://www.sbir.gov/sbirsearch/detail/1454561

Development and commercialization of mitochondrial uncouplers

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Virginia Commonwealth University
University of Virginia
Virginia Polytechnic Institute and State University

BrightSpec, Inc. **Company status: active**
Charlottesville, VA
http://brightspec.com/

A major new chiral analysis technique for new drug discovery, development, and process control

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Virginia Commonwealth University
George Mason University

Serpin Pharma, LLC **Company status: active**
Manassas, VA
http://www.serpinpharma.com/

Novel anti-inflammatory drug: strong neuroprotective properties for treatment of traumatic brain injury

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Old Dominion University
Eastern Virginia Medical School

LifeNet Health **Company status: active**
Global Headquarters: Virginia Beach, VA
United States offices: Jacksonville, FL; Pensacola, FL; Renton, WA
Austria office: Vienna
https://www.lifenethealth.org/

Tissue preparations for therapeutic use in cardiovascular applications

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Virginia Commonwealth University
University of Virginia

WynnVision, LLC **Company status: active**
Midlothian, VA
https://www.sbir.gov/node/1220367

Preventing Catheter Associated Infections

D.2 Press Release Round 7

VBHRC
VA CATALYST

FOR IMMEDIATE RELEASE

Media Contact:
A.J. Guenther
ConnellyWorks, Inc.
(571) 323-2585 ext. 2130
aj@connellyworks.com

Virginia Catalyst Awards $500,000 to Help Enhance the Recovery from Opioid Overdoses
VCU, Virginia Tech, Inova Health System and Indivior team to change the standard of care for opioid patients

RICHMOND, VA – December 4, 2017 – The Virginia Biosciences Health Research Corporation, known as Virginia Catalyst, today announced that it has awarded a $500,000 grant to a collaborative bioscience commercialization project including a team from Virginia Commonwealth University, Virginia Tech, Inova Health System and Indivior Inc., a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy. This grant, which includes matching funding of $500,000 provided by Indivior, is intended to catalyze the development and commercialization of life science projects that address major unmet needs for improving human health, while also contributing to Virginia's economic growth. This project is focused on addressing neuroscience initiatives involving the treatment and care of patients recovering from an opioid overdose.

"Bioscience continues to be a vital part of Virginia's economy and we are excited to continue our mission of helping to fuel innovation, collaboration and economic growth in our state," said Mike Grisham, CEO, Virginia Catalyst. "Virginia's research universities have long provided leadership on a national and global level in life sciences, combining their intellectual and scientific prowess through collaboration to achieve meaningful results. These achievements have attracted significant outside capital and industry participation to commercialize Virginia's innovations, creating high-paying jobs for Virginia while improving lives around the world."

The winning project for round seven is:

Project Focus: Novel Preventive Treatment Paradigm to Change the Standard of Care for Those Who Recover from Opioid Overdose

- Company: Indivior Inc. (Richmond, VA)
- University collaborators: Virginia Commonwealth University and Virginia Tech
- Additional collaborator: Inova Health System

- Funding amount: $500,000
- Matching funds: $500,000 provided by Indivior

Two additional projects are pending documentation.

Virginia Catalyst is a not-for-profit 501(c)(3) corporation funded by the Virginia General Assembly's general fund and seven of Virginia's research universities. The organization has now awarded 26 grants totaling over $10.5 million, combined with $20 million in matching funds, which financed the achievement of meaningful milestones. This has then resulted in follow-on funding of an additional $80 million and the creation of high-paying jobs throughout the Commonwealth.

Supporting Quotes

"This opioid overdose project seeks to develop and test a new treatment paradigm for patients who have an opioid overdose. We believe that our project will be the first to test medication treatment initiated in the emergency room after an opioid overdose followed by seamless outpatient treatment with a new once monthly injectable medication for chronic treatment of opioid use disorder. Our goal is to test whether this new paradigm significantly reduces repeat overdose rates and death. The funding from Virginia Catalyst was instrumental in supporting the Virginia collaborators to work together for this project." – Dr. F. Gerard Moeller, who directs VCU's Institute for Drug and Alcohol Studies

"We know that treatment programs work if they combine medication with continuing addiction health care and support. When people arrive at the emergency room to recover from an overdose, their withdrawal symptoms will be treated and they will receive behavioral counseling without delay. After treatment, continued help will only be a phone call away. With this new protocol, we expect to show the number of repeat overdoses will fall." – Dr. Warren Bickel, director of the Virginia Tech Carilion Research Institute's Addiction Recovery Research Center, whose research since 1983 has helped lead to opioid replacement therapies currently in use.

"Inova is privileged to be a partner in a multi-center study that aims to blunt the opioid overdose epidemic in our Northern Virginia community and across the Commonwealth. The novel preventive treatment approach used in this clinical trial has potential to be applied nationwide." – Dr. Robert H. Lipsky, Director, Translational Research, Inova Neuroscience Institute, Inova Center for Personalized Health

About the Virginia Catalyst

Virginia Biosciences Health Research Corporation (VBHRC), known as Virginia Catalyst, has a vision of advancing life sciences throughout Virginia as a means of addressing large unmet medical needs to improve human health and to create high-paying jobs throughout the Commonwealth. Funded by the Virginia General Assembly's General fund, the University of Virginia, Virginia Commonwealth University, Virginia Tech, Eastern Virginia Medical School, George Mason University, Old Dominion University, and William and Mary, Virginia Catalyst has funding opportunities to support collaborative projects in the Commonwealth and is home to the Virginia Neuroscience Initiative. For more information, visit www.virginiacatalyst.org.

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D.3 Press Release Round 8

FOR IMMEDIATE RELEASE

Media Contact:
A.J. Guenther
ConnellyWorks, Inc.
(571) 323-2585 ext. 2130
aj@connellyworks.com

Virginia Catalyst Announces $2.7 Million in Grants to Fund Collaborative Bioscience Research Initiatives

Six winning projects to address human health needs such as myocardial infarctions, traumatic brain injury, musculoskeletal injury and catheter associated infections

RICHMOND, VA – July 16, 2018 – The Virginia Biosciences Health Research Corporation (VBHRC), now known as Virginia Catalyst, today announced that it has awarded a total of $2.7 million to six life and bioscience projects in the Commonwealth of Virginia. These grants, which will be met with nearly $5.7 million in matching funds from partner companies, were awarded as Round 8 of Virginia Catalyst's ongoing mission to stimulate economic development by promoting collaborative projects that address large, unmet medical needs, and that can create high-paying jobs in the Commonwealth.

"With this eighth round of funding, Virginia Catalyst has now awarded $15.7 million to Virginia companies and universities working on incredible technologies that can benefit the whole of society," said Mike Grisham, CEO of Virginia Catalyst. "These six projects embody Virginia Catalyst's core mission in that not only can they help citizens in our state, and our country, treat diseases and to discover new forms of treatment, but they can also help keep Virginia's economy moving forward."

Round eight project winners, include:

Project Focus: Biofabrication of Regenerative Musculoskeletal Therapeutics

- Company: Embody, LLC (Norfolk, VA)
- University collaborators: Old Dominion University and University of Virginia
- Funding amount: $800,000
- Matching funds: $2,400,000 will be provided by Embody, LLC

Project Focus: Preventing Catheter Associated Infections

- Company: WynnVision LLC (Richmond, VA)

- University collaborators: Virginia Commonwealth University and University of Virginia
- Funding amount: $510,000
- Matching funds: $1,491,266 will be leveraged from a National Institutes of Health SBIR Phase II grant

Project Focus: Safe Mitochondrial Uncouplers for the Treatment of Human Disease

- Company: Continuum Biosciences, Inc. (Blacksburg, VA)
- University collaborators: Virginia Tech and University of Virginia
- Funding amount: $400,000
- Matching funds: $800,000 will be provided by Continuum Biosciences, Inc.

Project Focus: MRR: A Major New Chiral Analysis Technique for Drug Discovery, Development and Process Control

- Company: BrightSpec, Inc. (Charlottesville, VA)
- University collaborators: Virginia Commonwealth University, Virginia Tech and University of Virginia
- Funding amount: $400,000
- Matching funds: $400,000 will be provided by BrightSpec, Inc.

Project Focus: Novel Anti-inflammatory Drug with Strong Neuroprotective Properties for Treatment of Traumatic Brain Injury (TBI)

- Company: Serpin Pharma (Manassas, VA)
- University collaborators: Virginia Commonwealth University and George Mason University
- Funding amount: $350,000
- Matching funds: $350,000 will be provided by Serpin Pharma

Project Focus: Tissue Preparations for Therapeutic Use in Cardiovascular Applications

- Company: LifeNet Health (Virginia Beach, VA)
- University collaborators: Old Dominion University and Eastern Virginia Medical School
- Funding amount: $250,000
- Matching funds: $250,000 will be provided by LifeNet Health

Supporting Quotations

"We are incredibly grateful for Virginia Catalyst's support, which is a rare funding source for product development efforts and critical to early-stage medical device companies like Embody," said Dr. Michael Francis, CSO of Embody. "In partnership with a team of outstanding researchers (Dr. George Christ at UVA and Dr. Anna Bulysheva at ODU), our team will advance production of a collagen microfibrous ligament internal brace product for regenerating ruptured ligaments in the knee, ankle, elbow and other joints. Supporting next-generation therapeutics, our collagen microfiber biofabrication technology will be further advanced by 3D bioprinting of living musculoskeletal tissues, and by supplemental gene therapy for guiding graft angiogenesis and tissue integration. These

medical devices and therapeutics will be commercialized here in Virginia thanks to Virginia Catalyst's support."

"WynnVision is grateful for this important early stage VBHRC funding. Support from Virginia Catalyst will enable accelerated commercialization of nanotechnology aimed at preventing 50 percent of hospital acquired infections, namely, catheter associated urinary tract infections (CAUTIs). WynnVision nanocoatings have shown promise for preventing infections even from 'super-bugs' while being biocompatible. Virginia Catalyst funding will take these exciting findings to a new level as WynnVision carries out challenging commercialization activities. WynnVision is also grateful for an NIH SBIR Phase II grant and to the Bio+Tech Park for a great environment and administrative guidance," said Dr. Kenneth Wynne, president of WynnVision.

"We very much appreciate the support of Virginia Catalyst in helping us accelerate our efforts to develop and commercialize safe mitochondrial uncouplers as new medicines," said Dr. Simon Tucker, CEO, Continuum Biosciences, Inc.

"With the most recent funding, VBHRC has catalyzed close working relationships among VCU, UVA, Virginia Tech and BrightSpec to bring to market new analytical techniques for drug discovery and development. The immediate results arise from new insights on better synthetic routes for critical drugs to treat malaria and HIV. The long-term result is reflected in the increasing level of medicinal chemistry R&D here in Virginia. We greatly appreciate the support from Virginia Catalyst," said Robert W. Lloyd, CEO, BrightSpec, Inc.

"Virginia Catalyst funding will allow us to establish a partnership between Serpin Pharma, George Mason University and VCU to develop new therapeutic options for traumatic brain injury thanks to a novel technology that enables rational design of drugs. We are very excited to pursue the opportunity to address the unmet challenge of treating patients with acute brain injuries, which are the most common injuries worldwide," said Dr. Alessandra Luchini, Associate Professor at George Mason University.

About the Virginia Catalyst

Virginia Biosciences Health Research Corporation (VBHRC), known as Virginia Catalyst, has a vision of advancing life sciences throughout Virginia as a means of addressing large unmet medical needs to improve human health and to create high-paying jobs throughout the Commonwealth. Funded by the Virginia General Assembly's General fund, the University of Virginia, Virginia Commonwealth University, Virginia Tech, Eastern Virginia Medical School, George Mason University, Old Dominion University, and William and Mary, Virginia Catalyst has funding opportunities to support collaborative projects in the Commonwealth and is home to the Virginia Neuroscience Initiative. For more information, visit www.virginiacatalyst.org.

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D.4 Summary of Economic Returns to Date

	Collaborators		Date	Awarded Amount	Matching Funds	Follow on Funding	Net Job Creation
Grant Round 1	VT, VCU	BioTherapeutics Inc. Blacksburg, VA	Dec-13	$400,000	$400,000	$10,000,000	15
	UVA, GMU	Tau Therapeutics Charlottesville, VA	Dec-13	$200,000	$238,000	$26,100,000	2.5
	VT, UVA	First String Research Roanoke, VA	Dec-13	$200,000	$1,000,000	$3,000,000	10
	UVA, VCU	HemoShear LLC Charlottesville, VA	Dec-13	$450,000	$800,000	$14,000,000	5
	Subtotal Round 1			**$1,250,000**	**$2,438,000**	**$53,100,000**	**32.5**
Grant Round 2	VCU, UVA	Gencia, LLC Charlottesville, VA	Mar-14	$400,000	$400,000	$8,800,000	2
	UVA, VCU	Neoantigenics LLC Charlottesville, VA	Mar-14	$348,729	$2,000,000	$3,000,000	0
	VT, UVA	SphynKx Therapeutics Charlottesville, VA	Mar-14	$400,000	$400,000	$150,000	0
	EVMS, UVA	LifeNet Health Virginia Beach, VA	Mar-14	$255,000	$255,000	$5,000	1
	Subtotal Round 2			**$1,403,729**	**$3,055,000**	**$11,955,000**	**3**
Grant Round 3	VT, UVA	PhenoCHIP Blacksburg, VA	Aug-14	$270,000	$450,000	$450,000	0
	ODU, EVMS	OncoSec Medical San Diego, CA	Aug-14	$585,000	$2,750,000	$8,700,000	3.5
	VCU, ODU	US Probe Glen Allen, VA	Aug-14	$536,000	$536,000	$450,000	0
	Subtotal Round 3			**$1,391,000**	**$3,736,000**	**$9,600,000**	**3.5**
Grant Round 4	GMU, VT	Ceres Nanosciences Manassas, VA	Aug-15	$500,000	$746,000	$5,000,000	11
	VT, UVA	First String Research Roanoke, VA	Aug-15	$290,000	$500,000	$3,500,000	2
	ODU, EVMS	Embody LLC Norfolk, VA	Aug-15	$634,500	$725,000	$3,600,000	9
	VT, VCU	BioTherapeutics Inc. Blacksburg, VA	Aug-15	$400,000	$2,500,000	$2,500,000	14
	GMU, VT	BrightSpec, Inc Charlottesville, VA	Aug-15	$400,000	$400,000	$2,150,000	6
	Subtotal Round 4			**$2,224,500**	**$4,871,000**	**$16,750,000**	**42**
Grant Round 5	UVA, GMU	Cavion Charlottesville, VA	Dec-15	$307,057	$352,862	$26,100,000	2.5
	VT, UVA	VoltMed, Inc. Blacksburg, VA	Dec-15	$380,000	$1,800,000	$2,000,000	10
	Subtotal Round 5			**$687,057**	**$2,152,862**	**$28,100,000**	**12.5**

	Collaborators		Date	Awarded Amount	Matching Funds	Follow on Funding	Net Job Creation
Grant Round 6	VT, UVA	VoltMed, Inc. Blacksburg, VA	Oct-16	$800,000	$1,700,000	$1,825,000	14
	VT, VCU *completed*	BioTherapeutics Inc. Blacksburg, VA	Oct-16	$800,000	$800,000	$1,500,000	10
	GMU, VCU	Serpin Pharma Manassas, VA	Oct-16	$400,000	$3,400,000	$550,000	6.5
	EVMS, GMU	Sanyal Biotechnology Virginia Beach, VA	Oct-16	$100,000	$100,000	$2,000,000	9
	ODU, EVMS	Pulse Biosciences Burlingame, CA	Oct-16	$300,000	$300,000	$0	2
	VCU, UVA	Propagenix Rockville, MD	Oct-16	$425,000	$1,200,000	$500,000	1
	Subtotal Round 6			**$2,825,000**	**$7,500,000**	**$6,375,000**	**42.5**
					Round 6 Data Not Complete - Open Projects		
Grant Round 7	VCU, VT, GMU	Indivior, Inc. Richmond, VA	Jul-17	$500,000	$500,000		
	UVA, VT	BRAINBox, LLC Richmond, VA Carilion Medical Center Roanoke, VA	Jul-17	$500,000	$500,000		
	EVMS, VCU	ReAlta Life Sciences, LLC Norfolk, VA	Jul-17	$400,000	$800,000	$12,000,000	9
	Subtotal Round 7			**$1,400,000**	**$1,800,000**	**$12,000,000**	**9**
					Round 7 Data Not Complete - Open Projects		
Grant Round 8	ODU, UVA	Embody, LLC Vienna, VA	May-18	$800,000	$2,400,000		
	VT, UVA	Contnuum Biociences, Inc Blacksburg, VA	May-18	$400,000	$800,000		
	VCU, UVA, VT	BrightSpec, Inc Charlottesville, VA	May-18	$400,000	$400,000		
	VCU, GMU	Serpin Pharma, LLC Manassas, VA	May-18	$350,000	$350,000		
	ODU, EVMS	LifeNet Health Virginia Beach, VA	May-18	$250,000	$250,000		
	VCU, UVA	WynnVision, LLC Midlothian, VA	May-18	$510,000	$1,491,266		
	Subtotal Round 8			**$2,710,000**	**$5,691,266**		
					Round 8 Data Not Complete - Open Projects		

	Awarded Amount	Matching Funds	Follow-on Funding	Net Job Creation
TOTALS as of June 30, 2018	**$13,891,286**	**$31,244,128**	**$137,880,000**	**145**

Appendix E: Virginia Neuroscience Initiative

E.1 Memorandum of Understanding: Shared Core Facilities

(attached)

MEMORANDUM OF UNDERSTANDING AMONG ACADEMIC RESEARCH INSTITUTIONS REGARDING RECIPROCAL ACCESS TO SHARED RESOURCES

BACKGROUND

This Memorandum of Understanding ("MOU") is entered into by and between the seven undersigned academic research institutions: Virginia Commonwealth University, College of William & Mary, George Mason University, University of Virginia, Eastern Virginia Medical School, Old Dominion University, and Virginia Polytechnic Institute and State University (individually an "Institution" and collectively, the "Institutions"). The Institutions have been encouraged by the Virginia Biosciences Health Research Corporation ("VBHRC") to consider ways to enhance collaboration, cooperation and interaction between institutions of higher education within the Commonwealth of Virginia in a manner that effectively and efficiently uses existing resources at each Institution. The Institutions believe that such collaboration will be facilitated by execution of this MOU.

The Institutions have individually made significant investments to acquire specialized equipment and establish unique research cores supporting basic and clinical research. To further enhance the availability of these existing resources, the Institutions seek to share, in an economical manner, specialized technical services and access to equipment and expertise for research purposes.

This MOU sets forth the understanding of the Institutions concerning reciprocal access to shared resources. The purpose of the MOU is to document (a) the intent of each Institution to provide reasonable access, as capacity will permit, to its specifically identified shared resources and (b) the policies and conditions governing such access. For purposes of this MOU, "Shared Resources" means the research equipment and expertise, cores, facilities and/or services specifically identified by an Institution that shall be made available to the other Institutions pursuant to this MOU.

I. General Understanding:

A. The Institutions shall cooperate in good faith to encourage access to each Institution's respective Shared Resources, for research purposes. Pursuant to the MOU, an Institution may designate investigators as those faculty members of an Institution who seek to use Shared Resources in support of research ("Investigators").

1. Each Investigator must be a member of the faculty, or under the direct supervision of such a faculty member, at his/her respective

Institution. Each Institution is encouraged to send to the other Institutions quarterly updated lists of its Investigators and available Shared Resources. Each Institution shall appoint a Shared Resource Director who will serve as an Institutional point of contact for requests to use Shared Resources.

2. Investigators desiring to use a Shared Resource at another Institution must first contact the appropriate Shared Resource Director at the other Institution to confirm availability of access and learn of any specific policies governing access. Once this is done, the point of contact at both Institutions should be notified that samples and/or data will be sent and to arrange for billing information to be provided.

3. Fees charged to an Institution by another Institution shall equal the fees charged to the Investigators at their own Institution for internally funded activity. Further, the fees charged shall not include, and shall be in addition to, any expense properly allocated by the providing Institution as an indirect cost on Subawards or Subcontracts, in accordance with the providing Institution's indirect cost rate agreement.

4. Each Institution shall invoice for use of a Shared Resource as requested by each Investigator, with the requesting Investigator providing appropriate billing information to the Investigator before the Shared Resource is provided, as set forth in this MOU.

5. The Institutions shall review performance under this MOU biannually, and based on such review shall propose appropriate amendments to the MOU, including but not limited to soliciting other higher education institutions within the Commonwealth of Virginia to become signatories to this MOU. Any amendments to this MOU shall be binding as to an Institution only upon the execution of such amendment by a duly authorized signatory of the Institution.

B. Each Institution shall give priority for use of Shared Resources to Investigators at their home Institution. An Investigator at an Institution wishing to use a Shared Resource at another Institution may do so on an 'as available' basis. Investigators shall have priority for Shared Resource access at their home Institution. As availability permits, Investigators shall have access to the Shared Resources of other Institutions. In special recognition of the frequently irreplaceable nature of samples

housed within a Shared Resource primarily concerned with acquisition and distribution of clinical tissue samples (i.e., a biorepository), access to tissue samples from an Institution will require a determination by the respective scientific director of such resources at such Institution that granting access will not disruptively impact the potential future needs of investigators at the home Institution.

C. This MOU extends to the Shared Resources at the respective Institutions as indicated on Exhibit B.

II. Term; Renewal; Termination

A. This MOU shall be effective as of June 22, 2017 (the "Effective Date"), and shall remain in full force and effect until the 5th anniversary of the Effective Date, unless terminated earlier in accordance with this MOU. Unless terminated earlier, this MOU shall automatically renew for additional five year terms.

B. An Institution may terminate this MOU at will solely with respect to such Institution by providing 60 days advance written notice to the other Institutions.

III. Administration:

A. Investigators who seek to use a Shared Resource shall contact the specific Shared Resource Director and the Administrator at their home Institution as set forth on Exhibit A attached hereto. Before services are provided, the ordering Institution will provide order information to the supplying Institution. The point of contact at the supplying Institution will be responsible for submitting an invoice for payment for services provided to Investigators and for providing copies of the invoices to the point of contact at the ordering Institution. Shared Resource Directors will keep a log of all reciprocal users. Shared Resource Directors will submit a monthly report to the Shared Resource Directors who oversee all Shared Resources at their respective Institutions.

B. Each Institution will have an oversight committee to review usage capacity. If an Institution determines, in its sole discretion, that another Institution is making excessive use of Shared Resources, that Institution shall notify the relevant Administrator and the two Institutions shall work

in good faith to reach an understanding about future usage of Shared Resources. Such understanding may include a temporary or permanent moratorium on such usage of Shared Resources. If the relevant Institutions cannot reach an understanding, the Institution providing the Shared Resources may terminate this MOU with respect to the relevant Institution only, and/or with respect to specific Shared Resources. Such termination of access rights shall be made in a writing delivered to the Administrator of the Institution being denied access rights.

C. Investigators from the Institutions will be invited to attend annual Shared Resource Retreats to be held at times and locations to be mutually agreed upon by the Institutions.

IV. Intellectual Property:

A. Except in making the Shared Resources known to faculty, no Institution may use the other Institutions' names, logos or marks, or any derivative thereof, without the prior written permission of the Institution whose name, logo or marks, or derivative thereof, are proposed to be used.

B. Ownership and other rights in and to intellectual property of the Institutions shall not be affected by this MOU. The Institutions intend for ownership of intellectual property rights to vest in the employer of the individual inventors and/or authors according to the intellectual property policy of the Investigator's institution. Unless otherwise agreed to in a writing signed by duly authorized representatives of an Institution, mere usage of a Shared Resources shall not entitle the provider of the Shared Resource to any ownership or usage rights of intellectual property belonging to another Institution.

C. All right, title and interest in and to any data generated by the provider of the Shared Resources in performance of work for another Institution shall vest exclusively in the Institution paying for or receiving such Shared Resources (the "Requesting Institution"). Unless otherwise expressly agreed to by the Requesting Institution, any data generated by the provider of the Shared Resources as a result of performing work for the Requesting Institution shall not be retained by the provider Institution, but shall instead either be sent to the Requesting Institution or destroyed per the instructions of the Requesting Institution.

V. Liability and Insurance:

A. No Institution is, by virtue of this MOU, the agent of any of the other parties to this MOU, and no Institution shall be liable for the wrongful acts or negligence of the other parties to this MOU. Each Institution understands that use of the other Institutions' Shared Resources may involve exposure to potentially hazardous conditions.

B. IN NO EVENT SHALL ANY PARTY TO THIS MOU BE LIABLE TO ANOTHER PARTY HERETO FOR INCIDENTAL, SPECIAL, INDIRECT, LOST PROFITS, LOST REVENUE, LOST OPPORTUNITY OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE ARISING FROM OR IN RELATION TO THIS MOU.

VI. Confidentiality:

A. Each Institution agrees not to disclose, except as required by law, to any third party or to use, directly or indirectly, for a period of five years after disclosure, any proprietary and confidential research data or other similar information of which the Institution may become aware as a result of using Shared Resources of the other Institutions, or as a result of having other institutions use its Shared Resources. For the avoidance of doubt, such information shall be marked "confidential" and "proprietary" at the time of disclosure.

B. Notwithstanding the preceding provision, the obligations of the Institution receiving confidential information (the "Receiving Institution") from another Institution do not include: (i) information that, at the time of disclosure, was published, known publicly, or otherwise in the public domain; (ii) information that, after disclosure, is published, becomes known publicly, or otherwise becomes part of the public domain through no fault of the Receiving Institution; (iii) information that, prior to the time of disclosure, is known to the Receiving Institution as evidenced by its written records and is not then subject to an obligation of confidentiality to any third party; or (iv) information that, after disclosure, is made available to the Receiving Institution in good faith by a third party under no obligation of confidentiality and without restriction on its further disclosure by the Receiving Institution.

VII. Conduct Compliance:

A. Each Institution shall require all employees, agents and students (if applicable) who use Shared Resources provided under this MOU to observe all applicable policies, rules and regulations of the Institution providing the Shared Resources.

B. Each Institution shall comply with all applicable laws and legal requirements in connection with the activities contemplated by this MOU.

C. This MOU shall be governed in all respects by the laws of the Commonwealth of Virginia without regard to its rules regarding conflict of laws. Any action to enforce the obligations of this Agreement shall be brought and maintained exclusively in the state courts of the Commonwealth of Virginia.

[Signature Page Follows]

VIRGINIA COMMONWEALTH UNIVERSITY

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[NAME]

COLLEGE OF WILLIAM AND MARY

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[NAME]

GEORGE MASON UNIVERSITY

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[NAME]

UNIVERSITY OF VIRGINIA

Phillip A. Parrish

Dr. Phillip A. Parrish, Interim Vice President for Research

Robert Merhige

Robert Merhige
AVP for Commercialization

EASTERN VIRGINIA MEDICAL SCHOOL

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[NAME]

OLD DOMINION UNIVERSITY

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[NAME]

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

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[NAME]

EXHIBIT A

Shared Resource Directors for University of Virginia:

Jay W. Fox, Ph.D.; Professor of Microbiology, Immunology and Cancer Biology and Director of Shared Resources

EXHIBIT B

SHARED RESOURCES AVAILABLE AT University of Virginia

University of Virginia (https://med.virginia.edu/core-facilities/cores-2/)

- Advanced Microscopy Facility
- Antibody Engineering and Technology Core
- Bioinformatics Core
- Biomolecular Analysis Facility
- BioNMR Facility
- Biorepository and Tissue Research Facility
- Exercise Physiology Core
- DNA Sciences Core
- Flow Cytometry Core
- Genetically Engineered Murine Model Core
- Molecular Electron Microscopy Core
- Molecular Imaging and Radiochemistry Core
- Research Histology Core
- Stem Cell Core
- Tissue Culture Facility

VIRGINIA COMMONWEALTH UNIVERSITY

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COLLEGE OF WILLIAM AND MARY

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GEORGE MASON UNIVERSITY

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Deborah Crawford, Ph.D., Vice President for Research

UNIVERSITY OF VIRGINIA

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[NAME]

EASTERN VIRGINIA MEDICAL SCHOOL

_____

[NAME]

OLD DOMINION UNIVERSITY

_____

[NAME]

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

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[NAME]

EXHIBIT A

Shared Resource Directors for each Institution:

GEORGE MASON UNIVERSITY
Michael Laskofski, Associate Vice President of Research Operations
George Mason University
Office of Sponsored Programs
4400 University Drive, MSN: 4C6
Fairfax, Virginia 22030
Phone: (703) 993-4573
Email: mlaskofs@gmu.edu

EXHIBIT B
SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

GEORGE MASON UNIVERSITY
Core Laboratories at George Mason University

ANIMAL CARE AND USE:
George Mason University manages two state-of-the-art vivarium facilities that have capacity for rodents through primates up to BSL-3, one on the Fairfax Campus and one of the Science and Tech Campus. The contact for these core facilities is David Myers; Animal Care Program Manager, Research Development, Integrity, and Assurance; iacuc@gmu.edu; 703-993-6118; http://oria.gmu.edu/research-with-humans-or-animals/animal-care-and-use/

RESEARCH COMPUTING:
The Office of Research Computing offers the following on-campus research computation options are:

- The ARGO cluster which has been installed in the Aquia Data Center for large scale computation needs of researchers in the university.
- Requesting a virtual computer for research from ITU. This is for research related computations that cannot be done on university researchers' desktops or laptops.

The contact for these resources is: Jayshree Sarma; Interim Director of Research Computing; jsarma@gmu.edu; 703-993-4397; http://orc.gmu.edu/.

MICROSCOPY:
There are two confocals--one upright, one inverted a Zeiss AxioObserver with AxioCam and a Nikon C1si D-eclipse. Also, an Olympus/Provis with Neruolucida software. The contact for these resources is: Nadine Kabbani, Assistant Professor, Molecular Neuroscience, 703-993-4406 or nkabbani@gmu.edu.

MAGNETIC RESONANCE IMAGING:
The **Mason 3T MRI Facility** houses a Siemens Prisma 3T Magnetom for human brain and whole body MRI. This facility is equipped with 32 channel phased array head coil, 16 channel shoulder coil, and multiple other head/neck/ spine, body, and flex coils. Applications include sequences for neuro, angio, cardiac, body, onco, breast, ortho, 2D and 3D ASL, SWI, and spectroscopy imaging. A 64 channel, MR compatible EEG system is also available. Visual displays include an Eiki projector. An ARRT certified MR Technologist is available for scanner operation.

Contact:
James Thompson
Department of Pychology
jthompsz@gmu.edu
(703)993-9356

PROTEOMICS:
Center for Applied Proteomics and Molecular Medicine Laboratory

The Protein Microarray and Molecular Characterization Laboratory houses Aushon 2470 Automated, High-Throughput Protein Arrayers and Dako robotic autostainers utilized to generate protein arrays for analysis of tissue and cellular samples for biomarker discovery. The **Molecular Characterization Laboratory** is equipped with an Illumina Bead Array Reader for high density DNA single nucleotide polymorphism (SNP) analysis. The SNP analysis is used to assess genomic copy number variation and can be used to create a molecular karyotype.

The **Tissue Processing and Imaging Laboratory** is equipped with histology equipment to embed and cut paraffin and frozen tissue sections with a Tissue Tek VIP Tissue Processor, Thermo microtome MH325, Harvard Apparatus vibratome, and Leica CM1850UV cryostat. Five laser capture microdissection systems in the laboratory are used to isolate enriched cell populations under direct microscopic visualization (2 Arcturus XT Automated Laser Capture Microdissection Systems, and 3 Arcturus PixCell II/IIe Laser Capture Microdissection Systems). A cytospin centrifuge and RoboSep magnetic cell sorting instrument are also available for processing biological fluids.

Imaging capabilities include an Olympus BX51 microscope outfitted with a digital camera, phase contrast and fluorescence, as well as an Olympus BX51 dual head, light microscope with a digital camera.

The Mass Spectrometry Laboratory uses specialized chromatography, electrophoresis, and cell fractionation systems, combined with high-performance mass spectrometers (Orbitrap Fusion, LTQ-Orbitrap, Triple Quadrupole, and MALDI- TOF-TOF), to separate and analyze components of tissue, serum and other physiological samples, resulting in protein characterization, identification and biomarker discovery. The laboratory is equipped with 4 mass spectrometers that are capable of identifying and quantitating femtomole levels of biomolecules such as peptides and proteins.

The Nanofabrication Laboratory is equipped to manufacture hydrogel nanoparticles used for biomarker discovery and the development of diagnostic tests. A novel protein painting technology developed in the lab identifies hot spots of protein-protein interaction.

The CAP/CLIA Clinical Proteomics Laboratory, the first in the United States to be dedicated solely to proteomics translational research, operates under the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) guidelines to:
• Provide a unique opportunity to assess and evaluate new proteomic technologies under rigorous clinical guidelines
• Accelerate the verification and validation of promising candidate biomarkers in a clinical diagnostic setting
• Implement unique clinical trials and diagnostic tests

The CAP Clinical Proteomics Laboratory uses an Aushon 2470 Automated, High-Throughput Protein Arrayer, and a Dako robotic autostainer to generate protein arrays and perform immunohistochemistry for analysis of tissue and cellular samples for biomarker discovery. An

Immulite 1000 Immunoassay instrument is also available to measure protein analytes and perform clinical tests.

Contact:
Amy Adams
Center for Applied Proteomics and Molecular Medicine
avanmete@gmu.edu
(703)993-2672

METABOLOMICS SEQUENCING:
The **Metabolomics Laboratory** houses several chromatography instruments, including a GC-FID, GC-NPD, and semi-preparative and preparative HPLCs. The metabolomics platform is centered on an Agilent 7890A Gas Chromatograph with 5975C Mass Spectrometer, an Agilent 1290 Infinity LC with a 6530 QToF (MS/MS), and an Agilent 1100 LC-MSD (with interchangeable ESI, APPI, and APCI sources). Coupled with custom designed software algorithms and the commercially purchased Agilent Mass Profiler Professional software package, these instruments enable a comprehensive examination of volatile and non-volatile metabolites present in biological samples

Contact:
Robin Couch, PhD
Department of Chemistry & Biochemistry
rcouch@gmu.edu
(703)993-4770

GENOMIC SEQUENCING:
The **MicoBiome Analysis Center** has a separate PCR room with 10 PCR machines, an ABI 3130xl sequencer, a Life Technology RT PCR instrument, an Ion Torrent PGM sequencer (4 million reads/run), an Ion Torrent S5 (80 million reads/run), and high-end computational facilities. The computational facilities include 10 iMac computers, a 48 processor HP workstation, two development HP servers, and access to a 640 node SGI cluster. A wide array of bioinformatics software is accessible through networked computers within the DNA research labs.
Contact:
Pat Gillevet, PhD
Microbiome Analysis Center
pgilleve@gmu.edu
(703)993-1057

MACROMOLECULAR/SMALL MOLECULE ENGINEERING AND SPECTROSCOPY:
The **Small Molecule, Peptide, and Protein Engineering Spectroscopy Laboratory** is equipped for small molecule, protein, and peptide synthesis. Computational chemistry experiments are performed using a variety of available software on the Mason Argo cluster. Proteins are expressed in either bacterial or mammalian cells. Molecular characterizations are performed using a Bruker AVANCE III HD 400 MHz NMR.

The NMR Laboratory is equipped with a Bruker AVANCE III HD 400 MHz NMR instrument for multi-dimensional magnetic resonance spectroscopy experiments, including structure determination/confirmation of small molecules. It's Diffusion Ordered Spectroscopy (DOSY) capabilities enable investigation of intermolecular interactions. The instrument is equipped with Bruker's SMART Probe technology for enhanced resolution and an automatic sample changer for processing up to 24 samples.

The **Spectroscopy Laboratory** is also equipped with 1) Jasco FP-8300 Spectrofluorometer w/ Peltier temperature control and polarizers, 2) Jasco FTIR4100 Infrared Spectrometer w/ Peltier temperature control and protein secondary structure prediction software, 3) Bio-Tek Eon Microplate Spectrophotometer, 4) Molecular Devices SpectraMax Gemini EM Microplate Spectrofluorometer, 5) Tecan Spark 10M Spectrophotometer w/ AlphaScreen and chemiluminescence, 6) Rudolph AUTOPOL IV Polarimeter, 7) Rudolph J357 Automatic Refractometer, and 8) Jasco J-1500 Spectropolarimeter.

Contact:

Mikell Paige, PhD
Expertise: Small molecule design/synthesis and spectroscopy
Department of Chemistry & Biochemistry
mpaige3@gmu.edu
(703)993-1075

Barney Bishop, PhD
Expertise: Peptide engineering and macromolecular spectroscopy
Department of Chemistry & Biochemistry
bbishop1@gmu.edu
(703) 993-8302

Young-Ok You, PhD
Expertise: Protein engineering/enzymology
Department of Chemistry & Biochemistry
yyou@gmu.edu
(703) 993-7141

VIRGINIA COMMONWEALTH UNIVERSITY

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[NAME]

COLLEGE OF WILLIAM AND MARY

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[NAME]

GEORGE MASON UNIVERSITY

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[NAME]

UNIVERSITY OF VIRGINIA

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[NAME]

EASTERN VIRGINIA MEDICAL SCHOOL

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[NAME]

OLD DOMINION UNIVERSITY

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[Morris Foster, Vice President for Research]

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

_____

[NAME]

EXHIBIT A

Shared Resource Directors for each Institution:

Karen Eck, PhD
Assistant Vice President for Research
Office of Research
Old Dominion University
4111 Monarch Way, Suite 203
Norfolk, VA 23508
(757) 683-3707
keck@odu.edu

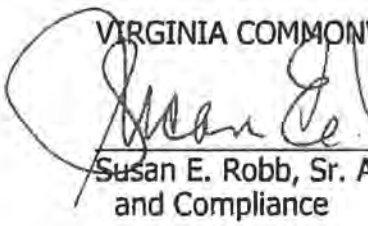
EXHIBIT B
SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

OLD DOMINION UNIVERSITY

Account Code	Project Director	Account Title	Account Short Title	Status	PI Home Department Code
956200-010	BRITCHER, C.	VIPER DYNAMOMETER / INSTRU LAB	VIPER LAB	A	MECHANICAL AND AEROSPACE ENGINEERIN(
956500-010	ELSAYED-ALI, H.	ARC EQUIPMENT USAGE	ARC EQUIPMENT	A	APPLIED RESEARCH CENT
957300-010	CATRAVAS, J.	FLOW CYTOMETRY FACILITY	FACS-ARIA	A	FRANK REIDY CENTER FO BIOELECTRICS
958100-010	PLATSOUCAS, C.	CENTER-ISOTOPE*TRACE ELEMENTS	CENTER-ISOTOPE*	A	BIOLOGICAL SCIENCES
958100-020	DAINES, D.	ELECTRON MICROSCOPY LAB	ELECTRON MICROS	A	BIOLOGICAL SCIENCES
958100-021	DAINES, D.	DNA SEQUENCER	DNA SEQUENCER	A	BIOLOGICAL SCIENCES
958100-022	DAINES, D.	BIOLOGY VEHICLE USAGE	BIOLOGY VEHICLE	A	BIOLOGICAL SCIENCES
958110-001	DAINES, D.	RESEARCH FACULTY-MARSHALL, H.	RES FAC-MARSHAL	A	BIOLOGICAL SCIENCES
958200-010	DONAT, J.	CBP WQL-CC AUTOANALYZER	CBP WQL-CC AUTO	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-011	DONAT, J.	CBP WQL-CC C/N ANALYZER	CBP WQL-CC C/N	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-012	DONAT, J.	CBP WQL-CC SPECTROPHOTO	CBP WQL-CC SPEC	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-013	DONAT, J.	CBP WQL-CC STD ANALYSES	CBP WQL-CC STD	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-014	DONAT, J.	CBP WQL-CC FIELD EQUIPMENT	CBP WQL-CC FIEL	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-015	DONAT, J.	CBP WQL-CC R/V BAYRUNNER	CBP WQL-CC R/V	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-020	HATCHER, P.	MAJOR INSTRUMENTATION CLUSTER	COSMIC	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200-021	HATCHER, P.	CENTER-IRMS	IRMS	A	CHEMISTRY & BIOCHEMISTRY DEPT
958500-010	HARVEY, R.	R/V FAY SLOVER	R/V FAY SLOVER	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958500-011	HARVEY, R.	RESEARCH VESSEL-SMALL BOATS	RESEARCH VESSEL	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958500-012	HARVEY, R.	ELECTRONIC SUPPORT	ELECTRONIC SUPP	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE

958500-020	DARBY, D.	ELECTRON PROBE MICROANALYZER	EPMA-ELECTRON	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958600-010	PLATSOUCAS, C.	VIRTUAL ENVIRONMENTS LABS	VIRTUAL ENVIRON	A	CTR FOR COASTAL PHYSICAL OCEAN
958600-011	ATKINSON, L.	CCPO PROFILER COST CTR	CCPO PROFILER C	A	CTR FOR COASTAL PHYSICAL OCEAN
958600-012	SEDWICK, P.	ICP - MS FACILITY	ICP - MS CC	A	CTR FOR COASTAL PHYSICAL OCEAN
958800-010	FOSTER, M.	ANIMAL CARE FACILITY	ANIMAL CARE FAC	A	OFFICE OF RESEARCH
958800-011	FOSTER, M.	ANIMAL CARE OPERATIONS	ANIMAL CARE OPS	A	OFFICE OF RESEARCH
959300-010	RANJAN, D.	CS COST CENTER	CS COST CENTER	A	COMPUTER SCIENCES

VIRGINIA COMMONWEALTH UNIVERSITY



Susan E. Robb, Sr. Assoc. VP for Research Administration and Compliance

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VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

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EXHIBIT A

Shared Resource Directors for each Institution:

Virginia Commonwealth University
Paul Fawcett, Ph.D.
Assistant Professor of Internal Medicine and
Director of Research Infrastructure
paul.fawcett@vcuhealth.org
(804) 827-0975

EXHIBIT B
SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

- Center for Molecular Imaging (http://www.molecularimaging.vcu.edu/)
- Chemical and Proteomic Mass Spectrometry Core Facility (https://chemistry.vcu.edu/research/facilities/chemical-and-proteomic-mass-spectrometry-core-facility/)
- Cancer Mouse Models Shared Resource (https://www.massey.vcu.edu/research/cores/cmmc/)
- Flow Cytometry Core Facility (https://www.massey.vcu.edu/research/cores/flow-cytometry/)
- Lipidomics & Metabolomics Core Facility (http://www.biochemistry.vcu.edu/Research/lipidomics_core.html)
- Microscopy Core Facility (http://www.anatomy.vcu.edu/microscopy/)
- Nanomaterials Characterization Core: (http://nano.vcu.edu/)
- Nucleic Acid Research Facilities / Genomics Core Facility (http://www.narf.vcu.edu/)
- Structural Biology Core Facility (https://www.massey.vcu.edu/research/cores/structural-biology/)
- Tissue and Data Acquisition and Analysis Core Facility (https://www.massey.vcu.edu/research/cores/tdaac/)
- Transgenic and Knock-out Mouse Core Facility (https://www.massey.vcu.edu/research/cores/tmf/)

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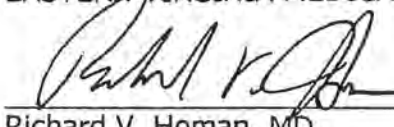

Richard V. Homan, MD — Date
President & Provost,
Dean of the School of Medicine

OLD DOMINION UNIVERSITY

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VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

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EXHIBIT A

Shared Resource Directors for each Institution:

EVMS Biorepository and Histology Core	Laurie Wellman PhD. wellmall@evms.edu
Flow Cytometry Core	Woong-Ki Kim PhD kimw@evms.edu
Microscopy and Imaging Core	Frank Lattanzio PhD Lattanfa@evms.edu
Proteomics Core	Julius Nywalwidhe PhD Nyalwijo@evms.edu
Molecular Core Facility	Julia Sharp PhD molecularcore@evms.edu
Bioinformatics and Bioanalytic Core	Patric Lundburg PhD lundbeps@evms.edu

Following added by UVA per email instruction from EMVS. The EMVS Point of Contact for Shared Resources is Dr. William J. Wasilenko, 757-446-8480

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VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

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Exhibit A

Shared Resource Director for Each Institution

William and Mary

Director: Christopher A. Del Negro, Ph.D.; Professor of Applied Science, Coordinator Core Resources
Deputy Director: Eric L. Bradley, Ph.D.; Professor of Biology, Science Precinct Coordinator and EMT Liaison

Exhibit B

William and Mary

(name is faculty contact for high-level advisory)

Bioengineering Core Lab (Saha)
Cellular and Cytometry (Saha)
Cellular Analytical Core (Bradley)
Imaging laboratories hard matter - non-ionizing methods (Cooke)
Biomaterial imaging Core (Cotton)
Imaging Laboratories soft matter - ionizing methods (Bradley)
Live-cell, in vitro, and in vivo multi-photon neuroscience neuroimaging lab (Del Negro)
Laser-scanning confocal (fixed tissue) imaging core lab (Del Negro)
Surface characterization core lab (Cooke)
Magnetic studies Core - 17.6T solid state NMR, Squid magnetometry, liquid NMR (Cotten)
Living Human subjects neurophysiology Lab (Burk)
Marine Biology Seawater Lab 1 (Luckenbach)
Marine seawater lab 2 (Luckenbach)
Marine cytometry center core (Luckenbach)
Marine research vessel core operations (Luckenbach)

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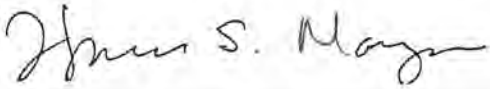

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[Theresa S. Mayer, Vice President for Research and Innovation]

EXHIBIT A

Shared Resource Directors for each Institution:

1) VTCRI Fluorescence Assisted Cell Sorting (FACS) Core Facility

The facility is equipped with instruments to separate cells of interest from tissue and from a heterogeneous population of cultured cells. The facility houses a fully equipped SH800 cell sorter (SONY). This cell sorter contains four laser lines (405, 488, 561 and 638 nm), 6 photomultipliers and a variety of filters to allow for the detection of most fluorescence signals. The facility houses a BD Accuri C6 flow cytometer equipped with a blue and red laser and four fluorescence detectors to count, phenotype and determine cytokines and growth factor levels in specific cells. The facility is also equipped with an automated cell fractionator that allows the separation of subcellular organelles, a SpeedVac to concentrate nucleic and protein samples (Fisher Scientific) and a the QX200 digital PCR reader equipped with a droplet generator (BioRad) to examine the transcriptome of single or subpopulations of cells.

2) VTCRI Super Resolution Core Microscopy Facility

The super-resolution microscopy facilities is located in a BSL-2 certified imaging suite. Equipment available includes a Bruker Vutara 350 super-resolution microscope with Okolab Bold Line incubation system, both of which are controlled by a high-end computer workstation for data acquisition and analysis. The Vutara 350 combines 1000 mW lasers and a sCMOS detector to enable researchers to undertake multi-color video-rate 3D particle tracking in living cells and tissues at a resolution within 20 nm lateral and 50 nm axial. Significant depth (>15 μm) of penetration can be achieved in both live and fixed specimens, which is enhanced, and scatter reduced, when utilizing the near infra-red 750 nm laser excitation. A sCMOS Hamamatsu ORCA Flash 4.0 camera permits frame rates necessary for dynamic super-resolution imaging, and an additional Interline CCD camera provides wide-field image acquisition. Experiments on live preparations can be performed in physiological oxygen levels in addition to automated initiation of insults such as hypoxia.

3) VTCRI animal behavioral core

The core provides resources for comprehensive behavioral and sensory-motor analyses in rodents. The facility includes a staging area and four independent testing rooms, which allow simultaneous work by up to four investigators. Available tests include those for learning and memory, depression and anxiety-related behaviors, social behaviors, operant tasks, sensory-motor gating, motor functions, circadian rhythm analysis, pain and analgesia. The facility equipment includes a custom built Morris water maze, a fear conditioning system, open field and AnyMaze video tracking systems, a three chamber social interaction apparatus, a rodent touch screen chambers, startle response and Gemini avoidance systems, a rotarod and 26 voluntary running wheel systems.

4) VTCRI Optical imaging core

The institute has a state-of-the-art light-based imaging facility staffed with expert support personnel. This facility was specifically designed to provide researchers with all major types of imaging modalities necessary for standard cell and molecular biology at multiple imaging scales. The core is directed by two faculty members (Dr. Michael Fox – Associate Professor and Dr. Greg

Valdez- an Assistant Professor) who provide training and support for other labs to use the facility and who manage the facility. Facility access is managed by a web based sign up system that allows investigators access. For relatively low magnification image analysis the imaging core is equipped with a Zeiss V20 fluorescent dissecting microscope (with MRc camera and computer) and numerous standard (non-fluorescence) dissecting microscopes. For higher magnification imaging, the facility is equipped with a Zeiss AxioVert epi-fluorescence microscope, a Zeiss Apotome with a Neurolucida package from MicroSystems Devices, and a Zeiss AxioImager A2 (with an AxioCam MRm camera and PC work station with ZEN imaging software). The facility is equipped with 2 Zeiss laser confocal microscopes: a Zeiss 710 confocal microscope with an AxioExaminer upright stage (4 laser lines – 488 / 555 / 594 / 633) and a Zeiss 700 confocal microscope with an AxioVert inverted stage (4 laser lines – 405 / 488 / 555 / 647). The imaging core is equipped with a Zeiss/Coherent 2 photon scanning upright microscope. The core also offers a Zeiss multi-photon optical imaging system with attached brain slice, in vivo and isolated cell electrophysiology systems.

5) VTCRI Core Human Neuroimaging Lab (HNL)

The VTCRI HNL houses two research-dedicated 3T Siemens MR scanners in Roanoke of hich one is a Trio and the other is a Prizma. A third scanner, also a 3.0 Tesla Siemnes Trio is located on the VT Blacksburg campus. Each scanner is 100% research-dedicated. Each scanner bay is equipped for 1) behavioral response acquisition: two-hand, four-button optical response pads with USB, serial, and TTL output (Current Designs, Inc.); 2) video stimulation: rear-projection video display (NEC GT2150) and corrective lenses for use with video stimulation (MR-compatible frames with insertable polycarbonate lenses by Solo Bambini); 3) eye-tracking: IR-illuminated CCD system, ViewPoint software (Arrington Research); 4) audio stimulation: dynamic and piezoelectric headphones (MR Confon, GmbH); 5) gustatory stimulation: dual-syringe pump (Harvard Apparatus HA33)); 6) real-time image reconstruction and online neurofeedback (LaConte et al., 2007). HNL director, Dr. P. Read Montague and his team of developers have designed, coded, and implemented a unique imaging technique for simultaneous scanner image acquisition from multiple scanners as behavioral data are also being acquired. The open-source software package allows for the simultaneous presentation of stimuli, acquisition of behavioral responses, and synchronized acquisition of functional imaging data from multiple scanners. The use of the internet as a communication channel between client and server computers allows for the study of real-time social interactions and for such interactions to be implemented across institutions. The freely available software is currently deployed at imaging facilities in hospitals, universities and health centers across the U.S. and on three continents. Critically, this technology allows for the direct measurement of multiple brains engaged in social and economic interactions and relies on straightforward multi-site synchronization of image acquisition. The hyperscan system, implemented with Network Experiment Management Objects (NEMO) includes 1) a client, 2) an application server, and 3) a public domain, SQL server database (called PostgreSQL). There is a separate authentication system for HIPAA compliant secure interactions. In addition to NEMO, Dr. Montague's team has also developed an easy-to-use scripting language so that scientists can specify experiments without detailed knowledge of how the hyperscan system functions. The software is available for public download through VTCRI. The CPU combines state-of-the-art technology with neuroscience, economics, and behavioral methods to understand the neural

computations involved in human cognition and psychiatric illness. In addition to the computer workstations and analysis tools in the PIs' independent laboratories, the VTCRI Human Neuroimaging Laboratory includes the following computing resources: 2 Penguin Computing servers (each with 4 dual core processors) available for image and data analysis; 26 Dell servers (dual processor Xeons) available for image and data analysis; 32 node, 64 processor Linux IBM cluster; 2 Gbit storage area network; 30 terabyte fast disk storage; 60 terabyte digital tape backup; daily backups with weekly off-site data storage at secure facility; 54 Mbit secure, encrypted, wireless network; 1Gbit Ethernet computer network (64 drops); MR stimulation software: NEMO: synchronized, multi-subject, multi-institution generalized stimulation presentation and data management framework; MR image retrieval software: Experiment Browser: secure web-based image retrieval using NEMO client with proper authorization; MR Analysis Tools: MATLAB with statistics and signal processing toolboxes, SPM8, AFNI, FSL, MRIcro, xjView, R, SAS; Productivity Tools: Adobe Suite, Microsoft Office Suite, OpenOffice.

6) VTCRI Cryo-electron microscopy facility

Appendix F: Virginia Catalyst Addiction Initiative

F.1 Deloitte Consulting

F.1.1 Overview

(attached)

F.1.2 Phase 1 Deliverables

(attached)

F.1.3 Options for Business Plan Development

The Virginia Catalyst – Business Plan Development

October 22, 2018

At the conclusion of the comparative analysis phase of the Virginia Catalyst business plan project, an inflection point has arisen surrounding the most advantageous path forward. Given the realities of the addiction research and treatment arena, two courses of actions have emerged as viable avenues to achieving the strategic objectives of the Consortia. The following information provides brief descriptions of both courses of action.

Remain focused on the existing addiction research and treatment market

In this course of action, Virginia will focus on improving their pursuits of traditional means of funding to support research and intervention strategies to address addiction. A significant challenge to this approach is the formulaic allocation of addiction-focused federal grant monies. This federal funding approach favors states with larger populations and states with a higher rate of addiction related deaths. As such, the business plan may focus on:

- An approach for improving the State's or Consortia members grant application processes
- Seeking an redress of formulaic grant funding distribution
- Inter-consortia resource sharing and teaming guidelines
- Community involvement strategies
- Expanding state, federal and private capital funding avenues
- An approach for improving commercialization of research
- Traditional business plan components like value proposition, product differentiation, talent, operating models, and costs, pricing and funding strategies.

Given the nature of existing funding and grant issuance models, optimizing the State's approach to this "market" presents an avenue to incremental funding increase.

Make a bold play in neuroscience as a means to healthier citizenry and increased investment and economic growth

In this course of action, Virginia will prioritize advancing neuroscientific understanding as a means to retaining, regaining, or enabling normal brain function relative to addiction, mental

health, traumatic brain injury, and neurological disorders. This "Bold play" is envisioned to serve as a beta or pilot for the nation. Planning activities and the resulting business plan may focus on:

- Strategic alignment of key stakeholders to vision and end state objectives
- Adjusting corresponding Consortia agreements
- An approach for creating a brand for Virginia as the Neurology state
- Resource sharing models across multiple involved entities e.g. public-private partnerships
- Funding models, including state funding, private funding, and federal funding
- A strategy for translating and commercializing neuroscience innovations across multiple industries e.g. health, defense, A.I, entertainment, etc.

Based on the current and foreseeable levels of drug use, addiction, and mental health and the corresponding societal costs of these factors, making a bold play to change the approach to understanding and addressing these issues may be appealing to the Federal government, industry, or other investors. Lead time to return on investment, and other decision considerations should be raised and addressed.

F.2 Catalyst Response to National Institute on Drug Abuse (NIDA)

July 2018: VBHRC Virginia Catalyst submitted the following response to the National Institute on Drug Abuse (NIDA) and Substance Abuse and Mental Health Services Administration (SAMHSA) Request for Information (RFI), Notice Number: NOT-DA-18-023: The HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis.

Response to RFI NOT-DA-18-023 "VOICE" (Virginia Opioid Integrated Crisis Enterprise)

Introduction: In 2017, Virginia experienced 1,200+ deaths from opioid overdoses and 10,000+ ER visits for opioid and heroin overdose treatment in 2017 (Virginia Department of Health) and Norton in southwestern Virginia had the highest opioid prescription rate (CDC). The affected populations are diverse in rural and urban areas and use a range of opioids. Virginia has research and public health expertise with VOICE-participating institutions having received NIH, SAMHSA, and HRSA funding related to opioids. Finally, Virginia can facilitate data sharing among/between agencies and political subdivisions, ensuring statewide compliance thanks to state legislation enacted and new Chief Data Officer position. **Therefore, VOICE is well-positioned to develop an evidence-based, integrated system of care based on addiction science and proven intervention effectiveness as a model for states to produce long-term results.**

Study Design: Leverage statewide network of academic, healthcare, and state government (including the criminal justice system) collaborators and data systems to develop an integrated approach to the opioid crisis. Using a place-based, socio-spatial approach, VOICE will maximize use of data sources by linking individual data to multiple geographically-referenced local, county, and state data sources through geo-IDs and ensure robust multi-level models with spatial analyses examining opioid misuse and OUD to detect critical pathways connecting factors shaping outcomes, including spatial boundaries in high-risk geographic areas. The initial target is opioid overdose.

Specific Aims:

1. Establish an accurate baseline to define heavily affected communities and determine numbers, characteristics, and outcomes of opioid overdoses across Virginia, utilizing novel bioinformatics methods to mine the major health systems' EHRs and combine this information with data from the state's death registry.
2. Based on Aim 1 data, establish an evidence-based protocol for ambulance and emergency care and community and specialty care settings, e.g. infectious disease and maternal health care, that actively engages patients surviving opioid overdose then initiates long-term treatment.
3. Collaborate and integrate with federal, state and local government and criminal justice programs to increase utilization of best practice evidence-based interventions, including pharmacotherapy in opioid users at high-risk for relapse/overdose.

Aim 1. Utilize death registry data (Figures 1-2.) with EHR data from collaborating statewide health systems (ConnectVirginia links all hospital ERs) to determine accurate numbers, characteristics, and outcomes for opioid overdose patients that survive the initial overdose. VOICE will leverage an established collaboration with four academic health centers to test novel informatics methods to define the state's overdose epidemic (Figure 3.).

Figure 2. Percentage of Opioid Overdose Deaths Related to Heroin

Figure 1. Percentage of Opioid Overdose Deaths Related to Prescription Opioids

Virginia has a range of opioids causing overdose deaths in rural and urban areas: western region has a high percentage of individuals dying from prescription opioid overdose, while the eastern region has a greater percentage of deaths due to intravenous opioid overdose, thus the ideal location to assess the baseline and develop treatment models for all opioid users.

Figure 3. Participating Institutions Collaborating on Informatics Overdose EHR data.

Institutions	Health Systems	Patient population	Patients in 2017
VCU	VCU Health	750,000 patients in Richmond and surrounding areas	240,000
UVA	UVA Health	559,000 patients in Charlottesville and surrounding areas	340,000
VT	Carilion	1.1 million patients in Roanoke and surrounding areas	500,000
EVMS	Sentara	Over 2.5 million patients in Norfolk – Virginia Beach and surrounding areas	1,050,000

VCU, UVA, VT-Carilion, and EVMS-Sentara use EPIC for EHRs, while VCU uses Cerner. However, all four sites efficiently extract the necessary clinical information from their EHR systems into their research data repositories to perform analyses. Vibrent Health in Fairfax, VA (Participant Technologies Center for NIH's Precision Medicine Initiative® Cohort Program, All of Us) will provide guidance on data collection, management and analysis for long-term accurate tracking of patients and producing valuable metrics. Several institutions have successfully piloted sharing their EHR data. A data governance committee will be established with the academic and healthcare organizations and Virginia Health Department to ensure data are

utilized following local and national data guidelines. Therefore, barriers to data harmonization, collection, integration, cleaning, analyses and dataset creation will be thoroughly addressed.

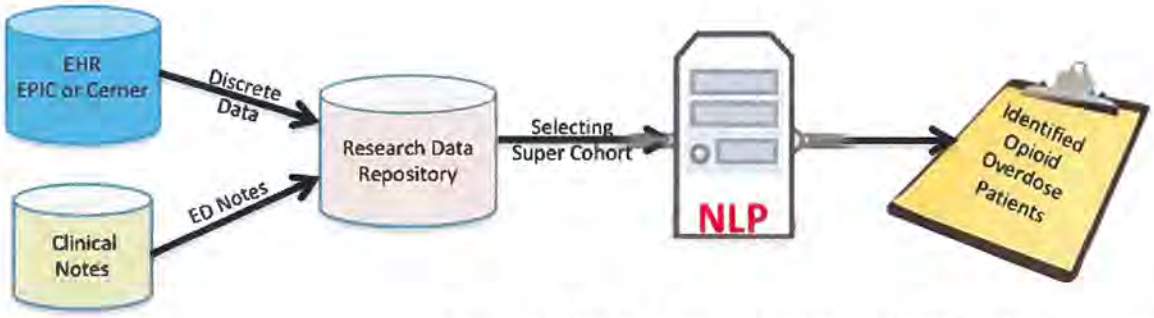


Figure 4. Opioid Overdose Patient Identification Workflow

To address privacy concerns, analyses will be performed locally at each site, and only de-identified aggregated data for a final analysis will be shared. Partner sites will do a similar pre-selection to create their super-cohorts and do manual chart reviews on at least 500 of their cases from their super-cohorts. These curated datasets will verify the validity of the VCU NLP classifier. Bi-weekly Zoom teleconferences will occur between sites to discuss protocol implementation and problems with NLP methods. Monthly in-person meetings will occur at rotating sites. Statistical methods will be utilized across sites to compare sensitivity and specificity for diagnoses. The goal is to implement and sustain the newly developed selection process to identify opioid overdose patients for state-wide integrated evidence-based interventions and best practices.

Aim 2: Utilize information on characteristics and outcomes of opioid overdose to develop best practices for initiation of treatment in EDs and long-term provision and effectiveness of treatment in facilities, with MAT beyond 6-months in community-based settings. Virginia has an existing collaborative research effort with overdose patients in EDs between VCU and VCU Health System, GMU and INOVA Health System, and VT and Carilion Clinic. Sites provide research expertise and diverse patient populations in rural and urban communities to support this:

VCU: Dr. Gerry Moeller is Director, Institute for Drug and Alcohol Studies, Division Chair of Addiction Psychiatry, and active in clinical trials for addictions for 20+ years (completed studies in patients with cocaine/alcohol/OUD). He led many multi-site addictions research teams.

VT: Dr. Warren Bickel is Director, Addiction Recovery Research Center and Co-Director, Center for Transformative Research on Health Behaviors. He worked in behavioral research in addictions focusing on decision-making in patients with OUD and was a leader in early research on buprenorphine in OUD-patients. Dr. Friedlander is Vice President, Health Sciences and Technology, a leader of the Virginia Catalyst's Neuroscience Initiative, and a leader of multiple collaborative programs.

Inova: Dr. Robert Lipsky is Director, Translational Research, Department of Neurosciences and Chief, Inova's translational research laboratory, Krasnow Institute for Advanced Study, GMU. He leads in behavioral genetics research, focusing on addictions.

GMU: Dr. William Hazel was former Secretary of Health and Human Resources, led the Opioids and Heroin Task Force and is Senior Advisor, Strategic Initiatives and Policy. GMU has expertise in data analytics, health policy and economics.

UVA: Dr. Nassima Ait-Daoud, MD, Director, Center Leading Edge Addiction Research. David Driscoll Director, Research Development, manages the Data Science Institute where the public health biosurveillance and health economics expertise in tracking OUD and overdosing rates will be instrumental.

Aim 3: Use established state collaborations with criminal justice programs to develop an evidence-based paradigm to proactively treat patients with depot formulations of agonists and antagonists to reduce overdose risks and develop a drug court using an integrated holistic approach to treatment and reduction of recidivism because patients with OUD are high-risk for overdose related to reduced tolerance to opioids after incarceration, and pharmacotherapy reduces repeat overdose risk. VOICE will measure the length of integrated interventions in place before expecting meaningful, long-term change in outcomes for incarcerated and all vulnerable populations.

It will address confounding variables and potential threats to study validity through characterization of the existing scope of the problem, use of innovative bioinformatics methods and mitigation of potential barriers in communications and outreach to local communities using the state's universities "collective impact" hubs for regional cooperation.

Outcomes: The identification of "at-risk" populations using precision medicine tools and better utilization of data, plus reduced rates of fatal and non-fatal opioid overdose as determined by Virginia Health Department and EHR informatics methods are the expected outcomes. The socio-spatial approach will inform spatial boundaries surrounding high-risk geographic areas to provide better understanding and enable pairing this information with participatory mapping, so communities can provide local knowledge to inform more effective engagement with researchers and intervention implementation. Specifically, VOICE will target a 50% reduction in fatal and non-fatal opioid overdoses compared to historical data determined through Aim 1. from EHR and Virginia overdose death data. A secondary outcome will be decreased OUD incidence, increased initiation of MAT and continued treatment beyond 6-months/long-term, and an increased number of individuals receiving recovery services as reported by Virginia Department of Medical Assistance Services.

Retention in Post-Acute Period. Factors determining continued participation retention include costs, e.g. cost of treatment, e.g. medications and travel time to clinic, and benefits, e.g. components of treatment. Methods to improve retention/participation include mobile treatment units and medication subsidies. A proven effective approach is incentives (contingency management): increasing treatment benefits by providing small monetary prizes/written

encouragement after completing designated actions. In post-acute phase, we will randomize individuals to receive contingency management for retention vs standard care for 6-months. The primary outcome data will be retention and drug use, indicated by urinalysis to inform the model.

Integrated Evidence-based Interventions: Based on data and outcomes, VOICE will apply geographic-cultural boundaries information to ensure communities are matched on factors correlated with targeted outcomes to establish tailored strategies for effective integrated evidence-based interventions, using NCI's Team Science Toolkit. It will measure intervention effectiveness with the data-tracking, NIDA-recommended measurement instruments and NIH's data harmonization, and develop a state model for meaningful penetration of evidence-based integration.

Health Economics: The economic impact of the multi-faceted opioid crisis includes substantial direct medical costs, lost productivity, multiplicative impact on families/co-workers/employers, reduced tax receipts, and overburdened government resources, including the justice system. For optimized deployment of resources, we will develop a database that amalgamates information from the judicial and health systems and employers at several sites. This will be analyzed to assess the costs to provide the resource allocation and coordination of agencies, community organizations and family support systems framework, comparing the ROI of treatment protocol, economic incentives and individual patient characteristics. We will examine the proposed interventions, including pharmacological, behavioral and judicial monitoring with evaluation of outcomes (quality-adjusted-life-years and income) vs existing standards of care/intervention.

Implementation Research: VOICE will develop best practices for ED and post-incarceration populations. Implementation research questions include: 1. How does treatment engagement at 1/3/6-months improve after opioid overdose if MAT is initiated in ED compared to historical controls? 2. Are repeat overdose rates reduced in patients with MAT initiated in ED compared to historical controls? 3. What are barriers to initiation of MAT in the ED after opioid overdose, and how can they be overcome? Implementation research expertise runs deep with VOICE as Dr. Joseph Ornato (VCU) led implementation research producing best practices for utilizing automatic electronic defibrillators nationwide and VT has extensive history addressing addiction. Dr. Warren Bickel (VT) has worked with opioid dependence since 1984, led research for MAT FDA-approval of buprenorphine, and was inaugural director of the first methadone treatment clinic in Vermont.

Infrastructure, Partnerships, Collaboration: VOICE is a collaborative effort by the seven research universities in Virginia, five major health systems, industry leaders, court systems, and state government, facilitated by the Virginia Catalyst, a 501(c)(3) corporation established in 2013 and funded by Virginia and its research universities. It established VOICE as part of the Virginia Catalyst's Neuroscience Initiative with a statewide interactive patient registry, including patients suffering from addiction, statewide clinical trials network, collaborative agreement in which active participation exists among the research universities to share access to core facilities, and statewide cross-functional interest groups, i.e. collaborations with opioid prevention and treatment facilities, community-based organizations and drug courts. A collaborative network and infrastructure already exist to accommodate this program, including NIH support, e.g. VCU

renewed its NIH CTSA program and UVA-VTC-Inova recently received overall impact score of 21 for its CTSA consortium application considered by NIH council in October. This infrastructure enables VOICE to serve this coordinating role producing the highest likelihood of sustainable prevention and treatment effectiveness.

Conclusion: Virginia has the expertise, infrastructure, and representative population of heavily affected rural and urban communities using all types of opioids to examine the opioid problem and provide a replicable model of evidence-based interventions for the nation.

End of VBHRC Virginia Catalyst: General Assembly Report FY18

Deloitte.

VA NEUROSCIENCE INITIATIVE

Strategy & Business Plan Implementation

August 22, 2018

Meeting Agenda

Time	Topic
9:00 – 9:05	Introduce Deloitte Team
9:05 – 9:15	Discuss Project Objectives and Expectations
9:15 – 9:35	Review Engagement Approach, Activities and Collaboration Points
9:35 – 9:55	Discuss Questions
9:55 – 10:00	Next Steps

VBHRC
VCATALYST

Introduce Deloitte Team

Deloitte's Delivery Team

Our team has significant expertise in strategy and business development in life sciences and healthcare nonprofit space.

Margaret Anderson – Project Principal

Margaret Anderson is a Managing Director based in Arlington. She joined from FasterCures, a Washington DC-based center of the Milken Institute, where she was the Executive Director and oversaw policy analysis and programs advancing the science of patient input and collaborative research models. She worked on public health issues at American Public Health Association, and began her career at the Congressional Office of Technology Assessment in the Biological Applications program.

Jon Baba – Project Principal

Jon Baba is a Principal in Deloitte's Global Public Sector practice. He has more than 20 years of experience in government consulting, supporting client executives focused on issues related to enterprise strategy, operational efficiency, and using collective intelligence and crowd sourcing to solve complex issues. Clients look to Jon to provide expertise on strategic simulation, talent innovation, cost analysis, and to present industry best practices affecting program success.

KC Decker – Senior Project Leader

KC Decker is a certified PMP and Senior Manager in Deloitte's Strategy Practice with over 15 years of professional experience advancing the science of analytics in health non profits through systems engineering, informatics, and strategy development. He is a board member of the ALS Association (Georgia Chapter) and Affiliate Faculty for health informatics at Emory University.

Keith Rodgers – Senior Project Leader

Keith Rodgers is a leader in enterprise strategy solutions, with 15 years of experience leveraging innovative techniques to assess organizations and provide high-stakes strategic solutions. He assists senior executives in wielding the power of the crowd to boost performance and anticipate change in an increasingly disruptive environment.

Charles Anamelechi – Project Manager

Charles Anamelechi is a Manager in Deloitte's federal health strategy practice. He has experience in healthcare strategy, organizational development & governance and clinical research development strategy. Dr. Anamelechi holds a Master's and Ph.D. in Biomedical Engineering from Duke University with a research focus on Tissue Engineering of Cardiovascular vessels and development of long term implantable Glucose Sensors for Diabetes management.

V4CATALYST

Our Team of Advisors

We will supplement the day-to-day team with subject matter experts in various parts of the market necessary for the sustainment of VA Catalyst.

Tom Davis – Managing Director

Tom is a director in Deloitte's Policy & Government Relations group where he advises firm leadership and clients on major trends, opportunities and challenges facing the federal government. A former 7-term congressman, representing Virginia's 11th district, Tom now leads the development and execution of Deloitte's legislative strategy to advance and protect the firm's business interests in Washington.

Lindsay Hough – Principal

Lindsay's career is focused on helping government agencies transform their operations in response to citizen demands, new legislation and budget pressures. Much of her current focus is on state health and human services programs and helping state governments fight the opioid epidemic. She has provided services to a number of states as well as the U.S. Federal government.

Tina Mendelson – Principal

Tina is a principal with Monitor Deloitte strategy practice with 18 years of experience advising government agencies on policy development, program strategy, stakeholder engagement, and organizational transformations. She has served USG clients in over 20 countries, effectively engaged Embassies, ministries of health, labs and accreditation agencies, academia, and clinics to build sustainable capacity and strengthened public health policy. She has published thought leadership on public-private partnerships.

Project Objective and Expectations

Project Overview and Expectations

Deloitte will develop a plan to establish Virginia as a leader in Neuroscience/Addiction research and implementation science and as a beta test site for the nation.

Our Approach:

Competitive Benchmarking

Determine Virginia's competitive advantages understand the best practices and value propositions Virginia may have in their current capabilities or operations. This will be gleaned from assessing similar initiatives in other leading regions or states.

Deliverable

Competitive landscape analysis results with recommendations for addressing market needs through presentation, findings, and supporting data analytics document.

Gap Analysis

Assist VA Catalyst in understanding their Strengths, Weaknesses, Opportunities and Threats (SWOT) including key personnel, technologies and facilities in order to sustain and bolster successful practices and mitigate risks to success both internal and external.

Deliverable

SWOT Analysis with validated internal data and external market assessment.

Resource Validation Assessment

Perform a market analysis to assess size of funding from federal government and other sources to projects in Neuroscience/Addiction . Identifying funding priorities will be informative in further shaping and refining VA Catalyst's areas of prioritization and focus.

Deliverable

Report outlining government spending trends over the last five years for treatment, prevention and recovery.

Strategy, Roadmap, Business Plan

Operationalize VA Catalyst with milestones towards success, Key Performance Measures and a shared understanding of process and governance for success.

Deliverable

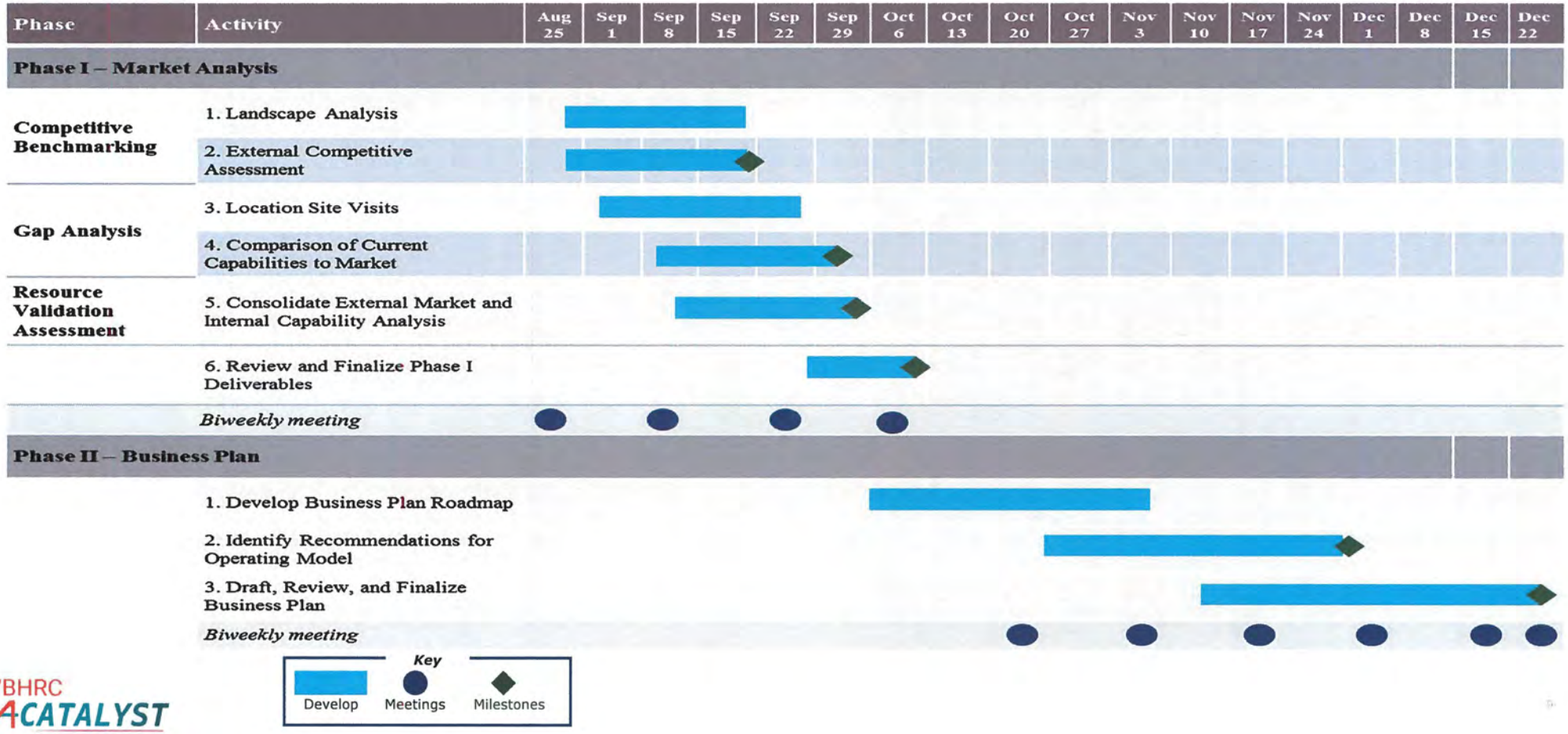
Roadmap and business plan.

VBHRC VA CATALYST

Review Engagement Approach, Activities and Collaboration Points

Proposed Project Timeline

The project timeline is 18 weeks and provides several opportunities to discuss progress and milestones.



VBHRC ACATALYST

Project Engagement and Collaboration Points

Our team will collaborate with members of the VA Catalyst organization to drive deliverable development and review throughout the project.

Milestone	Needs from VA Catalyst	VA Catalyst Owner(s)
Landscape & Competitive Assessment	Approval of final list of competitors, influencers and disrupters to evaluate	
Location Site Visits	Scheduling and access for site visits	
Comparison of Current Capabilities to Market	Data on current state capabilities, pricing, cost and sales	
Consolidate External Market and Internal Capability Analysis into Plan	Interviews (5), Review and approval of internal capability analysis	
Develop the Business Plan Roadmap	Review and approval	
Develop the Value Proposition and Mission Statement	Approval of final list of competitors, influencers and disrupters to evaluate	
Identify Recommendations for Operating Model	Participation in recommendation development and timelines	
Draft and Finalize Business Plan	Review and Approval	

Discuss Questions

Discussion Questions

It is important to clarify some operating assumptions ahead of the project to focus our efforts on mission critical activities.

- How did VA Catalyst determine the Centers of Excellence that they list in their strategy? Have any adjustments been made to that list?
  - Can this list be adjusted based on the outputs from this project?
- Are the technology alignments featured in the strategy final or will they be validated and reshape based on this analysis?
- What features and outcomes from the current industry leaders would VA Catalyst like to emulate?
- Would VA Catalyst structure support funding from government and private sector partners, e.g., AstraZeneca, GSK, Merck?
- The current scope will focus on Neuroscience/Addiction broadly but are there other data that VA Catalyst is using as a marker for a successful project?

Next Steps

Outlook for the Next Two Weeks

We are prepared to start Phase I of the project immediately

Activities

1 Landscape Analysis

- Identify similar programs engaged in research using a consortium model. Some programs include:
  - California Institute for Regenerative Medicine
  - Ohio River Valley Addiction Research Consortium
  - Wisconsin Alumni Research Foundation
  - The Global Cardiovascular Innovation Center
  - New York City Bioscience Initiative
  - Boston Biomedical Innovation Center

2 Finalize Framework and Execute Competitive Assessment

- Compare and contrast features from other programs to VA Catalyst. Points of comparison include:
  - Talent
  - Infrastructure
  - Budget
  - Publications
  - Patent Disclosures
  - Licenses
  - Follow-on Funding
  - New Companies

3 Confirm Meeting List and Schedule Site Visits

- Develop interview guide
- Identity SMEs at each site to interview
- Schedule interviews
- Conduct site visits

Appendix

Rules of the Road

A clear reporting structure and approval process is important for managing scope, deliverables and developing solutions to issues that arise along the way.

- → Adjustments to scope will require a change order and approval
- → VA Catalyst team will review and respond to requests in a timely manner
- → VA Catalyst will collate all edits from their members and share with Deloitte as a single communication to minimize version control issues

VBHRC
VA CATALYST

Project Activities: Competitive Analysis

Our team will collaborate with various members of the VA Catalyst organization to drive deliverable development and review throughout the project.

Milestone	Description	Needs from VA Catalyst
Landscape & Competitive Assessment	Perform research regarding similar programs and practices in the life sciences industry, other state initiatives and related policy areas	Decision on final list of competitors, influencers and disrupters to evaluate
Location Site Visits	Conduct site visits, in person and virtually, to gain additional and needed granular understanding of capabilities and other information across members of the VA Consortia	Scheduling and access for site visits
Comparison of Current Capabilities to Market	Comparison of internal and external market assessment to determine VA's competitive positioning	Data on current state capabilities, pricing, cost and sales
Consolidate External Market and Internal Capability Analysis into Plan	Produce report that contains the mission, vision, landscape, SWOT and Gaps analysis as well as risk and mitigation analysis	Interviews (5), Review and approval of internal capability analysis

Project Activities: Business Plan

Milestone	Description	Needs from VA Catalyst
Develop the Value Proposition and Mission Statement	Validate and update existing material to match current analysis	Decision on final list of competitors, influencers and disrupters to evaluate
Conduct Resourcing and Marketing Analysis	Evaluate current resourcing among consortium to expected demand	Provide resource data
Identify Recommendations for Operating Model	Develop recommendations, tested through analysis, for the operational processes needed to develop proposals and execute grants/contracts	Participation in recommendation development and timelines
Develop the Business Plan Roadmap	Develop process milestones and performance indicators to drive success and achieve stated goals	Review and approval
Draft and Finalize the Business Plan	Develop and document full plan and present findings internally and externally	Review and approval

Deloitte.

VACATALYST

The Virginia Catalyst – Phase I Deliverables

Deloitte Consulting LLP., October 2018

Deloitte Developed a Landscape Analysis, Funding Assessment and SWOT Analysis to Understand the Current Conditions Affecting the Commonwealth's Potential to Become the National Epicenter for Addiction Prevention, Treatment and Recovery

We found several themes that are important for Virginia in pursuing their dual goal of raising mega funding and becoming the national epicenter for addiction prevention, treatment and recovery.

- The need for advances in addiction treatment, specifically opioid addiction treatment, is strong and showing no signs of abating.
  - Opioid deaths (prescription, illicit, and synthetic) in Virginia increased by 34.7% from 2015 to 2016.[1]
  - Opioid deaths increased by 21.5% nationally in the same period. Opioid deaths are concentrated in the eastern half of the country.[1]
- There are addiction research programs (e.g., HEALing Communities Study) and new legislation (e.g., the SUPPORT for Patients and Communities Act) providing ongoing support for addiction and opioid solutions. However, public and private funding for Virginia and other organizations in the Commonwealth has remained relatively flat. Virginia does not rank in the top ten most funded states with respect to addiction.
- While Virginia has made an appreciable investment and advancements in prevention, treatment, & recovery programs, other factors impede the Commonwealth from being recognized as a unique addiction hub:
  - The opioid epidemic is not centered in Virginia.
  - Virginia is not a leader in reducing OUD fatalities through innovative evidence-based treatments.
  - The impressive research capabilities of the Commonwealth are not yet organized and operating in an effectively coordinated model.
- Virginia has the capabilities (and the nation has an ongoing need) to advance addiction research and treatment. Strategies, resources and research and treatment approaches must be organized, funded, and led towards making measurable addiction focused advancements that warrant the nationally recognized "beta/pilot" position.

[1] Drug Overdose Death Data. Opioid Overdose. Centers for Disease Control.

Section I: Landscape Analysis

Contents

Introduction

Competitive Landscape Approach

Deloitte gleaned insights from a range of sources to create this Competitive Landscape Analysis. Our methodology focused on gathering data from research professionals, luminaries in the field of addiction, and open source content.

Stakeholder Interviews

14 Researchers and Stakeholders

5 Public Research Universities

A complete list of names is available in Appendix IV - Interviewees

Electronic Surveys

- Distributed to **18** luminaries both within Virginia
- Received responses from **9** recipients for a total response rate of **50%**

Open and Proprietary Data Sources

- Gathered data from hundreds of government grant databases (such as USASpending.Gov), research journals, official press releases, open sourced data, and Deloitte proprietary knowledge repositories.

Competitive Landscape Analysis

- The Competitive Landscape Analysis (this document) details the current status of addiction prevention, treatment, and recovery in the United States.
- The Competitive Landscape Analysis is informed by the data sources shown on the left.

SWOT Analysis

- The SWOT Analysis (to be provided on September 28, 2018) will assess the strategic position of the Commonwealth of Virginia and Virginia Catalyst relative to other players in the addiction space, expected trends, and other forces.
- The SWOT Analysis will be informed by the data sources to the left, as well as the Landscape Analysis.

Addiction and Substance Abuse Cause 600K+ Deaths Annually in the U.S.

Addiction and substance abuse issues remain the top preventable cause of death in the United States.

Addiction and substance abuse disorder (SUD) is becoming increasingly prevalent in the United States of America. While opioids are often the focal point, addiction takes on many forms and may be triggered by a range of substances or behaviors, including alcohol, tobacco, illicit drugs, and prescription drugs. The negative impact of addiction is significant; addiction impacts the economy, social relationships, and public health.

- The economic toll of the opioid crisis since 2001 is estimated to be **$1 Trillion** (including lost productivity, criminal justice, and healthcare costs).[1]
- Excessive alcohol consumption costs Virginia more than **$5.3B per year**.[2]
- In 2016, **1,267** people died in Virginia of opioid overdoses. Of these, 803 were fentanyl and / or Heroin Overdoses, while 465 were prescription opioid overdoses.[3]
- Hepatitis C cases, which are positively correlated with injectable heroin use, increased by almost **three times** in the Commonwealth of Virginia between 2011 and 2017.[3]

480K

Cigarette related deaths

88K

Alcohol related deaths

42K

Opioid related deaths

Opioids Overdose Deaths in the U.S.

- Opioid (including illicit, synthetic and prescription opioids) overdose death rates have increased significantly over the last two decades (see chart to the right).
- Between 1999 and 2016, the number of opioid overdose deaths increased by **321%.**[4]
- There were **6.1** opioid overdose deaths per 100K people in 1999, 11.5 opioid overdose deaths in 2006, and **19.8** overdose deaths per 100,000 in 2016.[4]

[1] Litton, Sarah. Economic Toll of Opioid Crisis IN U.S. Exceeds $1 Trillion Since 2001. Altarum.
[2] Prevention Status Report 2013. Excessive Alcohol Use. Centers for Disease Control.
[3] Opioid Addiction. Virginia Department of Health.
[4] Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health.
Additional Sources: Alcohol Stats and Facts. NIH. ; The Health Consequences of Smoking –50 Years of Progress. A Report of the Surgeon General.

Major Themes

Major Takeaways from Landscape Analysis

Neither funding precedence, state of the epidemic impact, nor existing exercise of a coordinated statewide capability suggests an obvious path to the group's stated objectives.

Access to Funds:
Finding and acquiring "mega funding" up to $1B is an ambitious goal with significant challenges based on distributed funding streams from the government, government funding decision based on formulae rather than "best approach" and the diverse competitive pool of other states and leading non-profits.

Insights from Key Opinion Leaders:
Based on interviews with experts in the field, historic examples, and academic literature, the most effective treatment will likely include a combination of drugs, community engagement and technology to increase access to treatment and expedite sharing of information and data.

Private Giving:
There are few gifts by foundations and major donors to addiction prevention, treatment, and recovery.

Funding Position:
Virginia is not a leader in federal addiction related funding. Although Virginia receives significant federal funding for both research grants and grants for treatment and prevention of addictions, they are not one of the top 10 recipients.

States Showing Impact:
Vermont, Massachusetts, and Rhode Island are perceived to be leaders in addressing addiction but most of their progress is in prevention and treatment approaches, not in breakthrough therapies.[1] [2]

Virginia Catalyst Current State:
Virginia Catalyst has shown the ability to leverage their network and infrastructure to produce results in funding and research,[3] and Virginia has expertise, assets, leadership, and government support in place to help the state take a leading role in treatment and prevention.

[1] Brooklyn, John R. MD, and Sigmon, Stacey C PhD. Vermont Hub and Spoke Model of Care For Opioid Used Disorder: Development, Implementation, and Impact. Journal of Addition Medicine.
[2] Lopez, German. I looked for a state that's taken the opioid epidemic seriously. I found Vermont. Vox.
[3] Virginia Catalyst Website.

Funding Landscape

The Federal Government Obligated $4.8B* for Addiction Related Funding in 2018

There has been a 10% increase in addiction related federal funding since FY2017.

Federal Grants Nationwide in 2018

$3.6B	$501.0M	$361.2M	$130.8M	$1.0M	$222.7M
Substance Abuse	*Opioids*	*Alcohol*	*Smoking*	*Prescription Drugs*	*Public Health Emergency*

Grants to Virginia in 2018

$78.0M	$9.8M	$7.6M	$7.6M	N/A	$4.1M
Substance Abuse	*Opioids*	*Alcohol*	*Smoking*	*Prescription Drugs*	*Public Health Emergency*

Virginia's Ranking

14th	17th	16th	4th	N/A	17th
Substance Abuse	*Opioids*	*Alcohol*	*Smoking*	*Prescription Drugs*	*Public Health Emergency*

Comorbidity With Addiction†

$3.2B	$14.3M
HIV	*Hepatitis C*

$64.9M	$180K†
HIV	*Hepatitis C*

15th	27th
HIV	*Hepatitis C*

Formula Based Federal Funding

SAMHSA awarded more than $930M in State Opioid Response grants to support a comprehensive response to the opioid epidemic and **expand access to treatment and recovery support services.** However, this funding is based **on a formula** for state allocation. This formula considers the size of the state and the extent of the opioid problem in the state.[1]

HRSA is allocating $352M to **increase access to substance use disorder and mental health services** through the Expanding Access to Quality Substance Use Disorder and Mental Health Services to 1,232 community health centers across the nation. However, this funding is **also based on a formula**, which takes a state's MAT patients into account.[2]

Source: USASpending.Gov; Author's Calculations
Note: all rankings are based on a comparison of the 50 states in the U.S., tribes and territories
[1] State Targeted Response to the Opioid Crisis Grants, Funding Opportunity Announcement (FOA) No. TI-17-014
[2] HRSA, FY 2018 Expanding Access to Quality Substance Use Disorder and Mental Health Services (SUD-MH) Funding Opportunity
* Includes one time increase in Public Health Emergency grants
† Injection drug use increases the risk of blood-borne infections including HIV, hepatitis, and bacterial endocarditis, which spread efficiently through needle sharing. 2015 marked the first time in two decades where the number of HIV diagnoses attributed to IDU increased.

Major Private Funders for Addiction

While there are private donors and philanthropists gifting to addiction research, treatment, prevention and recovery, there has not been a great philanthropic response yet to addiction.

John and Eileen Grayken ($25M)

John and Eilene Grayken, in 2017, donated $25M to Boston Medical Center, the largest gift in the US in the last decade to addiction treatment. The money will establish the Grayken Center for Addiction Medicine at the hospital, and the hope is for it to become a hub for innovation in addiction treatment, and model for the rest of the nation to follow. The donors often donate privately and anonymously, but this time did so publically with the goal of "destigmatizing addiction and encouraging others to do the same."[1]

Conrad N. Hilton Foundation ($11.5M)

A multi-focused grant giving organization established through a major family gift. In 2017, the Conrad N. Hilton Foundation provided $11.5 M in substance abuse prevention grants to universities, non-profits and national associations, including National Opinion Research Center ($2.3), Friend Research Initiative ($1.8M) and Community Catalyst ($2.2M).[2]

Mark Pearson ($3M)

Originally donated anonymously in 2003, Mark Pearson eventually came forward as the founding donor for a center on Alcoholism and Addiction, within the Scripps Research institution. "It is my hope that by generating greater public awareness and additional financial support for biomedical and clinical research, future generations of families will be spared from the devastating effects of alcoholism and addiction."[3]

Smithers Foundation ($200K, annually)

Since 1956, the family charitable foundation has concentrated on alcohol use disorder, and educating the public that alcohol use disorder is a medical illness. In 2016, they gave out $200K in grants. Though Smithers Foundation's grants are smaller in scale, for six decades, Smithers has been one of the few funders out there paying attention to addiction medicine, mainly the prevention and treatment of alcoholism.[4][5]

In 2017, Inside Philanthropy, a leading publication tracking philanthropic donations, raised an alarm regarding addiction: *"Despite these alarming statistics, we're struck by **how few foundations and major donors** are dedicating resources to combating what's been called America's worst drug crisis ever. **Even fewer funders** are supporting the specific field of addiction medicine, which has a key role to play in addressing the crisis."*[5]

[1] Becker, Deborah, "With $25 Million Gift, Boston Medical Center Creates Hub For Addiction Medicine." CommonHealth.
[2] Hilton Foundation, "Substance Use Prevention Grantee, 2017"
[3] Pearson Center Website
[4] Smithers Foundation, "Annual Report FY2016"
[5] Moses, Sue-Lynn, "As the Toll from Opioids Grows, Who's Giving for Addiction Medicine?". Inside Philanthropy.

Major Funding Takeaways

Based on our analysis, we identified the following takeaways related to funding for addiction treatment and research.

The federal government allocates most of the **major grants based on a formula** (e.g., dependence or abuse of heroin or pain relievers who have not received any treatment), not by proposals or initiatives. This impacts the amount of funds that can be competed for **based on merit or initiative.**

There is **not a large revenue stream** coming from local or national nonprofit **organizations to address addiction or addiction research.**

There are limited **private donor dollars*** out in the market to be acquired (e.g. Boston Medical $25M gift), which are often going **to centers *treating* addiction, before research.**

**Limited reporting requirements present significant challenges to determining the total amount of funding from the private sector.*

Competitive Landscape

Competitive Landscape: States

California, Vermont, and Rhode Island highlighted below based on their funding streams or innovative programs. More extensive profiles of seven states with noteworthy characteristics in the battle on addiction may be found in Appendix II – Competitors.

California

California is the recipient of the largest sum of federal funding for the purpose of battling addiction.

- Using $90M of federal funding, California implemented "Medically Assisted Treatment (MAT) Expansion" in 2017. This expansion included the implementation of a Hub and Spoke model and increased attention to needs of California's underrepresented American Indian and Native Alaskan populations.
- California will receive an additional $69M beginning on September 30, 2018 to continue MAT Expansion. The second iteration will include Prevention & Treatment activities, such as developing additional MAT locations and providing MAT to priority communities, in addition to the above components.[1]

Why is it important?

Even with the largest sum of federal funds, California has not been the most effective state in reducing opioid overdose related deaths.

Vermont

Vermont's model has been validated in academic literature[2] and is being replicated in other states.

- Vermont pioneered the Hub and Spoke model of treatment and recovery in 2011, which uses specialized treatment facilities as central "hubs" and follow-up care units as "spokes."
- In 2015, Vermont had 15.8 opioid overdoes deaths per 100,000 people, below the national average (16.3 per 100,000) and well below the average in New England (24.6 per 100,000). The CDC predicts that Vermont will have an 8.6% decrease in opioid related deaths between February 2017 and February 2018 – the largest reduction in New England.[3]

Why is it important?

Vermont implemented a new model of treatment, to which the state attributes it's comparably low opioid overdose death rate.

Rhode Island

Rhode Island has implemented evidence based policies to reduce opioid deaths.

- Since 2016, Rhode Island Department of Corrections has screened inmates for opioid use disorder and provided medications for addiction treatment (methadone and buprenorphine) to those who need it. The program provides treatment to approximately 350 Rhode Islanders and costs $2M a year.
- In 2017, there was a 61% decrease in post incarceration deaths from opioid overdoses (as compared to 2016). This translates to a 12% reduction in death from opioid overdoses in the state's general population. Results published in JAMA, however, suggest that MAT was responsible for preventing death in 1 of 11 inmates treated.[4]

Why is it important?

By focusing on a population highly impacted by the opioid epidemic, Rhode Island has reduced the number of opioid overdose deaths statewide.

[1] California's Medication Assisted Treatment Expansion Project 2.0. California Department of Health Care Services.
[2] Brooklyn, John R. MD, and Sigmon, Stacey C PhD. Vermont Hub and Spoke Model of Care For Opioid Used Disorder: Development, Implementation, and Impact. Journal of Addition Medicine.
[3] Lopez, German. I looked for a state that's taken the opioid epidemic seriously. I found Vermont. Vox.
[4[Stacey, Kevin. Opioid addiction treatment behind bars reduced post-incarceration overdose deaths in Rhode Island. Brown University.

Competitive Landscape: Consortia

Many addiction and healthcare focused consortia exist across the country. A consortia model, wherein multiple institutions, agencies, or universities work together may enable each member to have a greater impact than they could have on their own. For The Virginia Catalyst, consortia serve as both competitors in the quest for funding, and organizational examples.

The Pearson Center For Alcoholism and Addiction Research

Researchers at The Pearson Center are galvanized by a shared a vision.

- As a research focused institution, the Pearson Center has leveraged the expertise of several independent research laboratories to produce novel treatments for substance abuse disorders.
- Labs have shown the effectiveness of cannabidiol in warding off memory impairment, discovered ways to "erase" memories associated with methamphetamine, and developed vaccines against methamphetamines.[2]
- Although acting independently, researchers at The Center share a vision and are committed to fighting addiction.

Why is it important?

A clear, shared vision provides a platform for members of a consortia to rally behind, potentially increasing output.

Colorado Consortium for Prescription Drug Abuse

Colorado successfully created an interagency team with state support.

- Focused on action, rather than biomedical research, the Colorado Consortium for Prescription Drug Abuse has fostered effective collaboration across government agencies and universities to provide education events, improving research and implementation projects, and over 220 overdose reversals reported via smartphone app.[2]
- While the consortia has saved lives, the total number of opioid overdose related deaths in Colorado has continued to rise.

Why is it important?

Even with state authority, the consortia has been unable to reduce the number of opioid related deaths.

California Institute for Regenerative Medicine

The Institute has achieved mega-funding through combined efforts from the state and private sector.

- CIRM aims to accelerate stem cell treatments to patients with unmet medical needs.
- CIRM's total budget exceeds $4.5B. Of this, $3B comes from the California State government in the form of bonds. More than $200M of funding comes from for-profit organizations.
- The Institute provides funding for researchers and institutions, investing almost $300M in research in 2017.[3]

Why is it important?

Combined with it's clearinghouse-like structure, CIRM was able to reach mega funding through a state referendum and private funding.

A complete list of the consortia researched for this initiative is available in Appendix II – Competitors. The consortia above were selected based on their ability to demonstrate a shared vision, interagency collaboration, and mega funding.

[1] Pearson Center for Alcoholism & Addiction Research website.
[2] Annual Report. Colorado Consortium for Prescription Drug Abuse Prevention.
[3] California Institute of Regenerative Medicine Website.

Competitive Landscape: Nonprofit Organizations

Combating addiction is a complex issue that involves action from organizations on all fronts. The addiction prevention, treatment, and recovery landscape includes a variety of players outside of government and research. The most prominent actors in this space are nonprofit organizations (NPOs).

Center on Addiction

Formerly the Center on Addiction at Columbia University, The Center recently reorganized and rebranded.

- The Center on Addiction underwent a transformation from a research enterprise to an action focused organization in 2017. Limited evidence exists to support the effectiveness of the new model.
- The Center has received significant funding from private organizations, with more than 40 private organizations donating more than $100K each.[1]

Why is it important?

Reorganizing as an independent action focused organization enabled The Center to shape their own path forward.

Hazelden Betty Ford Foundation

Hazelden Betty Ford Foundation is the world's largest nonprofit addiction treatment center.

- In 2014, the Betty Ford Center and Hazelden merged, forming the Hazelden Betty Ford Foundation. The Foundation treats all aspects of addiction as well as "co-occurring" disorders like depression and grief.[2]
- Key findings from a recent Butler Center for Research report on patient outcomes:
  - 85% to 95% of patients are abstinent from all other drugs nine months after rehab.
  - 80% of patients report improved quality of life and health after rehab.

Why is it important?

Hazelden Betty Ford has proven that they can deliver high treatment with results, even on a large scale.

PROACT

Modeled after Vermont's statewide approach, PROACT will open on October 1, 2018 in West Virginia.

- This outpatient medical facility will serve as a single regional referral point to assess patients following discharge from local emergency rooms and inpatient detox units and by other emergency medical response teams. PROACT is leveraging a hub and spoke model to relay care.
- PROACT is expected to support treatment for hundreds of individuals and significantly cut down on delay and waiting periods for those who want to seek treatment immediately as the facility will accept walk-ins as well as referrals.[3]

Why is it important?

PROACT is an example of a NPO mimicking a state program believed to be effective to address addiction.

A complete list of the NPOs researched for this initiative is available in Appendix II – Competitors. The NPOs above were selected based on their proximity to addiction.

[1] Center on Addiction website.
[2] Comparing Alcohol and Drug Rehab Success Rates. Hazelden Betty Ford Foundation Website.
[3] PROACT Website. T Website.

Major Competitor Takeaways and Outstanding Questions

Based on our analysis, we identified the following takeaways gathered from profiles of competing states, consortia, and nonprofit organizations.

The organizational structure of a consortia or nonprofit organization must be determined based on **that entity's mission**. There is not a single best way to structure an organization.

To achieve funding goals, nonprofit organizations and consortia often turn to **a variety of sources**, including state and local governments, the U.S. Federal Government, private donors and foundations, and other NPOs.

Large government grants **do not always lead to results**. Some of the highest funded organizations have been unsuccessful in reducing the prevalence of overdose related deaths.

Virginia's Position

Virginia Has Research Capabilities that Aim to Impact Addiction

The Commonwealth clearly possesses strong attributes required to achieve substantial advances in the field that must be operationalized to maximize advantage.

Physical Infrastructure

State of the art medical facilities and research laboratories exist across Virginia. For example, The Carilion Research Institute includes the Addiction and Recovery Research Center, a highly specialized facility for studying addiction. In addition, UVA is home to the UVA Research Park north of Charlottesville, which provides space for current and future studies. Furthermore, VCUHS MOTIVATE provides outpatient services for up to 600 patients a month, largely focused on opioid addiction.

Technical Infrastructure

Virginia is often regarded as a technology hub, especially Loudoun County. As a result of major private investments and other initiatives, data centers in Virginia process 70% of the world's internet traffic. The volume of activity may lead to opportunities for collaboration.

Technological innovations also exist that are specific to addiction, Virginia Tech created the VTRCI International Quit and Recovery Registry, a social platform through which participants access resources and meet virtually. At a city level, Richmond has analytics based tool that is used to predict when and where drug overdoses may occur. The city uses this for resource planning.

Research Projects

The seven universities included in The Virginia Catalyst are conducting research related to addiction. This research spans neurobiology, bioinformatics and computation, public health surveillance, and non-addictive pain treatment methods. While the outcome of these initiatives is currently unclear, they may bring new insights into the best approach for fighting addiction.

What does this mean for The Virginia Catalyst?

Virginia has already made significant investments to stand up resources that may be used as the Commonwealth seeks to address the opioid epidemic and addiction as a whole. Other states, such as California, have dedicated more funding toward biomedical research (i.e. $3B to CIRM, discussed in later slides) or are better known than Virginia as biomedical innovation hubs (i.e. Cambridge, Massachusetts). Even so, Virginia has top ranked research institutions that could be leveraged to strengthen the Commonwealth's position. Many of these resources (and the associated talent) are currently linked to The Virginia Catalyst and may provide a foundation for Virginia to build upon.

[1] Stakeholder Interviews.
[2] VA Catalyst Documentation.
[3] Neibaur, Michael. Microsoft makes a massive buy in Loudoun County. Washington Business Journal. September 23, 2018.

Virginia Has Launched Statewide Programs to Combat Addiction

The Commonwealth has statewide programs focused on expanding access to treatment that will help position Virginia to be a leader in the field of addiction.

Addiction and Recovery Treatment Services (ARTS)

The ARTS is a waiver program that expands access to residential treatment for all Medicaid members. Virginia was the fourth state to obtain permission from federal health officials to use Medicaid funds for residential treatment facilities with more than 16 beds. As of April 2018, a total of 10 states had applied for waivers and 11 additional states had applications pending.*

Impact

Following Medicaid expansion, Virginia has more than **400K** Medicaid eligible citizens.[1] Each of these citizens will be able to receive treatment if needed.

REVIVE!

REVIVE! is the Opioid Overdose and Naloxone Education program supported by the Virginia Department of Behavioral Health and Developmental Sciences (DBHDS) and the Virginia Department of Health (VDH) that provides training to laypeople on how to recognize and respond to a potential opioid overdose. In addition to training, VDH will also provide Narcan at no charge through the local health department.

Impact

In the first five months of 2018, the program trained **2959** Lay Rescuers and **1662** Law Enforcement Rescuers.[3]

Virginia Project ECHO

The Virginia Department of Health (VDH) is developing "Extension for Community Healthcare Outcomes" (Project ECHO). The ECHO model is a telehealth platform focused on fostering knowledge sharing and collaboration among medical professionals and addiction specialists.

Impact

Virginia ECHO is currently seeking a partner institution to serve as their hub. According to the most recent public information, ECHO is not yet in full operation.

Political Support may Lead to Future Programs

Virginia's statewide programs have increased access to treatment by providing expanded coverage for those who need it and creating a community that is more prepared to address the crisis. Politicians on both sides of the political aisle, including Governor Ralph Northam, Senator Tim Kaine, opposing senatorial candidate Cory Stewart, have all publicly acknowledged the opioid epidemic and committed to addressing the challenge (albeit in different ways).[2] Virginia also declared the opioid epidemic a public health emergency in 2016.[4] These actions indicate a dedication to fighting addiction, especially opioid addiction, in the Commonwealth.

*As of April 2018, ten states had received waivers: California, Indiana, Kentucky, Louisiana, Maryland, Massachusetts, New Jersey, Utah, Virginia, and West Virginia. 11 states had waivers pending: Alaska, Arizona, Illinois, Kansas, Michigan, North Carolina, New Mexico, Pennsylvania, Vermont, Washington, and Wisconsin

[1] Opioid Program Increases Access to Treatment Across the Commonwealth. Office of the Governor. April 23, 2018.
[2] Olivo, Anthonio. In Va., Kaine and Stewart offer differing views on the opioid crisis. The Washington Post. September 3, 2108.
[3] REVIVE! Opioid Overdose Reversal for Virginia. May 2018.
[4] Schneider, Gregory S. Virginia declares opioid emergency, makes antidote available to all. The Washington Post. November 21, 2016.

Key Themes from Interviews

Thought leaders on addiction in the Commonwealth shared suggestions and insights for how Virginia can succeed in efforts to address the addiction issue in Virginia.

Summarized Themes

- A holistic solution that includes medication, data analysis, behavioral therapy, and other community-based interventions is going to be needed to make an impact on addiction.
- Consortia models tend to benefit from having a central hub with resources and personnel with decision making authority to guide the efforts of the consortium.
- Virginia has to work with what we have now, not wait for HEAL or other programs to create drugs and therapies in the future.
- An integrated system that leverages technology innovation for interoperability and data sharing will contribute to making Virginia a leader in this area.
- The Commonwealth lacks sufficient treatment approaches for marginalized individuals, rural communities, and pregnant women.

Sound Bites

Addiction has many forms. A strategy to address addiction must include food, alcohol, and other areas.

Any approach to addiction must be multifaceted and address both the science, as well the behavioral piece and treatment.

The budget required for the Catalyst to be successful is way in excess of current funding, and Virginia will need to be creative and collaborative in order to achieve its goals.

We must address the root cause of addiction, instead of treating the symptom.

Nobody is doing anything very different. The work we are doing doesn't stand out.

Major Takeaways Regarding Virginia's Current Position

Based on our analysis, we identified the following takeaways related to Virginia's current position.

Virginia's robust research and technological infrastructure, community program, and political support make the Commonwealth **well positioned** to address addiction.

Many stakeholders believe that Virginia falls short of delivering an **integrated solution** that bridges the gap between research, clinical, and community program. Instead these components exist in silos.

Virginia has taken significant action to address addiction, especially opioid addictions in the last 5 years. However, many feel **Virginia has not gone far enough.**

Case Study: HIV/AIDS

Case Study: HIV/AIDS

Virginia may be able to glean important takeaways or best practices from the HIV/AIDS epidemic of the 1980's and 1990's as it seeks to be recognized as a leader in addiction prevention, treatment, and recovery.

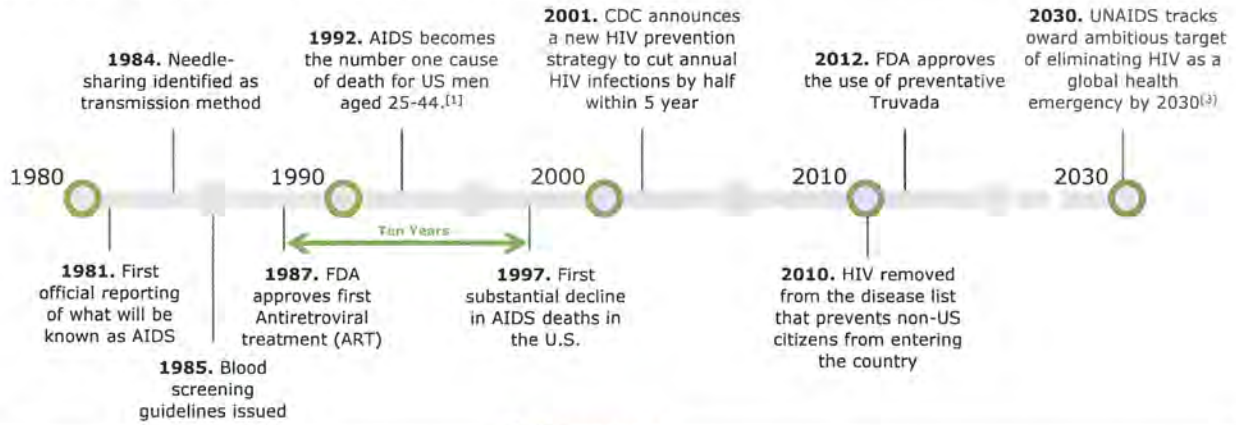
Similar Characteristics

The HIV/AIDS crisis of the 1980s and 1990s is **analogous to today's opioid epidemic** in many ways. Both epidemics:

- Emerged rapidly
- Disproportionally affect underserved communities
- Are or have been sources of social stigma

Key Facts

- Many doctors initially stigmatized HIV/AIDS as a GRID or "Gay- Related Immunodeficiency." This terminology increased stigma and had serious long term consequences for women, heterosexual men, and those who inject drugs.[2]
- Social pressure galvanized political action and increased funding for HIV/AIDS related programs.
- The first medical treatment for HIV was approved by the FDA in 1987, 6 years after the first report of AIDS.
- Funding for HIV/AIDS research, prevention, and treatment came from sources across sectors, including domestic funding, international funding, bilateral and multilateral assistance, and private funding. In 2003, PEPFAR committed $15B USD to tackle the crisis. The Bill and Melinda Gate Foundation has provided more than $3B in grants to date.[4]



Takeaways

- **The pipeline from drug discovery to impact in society can be long**. Ten years passed between FDA approval of the first ART and the first substantial decline in AIDS deaths in the U.S.
- **Funding to combat HIV/AIDS comes from a range of sources.** Federal funding, international funding, and private donors have contributed to the battle. International funding (bilateral, multilateral, etc.) makes up a significant portion of funding.
- **Surveillance** is critical to responding to the epidemic. Monitoring cases increases public health officials' ability to track the epidemic and deploy responses effectively.
- Destigmatizing the condition increases public support and drives political will, leading to more funding.
- **Prevention** deserves primacy. Even as the death rate associated with the disease decreases, sustained education and prevention is required to control the epidemic.
- **Innovative science exceeded the expectations of skeptics**. Major improvements have been made in diagnosis, prevention, and treatment of HIV/AIDS.[1]

[1] HIV and AIDS Timeline. CDC.
[2] A Timeline of HIV/AIDS. AIDS.gov
[3] Fast Track Strategy to end the AIDS epidemic by 2030. UNAIDS.
[4] Funding for HIV and AIDS. Avert.

Next Steps from the Landscape Analysis

The landscape analysis identified key areas for further exploration that will inform the identification of gaps, opportunity areas for Virginia Catalyst, and an approach to become a leader in the market for solutions to address additions.

- Update initial findings of the landscape analysis after completion of electronic survey and remaining interviews.
- Identify and categorize gaps in the current portfolio of solutions being offered by the states, nonprofits and consortia competing with Virginia Catalyst.
- Develop SWOT as a guiding structure to map internal resources and capabilities to identified opportunity areas.
    - Create maps of areas to focus on and enhance.
- Develop a plan forward for Virginia Catalyst to become a national leader in addiction research.

Upcoming Deliverable Timeline

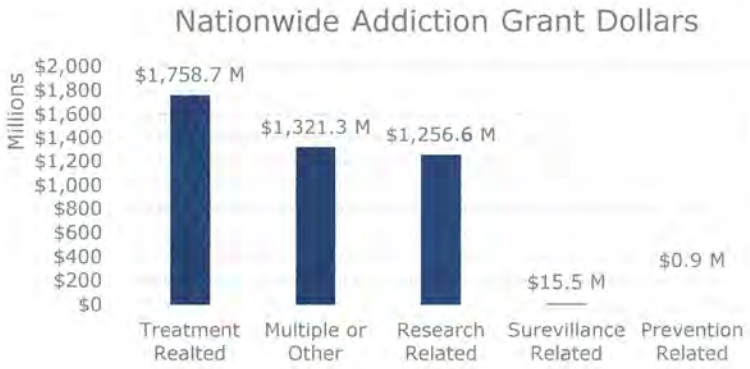
The table below shows each of the upcoming deliverables and their current due dates. This information has been populated based on the initial project proposal and follow up conversations with The Virginia Catalyst leadership.

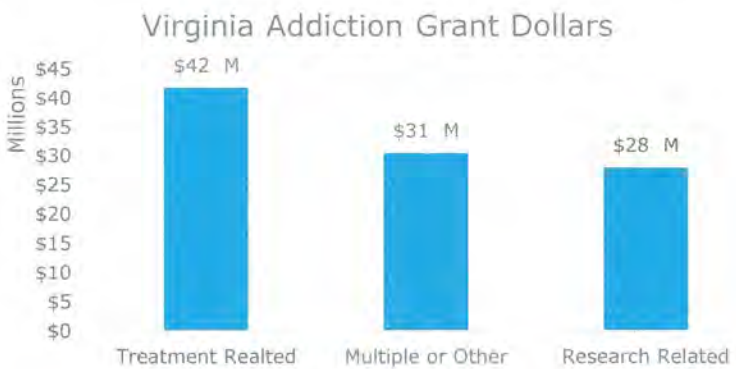
Deliverable	Due Date	
Competitive Landscape Analysis	9/24	This Deliverable
SWOT Analysis	9/28	
Resource Validation Report	10/5	
Roadmap and Business Plan	12/15	

Appendix I – Financing Data

Funding Landscape

Grant dollars for addiction can be categorized into research, prevention, treatment, surveillance or other, with "Multiple or Other" grants including the State Targeted Response to Opioids (STR), as well as SAMHSA "Projects of Regional and National Significance."





Virginia's dollar allocation is in proportion to what the overall federal landscape is, with Treatment being 41%, Multiple being 31% and Research being 28%.

Other US States

Across the country, other states with major funding have received different proportions of funds, as well as access to other revenue sources

California received slightly more proportioned dollars for addiction Research (35%) than the national average.

Texas received close to 60% of their addiction related funds within Treatment, and only 19% within Research.

California, Florida, New York and Massachusetts (as well as 16 other states) received addiction Surveillance and Monitoring funding through the Department of Justice. Virginia was not a recipient.

Of funding to Connecticut, Maryland and North Carolina, 50% of it was to Research related activities.

* Source: USASpending.Gov

**Grant CFDA Titles Include: Alcohol Research Program, Comprehensive Opioid Abuse Site-based Program, Consortium For Tobacco Use Cessation Technical Assistance Financed Solely By Prevention And Public Health Funds, Drug Abuse And Addiction Research Programs, Drug Abuse National Research Service Awards For Research Training, Drug Court Discretionary Grant Program, Drug-free Communities Support Program Grants, Family Smoking Prevention And Tobacco Control Act Regulatory Research, Harold Rogers Prescription Drug Monitoring Program, Indian Country Alcohol And Drug Prevention, National State Based Tobacco Control Programs, Opioid Str, Pphf-2012 Cooperative Agreements For Prescription Drug Monitoring Program Electronic Health Record (EHR) Integration And Interoperability Expansion, Tobacco Prevention And Control Legal Technical Assistance, Tribal Justice Systems And Alcohol And Substance Abuse

† Hepatitis Related funding is from 2018, due to 2018 being the first year of Hepatitis specific funding, in response to larger instances of the disease

Targeted Areas for Federal Government Funding

On September 18th 2018, HHS announced an additional $1B in funding to target specifically the opioid epidemic. Although the Catalyst mission is larger than just opioids, this disbursement of funds mirrors how dollars for other addictions are distributed.

SAMHSA awarded more than $930 million in State Opioid Response grants to support a comprehensive response to the opioid epidemic and **expand access to treatment and recovery support services.**

The grants aim to address the opioid crisis by **increasing access to medication-assisted treatment** using the three FDA approved medications for the treatment of opioid use disorder, reducing unmet treatment needs, and reducing opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder.

States received funding ***based on a formula***, with a 15 percent set-aside for the ten states with the highest mortality rate related to drug overdose deaths.

In addition, SAMHSA also awarded about $90 million to other programming for states and communities to **expand access to medication-assisted treatment, increase distribution and use of overdose reversal drugs, and increase workforce development activities.**

HRSA awarded over $396 million to combat the opioid crisis. The investments will enable HRSA-funded community health centers, academic institutions, and rural organizations to expand access to integrated substance use disorder and mental health services.

$352 million awarded to **increase access to substance use disorder and mental health services** through the Expanding Access to Quality Substance Use Disorder and Mental Health Services to 1,232 community health centers across the nation.

$18.5 million to support **Behavioral Health Workforce Education and Training** and Enhancing Behavioral Health Workforce.

$25.5 million to over 120 **rural organizations** to increase access to substance abuse prevention and treatment services serving rural populations across the country.

The **CDC** awarded $155.5 million to increase support for states and territories working to **prevent opioid-related overdoses, deaths, and other outcomes**. This funding will advance the understanding of the opioid overdose epidemic and **scale-up prevention and response activities**, including improving the timeliness and quality of surveillance data.

In addition, CDC awarded $12 million in funds to support 11 Tribal Epidemiology Centers and 15 tribal entities. These funds will improve opioid overdose surveillance so that prevention strategies can be targeted to better address this threat to tribal communities.

CDC is also distributing an additional $27 million to nine non-governmental organizations, which will support states and territories with **staffing, procurement, and training to enhance local public health capacity**.

NIH HEAL

A $500 M funded program at NIH, with an ambitious and targeted research plan focused on tackling unmet needs of those with opioid addiction and chronic pain. These research priorities **include *Improve Treatments for Opioid Misuse and Addiction*** through expanding therapeutic options for opioid addiction, overdose prevention and reversal, enhancing treatments for infants born with Neonatal Abstinence Syndrome (NAS)/Neonatal opioid withdrawal syndrome (NOWs) and optimizing effective treatment strategies for opioid addiction. The second research priority is to ***Enhance Pain Management*** through understanding the biological underpinnings of chronic pain, accelerating the discovery and pre-clinical development of non-addictive pain treatments and advancing new non-addictive pain treatments through the clinical pipeline. Improve Treatments for Opioid Misuse has an allocated $217 M, and *Enhance Pain Management* has an allocated $48.5 M. There is an additional $234 M in carryover funding that will be allocated as well.

Appendix II – Competitors

Competitive Landscape: California

California, the number one state in terms of funding dollars from the federal government, has introduced several programs to address the opioid crisis and the larger addiction problem.

- Using $90M of federal funding, California implemented "Medically Assisted Treatment (MAT) Expansion" in 2017. This included two major components:
  - In The California Hub and Spoke System, modeled after Vermont's system, Narcotics treatment Programs (NTPs) serve as the hubs, while physicians serve as the spokes.
  - Tribal MAT Project is designed to meet the specific needs of California's American Indian and Native Alaskan tribal communities.
- California will receive an additional $69M beginning on September 30, 2018 to continue MAT Expansion. The second iteration will include Prevention & Treatment activities in addition to building on the two components above.
- The second wave of expansion will develop additional MAT locations, provide MAT to priority communities, and enact additional opioid overdose prevention activities.

California has received the most addiction related grant money, but there haven't been any major innovations in treatment or research.

Source: California's Medication Assisted Treatment Expansion Project 2.0. California Department of Health Care Services.

Competitive Landscape: Massachusetts

Massachusetts has deployed very successful community based programs in regions throughout the state, reducing substance use, especially for young adults and teens.

- In the rural Franklin County and North Quabbin region of Massachusetts, the **Communities that Care** coalition model was adopted more than a decade ago with the goal of building community capacity to implement evidence-based approaches to improving youth health and well-being.
- Since the coalition's work began 15 years ago, the region has seen dramatic reductions in youth substance use and a substantial reduction in the number of risk factors per youth in the community. A recent independent review of the program found compelling evidence that the coalition's efforts undoubtedly contributed to these reductions. Between 2003 and 2017, the region has seen a 54 percent reduction in alcohol use, a 63 percent reduction in binge drinking, and a 33 percent reduction in marijuana use. And from 2014 to 2017, the region had a reduction in the number of 12th graders who used prescription drugs overall and opioids specifically.[1]
- The Coalition is currently funded by a local nonprofit hospital that provides them with community benefit funds, but for much of its existence, the staff that supported the basic functions of the coalition was financed through time-limited grants, which meant some activities had to be postponed until the coalition could shore up additional grant funding.

Sustainable funding is critical since funding gaps can put stress even on successful programs and threaten a program's effectiveness and long-term viability.

Source: Franklin County/North Quabbin Teen Health Survey 2003-2017

Competitive Landscape: New York

New York's operating model has been in action for decades. While New Yorkers have greater access to treatment than many others in the country, the system in New York can be costly.

- The state of New York has an autonomous Office of Alcoholism and Substance Abuse (OASA) within the Department of Mental Hygiene, which sits outside of the Department of Health.
- OASA provides services across prevention, treatment, and recovery, including 24/7 treatment facilities, and supportive housing for eligible individuals or families.
- OASA has an annual operating budget of $322M. Of that, $118M went to outpatient support (2018).
- In 2017, OASAS provided funding for a $25.6M substance use disorder treatment center on Wards Island.
- In response to the opioid crisis, the state now requires insurers to allow consumers to appeal coverage denials for medically necessary addiction medications.

New York receives significant federal funding, which they use to target community programs operated by the Department of Mental Hygiene.

Competitive Landscape: Ohio

Ohio has reduced access to opioids and increased access to MATs.

- Governor John Kasich created the Governor's cabinet Opiate Action Team to attach opiate abuse "on every front".
- Since the creation of this team, the state has taken a number of actions to **increase access to MAT** and **reduce the availability of opioids**. Many of these changes were included in SB319.
- As a result of these efforts
  - Doctor shopping for opiates has been reduced by **78%**, as compared to 2012.
  - The number of opioid doses dispensed to Ohio patients decreased by almost **92M** from 2012 to 2015.
  - The number of patients prescribed opioid doses higher than chronic pain guidelines dropped by **11%** (from Q4 2013 to 2015).
- Even with reduced access to opioids, and increased availability of MATs, the number of opioid related deaths in Ohio has risen, and is expected to continue to rise. This raises questions as to the effectiveness of Ohio's efforts.

Even with reduced access to opioids, and increased availability of MATs, the number of opioid related deaths in Ohio has risen, and is expected to continue to rise.

Competitive Landscape: Rhode Island

Rhode Island has developed incarceration treatment programs that have reduced deaths in the state.

- Since 2016, Rhode Island Department of Corrections has screened inmates for opioid use disorder and **provided medications for addiction treatment** (methadone and buprenorphine) to those who need it.
- In 2017, there was a 61% decrease in post incarceration deaths from opioid overdoses (as compared to 2016). This translates to a **12% reduction in death from opioid** overdoses in the state's general population.

Medically Assisted Treatment (MAT) in Prisons:

- The State of Rhode Island, and communities such as New Haven and Bridgeport, provide MAT to incarcerated individuals who show signs of opioid addiction.
- The precise effectiveness of these treatments is unclear, with anecdotal evidence suggesting a 61% reduction and the academic literature (JAMA) suggesting that MAT treatment in prison could prevent opioid related deaths in at least 1 out of 11 inmates treated.
- Studies also suggest that inmates who receive MAT in conjunction with counseling spend seven times as many days in drug abuse treatment in their first year after release, as compared to those who receive counseling alone.

Rhode Island was able to dramatically impact post incarceration deaths by providing MAT within the prison system.

Source: Trickey, Erick. How the Smallest State is Defeating America's Biggest Addiction Crisis. Politico Magazine.

Competitive Landscape: Texas

Texas received significant federal funding, but has limited programs that impact the state's substance abuse population.

- Texas received a total of $255M in federal funds for addiction related activities.
- Texas provides treatment to individuals seeking help with substance abuse via the states Outreach, Screening, Assessment and Referral Centers (OSARS). While immediate help is provided 24 hours a day via a phoneline, specific populations (i.e. pregnant women) are given priority when waiting lists form.
- In response to the opioid epidemic, Texas formed Texas Targeted Opioid Response (TTOR).
- TTOR provides a range of services across the state, covering prevention, opioid specialized crisis services, and providing re-entry support for incarcerated individuals.

Texas received major federal funding, but has limited innovative approaches to addressing addiction.

Source: Summary of Initial Report of Recommended Strategies to Governor Phil Scott. Vermont Opioid Coordination Council. January 2018.
Lopez, German. I looked for a state that's taken the opioid epidemic seriously. I found Vermont. Vox.

Competitive Landscape: Vermont

Vermont has taken notable actions to address the opioid epidemic, including the development of the Hub and Spoke treatment model. This model has been duplicated by other states.

- The Governor's Opioid Coordination Council was created in January 2017 to "lead and strengthen Vermont's response to the opioid crisis by ensuring full interagency and intra-agency coordination between state and local."
- The Council issued their first set of recommendations in January 2018. It included developing a continuum of care, improving Vermont's statewide data collection and analysis capabilities, and expanding access to MAT in all Vermont correctional facilities.
- Additionally, the recommendations called to support, evaluate and improve Vermont's Hub and Spoke model for opioid treatment.
  - This model has reduced the number or patients waiting for treatment by almost 80% between 2014 to 2017.
  - As a result of Medicare expansion associated with the Affordable Care Act (ACA), most of the expenses incurred by the system's patients are absorbed by the federal government.
  - In 2015, Vermont had 15.8 opioid overdoes deaths per 100,000 people, below the national average (16.3 per 100,000) and well below the average in New England (24.6 per 100,000).

Vermont's Hub and Spoke Model has been identified nationally as something for other states to adopt.

Competitive Landscape: The Pearson Center for Alcoholism and Addiction Research

An example of how a private gift creating a strong vision galvanizes research.

- Established in part due to a private donation by an individual for $3M in 2003 to establish the center as a part of the Scripps Research Center.
- As a research focused institution, the Pearson Center for Alcoholism and Addiction Research has leveraged the expertise of several independent research laboratories to produce novel treatments for substance abuse disorders.
- Labs have shown the effectiveness of cannabidiol in warding off memory impairment, discovered ways to "erase" memories associated with methamphetamine, and developed vaccines against methamphetamines.
- Housed within the Scripps Research Institute, researchers have access to a range of cutting edge equipment and technologies.
- Although acting independently, researchers within the Pearson Center share a vision and are committed to fighting alcoholism and addiction.

Pearson was able to secure a multimillion dollar private gift donation, which shows precedent for philanthropic dollars for addiction research initiatives.

Pearson Center
for Alcoholism & Addiction Research

Competitive Landscape: Colorado Consortium for Prescription Drug Abuse

Collaborative consortiums models increase impact and promote fund raising.

- Focused on action, rather than biomedical research, the Colorado Consortium for Prescription Drug Abuse has fostered effective collaboration across government agencies and universities.
- Provides education events, improving research and implementation projects, and over 220 overdose reversals reported via smartphone app.
- Created the Consortium based on an approach to collaborative work by the Collective Impact Forum, a nonprofit that exists to provide tools and training to support the efforts of a collaborative approach.
- Action driven by ten working groups focused on various intervention areas, e.g. public awareness, Heroin response, data.
- Develop policies, programs, and partnerships with Colorado agencies, organizations, and community coalitions.
- Colorado Consortium is a state funded enterprise, it does not receive federal funds directly.

Colorado Consortium, while demonstrating a coordinated organizational model, still has seen significant deaths related to opioids this year.

COLORADO CONSORTIUM
for Prescription Drug Abuse Prevention

Competitive Landscape: CIRM

A California nonprofit with a unified mission that has received major public and private funding but has had no impact currently on addiction research or treatment.

- While CIRM is not focused on addiction, the Institute has achieved **mega-funding** through combined efforts from the state and private sector.
- Established in 2004, the CIRM aims to accelerate stem cell treatments to patients with unmet medical needs.
- CIRM's total **budget exceeds $4.5B**. Of this, $3B comes from the California State government in the form of bonds.
  - More than $200M of funding comes from for-profit organizations.
- The Institute provides funding for researchers and institutions, investing almost **$300M** in research in 2017.
- Five program areas that CIRM focuses on: Infrastructure, Education, Translation, Discovery, and Clinical.

CIRM has created an organizational structure that allows for thriving partnerships with private industry, allowing for more revenue streams for research.

CIRM
CALIFORNIA'S STEM CELL AGENCY

Competitive Landscape: Center on Addiction

A nonprofit that recently changed their mission in response to ongoing epidemics, and is positioned to become a thought leader and competitor for a larger share of resources.

- In 2017, The Center on Addiction, formerly The Center on Addiction and Substance abuse at Columbia University, underwent a transformation from a research repository into an **action focused organization**. This was coupled with a complete rebrand in 2018.
- The Center has received significant funding from private organizations, with more than 40 private organizations donating more than $100K each.
- Along with private organizations, Center on Addiction released The SIRT for Health Professionals app and LOCADTR 3.0, both of which support which guides providers treating patients with addiction.
- The Center translates decades of research into tools for policy makers, healthcare professionals, and community members as these groups combat addiction.

Center on Addiction has reorganized their structure and separated from universities to better attract outside funding.

Center on Addiction

Competitive Landscape: Hazelden Betty Ford Addiction

The leading treatment and recovery center for all addictions, with major private funding.

- In 2014, the Betty Ford Center and Hazelden merged, forming the nation's largest nonprofit addiction treatment center, the Hazelden Betty Ford Foundation. The Foundation treats all aspects of addiction as well as "co-occurring" disorders like depression, anxiety and grief.
- In 2012, Hazelden launched a new addiction treatment protocol designed to address the issue that more people were becoming addicted to heroin and other opioids, and dying from overdose.
- Key findings from a recent Butler Center for Research report on patient outcomes:
  - 88.64% of patients are alcohol-free one month after rehab.
  - 85% to 95% of patients are abstinent from all other drugs nine months after rehab.
  - 80% of patients report improved quality of life and health after rehab.
- Providing small instances of tele-health and other long term recovery programs.
- Annual operating revenue: $182 M.

Hazelden Betty Ford continues to provide and adapt treatments to new addictions, but is reactive and not necessarily novel in it's approaches.

Hazelden Betty Ford Foundation

Competitive Landscape: PROACT

A West Virginian nonprofit that is quickly being established, modeled after the Vermont approach to referrals and treatment, to help reduce mortality.

- Provider Response Organization for Addiction Care & Treatment, a West Virginia nonprofit established in 2018 and opening their doors on Oct 1.
- This outpatient medical facility will serve as a single regional referral point to assess patients following discharge from local emergency rooms and inpatient detox units and by referral from our quick response teams and other emergency medical response teams. PROACT is leveraging a **hub and spoke** model to relay care.
- PROACT is expected to support treatment for hundreds of individuals and significantly cut down on delay and waiting periods for those who want to seek treatment immediately as the facility will accept walk-ins as well as referrals.
- The program is funded in part by a $332,601 grant from the West Virginia Department of Health and Human Resources.

PROACT hasn't started yet, but leverages best practices from other states to reduce treatment wait times in West Virginia.

PROVIDER RESPONSE ORGANIZATION
PROACT
FOR ADDICTION CARE & TREATMENT

Competitive Landscape: Howard Hughes Janelia Research Campus

A Virginia research institute, that while not addiction focused, is a leader in scientific breakthroughs and looking in 2018 for the next area to invest their resources.

- Located in Ashburn, Virginia, Jenelia Research Campus is cracking open scientific fields by breaking through technical and intellectual barriers.
- In 2017, they moved to a 15-year research model in which a given research area is focused on for 15 years to gain traction and attract outside interest. This approach enables Janelia to stay at the frontier of science, advancing 1-3 research areas at any point in time.
- Their first new research area leverages and transforms Janelia's program on neural circuits and behavior, pursing one of the biggest questions in brain science. This integrated program enables tool-builders, biologists, and theorists to **collaborate** to clear the technical, conceptual, and computational hurdles that have kept the most intriguing aspects of cognition beyond the purview of mechanistic investigation.
- Going forward, HHMI will hold open competitions to determine Janelia's future research areas. They plan to announce their first competition for new or novel research areas later in 2018.

Janelia, though not addiction focused, uses a collaborative model to bring difference sciences together to bring forward cutting edge discoveries.

Competitive Landscape: McShin Foundation

A Virginia based nonprofit that works hand in hand with the community to deliver treatments for alcohol and substance abuse.

- "Virginia's leading nonprofit", McShin Foundation is a full-service Recovery Community Organization (RCO), committed to serving individuals and families in their fight against Substance Use Disorders. While providing the tools for recovering individuals to create positive lifestyles, they aim to spread the word of recovery and educate families, communities, and government regarding SUDs as well as reduce the stigma attached to them.
- The McShin Foundation is an alternative to drug and alcohol treatment, drug and alcohol rehab, and drug and alcohol detox.
- McShin's operating budget is approximately $2M annually, predominately going directly to treatment centers or "scholarships" for uncovered individuals.

McShin has worked hand in hand with Virginia communities but is limited in ability to assist all constituents due to resource demands.

McShin
a Recovery
Resource Foundation

Competitive Landscape: SAARA

Substance Abuse & Addiction Recovery Alliance is an advocacy grassroots organization within Virginia serving the constituents in all matters related to addiction within the commonwealth.

- SAARA, the Substance Abuse & Addiction Recovery Alliance, "maximizes the power of the people" to advocate for treatment and recovery in order to prevent the harmful effects of substance abuse upon families, businesses, and the community.
- SAARA promotes social, educational, legal, research and health care resources and services that support accessible, effective and accountable addiction prevention, treatment and recovery.
- SAARA's funding is supported by the Substance Abuse Prevention and Treatment Block Grant by contract with the Virginia Department of Behavioral Health and Developmental Services and funding from Richmond Behavioral Health Authority.

SAARA is the leading addiction advocacy alliance in Virginia, and will have influence and insight for any new addiction organizations within Virginia.

SAARA

Appendix III – Research Capabilities

Research Institutions in The Virginia Catalyst

The Virginia Catalyst is composed of strong research institutions, with exceptional capabilities in the biological sciences, computation, and neurobiology.

Virginia Tech

- The Carilion Research Institute includes the **Addiction and Recovery Research Center** with state of the art resources.
- The VTRCI **International Quit and Recovery Registry** is an online social platform where participants can access resources and have virtual meetings.
- Brain imaging studies research how the **brain responds to addiction.**

Virginia Commonwealth University

- Receives the ninth largest sum from NIH for studying addiction.
- Research into the genetic indicators of alcohol addiction.
- VCUHS MOTIVATE provides outpatient services for up to 600 patients a month, largely focused on opioid addiction.

University of Virginia

- Center for Addiction & Prevention Research has expertise in health promotion and disease settings, especially in military settings.
- Extensive public health **surveillance** capabilities.
- Research focused on non addictive approaches to **pain management.**
- **UVA Research Park** north of Charlottesville provides space for current and future studies.

George Mason University

- Strong **proteomics** and patented protein painting technologies drive drug discovery.
- Center for Adaptive Systems of Brain- Body Interactions is currently searching for **non addictive pain therapies** and imaging children's brains to predict addictive behavior.
- Specialized research in bioinformatics, **computational neuroanatomy**, and Geoinformation science.

Eastern Virginia Medical School

- Medical school with specialized training in addiction and substance abuse.
- Geographically located in one of the areas hardest hit by the opioid epidemic.

William and Mary

- Microscopy and Photography Facilities.
- Molecular Core Facility.

Old Dominion

- Research facilities in Norfolk.
- Geographically located in one of the areas hardest hit by the opioid epidemic.

Appendix IV – Interviewees

Interviewees

The list below details with which luminaries the Deloitte team interviewed and the method used to do so.

Type	Interviewee
Interview	Michael J. Friedlander, Ph.D.
Interview	Warren K. Bickel, Ph.D.
Interview	Robert Trestman, Ph.D., M.D.
Interview	David L. Driscoll, Ph.D.
Interview	F. Gerard Moeller, M.D
Interview	Arun Sanyal, M.B.B.S, M.D., F.A.A.S.L.D.
Interview	David X. Cifu, M.D.
Interview	Joseph P. Ornato, M.D., FACP, FACC, FACEP
Interview	Jeffrey M. Gallagher, CEO
Interview	William A. Hazel, Jr. M.D.
Interview	Robert H. Lipsky, Ph.D.
Interview	James L. Olds Ph.D.
Interview	Jerry L. Nadler, MD, FAHA, MACP
Interview	Jordan Asher, M.D.
Interview	Read Montague, Ph.D
Interview	Stephen LaConte
Interview	Pearl Chiu
Interview	Micky Koffarnus
Interview	Jungmeen Kim-Spoon

Type	Interviewee
Survey	Brooks King-Casas
Survey	Mishkta Terplan, M.D.
Survey	William Dewey, Ph.D
Survey	Thomas Eissenbery, PhD
Survey	Kenneth, Kendler, M.D.
Survey	Nassima Ait-Daoud Tiouririne, M.D.
Survey	Katherine Neuhausen, M.D, MPH
Survey	Kelli England Will, Ph.D.
Survey	Stepheanie Lee Peglow, D.O., MPH
Survey	Paul T. Harrell, Ph.D.
Survey	Andrew D. Plunk, Ph.D., MPH
Survey	Stacy Kern-Scheerer
Survey	Rick Gressard
Survey	Elizabeth Raposa
Survey	Daniel Gutierrez
Survey	Danielle Dallaire
Survey	Catherine Forestell
Survey	Jen Mellor
Interview	Bill Wasilenko

Appendix V – Additional Case Study

Case Study: Mars

Virginia may be able to glean important takeaways or best practices from the current national mustering around the "Mars Mission."

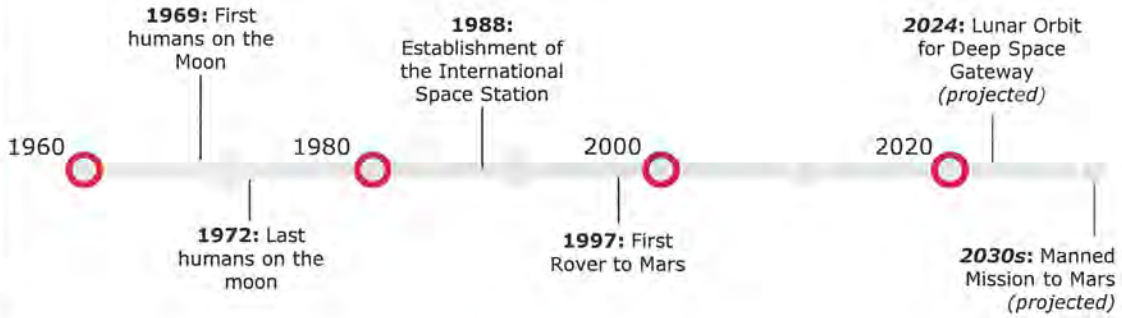
Similar Characteristics

Much like the opioid epidemic, the Mars Mission:

- Requires ***new discoveries and developments*** in order to be successful.
- Brings in ***experts from multiples areas of science*** to work together to achieve success.
- Received ***major funding investments*** from both the federal government as well as private companies.
- Focus of three administrations.

Key Facts

- Getting to Mars is phase two of a larger project to establish the "deep space gateway" in lunar orbit around the moon.
- The Deep Space Gateway is the most challenging piece of getting to Mars. Bringing together multiple pieces of the Mars Habitat built by different companies in different countries will require expert coordination, communication, and reliability.
- **The "Big Bet" of the Mars Mission:** Will all these pieces of the Habitat (and propulsion stage) integrate with 99.99999% reliability? If not, the mission is a No Go.
- Funding for the Mars Mission is predominantly coming from the Federal government, which creates contracts with private companies for building and construction.



Takeaways

- Developing and building the Mars Habitat requires collaboration across multiple disciplines (chemical engineering, human factor engineering, materials engineering, etc.) to make something that is safe, usable, reliable, and repeatable.
- Major funding sources are coming from within the federal government, with private funding offsetting, but not dramatically changing, the financial landscape.
- There will be ongoing relationships with the government, as NASA owns all communication in deep space, and oversight over all privately constructed pieces that will be part of the Mars Habitat.
- Major setbacks have occurred due to shifting focuses of administrations from the moon, to mars, to near-earth asteroids, impacting scientific discoveries and resource deployment.

Source: Patrick D. Dees and Mathew R. Zwack. "Automation of POST Cases via External Optimizer and "Artificial p2" Calculation", AIAA SPACE and Astronautics Forum and Exposition, AIAA SPACE Forum, (AIAA 2017-5353); Patrick D. Dees and Mathew R. Zwack. "Program to Optimize Simulated Trajectories II (POST2) Surrogate Models for Mars Ascent Vehicle (MAV) Performance Assessment", NASA Technical Report

Section II: Resource Validation

Contents

Deloitte Analyzed Addiction Funding Patterns and Projected Future Trends

The Deloitte methodology for resource validation is below.

Data Gathering

- Information was collected from federal spending databases, financial reports and documents, open source data, and 14 stakeholder interviews.
  - USAspending.gov
  - NIH/NIDA grant lists
  - Nonprofit financial reports

Data Processing

- Relevant information was extracted from data sets using addiction related key words.
  - Topics were grouped into categories based on grant titles.
  - Dashboards and projections were made using data visualization software based on trends within each category.
- Patterns were manually identified when necessary.

Resource Validation

- This Resource Validation document was created to describe retrospective and future trends in addiction financing.
- Understanding funding trends across segments is essential for The Virginia Catalyst as it develops a plan to capture more funding.

Governments, Nonprofit Organizations, and Private Sources are Vital to Driving Addiction Research and Programs

The landscape of addiction-related funding provides insight into potential opportunities to grow Virginia's market share in addiction prevention, treatment, and recovery.

Federal Government

The government recognizes the opioid epidemic as a national priority and is therefore allocating funds to combat the epidemic and addiction.

- Block grants
- Special programs

Nonprofit Organizations

Nonprofit organizations, including foundations, are funding research and community projects in the addiction space.

- Nonprofit treatment centers
- Community facing organizations
- Foundations

Private Sources

Private sources and individual donors may be able to bring capital and talent to Virginia.

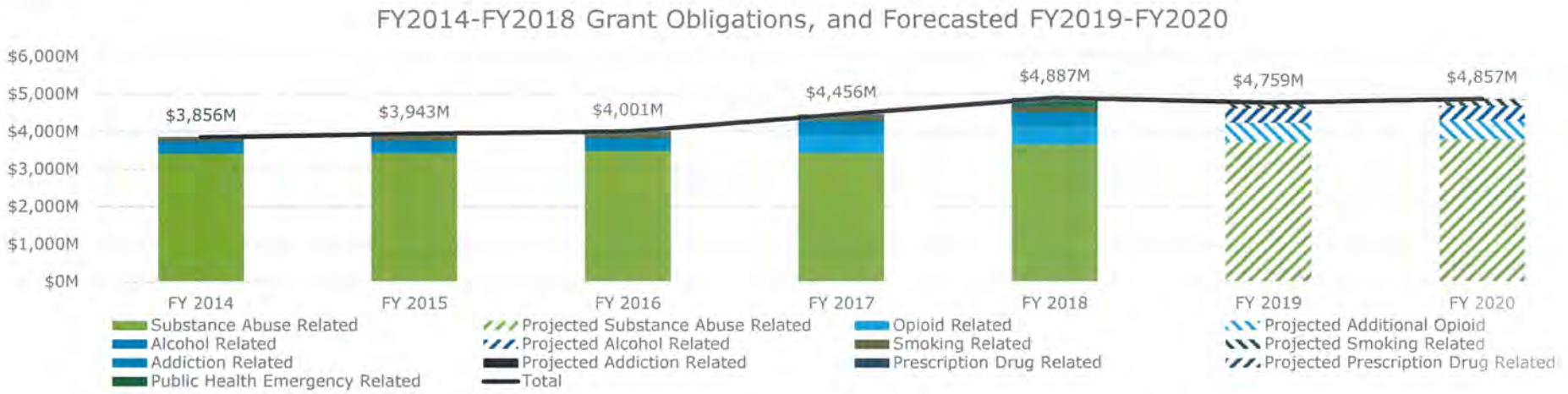
- Privately held companies
- Individual donors
- Private equity and venture capital

The following slides depict the federal funding landscape and innovative methods of funding that may assist The Virginia Catalyst in its goal of obtaining mega funding and reducing the impact of the addiction epidemic.

Federal Government

Federal Substance Abuse Funding has Increased by an Average of 4% Per Year Over the Last Five Years

The Virginia Catalyst may not be able to rely on federal grants to secure mega funding.

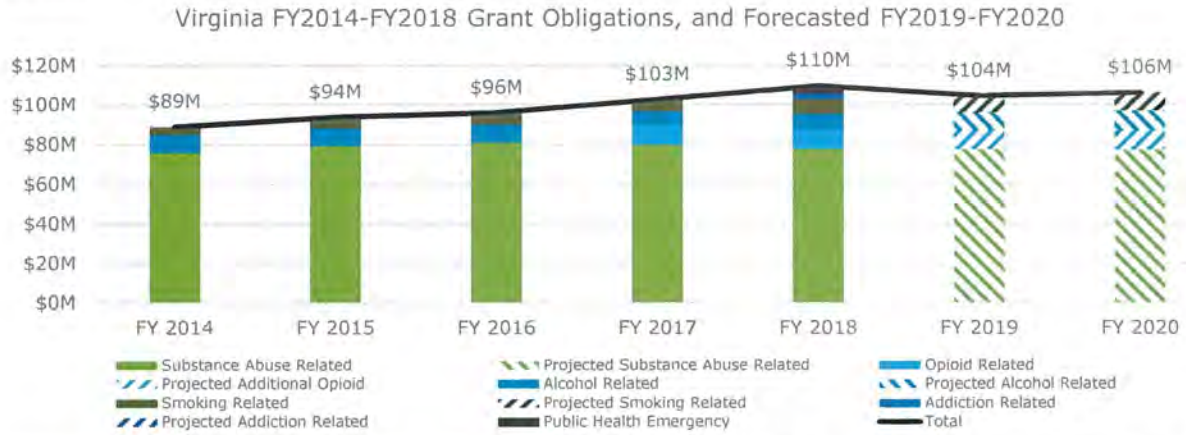


- There have been **slight increases** in substance abuse funding in the past five years, but there are limited dramatic increases in funding forecasts, creating a status quo environment for federal funding.
- The Public Health Emergency Grant (included in 2018) is **not specific to substance abuse.** However, the opioid epidemic qualifies as a public health emergency so funds may be available through this grant. There are no FY2019 of FY2020 projection for the grant.
- The largest addiction related funding comes from the Block Grant for Prevention and Treatment of Substance Abuse, which on average obligated $1.7B per year over the past five years.
- Other major grants include the Substance Abuse and Mental Health Services Administration (SAMHSA) Projects of Regional or National Significance (avg. $837M per year), Drug Abuse and Addiction Research Programs from the National Institutes of Health (NIH) (avg. $810M per year), and as of 2017, the Opioid State Targeted Response Grant from SAMHSA (avg. $500M per year).

Source: USASpending.Gov; Author's calculations

Addiction Related Funding to Virginia has Increased by an Average of 3% per Year Over the Last Five Years

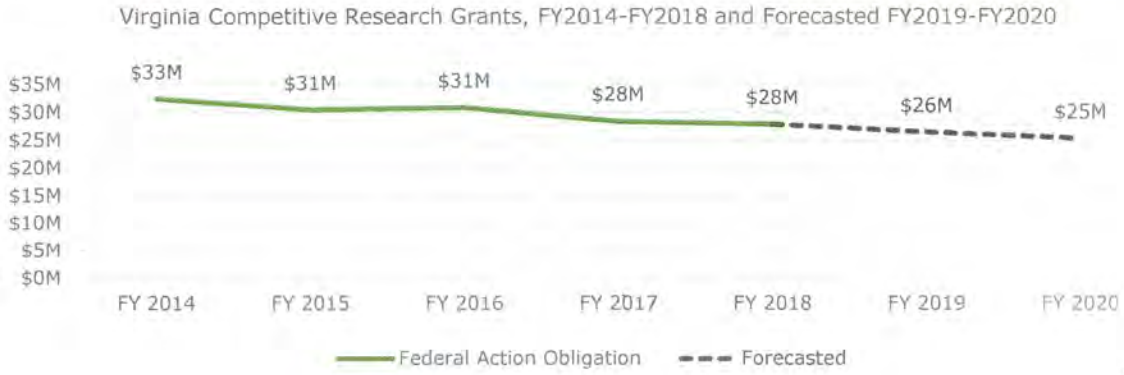
The only dramatic increase in funding occurred in FY2017 with the introduction of the Opioid State Targeted Response Grant.



- Major recipients of grants in Virginia over the past five years include: VA St Department Of Mental Health (Five Year Total (FYT):$137M), Department Of Behavioral Health And Developmental Services (FYT:$114M), Virginia Commonwealth University (FYT:$105M), Virginia Polytechnic Institute & State University (FYT:$13M), Community Anti-drug Coalitions Of America (FYT:$13M).
- Virginia is not forecasted to see a dramatic increase in funding in the next few years.
  - Virginia receives the majority of their substance abuse funding through **formulaic block grants.**

Competitive Research Grant Dollars in Virginia

- Looking at the three major research grants for substance abuse that are competitive (Alcohol Research Programs, Drug Abuse and Addiction Research Programs, Family Smoking and Prevention Research), Virginia has continued to decline in levels of funding.
- Virginia is forecasted to continue to decline in competitive research grants, based on historical data and trends.



Source: USASpending.Gov; Author's calculations

The Federal Government Obligated $4.8B* for Addiction Related Funding in 2018

There has been a 10% increase in addiction related federal funding since FY2017.

Federal Grants Nationwide in 2018

Substance Abuse	Opioids	Alcohol	Smoking	Prescription Drugs	Public Health Emergency	Comorbidity With Addiction: HIV	Comorbidity With Addiction: Hepatitis C
$3.6B	$501.0M	$361.2M	$130.8M	$1.0M	$222.7M	$3.2B	$14.3M

Grants to Virginia in 2018

Substance Abuse	Opioids	Alcohol	Smoking	Prescription Drugs	Public Health Emergency	HIV	Hepatitis C
$78.0M	$9.8M	$7.6M	$7.6M	N/A	$4.1M	$64.9M	$180K†

Virginia's Ranking

Substance Abuse	Opioids	Alcohol	Smoking	Prescription Drugs	Public Health Emergency	HIV	Hepatitis C
14th	17th	16th	4th	N/A	17th	15th	27th

Formula Based Federal Funding

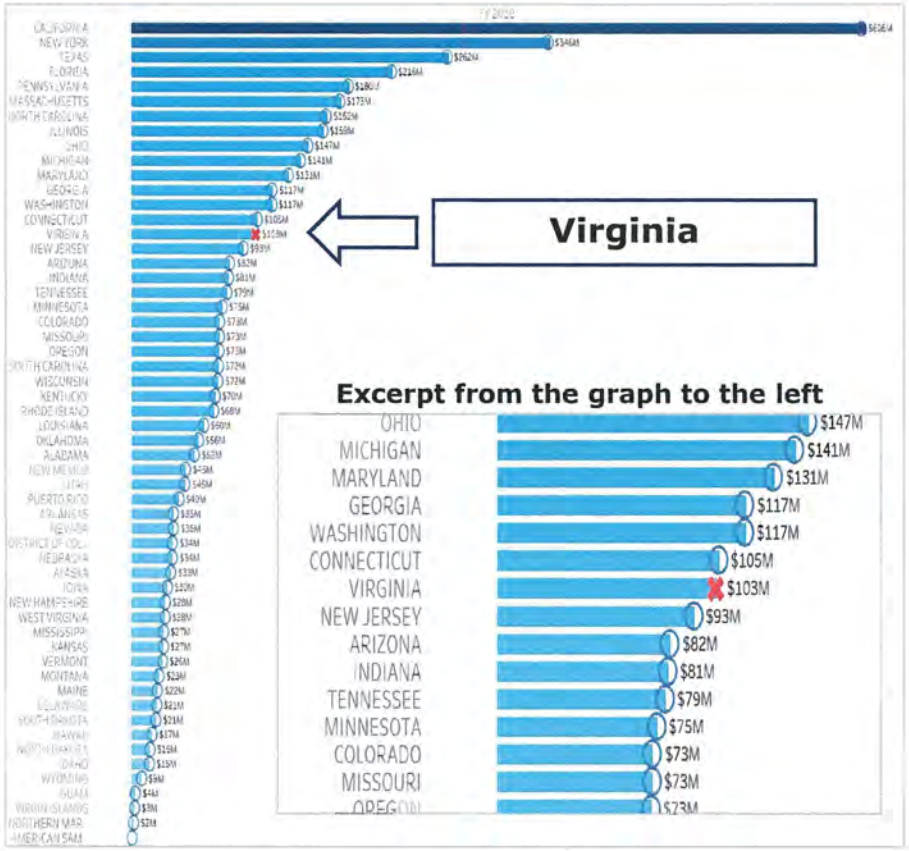
SAMHSA awarded more than $930M in State Opioid Response grants to support a comprehensive response to the opioid epidemic and **expand access to treatment and recovery support services.** However, this funding is based **on a formula** for state allocation. This formula considers the size of the state and the extent of the opioid problem in the state.[1]

HRSA is allocating $352M to **increase access to substance use disorder and mental health services** through the Expanding Access to Quality Substance Use Disorder and Mental Health Services to 1,232 community health centers across the nation. However, this funding is **also based on a formula**, which takes a state's MAT patients into account.[2]

Source: USASpending.Gov; Author's Calculations
Note: all rankings are based on a comparison of the 50 states in the U.S., tribes and territories
[1] State Targeted Response to the Opioid Crisis Grants, Funding Opportunity Announcement (FOA) No. TI-17-014
[2] HRSA, FY2018 Expanding Access to Quality Substance Use Disorder and Mental Health Services (SUD-MH) Funding Opportunity
* Includes one time increase in Public Health Emergency grants
† Injection drug use increases the risk of blood-borne infections including HIV, hepatitis, and bacterial endocarditis, which spread efficiently through needle sharing. 2015 marked the first time in two decades where the number of HIV diagnoses attributed to IDU increased.

Virginia Ranks 15th in Addiction Related Funding in FY2018 Compared to Other States

Large federal grants in addiction are often distributed based on a formula that heavily weights prevalence of disease over other factors, making it difficult for Virginia to compete with other states that have higher addiction prevalence.



- Only **four states** received more than $200M in addiction related federal funding in any given year between 2013 and 2018.
- In FY2018, Virginia received **2.1%** of total federal funding for addiction, making Virginia the 15th most funded state in the United States.
  - This is on par with the portion of Federal funding Virginia received over the last 5 years.
- Block grants are formulaic and set by Congress.
  - This includes the largest grant from SAMHSA, the Substance Abuse Prevention and Treatment grant.
  - Few of the major grants are distributed based on merit.

Note: all rankings are based on a comparison of the 50 states in the U.S., tribes and territories
Source: USASpending.Gov; Author's calculations

Federal Sources Will Increase Slowly and Provide Steady Funding

Sharp increases in federal funding will not be reliable long term funding sources.

Looking to the future

- Federal funding is projected to show **little to no growth** across each of the addiction areas.
  - Federal funds may provide a stable foundation to continue current programs, but they are unlikely to significantly increase overall addiction funding in Virginia.

- One time emergency response disbursements may cause **irregularities in the future projections**, but these disbursements are difficult to predict.
  - Public health emergency disbursements may cease when the opioid epidemic wanes.

What does this mean for The Catalyst?

- The Virginia Catalyst may be **unable to rely on federal funds** to achieve mega funding.

- The Virginia Catalyst may consider pursuing more **one time or short term** grants, such as the NIH HEALing Communities Study.

- The Virginia Catalyst may be able to **lobby Congress** to update their funding approach or provide additional merit based funding opportunities.
  - Virginia's comparative position as it relates to the opioid epidemic may not be compelling enough to secure merit based grants.

Nonprofit Organizations and Foundations

Nonprofit Organizations may Attract External Funding

Private sources and foundations may be more inclined to contribute to nonprofit organizations than to the Commonwealth.

State budgets overshadow the total annual revenue of addiction nonprofit organizations.

- Large national nonprofit organizations tend to have annual revenues around or under $10M.
  - Typically less than 5% of revenue within these organizations was distributed as grants.[1]
- These organizations are unlikely to distribute funds to The Virginia Catalyst or the Commonwealth of Virginia.

Few national addiction nonprofit organizations are based in Virginia.

- National addiction nonprofits tend to be based in densely populated urban areas with access to capital.
  - Many have operations or branches in Virginia.
- Those based in Virginia tend to be community focused.

Community facing nonprofit organizations my be able to attract external capital not accessible to the government of the Commonwealth.

- Funding may come from individuals, private organizations, or foundations.
- Nonprofit organizations may be less beholden to political objectives than state-run programs.

[1] Financial Statements from: Mental Health America, Shatterproof, To Write Love on Her Arms, Partnership for Drug-Free Kids, Phoenix House California, Phoenix House Texas, The National Center on Addiction and Substance Abuse

Foundations may Provide Limited Funding Opportunities for The Virginia Catalyst

Funding from nonprofits and foundations traditionally goes to community facing nonprofits.

Significant gifts have already been made from foundations to addiction related nonprofit organizations in 2018.

- The largest of these, $30M from the Howard G. Buffett Foundation, was earmarked for the construction of a **healthcare and social services campus**, with a focus on addiction treatment.[1]

Foundations associated with large insurance or pharmaceutical companies have recently increased efforts to address opioid abuse.

- This funding often goes to **nonprofit organizations** promoting community based work, as opposed to state governments.

Foundations are funding research and projects in the addiction space. Their funding streams tend to be:

- Targeted at the organizations in states with the **highest prevalence** of addiction related deaths
- One-off and ***ad hoc***
- **Small** relative to federal contributions

"Few foundations and major donors are dedicating resources to combating what's been called America's worst drug crisis ever"[2]
– Inside Philanthropy, 2017

Panel Source: Reilly, Caitlin. Epidemic: Two Recent Gifts to Fight Drug Addiction Are the Exception, Not the Rule. Inside Philanthropy.
[1] Reilly, Caitlin. Epidemic: Two Recent Gifts to Fight Drug Addiction Are the Exception, Not the Rule. Inside Philanthropy.
[2] Moses, Sue-Lynn. Out of the "Philanthropic Shadows." As the Toll from Opioids Grows, Who's Giving for Addiction Medicine? Inside Philanthropy.

Foundations may be Promising Funding Sources for One-Time Contributions

Funding from foundations can be impactful, but unsustainable for long term funding.

Looking to the future

- Foundations have **recently increased** funding to address the opioid epidemic.
  - This is especially true of foundations linked to healthcare firms.
  - The future pattern of these contributions is unclear, especially if the opioid crisis receives less attention in coming years.

- Some foundations are **shifting away** from substance abuse funding.
  - The Conrad N. Hilton foundation eliminated four focus areas, one of which was substance abuse funding.[1]

What does this mean for The Catalyst?

- The Catalyst should not rely on foundations for significant, sustainable funding.

- Foundations are unlikely to give directly to statewide programs.
  - The Virginia Catalyst may serve as a **pass through agency**.
  - Foundations may be more inclined to give to community facing nonprofit organizations.

[1] Callahan, David. Hard Choices: A Big Foundation Gets More Focused. Inside Philanthropy. 2018.

Private Sources

Virginia's Private Funding Sources Are Comparatively Weak

While private sources have allocated money to addiction science in other states, The Commonwealth has fewer large private companies and venture capitalists (VC) to provide support.

Established Companies

- Large, established companies may provide funding to support addiction prevention, treatment, or recovery in Virginia.
- Addiction focused nonprofit organizations throughout the country have seen **large contributions** from private organizations.
  - The Center on Addiction and Substance Abuse in New York has received gifts greater than $1M from JPMorgan Chase, American Express, and Coca Cola.[1]
- It may be difficult to **secure substantial funding** from companies within the Commonwealth.
  - Only 2 of the Fortune 100 companies (Freddie Mac and General Dynamics) are headquartered in Virginia.[2]
- Mars Inc. is the 6th largest privately held company in the world and is located in Virginia.
  - The company has traditionally been uninvolved in the field of addiction.

Startups and Venture Capital

- Successful startups focused on addiction in Virginia may bring in capital from VC and Private Equity (PE) firms.
- Many mental health tech startups raising funds are working to increase access to mental healthcare through digitally enabled treatment modalities, such as:
  - **Telemedicine platforms** that enable remote access to care and **interactive apps** that track fluctuations in emotional states.
- As the sector matures, VCs are beginning to back later rounds of funding, specifically larger series A and B rounds.
- PE investment into the addiction treatment community has been increasing, largely due to the Affordable Care Act's requirement that health plans cover treatment for substance abuse disorders.
  - Acadia bought a portfolio of **100 treatment facilities** from Bain Capital for $1.18B.[3]

[1] Annual Report 2017, Imagine the End of Addiction. The National Center on Addiction and Substance Abuse.
[2] Fortune 500. Fortune.
[3] Kodjak, Allison. Investors See Big Opportunities In Opioid Addiction Treatment. NPR.

Additional Future Funding Streams May be able to Complement Traditional Sources

Innovative funding sources may provide additional funding streams that will assist Virginia in obtaining mega funding.

Innovation Culture

- Addiction related startups have been successful in garnering venture funding upwards of $100M.
- The Virginia Catalyst could focus efforts on developing Virginia into an addiction startup and innovation hub, thus stimulating the economy around addiction.

Support From High Net Worth Champions

- Virginia may be able to secure significant, sustained funding from high net worth individuals in exchange for endowing an initiative in their name and appointing him or her as a champion.
- This would require sustained involvement from each champion, as opposed to a single gift.
- Individuals do not need to be in Virginia, but strong ties to the Commonwealth will make securing funds more likely.

Large Scale Projects

- Virginia may be able to bring additional talent to the Commonwealth through corporate engagements.
  - Implementation or development projects (such as an integrated data sharing center) will bring talent and capital into the Commonwealth while potentially creating jobs for Virginians.
  - Offering innovative financing incentives, such as tax breaks for companies focused on addiction research, may attract businesses to Virginia.

Virginia's Best Source for Private Funding will Likely Come From an Economy Focused on Addressing the Opioid Addiction

Private corporations and high net worth individuals are more likely to invest in addiction related startups and incubators.

Looking to the future

- Opportunities exist for the Commonwealth to create a **supportive environment** for startups and incubators focused on addiction to bring funds into Virginia.
  - Students and professors from universities could contribute to this culture.
  - Virginia could use tax breaks or capital injections to support local startups and reduce risk.
- **High net worth individuals** may be able to provide single installment funds for kickstarting innovation or sustaining funding for endowed initiatives.
- Engaging large technical and infrastructure companies will **bring talent** to the region that can help Virginia address addiction by sharing their expertise.

What does this mean for The Catalyst?

- The Virginia Catalyst may be able to stimulate economic growth by **serving as a conduit** between addiction related companies and the government of the Commonwealth.
- The Virginia Catalyst could serve as an incubator for startups by mentoring nascent talent.
  - Mentoring talent may increase the success of startups, thus garnering interest and funding from VC and PE firms.

Virginia Should Consider a Diversified Portfolio of Sources to Achieve Mega Funding

The Federal Government will likely be the most stable source of funding, but reaching to a broad network of funders will be critical to supplement the government's offering and achieve mega funding.

A diversified funding approach will enable Virginia to benefit from reliable funding sources, such as the Federal Government, while pursuing more risky funding vehicles, such as building a culture of innovation and attracting startups.

Federal Government

- Relying solely on federal funding will likely prevent The Virginia Catalyst from achieving mega funding due to the rigid formula-based approach.

Foundations

- Foundations have historically invested in community facing nonprofits but may be able to serve as ad hoc sources of funding.

Nonprofit Organizations

- Private sources may be more inclined to contribute to nonprofit organizations, which can be used as a conduit to bringing more funding into the Commonwealth.

Startup Culture

- Virginia can stimulate economic growth by fostering innovative culture and serving as an incubator for startups.

High Net Worth Individuals

- Virginia may be able to secure significant, sustained funding in exchange for endowing an initiative in an individuals name.

Private Equity and Venture Capital

- VC and PE firms have shown increasing interest in investing in mental health startups and treatment facilities, which The Virginia Catalyst may be able to bring to the Commonwealth.

Section III: SWOT Analysis

Contents

Methodology

A SWOT Analysis Was Used to Examine Virginia's Strategic Position

With the dual focus of advancing solutions for the opioid epidemic and positioning Virginia in the broader addiction marketplace, this SWOT Analysis evaluates components of Virginia's capabilities that are applicable to both goals.

A SWOT analysis covers four categories:

SWOT Approach

- Deloitte looked at the structure and operations of The Virginia Catalyst and Virginia's ability to become a leader in addiction.
- Understanding the capabilities in both domains, those of The Virginia Catalyst and those of the Commonwealth of Virginia, is fundamental to Virginia's efforts to pursue mega funding and become the national leader in addiction prevention, treatment, and recovery.

SWOT Analysis

Strengths

Virginia is utilizing its capabilities to build and implement programs that position the commonwealth to better address addiction and drive economic development in the Commonwealth.

- **The Virginia Catalyst is a legislated and Commonwealth-funded entity, with reputable research institutions with talent, assets, and capabilities targeted at addiction. .**
  - The Virginia Catalyst exists as a coordinating body across seven research institutions and the five largest medical centers in Virginia, providing a foundation for future efforts.
  - The Virginia Catalyst has ties to the state legislature, which may be necessary to influence policy.
  - Researchers at Virginia Tech are looking into predictors of addiction, real-time reward signals, and the effectiveness of early childhood intervention.
  - Researchers at VCU are studying ways to address addiction through translation research, molecular modeling based drug design, and the genetics of addiction.
  - Center For Addiction and Prevention Research at UVA has ongoing studies focused on the reach of telemedicine, public health surveillance, and novel addiction treatments.
- **Virginia has a history of success receiving NIH and other federal funding.**
  - VCU receives the ninth highest amount of addiction funding from NIH.
  - Virginia received $110M in addiction related funding from the Federal Government in 2018.[1]
  - Virginia ranked 15th overall in federal funding for addiction in 2018.[1]
- **The Virginia Catalyst has a vision for the Commonwealth as a national addiction pilot/*beta*.**
  - The Virginia Catalyst strives to achieve mega funding for addiction research and programs and make Virginia a leader in addiction prevention, treatment, and recovery.
  - The Virginia Catalyst is working toward this vision by securing federal funding (e.g. the NIH HEAL Initiative) and creating a climate to promote private investment.

[1] USAspending.gov

Strengths

Virginia is utilizing its capabilities to build and implement programs that position the commonwealth to better address addiction and drive economic development in the Commonwealth.

- **Political leadership supports The Virginia Catalyst and addressing addiction.**
  - Governor Northam has publicly supported efforts to address the opioid epidemic.
  - Tim Kaine and his congressional opponent have both expressed strong support for addressing the epidemic, albeit through different means.
  - Virginia passed Medicaid expansion in 2018.
- **Virginia has provided access to specialized treatments through Medicaid and the ARTS program.**
  - Medicaid expansion provided access to 400,000 more Virginians.
  - The ARTS waiver enables these people access to specialized addiction treatment options that were previously unavailable to Medicaid patients.
- **Virginia has made advances in preventing and treating addiction.**
  - Through the Prescription Monitoring Program (PMP), Virginia has reduced the number of individuals receiving greater than 100 morphine milligram equivalents (MME) per day by 18.6% from Q4 2016 to Q3 2017.[1]
  - Prescription guidelines set by the Commonwealth limit the number of opioid prescriptions a doctor can make each year.
  - The REVIVE! program has trained more than 4,000 Virginians to be first responders to opioid overdoses.[2]
  - Naloxone is available at all Virginia Department of Health Locations.

[1] 2017 Annual Report of Virginia's Prescription Monitoring Program. Department of Health Professions.
[2] REVIVE! Opioid Overdose Reversal for Virginia. May 2018.

Weaknesses

The weaknesses below may limit Virginia's ability to become the leader in addiction prevention, treatment, and recovery.

- **Virginia lacks a proven and unique comprehensive lifecycle of addiction care from prevention to treatment to long term recovery.**
  - No clear bridge exists between prevention, treatment, and recovery programs.
  - Law enforcement, MAT facilities, recovery centers, and CSBs do not work in a coordinated way to see a patient through the lifecycle.
- **The Virginia Catalyst lacks the centralized positional and funding authorities to direct efforts in addiction within a unifying office.**
  - The Virginia Catalyst does not control funding streams to partner organizations, limiting the Catalyst's ability to align incentives.
  - The Virginia Catalyst has limited authority over partner organizations.
- **The opioid epidemic is not significantly elevated in Virginia compared to other states.**
  - West Virginia has been hardest hit by the epidemic with the greatest number of opioid overdose deaths per 100K people.
  - Virginia ranks 25th (out of the 50 states and D.C) in the number of opioid overdose deaths, with 13.5 deaths per 100K.[1]
- **There is not a history of leading private capital and federal funding in the Commonwealth as a basis to build the *beta*/pilot in addiction.**
  - Limited capital has prevented new companies from coming to Virginia.[3]
  - Federal funding to the Commonwealth is largely based on a formula, which places Virginia at 15th in terms of addiction related funding (2018).[2]

[1] Opioid Summaries by State. National Institute on Drug Abuse. 2018.
[2] USAspending.gov
[3] Barid, Ross. Introducing Virginia is for Entrepreneurs and the Investment Marketplace. Village Capital. 2017.

Opportunities

There are opportunities Virginia may leverage to become a leader in addiction prevention, treatment, and recovery.

- **Opioid and addiction funding (from NIH, SAMSHA, and other agencies) continues to expand.**
  - The NIH HEAL Initiative offers funding through multiple streams, including the HEALing Communities Study.
  - The President proposed the allocation of an additional $7B to address opioids.[1]
  - The Public Health Emergency fund provided $227M in 2018.[2]
- **There has not been a systemic accepted breakthrough in addiction intervention that dominates the market.**
  - Evidence has shown that integrated systems of care are more effective than disjointed systems, yet few states offer integrated care, largely due to costs.[3]
  - Research or programs that significantly improve any link in the prevention, treatment, and recovery pipeline could bring capital to Virginia and build a stronger reputation for the Commonwealth.
- **There has not been a signature investment in addiction from a high net worth individual. So, the opportunity to pursue one still exists.**
  - The Buffett family and Jeff Bezos have both given significant funding to address issues tangentially associated with addiction, but no high net worth individual has targeted addiction head on.
  - Virginia may be able to engage a high net worth individual or group of individuals by endowing an initiative in their name.
- **With a trillion dollar annual "cost" of addiction, a "market" for addiction advancement at the intersection of private capital, talent, federal funding and industry can be launched.**
  - Resources and talent from universities in The Virginia Catalyst could be leveraged to jumpstart the creation of such a market.
  - The Kauffman Index ranked Virginia the top place in the country to grow a startup in 2016.[4]

[1] An American Budget. Budget of the U.S. Government.
[2] USAspending.gov
[3] Brooklyn, John R. MD, and Sigmon, Stacey C PhD. Vermont Hub and Spoke Model of Care For Opioid Used Disorder: Development, Implementation, and Impact. Journal of Addition Medicine.
[4] Barid, Ross. Introducing Virginia is for Entrepreneurs and the Investment Marketplace. Village Capital. 2017.

Threats

To reach their desired goal, Virginia must overcome certain challenges, including competition, to secure government, nonprofit, and private sector funding.

- **Changing priorities deemphasizes focus and funding on the opioid epidemic.**
  - $227M was provided in Public Health Emergency funding in 2018. However, there is no confirmation that this funding will be disbursed in 2019 or 2020.[1]
  - Similar single installment funds may disappear as emphasis shifts from opioids.
- **The states that receive funding from the HEALing Communities Study will be better equipped to lead in the application of evidence-based treatment.**
  - The HEALing Communities Study grant is tied to significant funding.
  - The nature of the HEALing Communities Study award pushes the states selected to the forefront of addiction prevention, treatment, and recovery.
- **A therapy-based solution significantly changes treatment dynamics.**
  - The impact of investments in pharmaceuticals may be reduced if a behavioral therapy-based solution comes to market.
  - Solutions developed outside of Virginia may pull capital from Virginia to support growth in other states.
- **Substantial private resourcing goes to a specific institution outside Virginia.**
  - Indiana University has launched an initiative to address opioid overdose deaths in Indiana. If this program is successful, Indiana University may garner a reputation as a leader in addiction.[2]

[1] USAspending.gov
[2] About Responding to the Addictions Crisis. Grand Challenges. Indiana University.