

AWARD NUMBER: CDMRPRL-16-0-DM160469

TITLE: The Pap Smear Challenge: Comparing Clinical Performance of a Novel "Molecular Pap"  
Based on Next-Generation Sequencing to Traditional Cervical Cancer Screening

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REPORT DATE: APRIL 2019

TYPE OF REPORT: ANNUAL

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

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# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

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<b>1. REPORT DATE</b> APR 2019		<b>2. REPORT TYPE</b> ANNUAL		<b>3. DATES COVERED</b> 1APR2018 - 31MAR2019	
<b>4. TITLE AND SUBTITLE</b> The Pap Smear Challenge: Comparing Clinical Performance of a Novel "Molecular Pap" Based on Next-Generation Sequencing to Traditional Cervical Cancer Screening				<b>5a. CONTRACT NUMBER</b> CDMRPRL-16-0-DM160469	
				<b>5b. GRANT NUMBER</b> DM160469	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> JANE SHEN-GUNTHER, MD, PHD, COL, MC, US ARMY  E-Mail: jane.shengunther.mil@mail.mil				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  US ARMY BROOKE ARMY MEDICAL CENTER BAMC) ATTN: MCHE-CI 3698 CHAMBERS PASS FORT SAM HOUSTON, TX 78234-6315				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> <b>Objective:</b> The "Molecular Pap" is an integrated panel of biomarkers based on Human Papillomavirus (HPV) deep sequencing and quantitative DNA methylation of 3 human genes by pyrosequencing. To validate our biomarker panel and predictive model for Pap smear classification, we proposed to collect 700 Pap smear samples from each of 6 diagnostic categories for HPV genotyping and methylation quantification for direct comparison to traditional cervical cancer screening (cytology +/- cobas® HPV). <b>Methods:</b> This prospective, cross-sectional study uses residual liquid-based cytology samples for HPV genotyping and epigenetic analysis by pyrosequencing. A total of 3,037 Pap samples have been collected to date and have undergone various stages of DNA extraction, HPV DNA amplification, Sanger and deep sequencing, and bioinformatics analysis. <b>Results:</b> NA. Study is on-going. <b>Accomplishments (Year 2):</b> Pap sample collection has reached 80% of target accrual and molecular analyses are in-progress. <b>Six</b> contracts for supplies, software, cloud-based bioinformatics, and taxonomic profiling have been awarded. The development of a real-world, automated, data science pipeline for multiple types of genomics data has been initiated.					
<b>15. SUBJECT TERMS</b> Human Papillomavirus, HPV, HPV genotyping, Deep sequencing, DNA methylation, Pap smear, Pyrosequencing, Molecular diagnostics, Molecular biomarkers, Virome, NILM, ASCUS, LSIL, HSIL.					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	17	<b>19b. TELEPHONE NUMBER</b> (include area code)

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1. **INTRODUCTION:** The “Molecular Pap” is an integrated panel of biomarkers based on Human Papillomavirus (HPV) deep sequencing and quantitative DNA methylation of 3 human genes by pyrosequencing. To validate our biomarker panel and predictive model for Pap smear classification, we proposed to collect 700 Pap smear samples from each of 6 diagnostic categories for HPV genotyping and methylation quantification for direct comparison to traditional cervical cancer screening (cytology +/- cobas® HPV). Concurrently, a bioinformatics pipeline for automated data collection, analysis, modeling and visualization via a cloud-based computing system will also be developed.
2. **KEYWORDS:** Human Papillomavirus, HPV, HPV genotyping, Deep sequencing, DNA methylation, Pap smear, Pyrosequencing, Molecular diagnostics, Molecular biomarkers, Virome, NILM, ASCUS, LSIL, HSIL.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

Major goals of the project:

- a. CY17 Goals: Expand the applicability of the “Molecular Pap”
  - i. Obtain IRB protocol approval.
  - ii. Collect Pap smear samples from BAMC Cytopathology Laboratory.
  - iii. Determine HPV genotype(s) by next-generation sequencing.
  - iv. Quantify DNA methylation of 3 tumor suppressor genes.
- b. CY18-19 Goals: Compare clinical performance of the “Molecular Pap” to traditional Pap/HPV screening
  - i. Use biomarkers & predictive modeling to classify Pap smears.
  - ii. Compare “Molecular Pap” results to traditional Pap/HPV screening.
  - iii. Implement bioinformatics pipeline via cloud computing.

- **What was accomplished under these goals?**

Major activities accomplished:

- a. Research regulatory activities
  - i. BAMC IRB protocol submitted: 07 MARCH 2017
  - ii. BAMC IRB protocol approved: 09 JUNE 2017
  - iii. BAMC IRB protocol Continuing Review approved: 08 JUNE 2018
  - iv. ORP HRPO protocol submitted: 12 JUNE 2017
  - v. ORP HRPO protocol approved: 12 JULY 2017

- vi. ORP HRPO protocol Continuing Review approved: 12 JUNE 2018
- b. Services contract activities
  - i. Services contract for HPV next-gen sequencing (NGS) approved by MTF: 7 MAY 2017
    - a) Services Contract awarded to **Lucigen Corporation** for HPV NGS (2,016 samples): 07 AUG 2017.
    - b) POP: 15 AUG 17 TO 14 AUG 2018.
    - c) First plate (96 samples) sent for NGS: 21 SEP 2017 (successful results received)
    - d) 25th plate (2,400 samples) NGS'd: 26 DEC 2018 (successful results received)
  - ii. Laboratory Supplies Contract approved by MTF: 07 MAY 2017
    - a) Laboratory Supplies Contract Awarded to **Government Scientific Source (GSS)**: 11 AUG 2017.
    - b) POP: 21 AUG 2017 TO 20 AUG 2018.
  - iii. Software Contract for NGS data analysis approved by MTF: 04 DEC 2017.
    - a) Software contract awarded to **Qiagen Bioinformatics** for CLC Genomics Workbench & Microbial Genomics: 23 APR 2018
    - b) POP: 25 APR 2018 TO 24 APR 2020.
  - iv. Software & IT Services Non-disclosure Agreement (NDA) with Wolfram Solutions signed by Wolfram Research & USAMRMC Medical Tech Transfer: 17 NOV 2017.
    - a) Software & IT Services contract to Wolfram Solutions for Cloud-based bioinformatics pipeline approved by MTF: 6 MAR 2018.
    - b) Software & IT Services contract awarded to **Wolfram Solutions** for Cloud-based bioinformatics pipeline development and automation: 10 APR 2018.
    - c) POP: 10 APR 2018 TO 9 APR 2019.
  - v. Custom Pyrosequencing Laboratory Supplies (Kits) Contract with **Qiagen** approved by MTF: 10 SEP 2018
    - a) POP: 27 SEP 2018 TO 30 SEP 2018.
  - vi. **Amazon GovCloud Account** & IT support service purchased through **Four Points Technology**, LLC (3<sup>rd</sup> party vendor for Amazon): 09 JAN 2019.

- vii. Services contract paperwork submitted for collaboration with **University of Texas at San Antonio (UTSA)** for in-depth bioinformatics analysis of HPV+ samples to include: metagenomics, phylogenetics, taxonomic profiling, and functional genomics.
  - a) Services contract paperwork submitted: 17 OCT 18
  - b) Awaiting award by Regional Health Command Central (RHC-C).
  - c) Projected POP: 15 MAR 2019 TO 14 MAR 2020.
  
- c. BAMC DCI Biomedical laboratory activities
  - i. Pap smear samples collected to date (15 MAR 19): N = **3,037**
  
  - ii. Pap smear samples extracted of total DNA to date (15 MAR 19): N = **2,521**
  
  - iii. PCR for HPV DNA detection in genomic DNA derived from Pap samples to date (15 MAR 19): N = **2,521**
  
  - iv. Bisulfite conversion of gDNA derived from Pap samples to date (15 MAR 19): N = **2,496**
  
  - v. Pyrosequencing on the PyroMark Q48 instrument: ADCY8 amplicons N = **1,094**; CDH8 amplicons N = **366**; ZNF582 amplicons N = **1,104**.
  
  - vi. Plates (96 samples/plate) sent for NGS to date (15 MAR 19): N = **25** (Total N samples = **2,400**) (successful results received)
  
  - vii. Plates (96 samples/plate) sent for Sanger sequencing to date (15 MAR 19): N = **17** (Total N samples = **1,598**) (successful results received)
  
- d. Bioinformatics and Data Science pipeline development
  - i. Account with **Amazon Web Services (AWS) GovCloud** established: BAMC Information Management Division (IMD) approval received. Purchased: 01 JAN 19. Cloud connections established 09 JAN 19.
  
  - ii. Data pipeline between **AWS GovCloud S3 data storage and CLC Genomics platforms** (CLC Genomics Cloud Engine, CLC Genomics Workbench (WB), and CLC Microbial Genomics plugin): BAMC IMD approval received. Cloud connections to be completed on 22 MAR 19.

- iii. Cloud-based **data science workflow and analytics** via **Wolfram Solutions** to include setup of real-world data science pipeline starting with curation of computable data, statistical analysis, predictive analytics, classification algorithms, and ending with results in written and graphical forms: desktop data science workflow and predictive analytics prototype software (contracted tasks) **completed** by Wolfram Solutions on **16 JAN 19**. Cloud-based version of data science workflow and predictive analytics in-progress.
  - iv. **Abstract clinical data** from electronic medical records: N = **2,521**.
- **What opportunities for training and professional development has the project provided?**

Army active duty laboratory technicians (N= 3) and laboratory manager (N = 1) assigned to BAMC Dept. of Clinical Investigation have learned numerous molecular biology techniques, processes, instrumentation, and informatics as a results of this project. Furthermore, our three doctoral-level scientists (contract microbiologist, cancer biologist/experimental therapeutics, data scientist/bioinformatician) working on the current project have grown professionally by broadening their scope and knowledge in virology, oncology, genomics, deep sequencing, pyrosequencing, bioinformatics, and cloud-based computing.

- **How were the results disseminated to communities of interest?**
- Nothing to Report
- **What do you plan to do during the next reporting period to accomplish the goals?**

- a. Bioinformatics pipeline and predictive modeling via cloud computing
  - i. Finish development and “cloudification” of bioinformatics pipeline and predictive modeling with Wolfram Solutions to include: setup of real-world data science pipeline starting with curation of computable data, statistical analysis, predictive analytics, classification algorithms, and ending with results in written and graphical forms.

- ii. Use the data science/analytics pipeline developed above to compare “Molecular Pap” results to traditional Pap/HPV screening results.

b. HPV in-depth bioinformatics analysis

- i. Work in collaboration with Geneticist/Evolutionary Biologist at University of Texas at San Antonio (UTSA) to finish in-depth bioinformatics analysis of HPV-positive samples to include: metagenomics, phylogenetics, taxonomic profiling, and functional genomics.

c. BAMC DCI Biomedical laboratory activities

- i. Collect remaining Pap smear samples to reach target accrual numbers.
- ii. Finish HPV genotyping and pyrosequencing of remaining Pap samples.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report

- **What was the impact on other disciplines?**

Nothing to Report

- **What was the impact on technology transfer?**

USAMRMC Technology Transfer Office is currently working on licensing the *Molecular Pap*. Through their work, the *Molecular Pap* was selected as one of the 100+ cancer inventions to create high-impact startups through the Freedom from Cancer Startup Challenge in 2017-2018 (<https://www.freedomfromcancerchallenge.org/>). A team of scientists, entrepreneurs and business leaders from the University of Pennsylvania formed a team to pitch the *Molecular Pap* in this startup competition. (See Appendix B for Press Release)



Another team of scientists and entrepreneurs have submitted a licensing application for the *Molecular Pap/HPV Discover* technology. Discussions with USAMRMC and TechLink Technology Transfer (T2) offices are on-going.

- **What was the impact on society beyond science and technology?**

Nothing to Report

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

Nothing to Report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

Nothing to Report

- **Changes that had a significant impact on expenditures**

Nothing to Report

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

None

- **Significant changes in use or care of human subjects**

None

- **Significant changes in use or care of vertebrate animals.**

NA

- **Significant changes in use of biohazards and/or select agents**

NA

## 6. PRODUCTS:

- **Publications, conference papers, and presentations**

Nothing to Report

- **Journal publications.**

Nothing to Report

- **Books or other non-periodical, one-time publications.**

Nothing to Report

- **Other publications, conference papers, and presentations.**

Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

The current project seeks to expand the applicability of the *Molecular Pap* to other cytological categories not previously tested. The molecular markers of the *Molecular Pap*, i.e. HPV genotype and *ADCY8*, *CDH8*, and *ZNF582* promoter methylation discovered in our previous project and the methods for Pap smear classification have been submitted to the World International Patent Organization (WIPO) for an international patent application (below). The application is currently in the second or "National" phase.

Shen-Gunther J, inventor.

United States Army, assignee.

Title: Methods for molecularly characterizing cervical cell samples.

United States Provisional Application 62/212,555. 2015 Sep 1.  
 International Application Filing No. PCT/US2016/049426 2016 Aug 30.  
 WIPO Pub. No. WO/2017/040491 Publication Date: 2017 Sep 03

▪ **Other Products**

Biospecimen collections:

- Genomic DNA derived from cervical cytology (N = **2,521**)
- HPV DNA of various genotypes derived from cervical cytology

Research materials: unique PCR primers developed for pyrosequencing; laboratory protocols developed and validated for HPV deep sequencing & pyrosequencing.

Bioinformatics: pipeline for HPV genotyping and metagenome analysis; pipeline for *Molecular Pap* data processing, predictive analytics, and automated classification

Data or databases:

- HPV DNA sequences and genotyping data
- Pyrosequencing data categorized by cervical pathology
- HPV BLAST reference database created for CLC Genomics workbench

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

▪ **What individuals have worked on the project?**

Name:	Jane Shen-Gunther, MD, PhD, COL, MC, US ARMY
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	<a href="https://orcid.org/0000-0002-0876-9338">https://orcid.org/0000-0002-0876-9338</a>
Nearest person month worked:	26
Contribution to Project:	Responsible for identifying patient records and samples applicable for study and de-identifying information; responsible for project oversight and coordination of all activities outlined in protocol and required IRB documentation. Conduct cellular and molecular testing and analysis of specimens (DNA extraction, PCR, next-

	generation sequencing (NGS), and pyrosequencing), data analysis and manuscript preparation. Coordinate development of bioinformatics pipeline with commercial entities and collaborators at UTSA and UTHSCSA.
Funding Support:	DoD US Army – Active Duty physician

Name:	Andrea Garcia, PhD
Project Role:	Sub-Investigator and Research Staff: Contract Biological Research Scientist with expertise in cancer/molecular biology, experimental therapeutics and bioinformatics
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	22
Contribution to Project:	Responsibilities: Cytology sample processing, cellular and molecular testing and analysis (DNA extraction, PCR, next-generation sequencing (NGS), and pyrosequencing), de-identified data analysis and manuscript preparation.
Funding Support:	Defense Health Program (DHP) Clinical Trial Infrastructure Support funds

Name:	Qingqing Xia, PhD
Project Role:	Sub-Investigator and Research Staff: Contract Biological Research Scientist with expertise in microbiology and molecular biology
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	19
Contribution to Project:	Responsibilities: Cytology sample processing, cellular and molecular testing and analysis (DNA extraction, PCR, next-generation sequencing (NGS), and pyrosequencing), de-identified data analysis and manuscript preparation.

Funding Support:	Defense Health Program (DHP) Clinical Trial Infrastructure Support funds
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Name:	Winfred Stacey, PhD
Project Role:	Sub-Investigator and Research Staff: Contract Biological Research Scientist with expertise in data science and bioinformatics.
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	8
Contribution to Project:	Responsibilities: Clinical data extraction, data preparation for cloud processing, next-generation sequencing (NGS), and pyrosequencing data analysis and manuscript preparation.
Funding Support:	Defense Health Program (DHP) Clinical Trial Infrastructure Support funds

Name:	SPC Edetsira Kouame
Project Role:	Research Staff: Army Laboratory Technician
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	18
Contribution to Project:	Responsibilities: Assist with cytology sample processing, cellular and molecular testing and analysis (DNA extraction, PCR, next-generation sequencing (NGS), and pyrosequencing.
Funding Support:	DoD US Army – Active Duty Laboratory Technician

Name:	SPC Taylor Quickley
Project Role:	Research Staff: Army Laboratory Technician
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	17
Contribution to Project:	Responsibilities: Assist with cytology sample processing, cellular and molecular testing and analysis (DNA extraction, PCR, next-generation sequencing (NGS), and pyrosequencing.
Funding Support:	DoD US Army – Active Duty Laboratory Technician

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to Report

- **What other organizations were involved as partners?**

Nothing to Report

- **Organization Name**
- **Location of Organization**
- **Partner's contribution to the project**
- **Financial support**
- **In-kind support**
- **Facilities**
- **Collaboration**
- **Personnel exchanges**
- **Other**

## 8. SPECIAL REPORTING REQUIREMENTS

- **COLLABORATIVE AWARDS:** NA

## 9. APPENDICES:

- **Appendix A: QUAD CHART**
- **Appendix B: TECHNOLOGY TRANSFER**

## APPENDIX A. QUAD CHART

The Pap smear challenge: Comparing the clinical performance of a novel “Molecular Pap” based on next-generation sequencing to traditional cervical cancer screening.



PI: COL Jane Shen-Gunther    Org: Brooke Army Medical Center Department of Clinical Investigation    Budget Amount: \$750,000

### Study/Product Aim(s)

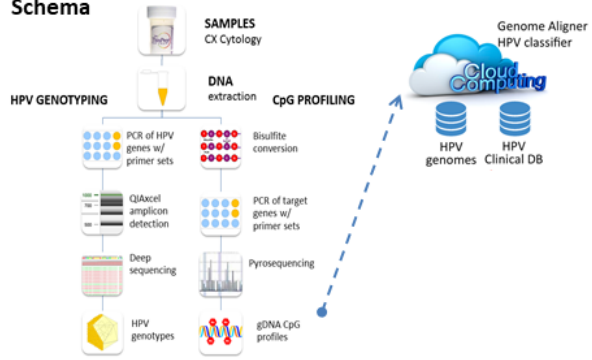
**Aim 1:** Expand the applicability of the “Molecular Pap” based on a panel of molecular biomarkers

**Aim 2:** Compare the clinical performance of the “Molecular Pap” to traditional Pap/HPV screening

#### Approach

The “Molecular Pap” is an integrated panel of biomarkers based on Human Papillomavirus (HPV) deep sequencing and quantitative DNA methylation of 3 human genes by pyrosequencing. To validate our biomarker panel and predictive model for Pap smear classification, we propose to collect 700 Pap smear samples from each of 6 diagnostic categories for HPV genotyping and methylation quantification for direct comparison to traditional cervical cancer screening (cytology +/- cobas® HPV). Concurrently, a bioinformatics pipeline for automated data collection, analysis, modeling and visualization via a cloud-based computing system will also be developed.

### Schema



### Timeline and Cost

Activities	CY	16	17	18	19
Collect Pap smear samples for HPV next-gen sequencing & genotyping					
Quantify DNA methylation of 3 tumor suppressor genes.					
Compare “Molecular Pap” results to traditional Pap/HPV screening					
Develop & implement bioinformatics pipeline					
<b>Estimated Budget (\$K)</b>		<b>\$000</b>	<b>\$250</b>	<b>\$250</b>	<b>\$250</b>

Updated: 7 September 2016

### Goals/Milestones

#### CY16 – 17 Goals: Expand the applicability of the “Molecular Pap”

- Obtain IRB protocol approval
- Collect Pap smear samples from BAMC Cytopathology Laboratory.
- Determine HPV genotype(s) by next-generation sequencing.
- Quantify DNA methylation of 3 tumor suppressor genes.

#### CY18 Goals: Compare clinical performance of the “Molecular Pap” to traditional Pap/HPV screening

- Use biomarkers & predictive modeling to classify Pap smears
- Compare “Molecular Pap” results to traditional Pap/HPV screening.
- Implement bioinformatics pipeline via cloud computing.

#### Potential Challenges

- Bioinformatics pipeline development.



## APPENDIX B. TECHNOLOGY TRANSFER

Wednesday, April 25, 2018



### 100+ Cancer Inventions Selected to Create High-Impact Startups through the Freedom from Cancer Startup Challenge

The Center for Advancing Innovation, the world's largest virtual startup challenge-based accelerator, announced today the 100+ breakthrough cancer inventions that will be commercialized through the Freedom from Cancer Startup Challenge (FCSC).

**BETHESDA, MD (PRWEB) JULY 07, 2017**

The Center for Advancing Innovation, the world's largest virtual startup challenge-based accelerator, announced today the 100+ breakthrough cancer inventions that will be commercialized through the Freedom from Cancer Startup Challenge (FCSC).

As CAI's largest challenge to date, the FCSC has the potential to create as many as 10,000 knowledge-based jobs and 100 oncology-focused startups. The Laura and John Arnold Foundation has committed \$1.2 million in funding towards the FCSC. The challenge was also launched with support from MedImmune, the global biologics research and development arm of AstraZeneca.

The breakthrough inventions came from 55 institutions, including the National Institutes of Health (National Cancer Institute, National Heart, Lung, and Blood Institute, and National Institute of Biomedical Imaging and Bioengineering), the United States Army, and more than fifty American universities and hospitals. To identify these breakthrough inventions, CAI reviewed over 120,000 cancer-related patent applications, filed since 2005, and selected the top 1% from a total of 134 research institutions for deep dive due diligence. CAI then shortlisted the most promising 200 cancer-related inventions from a list of 400 technologies, made available for exclusive licensing by 63 research institutions that CAI engaged. From this short list, CAI and a 15-member FCSC invention selections committee cherry-picked 100+ commercially viable inventions to feature in the competition. Members of the selection committee included senior executives from MedImmune, Pfizer, and Novartis, as well as super angels, serial entrepreneurs, venture capitalists, and foundations.

"CAI's track record in launching Life Sciences startups is outstanding and the FCSC initiative further establishes a new paradigm to kick start new cancer companies and is a force multiplier for the oncology ecosystem. CAI's systematic model establishes the trifecta necessary for high performing biotech companies - commercially viable inventions, rock star teams and funding - to get treatments to patients faster." - Jim Greenwood, BIO's President and CEO. Rosemarie Truman, Founder and CEO of CAI added, "The intentional architecture and engineering of CAI's commercialization of cancer inventions in this challenge will serve to create a new paradigm to drive positive industry disruption, economic impact, and most importantly, social impact."



Participating Technology Transfer Offices

"The intentional architecture and engineering of CAI's commercialization of cancer inventions in this challenge will serve to create a new paradigm to drive positive industry disruption, economic impact, and most importantly, social impact. - R. Truman"

web.com/recentnews/