

The background features large, stylized letters in a dark red color. On the left, a large 'O' is partially visible. At the bottom left, a large 'N' is partially visible. On the right side, a large 'R' is partially visible, and at the top right, another large 'O' is partially visible. The text 'ANNUAL REPORT 2018' is centered in white, bold, sans-serif font.

ANNUAL REPORT 2018

Harvard Pilgrim Health
Care Institute

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PRIMARY PHOTOGRAPHY:

Elisif Photography

ADDITIONAL PHOTOGRAPHY:

Bob Wyllie Photography,
Institute staff and collaborators

STORIES



WHO WE ARE

The Harvard Pilgrim Health Care Institute is a research and academic partnership between Harvard Pilgrim Health Care and Harvard Medical School. As the nation's first medical school appointing department based in a health plan, we're strategically positioned to improve population health and health care delivery locally, nationally and internationally. We're distinctive for our scope, expertise and collaborations.

We are **38 core faculty, 9 research scientists, 20 fellows, and 157 staff** working with hundreds of institutional and individual collaborators around the globe.

WHAT WE DO

We leverage our position within both a medical school and a health plan to conduct research that seeks to identify effective interventions and systems of care that can improve health care delivery, inform and enhance prevention efforts, evaluate and inform health care policy, and contribute to public health.

We lead national networks of the Food and Drug Administration (Sentinel), the National Institutes of Health (the NIH Distributed Research Network), the Patient-Centered Outcomes Research Institute (PCORnet), and a Centers for Disease Control and Prevention Epicenter.

International programs include leadership of the Medicines and Insurance Coverage (MedIC) Initiative, a range of research on improving health systems in low- and middle-income countries, highlighted by a growing network of teaching and research collaborations in China.

Teaching activities include leadership of Harvard Medical School's *Clinical Epidemiology and Population Health* 4-year longitudinal component, required for all medical students, joint leadership of a primary care residency training program, leadership of a fellowship in Health Policy and Insurance Research, and participation in Harvard-wide fellowships in General Internal Medicine and Primary Care as well as Pediatric Health Services Research.

MISSION

The Institute's mission is to improve health care delivery and population health through innovative research and teaching. Our mission and activities are highly consonant with the Institute of Medicine's advocacy for a national Learning Health System — one that incorporates evidence-based practices into routine care, captures new knowledge as part of the ongoing delivery of care, and then applies new knowledge in a timely manner.



Dear Colleagues,

It is my pleasure to present to you our Executive Director's Annual Report on the activities and achievements of the Harvard Pilgrim Health Care Institute for 2018.

In 2018, there were 145 multiyear grants and contracts in progress. For research highlights, see page 16. As active studies returned results, they were translated into 257 peer-reviewed papers, contributing to our vast repository of literature focused on improving population health. We are exploring new ways of spreading the word about this research. We have expanded our presence on social media (engage with us on Twitter: @DeptPopMed) and published thoughtful opinion pieces in high impact biomedical journals as well as in the national media (see page 21).

Meanwhile, investigators found time to submit nearly 100 new proposals responding to funders' most challenging inquiries—proving that as quickly as we mobilize to address today's health challenges, there are always new questions needing answers, and policies requiring close evaluation. Federal, industry, and foundation-based funders responded in kind, awarding us 38 new grants and contracts. Our grant and contract revenue for the year totaled \$57.97 million.

In response to new initiatives, growing to-do lists, and the evolving needs of the Institute, we expanded our ranks by 37, welcoming one new faculty member, one research scientist, and 35 new staff members in various roles. For details on our commitment to education, see page 8.

In short, 2018 was a year of great achievement and growth. We have continued to publish in high-impact journals, secure funding for important work, and present our work across the globe. Moreover, we have spent countless hours giving back to the community and gathered to celebrate births, promotions, and holidays.

I invite you to take a look and to tell me what you think. Please feel free to reach out—my door and inbox are always open.

Sincerely,

A handwritten signature in black ink that reads "Richard Platt". The signature is written in a cursive, flowing style.

Richard Platt, MD, MSc

Professor and Chair, Department of Population Medicine
Executive Director, Harvard Pilgrim Health Care Institute



Engage with us
on Twitter!

@DeptPopMed



37

NEW TEAM
MEMBERS



145

MULTIYEAR GRANTS
AND CONTRACTS



38

NEW GRANTS AND
CONTRACTS AWARDED



100

NEW PROPOSALS



257

PEER-REVIEWED
PAPERS



\$57.97M

GRANT/CONTRACT REVENUE

TEACH

ING

TEACHING

We were founded on the belief that adaptable teaching programs that go beyond the classroom are the key to giving physicians and population scientists-in-training the tools they need to become future health care leaders. Our teaching programs are built on four pillars: coursework; mentoring activities; training programs; and national leadership of training in systems and practice improvement. Our focus on the health of populations, combined with our perspective on the diverse health issues of today, helps our teaching programs produce rewarding experiences for faculty and trainees alike.

CLASSROOM TEACHING

HARVARD MEDICAL SCHOOL

Clinical Epidemiology and Population Health: Nuanced medical education responding to the ever-changing health policy landscape

Since 1996, our faculty have led the Harvard Medical School (HMS) Clinical Epidemiology and Population Health course, a requirement for first-year medical and dental students. In 2018 alone, faculty taught nearly 300 students. The course has evolved, along with the medical profession, over the years, and is now a part of the integrated Essentials of the Profession I course, a required course in the first year of the medical school curriculum. Developing curricula and fine-tuning them as the health care landscape changes is something of an Institute specialty, proven again in 2018 by faculty members Laura Garabedian, PhD, MPH and Jason Block, MD, MPH when they created and launched a new required course for third- and fourth-year students, known as Essentials of the Profession II.

The Clinical Epidemiology and Population Health component of the Essentials II course focuses on identifying population health problems using real-world data from various sources and developing evidence-based strategies to improve population health. Understanding that these skills cannot be taught through a textbook approach alone, the new curriculum includes interactive lectures on timely population health topics by local and national experts and student-led journal clubs to apply clinical epidemiology concepts to critically appraise population health research studies. This curriculum is integrated with the disciplines of health policy, social medicine, and ethics and includes a novel collaboration with Harvard Business School to lead discussions on principles of value-based care based on real-world case studies.



The Clinical Epidemiology and Population Health component of the Essentials II course focuses on identifying population health problems using real-world data from various sources and developing evidence-based strategies to improve population health.

Thirteen of our faculty members, representing four research divisions, taught across both Essentials of the Profession courses in 2018. Their contributions focus on teaching the skills needed to interpret and critique data from various sources to explore and improve population health problems.

HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

The mission of the Harvard T.H. Chan School of Public Health (HSPH) is to bring together dedicated experts from a variety of disciplines to educate new generations of global health leaders. The Institute is proud to have faculty that lend their analytical and statistical methods expertise to lead several courses at HSPH.



Epidemiologic Methods in Health Services Research

Associate Professor Darren Toh, scD serves as co-instructor of this course in the Department of Epidemiology. The course is designed to introduce students to the application of standard and advanced epidemiologic methods to health services research, comparative effectiveness research, and patient-centered outcomes research. Faculty members Jeffrey Brown, scD, Richard Platt, MD, MSc, Dennis Ross-Degnan, scD and Frank Wharam, MB, BCh, BAO, MPH served as guest lecturers, discussing interrupted time series as a method to produce rigorous evidence, using electronic healthcare databases in health services research, and cluster pragmatic trials within healthcare systems.

Statistical Inference II

Associate Professor Rui Wang, PhD leads this advanced statistical course offered by the Department of Biostatistics. Geared towards doctoral students, the course addresses several advanced topics in statistical inference including limit theorems, multivariate delta method, properties of maximum likelihood estimators, asymptotic relative efficiency, robust and rank-based procedures,

Developing curricula and fine-tuning them as the health care landscape changes is something of an Institute specialty.

resampling methods, and nonparametric density estimation. Assistant Professor Jessica Young, PhD serves as a guest lecturer, discussing causal inference.

Applied Regression Analysis

Assistant Professor Sharon Lutz, PhD leads this course offered by the Department of Biostatistics. Topics include model interpretation, model building, and model assessment for linear regression with continuous outcomes, logistic regression with binary outcomes, and proportional hazards regression with survival time outcomes. The course is designed to provide students with the skills necessary to perform regression analyses and to critically interpret statistical issues related to regression applications in the public health literature.

Professor and Vice Chair Emily Oken teaches in Essentials of the Profession I and II.





2018-19 Institute Fellows.

FELLOWSHIPS

The Institute is home to several postdoctoral fellowships that serve trainees from several clinical and research disciplines. Each fellowship has its own structured curriculum, mentored research, and connection to other Harvard resources, but they share a foundation: health system and population foci.

HARVARD MEDICAL SCHOOL FELLOWSHIP IN GENERAL MEDICINE AND PRIMARY CARE

The Institute is one of seven sites for HMS's Fellowship Program in General Internal Medicine and Primary Care, one of the leading training programs in the nation. For over two decades, the Fellowship has provided research training and experience under the direction of highly qualified mentors. New 2018 fellows include:

Amir Meiri, MD

MENTORS: Dennis Ross-Degnan, ScD • Frank Wharam, MB, BCh, BAO, MPH

FOCUS: Evaluation of the use of care facilitators to coordinate the care of behavioral health patients with complex social needs, and the impact of rising insulin prices on utilization and outcomes for patients with diabetes.

FELLOWSHIP IN HEALTH POLICY AND INSURANCE RESEARCH

As health care delivery and health insurance systems rapidly change, the need for individuals trained in novel methods to produce sound evidence—the kind that will inform policy and program changes for the betterment of population health—grows more urgent. The Fellowship in Health Policy and Insurance Research has trained these individuals since 2001, mentoring nearly 50 fellows and visiting scholars from around the world. New 2018 fellows include:

Saumya Chatrath, PhD student

MENTORS: Laura Garabedian, PhD, MPH • Frank Wharam, MB, BCh, BAO, MPH

FOCUS: Evaluating the variation in the value and intensity of care that physicians provide in the United States.

Xiaodong Guan, PhD

MENTORS: Dennis Ross-Degnan, ScD • Anita Wagner, PharmD, MPH, DrPH

FOCUS: The impact of cost-sharing on access to expensive cancer medications in different provincial insurance systems in China.

Unni Gopinathan, MD, PhD

MENTORS: Dennis Ross-Degnan, ScD • Frank Wharam, MB, BCh, BAO, MPH

FOCUS: Using interrupted time series study designs to study U.S. health policy effects on preventive care.

THOMAS O. PYLE FELLOWSHIP

Endowed by Harvard Community Health Plan to honor its former Chief Executive Officer, the Thomas O. Pyle Fellowship Fund provides funding for individuals studying critical topics in domestic health policy and health care systems. Since its inception, the Fellowship has supported over 40 trainees. New 2018 fellows include:

Tom Chen, PhD

MENTOR: Rui Wang, PhD

FOCUS: Developing robust methods for clustered or longitudinal data and recurrent time-to-event data, working closely with Dr. Wang to investigate in-depth the comparisons between two popular statistical methods for correlated data: generalized estimating equations and generalized linear mixed models as they pertain to an existing study.

Rachele Hendricks-Sturupp, DHSc, MSc, MA

MENTOR: Christine Lu, MSc, PhD

FOCUS: Robust analysis of stakeholders' top concerns about employer-sponsored wellness programs and the role of nondiscrimination laws, such as the Genetic Information and Nondiscrimination Act.

Mei-Sing Ong, PhD

MENTOR: Dennis Ross-Degnan, ScD

FOCUS: Creating clinically meaningful predictive models of readmission risk in a target population of patients with serious mental illness (SMI) to provide health care practitioners and administrators with insights into which interventions will have the greatest potential for reducing risk of hospital readmissions associated with SMI.

Jenna Wong, PhD, MSc

MENTOR: Darren Toh, ScD

FOCUS: Using machine learning and natural language processing techniques to extract information on treatment indications and medication-related outcomes from unstructured electronic health records data, with the aim of improving the capacity to conduct valid and precise epidemiological analyses of real-world drug safety and effectiveness.

Training as a Springboard to a Research Career

While it is always bittersweet to bid research fellows adieu, we are proud of their achievements and look forward to future collaborations. We wished the best of luck to these fellows who departed in 2018:

DANIEL CAROFF, MD (THOMAS O. PYLE FELLOWSHIP)

Infectious disease specialist, Lahey Hospital & Medical Center and Winchester Hospital • Assistant Professor of Medicine, Tufts University School of Medicine

HEATHER HSU, MD, MPH (PEDIATRIC HEALTH SERVICES RESEARCH FELLOWSHIP)

Pediatric hospitalist, Boston Medical Center • Assistant Professor of Pediatrics, Boston University School of Medicine • Member, BMC's Medicaid Accountable Care Organization research team

MELANIE KORNIDES, ScD, RN, FNP-BC (THOMAS O. PYLE FELLOWSHIP)

Assistant Professor of Nursing, University of Pennsylvania School of Nursing, Department of Family and Community Health • 2018–2020 University of Pennsylvania Building Interdisciplinary Research Careers in Women's Health K12 Scholar

CHRISTINE LEOPOLD, MSc, PhD (THOMAS O. PYLE FELLOWSHIP)

Continuing her research on cancer therapeutics in health systems in her native Vienna.

TEACHING UPDATES

NEW DIRECTOR OF TEACHING PROGRAMS: LAURA GARABEDIAN

Assistant Professor Laura Garabedian, PhD, MPH assumed the role of Director of Teaching Programs in Fall 2018. Dr. Garabedian increased her focus on teaching in 2016, when she took on the role of Co-director of the Clinical Epidemiology and Population Health (CEPH) component of the Harvard Medical School Essentials of the Profession I and II courses, as well as led the Public Health module of the PhD in Health Policy Core Course. She is well-regarded by administrators, peers, and students alike, receiving the highest possible teaching evaluation from students in her small group sessions last year.

Assistant Professor Laura Garabedian is the Institute's new Director of Teaching Programs.

Dr. Garabedian provides leadership and oversight of the HMS longitudinal CEPH Curriculum, co-directs the Fellowship in Health Policy and Insurance Research with Associate Professor Anita Wagner, and serves as our liaison to the HMS Scholars in Medicine Program. She also facilitates teaching opportunities for faculty.

CHINA PROGRAM FOR HEALTH INNOVATION AND TRANSFORMATION

The Institute launched its new China Program for Health Innovation and Transformation in 2018 under the leadership of Associate Professor Jing Ma, MD, PhD. The program will expand our range of collaborations in teaching and research with leading Chinese academic institutions, health delivery systems, and insurance organizations. Early activities included the establishment of three recurring one-week training courses at the Institute for Chinese academics and health professionals on Integrated Management of Diabetes, Life Course Health, and Healthcare Executive Leadership.



New Initiatives

THE INSTITUTE IS ON TWITTER!

Follow us @DeptPopMed to connect with us and keep up to date with news, publications, and events.

DIVERSITY AND INCLUSION

In 2018 the Institute formed a Diversity and Inclusion Committee with a primary aim of creating a more inclusive workplace that will enable us to recruit, retain and develop a diverse pool of talent. We are committed to building and nurturing an inclusive professional community in which diversity is valued and every person feels they have a rightful place, are welcome and respected, and are supported in their endeavors. Developing from the Committee, an Institute statement on diversity was established along with three subcommittees focused on recruitment, community engagement, and assessment.

SUZANNE AND ROBERT FLETCHER PRIZE IN POPULATION MEDICINE

In 2018, the Institute awarded the first annual Suzanne and Robert Fletcher Prize in Population Medicine, named for Professors Emeriti Suzanne and Robert Fletcher, who have been national leaders in advancing the field of clinical epidemiology. An expert panel of Institute faculty reviewed submissions from Harvard Medical School and Harvard School of Dental Medicine students, judging each by the importance of the topic for population health, clarity of expression, and quality of writing.

- **Awardee: Suhas Gondi, First Year HMS Student**
Paper: “Negotiating Prescription Drug Prices to Improve Access and Reduce Costs”, which highlighted an important public health problem, high U.S. drug prices, and a promising solution, negotiating prices in the private sector.

RES

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RESEARCH

Our research spans many axes: from prenatal care to palliative care; from ambulatory clinics to intensive care units; and from policy to practice. Although investigator research interests are diverse, the common thread is a focus on **population health**. This big-picture perspective connects individual care to wider systems of care to improve health across the country and the world.

RESEARCH: A SHARP FOCUS ON ACTIONABLE FINDINGS

Much of our research generates immediately actionable findings that lead to concrete changes in local, national, and international policies and programs. Read on for our 2018 research highlights.

HEALTH INSURANCE POLICY

Institute researchers study the effects of health policies on patient health with the goal of informing solutions that improve health care costs, quality, and equity. A major focus of this work has been the impact of high-deductible health plans on health care quality, costs, and

disparities. New Institute research¹ led by Associate Professor Frank Wharam, MB, BCh, BAO, MPH, and published in the *Annals of Internal Medicine* shows that, among individuals with diabetes, mandated enrollment in a high-deductible insurance plan was associated with delays in seeking care for concerning symptoms of blood vessel disease such as cardiac chest pain and transient ischemic attack. Delays in diagnostic testing and treatment for such symptoms were also found. These results suggest these patients change their health care behavior in response to the increased out-of-pocket costs they face for medical services. Further research is required to determine if these delays increase adverse events such as heart attacks, strokes, and amputations.

RESEARCH ACROSS THE LIFECOURSE

Taking a life course approach to chronic disease, Institute researchers conduct interdisciplinary research within defined populations to better understand the etiologic factors working at the earliest stages of human

¹ Wharam JF, Lu CY, Zhang F, Callahan M, Xu X, Wallace J, et al. High-Deductible Insurance and Delay in Care for the Macrovascular Complications of Diabetes. *Ann Intern Med*. 2018.

Our research is focused in the following areas:

COMPARATIVE EFFECTIVENESS

Which strategies are best to optimize outcomes for individuals and populations?

DELIVERY SYSTEMS

How best to improve clinical care processes and outcomes?

PREVENTION

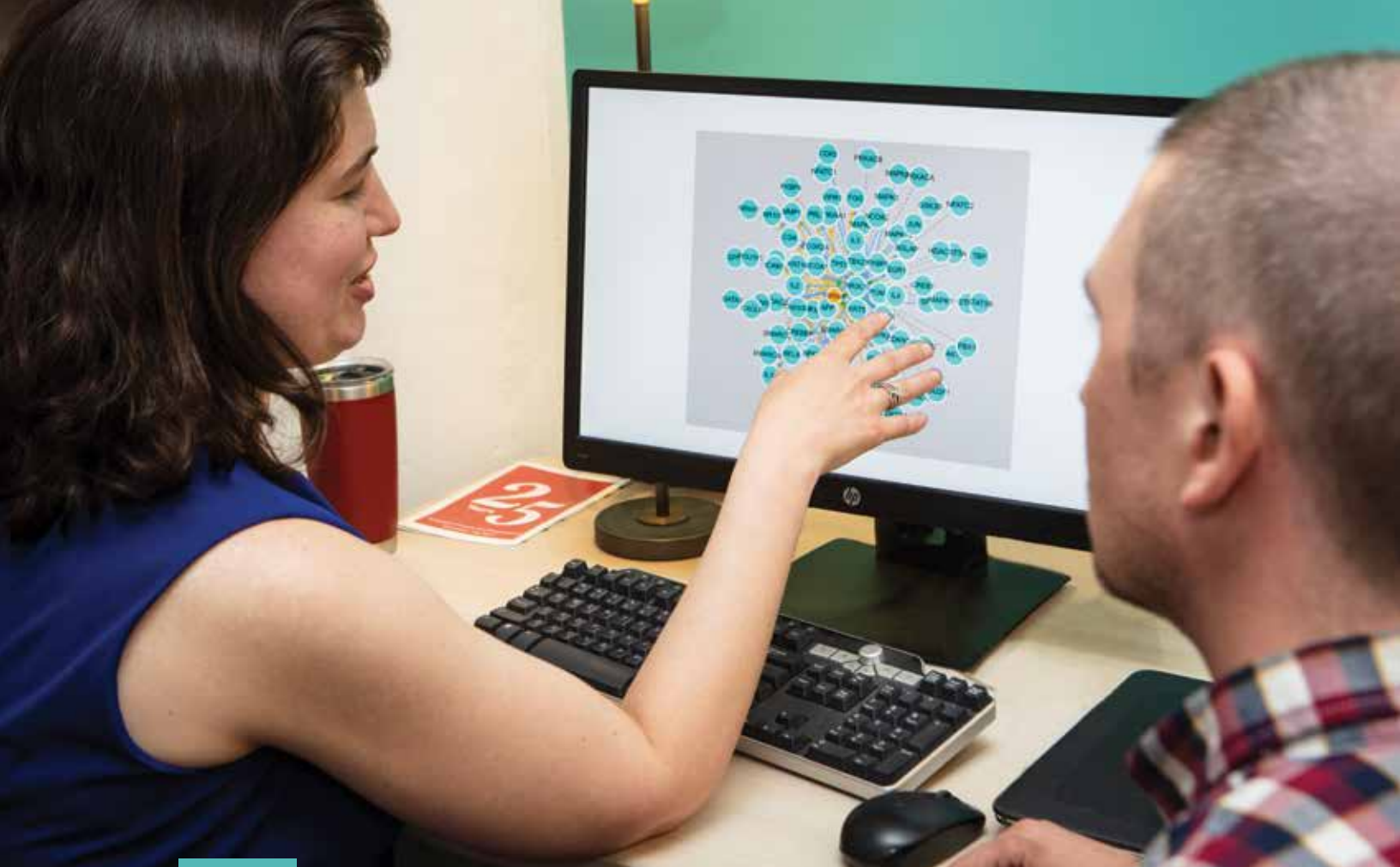
How to modify the risk of acquiring diseases and/or to prevent their secondary consequences?

POLICY

What is the impact of different approaches to health policy, financing, or administering health care insurance?

SURVEILLANCE AND PUBLIC HEALTH

How can health care data be used to support public health?



Research Scientist Joanne Sordillo reviews a network of age-related gene expression and response to asthma medications.

development. Lead Research Analyst Sheryl Rifas-Shiman, MPH examined previous reports that birth by cesarean delivery is associated with increased body mass index in childhood. Study results², published in *JAMA Pediatrics*, showed that compared with siblings born vaginally, those born via cesarean delivery did not have higher scores at five years. The findings suggest that other unmeasured variables might account for the associations seen in earlier studies.

THE FUTURE OF PRECISION MEDICINE

Rapid advances in genomic technologies and the availability of increasing amounts of genomic information influence how health care is provided. Institute

² Rifas-Shiman SL, Gillman MW, Hawkins SS, Oken E, Taveras EM, Kleinman KP. Association of Cesarean Delivery with Body Mass Index z Score at Age 5 Years. *JAMA Pediatr*. 2018 Aug 1;172(8):777-779.

researchers identify and evaluate genomics practices to improve individual and population health. In 2018, Associate Professor Ann Wu, MD, MPH led the development of a research statement³ from the American Thoracic Society and the National Heart, Lung, and Blood Institute on the current status and future opportunities in lung precision medicine research with a focus on biomarkers. The report provides an overview of the status of biomarker tests for lung diseases and identifies knowledge gaps that future research studies can address to efficiently translate biomarker tests into clinical practice.

³ Wu AC, Kiley JP, Noel PJ, Amur S, Burchard EG, Clancy JP, Galanter J, Inada M, Jones TK, Kropski JA, Loyd JE, Nogee LM, Raby BA, Rogers AJ, Schwartz DA, Sin DD, Spira A, Weiss ST, Young LR, Himes BE. Current Status and Future Opportunities in Lung Precision Medicine Research with a Focus on Biomarkers: an ATS/NHLBI Research Statement. *Am J Respir Crit Care Med*. 2018 Dec 15;198(12).

Research Divisions

CENTER FOR HEALTHCARE RESEARCH IN PEDIATRICS (CHERP)

CHERP leads population-based research in pediatrics. Its work in asthma, childhood infections, vaccines, and health policy has directly shaped national policy recommendations in these areas.

CHRONIC DISEASE RESEARCH ACROSS THE LIFECOURSE (CoRAL)

CoRAL focuses on developing innovative interventions and generating new knowledge regarding the origins of chronic disease, obesity, and consequences through the lifecourse.

HEALTH POLICY AND INSURANCE RESEARCH (HPI)

HPI research areas include understanding effects of high-cost medical care, pharmaceutical policies, health insurance innovations, personalized medicine, delivery system changes, behavioral interventions, and cost-quality trade-offs.

THERAPEUTICS RESEARCH AND INFECTIOUS DISEASE EPIDEMIOLOGY (TIDE)

TIDE assesses the safety of medical products, novel methods for illness surveillance and control of both health care and community acquired infections.

BIOSTATISTICS

The Biostatistics division is the home for statistical consultation and research at the Institute. The group collaborates widely on causal inference, observational epidemiology, bioinformatics, microsimulation, statistical software and graphics, and general statistical applications.

CENTERS OF EXCELLENCE

We are also home to three Centers of Excellence. These centers' primary purpose is to foster intellectual collaboration among faculty across Divisions that have shared research interests, and to promote the expertise of these individuals to the outside world.

- The Center for Cancer Policy and Program Evaluation (CarPE) conducts collaborative research on cancer control in the United States and international health systems.
- The PREcisiOn Medicine Translational Research (PROMoTeR) Center works to improve individual and population health outcomes by advancing precision medicine research and integrating use of genomic information into clinical care.
- The China Program for Health Innovation and Transformation (China Program) promotes research and education on population health and sustainable health care in China through innovation, collaboration, and transformation.



For over thirty years, Associate Professor Dennis Ross-Degnan's work has focused on improving health systems in the United States and low- and middle-income countries.

IMPROVING HEALTH WORKER PERFORMANCE IN LOW- AND MIDDLE-INCOME COUNTRIES

Our research geared toward facilitating the best possible health of individuals and populations in sustainable health systems often takes a global focus. Low- and middle-income countries face multiple challenges to health, a key one being inadequate health-care provider performance. A global team of researchers, under the senior leadership of Associate Professor Dennis Ross-Degnan, scD, published⁴ in *Lancet Global Health* a comprehensive systematic review of 337 well-designed studies on strategies to improve the performance of health workers in these countries. The breadth of the review and consistency of findings about certain strategies makes its results valuable for decision makers in health systems seeking to implement effective quality improvement strategies.

4 Rowe AK, Rowe SY, Peters DH, Holloway KA, Chalker J, Ross-Degnan D. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. *Lancet Glob Health*. 2018 Nov;6(11):e1163-e1175.

SEPSIS

Sepsis is a leading cause of death, disability, and cost worldwide. Given sepsis' frequency, its devastating morbidity and mortality, and ongoing high-profile initiatives to improve sepsis detection and care there is a critical need for better measures of sepsis incidence, trends, and outcomes. Faculty members Michael Klompas, MD, MPH and Chanu Rhee, MD, MPH led the development of Center for Disease Control's (CDC) Adult Sepsis Event definition in 2018. The CDC released an online toolkit in March 2018 to help hospitals implement this surveillance definition for sepsis based on objective clinical data to better track their sepsis incidence rates and outcomes. This definition was a product of CDC-funded work led by Drs. Klompas and Rhee over the past several years.

Although investigator research interests are diverse, the common thread is a focus on population health.

LOCAL AND NATIONAL NETWORKS

Institute researchers lead large local and national networks that use electronic health data to support clinical trials, comparative effectiveness research, health policy, and health services research.

NATIONAL PATIENT CENTERED CLINICAL RESEARCH NETWORK

Institute researchers play a lead role in the National Patient Centered Clinical Research Network (PCORnet), an innovative research network that facilitates clinical research by creating a large, highly representative network that directly involves patients in the development and execution of research. In a pioneering study conducted within PCORnet, Associate Professor Jason Block, MD, MPH, led a team examining the impact of antibiotic use in children on their subsequent weight. Previous studies have had conflicting results regarding the potential effect of antibiotics on weight. This study is the largest to tackle the issue, involving a sample of over 360,000 children from 35 institutions across the

[Associate Professor Jason Block and Research Associate Lauren Cleveland work on the PCORnet Antibiotics and Childhood Growth Study.](#)

country. The study⁵, published in *Pediatrics*, showed that the effect of antibiotic use in early childhood on weight around age five was small — less than a pound difference in weight for children of average height and weight receiving four or more courses of antibiotics, compared to children who received none.

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) SENTINEL SYSTEM

The FDA Sentinel Initiative, based in the HPHC Institute, has created a national infrastructure for the FDA to monitor the safety and effectiveness of marketed medical products while providing a high level of protection for the privacy and security of patients' health information. Led by Institute faculty and staff, the program uses curated electronic health data from 18 health plans and

5 Block JP, Bailey LC, Gillman MW, Lunsford D, Daley MF, Finkelstein J, Heerman W, Horgan CE, Hsia DS, Jay M, Rao G, Reynolds JS, Rifas-Shiman SL, Sturtevant JL, Toh S, Trasande L, Young J, Forrest CB; PCORnet Antibiotics and Childhood Growth Study Group. Early Antibiotic Exposure and Weight Outcomes in Young Children. *Pediatrics*. 2018; 142(6).





Professor Michael Klompas's work focuses on practice, research, and education in infection control.

hospital systems, covering > 100 million people. Using this national data network, FDA regularly conducts safety analyses of the billions of hospital stays, outpatient visits, and pharmaceutical dispensings included in the Sentinel system. These analyses have informed many regulatory decisions made by the FDA and, in the past two years, have eliminated the need for postmarketing studies on nine potential safety issues associated with five products. Through 2018, FDA has used Sentinel analyses to address 38 regulatory decisions.

MDPHNET: INFECTIOUS AND CHRONIC DISEASE SURVEILLANCE

Institute researchers have a longstanding partnership with the Massachusetts Department of Public Health (MDPH) to build and maintain a distributed data network that uses large practices' electronic health record data to support next day detection of notifiable diseases such as hepatitis, HIV and tuberculosis, weekly assessment of influenza-like illness, and as-needed monitoring of chronic illness and its treatment. In 2018, researchers implemented a new program that enables the public health department to better monitor HIV care and response to treatment for people living with HIV/

AIDS and chronic Hepatitis C. These enhancements are expected to improve patient-level health outcomes and assist providers and the Department of Public Health with quality improvement activities. Our researchers, in conjunction with MDPH, also completed analyses of patients with multiple sexually transmitted infections to identify risk factors and potential points of intervention for MDPH.

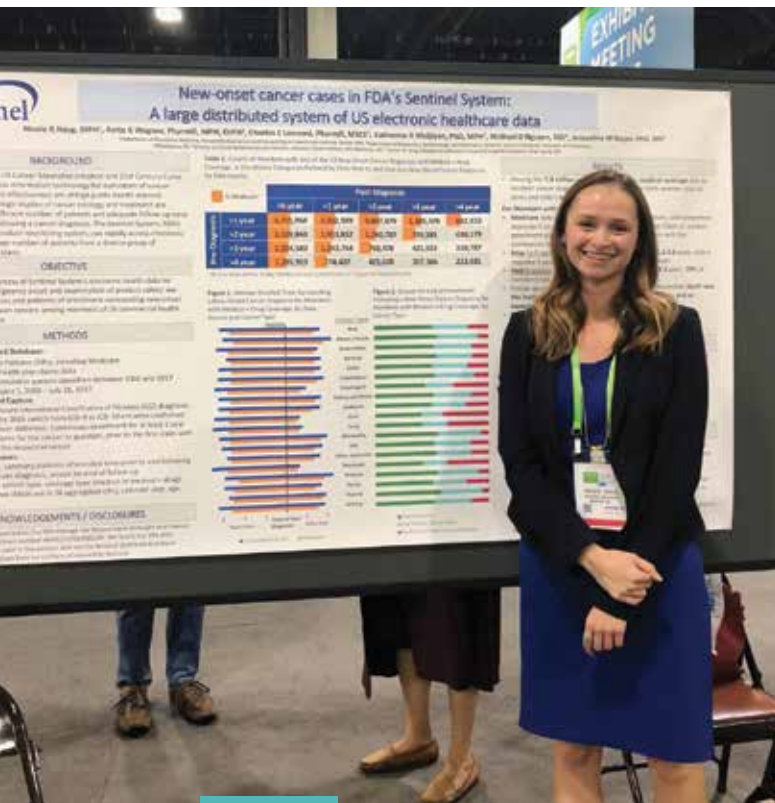
THOUGHT LEADERSHIP: WEIGHING IN ON TODAY'S PRESSING ISSUES

In addition to publishing solid scholarship based on research findings, faculty often pen think pieces on relevant, timely topics in health care and medicine in high-impact journals. Here are a few highlights from 2018:

ANTIBIOTICS FOR SEPSIS — FINDING THE EQUILIBRIUM

Professor Michael Klompas, MD, MPH and colleagues make the case in this *Journal of the American Medical Association (JAMA) Viewpoint*⁶ that it is time to balance the recommendation for early and aggressive antibiotics for all patients with possible sepsis with the diagnostic uncertainty regarding sepsis and the possible harm associated with unnecessary antibiotics. The authors suggest testing to confirm infection in non-shock patients in place of rapid empirical antimicrobial treatment.

6 Klompas M, Calandra T, Singer M. Antibiotics for Sepsis — Finding the Equilibrium. *JAMA*. 2018;320(14):1433-1434. doi:10.1001/jama.2018.12179



Research Analyst Nicole Haug presents findings based in the FDA Sentinel Initiative.

DATA ENCLAVES FOR SHARING INFORMATION DERIVED FROM CLINICAL AND ADMINISTRATIVE DATA

Professor Richard Platt, MD, MSc and former Institute faculty member Tracy Lieu, MD, MPH discuss the barriers to sharing raw institutional data for developing evidence-based treatment protocols and discuss sharing information, as part of a data enclave, rather than data, as a possible solution. This *JAMA Viewpoint*⁷ suggests data enclaves enable involved parties to minimize the risks of data sharing and focus on the benefits of proposed analyses.

7 Platt R, Lieu T. Data Enclaves for Sharing Information Derived From Clinical and Administrative Data. *JAMA*. 2018;320(8):753-754. doi:10.1001/jama.2018.9342

POSTPARTUM CARE IN THE UNITED STATES — NEW POLICIES FOR A NEW PARADIGM

In this *New England Journal of Medicine (NEJM) Perspective*⁸, Institute fellow Mara Murray Horwitz, MD and colleagues discuss postpartum care and outcomes in the United States and the relationship to insurance reimbursement and parental leave policies. The authors argue that broader policy changes can support effective, woman-centered, and equitable postpartum care.

THE CALORIE-LABELING SAGA — FEDERAL PREEMPTION AND DELAYED IMPLEMENTATION OF PUBLIC HEALTH

Jason Block, MD, MPH, authored this *NEJM Perspective*⁹ on the delayed implementation of the Affordable Care Act's calorie labeling law and the challenges presented by federal preemption. The piece offers key lessons for future policies on obesity prevention.

THE FDA SENTINEL INITIATIVE — AN EVOLVING NATIONAL RESOURCE

Faculty members Richard Platt, MD, MSc, Jeffrey Brown, PhD, and colleagues authored a *Perspective*¹⁰ in the *NEJM* discussing the evolution of the FDA Sentinel Initiative since its launch in 2008. The piece describes the evolution of the Sentinel Initiative from a pilot program designed to assess potential drug-safety signals in insurance claims into a core component of the FDA's evolving safety surveillance system.

8 Murray Horwitz ME, Molina RL, Snowden JM. Postpartum Care in the United States — New Policies for a New Paradigm. *N Engl J Med*. 2018 Nov 1;379(18):1691-1693.

9 Block JP. The Calorie-Labeling Saga — Federal Preemption and Delayed Implementation of Public Health Law. *N Engl J Med*. 2018; 379(2): 103-105.

10 Platt R, Brown JS, Robb, M, McClellan, M, Ball R, Nguyen MD, Sherman RE. The FDA Sentinel Initiative — An Evolving National Resource. *N Engl J Med* 2018; 379:2091-2093



Institute Endowed Chairs, left to right:
Michael Klompas, Emily Oken, Frank Wharam, and Ann Wu.

NATIONAL LEADERSHIP POSITIONS

Maryam Asgari

- Chair, Epidemiology Interest Group, American Academy of Dermatology
- President, American DermatoEpidemiology Network
- Board of Directors, Society for Investigative Dermatology
- Elected Member, American Dermatologic Association

Jason Block

- Chair, Policy Track, Annual Meeting Program Committee, The Obesity Society

Jeffrey Brown

- Commissioner, Clinical Data Interchange Standards Consortium Blue Ribbon Commission
- National Evaluation System for Health Technology Coordinating Center
- Medical Device Innovation Consortium Data Quality Subcommittee

Maureen Connelly

- Chair, Group on Faculty Affairs, Association of American Medical Colleges

Marie-France Hivert

- Advisory Committee, Environmental Influences on Children Health Outcomes program Epigenetics and Genetics Workshop, National Institutes of Health

- Leadership and Nominating Committees, Council on Lifestyle and Cardiometabolic Health, American Heart Association
- Primary Prevention of Cardiovascular Disease & Type 2 Diabetes in Patients at Metabolic Risk Task Force (Primary Prevention Guidelines Writing Committee), Endocrine Society

Christine Lu

- Advisory Board, New England Comparative Effectiveness Public Advisory Council, Institute for Clinical and Economic Review

Michael Klompas

- Sepsis Task Force and Standards and Guidelines Committee, Infectious Disease Society of America
- Pediatric Sepsis Surveillance Working Group, Centers for Disease Control and Prevention
- Surviving Sepsis Campaign Guidelines Committee
- Chair, Healthcare Safety and Quality Improvement Study Section, Agency for Healthcare Research and Quality
- Guidelines Committee, Society for Healthcare Epidemiology of America

Julia Marcus

- HIV Prevention Trial Design Project, Forum for Collaborative Research

Catherine Panozzo

- Secretary, Vaccine Special Interest Group, International Society for Pharmacoepidemiology and Risk Management
- Acute Aseptic Arthritis Working Group, Brighton Collaboration

Emily Oken

- Co-chair, Protocol Implementation and Evaluation Committee, Environmental Influences on Child Health Outcomes program, National Institutes of Health
- Technical Expert Collaborative on the Dietary Guidance Development Project for Birth to 24 Months and Pregnancy, United States Department of Agriculture Nutrition Evidence Library

Richard Platt

- Co-chair, Comparative Effectiveness Research Innovation Collaborative, Leadership Consortium on Value and Science-Driven Health Care, National Academy of Medicine
- Advisory Panel on Research, Association of American Medical Colleges

Chanu Rhee

- Sepsis Task Force, Infectious Disease Society of America
- Pediatric Sepsis Surveillance Working Group, Centers for Disease Control and Prevention

James Sabin

- Chair, Council on Ethical & Judicial Affairs, American Medical Association

Kenneth Sands

- Advisory Board, Leapfrog Hospital
- National Quality Partners Leadership Consortium

Edward Septimus

- Co-chair, Patient Safety Committee, National Quality Forum
- Sepsis Task Force, Infectious Disease Society of America

Natasha Stout

- Secretary/Treasurer, Society for Medical Decision Making

William Taylor

- Primary Care and Chronic Illness Standing Committee, National Quality Forum

Darren Toh

- Board of Directors, International Society for Pharmacoepidemiology

Anita Wagner

- Chair, Committee to conduct an external review of National Prescribing Service MedicineWise Australia evaluation methods

Frank Wharam

- Advisory Panel on Improving Healthcare Systems, Patient-centered Outcomes Research Institute

Ann Wu

- Executive Committee, Behavioral Science Health Services Research Assembly, American Thoracic Society

HONORS/ AWARDS

Harvard Medical School Harold Amos Faculty Diversity Award

Emily Oken, MD, MPH

Institute

INSTITUTE ENDOWED CHAIRS

Michael Klompas, MD, MPH; Emily Oken, MD, MPH; Frank Wharam, MB, BCh, BAO, MPH; and Ann Wu, MD, MPH

EBERT FELLOWSHIP, HARVARD MEDICAL SCHOOL 50TH ANNIVERSARY PROGRAM FOR SCHOLARS IN MEDICINE

Julia Marcus, PhD, MPH

EBERT CAREER DEVELOPMENT AWARDS

Jason Block, MD, MPH; Katherine Yih, PhD, MPH; Christine Lu, PhD, MSc

PYLE FELLOWSHIPS

Tom Chen, PhD; Rachele Hendricks-Sturup, DHSc, MSc, MA; Mei-Sing Ong, PhD, MS; and Jenna Wong, PhD, MSc

External Awards

MASSACHUSETTS PSYCHIATRIC SOCIETY LIFETIME ACHIEVEMENT AWARD

James Sabin, MD

HELEN CLARK-JOURNAL OF PHARMACEUTICAL POLICY AND PRACTICE AWARD FOR PHARMACEUTICAL POLICY AND PRACTICE RESEARCH

Stephen Soumerai, ScD

Robert H. Ebert Faculty Development Awards

The Robert H. Ebert Career Development awards, named for the founder of Harvard Community Health Plan and former Dean of Harvard Medical School, support the work of Institute faculty who demonstrate exceptional promise in the area of ambulatory care, primary care, or preventive medicine. These awards provide resources to develop leading-edge programs in teaching and research and to pursue scientific and professional activities consistent with the department's mission. In 2018, three new awards were given to Harvard Pilgrim Health Care Institute faculty.

Jason Block, MD, MPH

GENERAL INTERNAL MEDICINE PHYSICIAN • RESEARCHER

RESEARCH INTERESTS: neighborhood-level determinants of weight gain and obesity • evaluating governmental and institutional policies • novel interventions to improve diet • leveraging electronic health record data for observational research and public health surveillance

TESTING THE POTENTIAL OF RELIABLE, ROBUST DATASETS

Dr. Block will use his Ebert award to explore the use of PCORnet for surveillance of chronic diseases beyond obesity, including diabetes and hypertension. Working with the PCORnet Coordinating Center, he and his team will investigate how to utilize geographic data in the distributed data network and to determine PCORnet's capacity to make prevalence estimates by geographic units; develop reusable queries that can be utilized to assess disease surveillance over time; and seek opportunities to link state- and city-level obesity prevention policies to PCORnet data, to facilitate policy evaluation.

Christine Lu, MSc, PhD

PHARMACIST • HEALTH POLICY SCIENTIST • PHARMACOEPIDEMIOLOGIST

RESEARCH INTERESTS: generating evidence to support policy and clinical decisions to enhance equitable and affordable access to, and rational use of, precision medicine technologies

EXPANDING AN EMERGING APPROACH TO DISEASE PREVENTION AND TREATMENT

Dr. Lu's Ebert award provides support for her to expand the Institute's existing precision medicine research portfolio, to obtain competitive funding, and to build a network of partners in the field of genomics.

Katherine Yih, PhD, MPH

BIOLOGIST • EPIDEMIOLOGIST

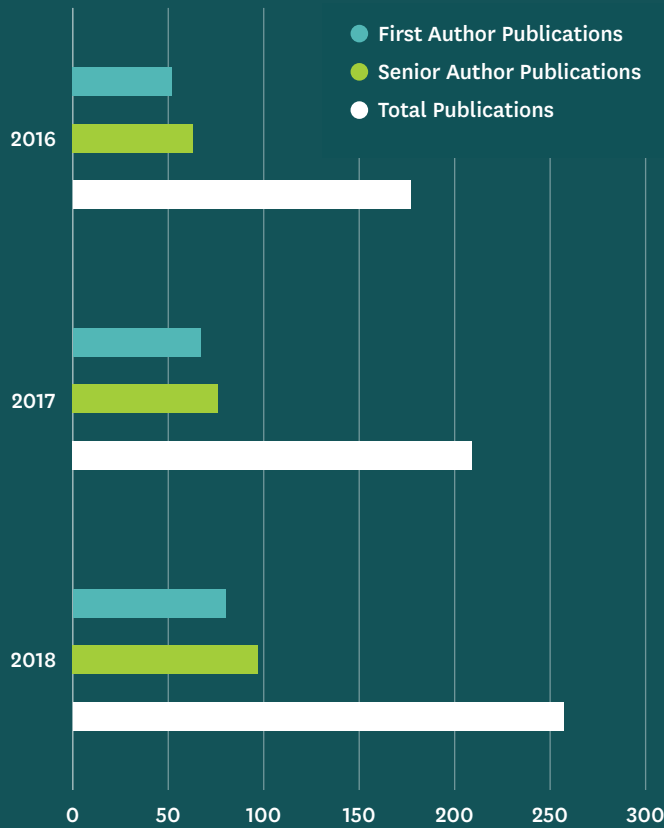
RESEARCH INTERESTS: domestic and international surveillance of infectious disease and immunization • vaccine safety monitoring

LEADING THE CHARGE IN NOVEL METHODS TO MONITOR VACCINE SAFETY

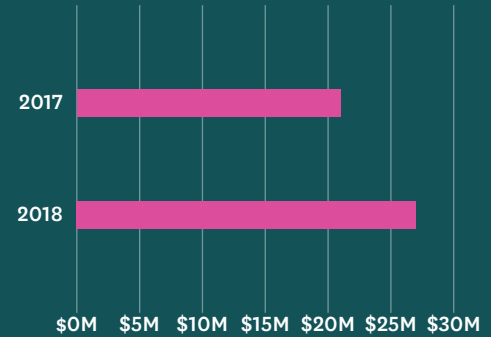
Dr. Yih's work will expand upon pilot work conducted with new, novel Institute-developed methods to direct safety studies on two new vaccines: the newest human papillomavirus vaccine, Gardasil 9, and the brand-new recombinant zoster vaccine, Shingrix. Dr. Yih's proposed work will help the Institute maintain its productivity and reputation as a center of post-licensure vaccine safety research.

2018 BY THE NUMBERS

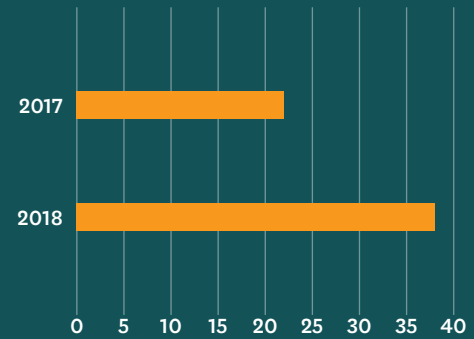
PUBLICATIONS IN PEER-REVIEWED JOURNALS



DOLLAR AMOUNT OF NEW AWARDS



NEWLY FUNDED PROPOSALS (TOTAL #)



38

Core Faculty

17

Affiliated Faculty

53

Affiliated Clinical Faculty

9

Research Scientists

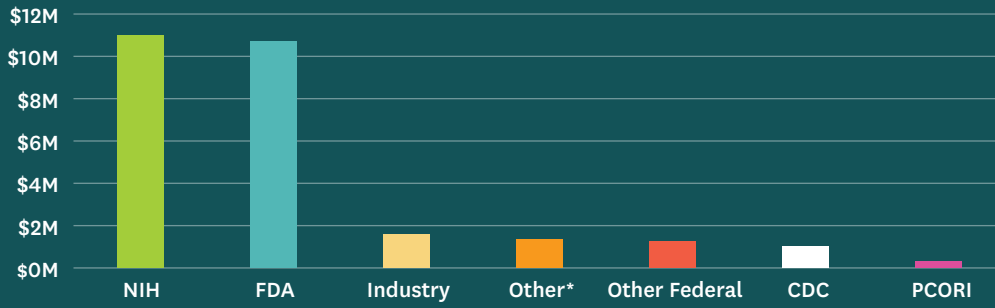
20

Fellows

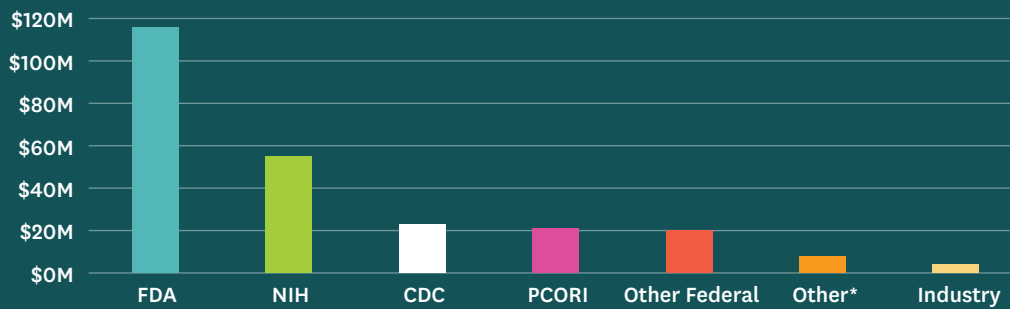
157

Staff

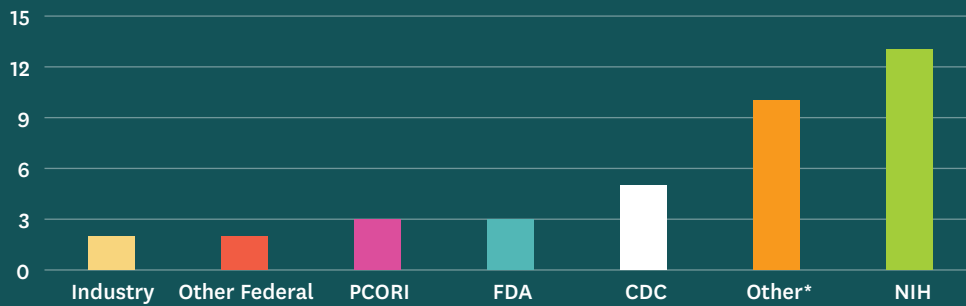
DISTRIBUTION OF NEW 2018 AWARDS (BY FUNDED AMOUNT)



DISTRIBUTION OF ALL ACTIVE AWARDS (BY FUNDED AMOUNT)



NUMBER OF NEW 2018 AWARDS (BY FUNDER)



*(Foundation/Internal/State)

145

Active Grants

38

New Awards

\$27.27M

In New Awards

\$57.97M

In Grant/Contract Revenue

Mission

To improve health care
delivery and population
health through innovative
research and teaching

DEPARTMENT OF POPULATION MEDICINE



HARVARD
MEDICAL SCHOOL



Harvard Pilgrim
Health Care Institute

HARVARD PILGRIM HEALTH CARE INSTITUTE

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