Harvard Catalyst

2021 Update

HARVARD CATALYST — Harvard Clinical & Translational Science Center

About Harvard Catalyst

The Harvard Clinical and Translational Science Center

Harvard Catalyst is devoted to advancing human health by supporting and innovating clinical and translational science, and training the next generation of researchers.

Founded in 2008, Harvard Catalyst is a shared enterprise of Harvard University, funded by the NIH through its Clinical and Translational Science Awards (CTSA) Program, the university, and several of our affiliated academic healthcare centers. The CTSA consortium is a network of approximately 60 centers throughout the U.S. funded by the NIH's National Center for Advancing Translational Sciences (NCATS). The center works across the university and affiliate academic healthcare centers to provide training, support, funding, and opportunities for collaboration among clinical and translational (C/T) researchers.

Harvard Catalyst's 13 programs train, connect, and support Harvard's biomedical and public health faculty by providing research resources, pilot grant funding, education/training programs, data tools, and other forms of support. Throughout all of our initiatives, we are committed to building a diverse and inclusive biomedical workforce.

This update reflects several of Harvard Catalyst's key activities between 2018 and 2021. It includes data culled from each of our programs and, where appropriate, associated data from Harvard-affiliated academic healthcare centers. While not intended as a comprehensive report outlining all of Harvard Catalyst's activities and initiatives during this period, it provides a snapshot of several projects of particular importance for the C/T community.
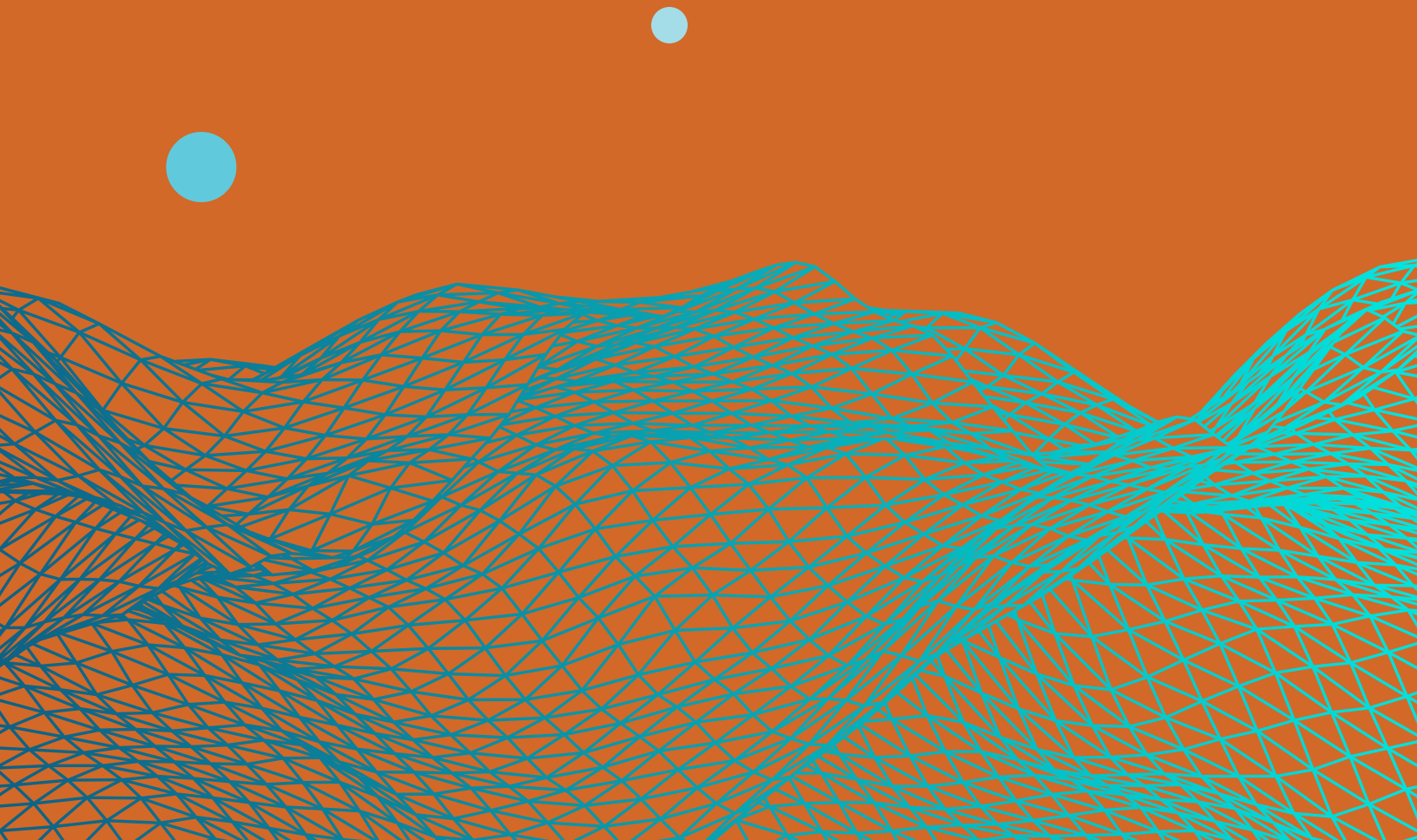
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Train

Education is at the core of Harvard Catalyst's mission. We work to develop the next generation of clinical and translational researchers by offering dozens of courses, training programs, and workshops ranging from seminars to multi-week courses. Topics range from successful grant writing strategies, omics research, clinical trial design, research leadership, and more.

Our Postgraduate Education program, C/T Research Academy, and KL2/CMeRIT program constitute the three pillars of our educational and training offerings.
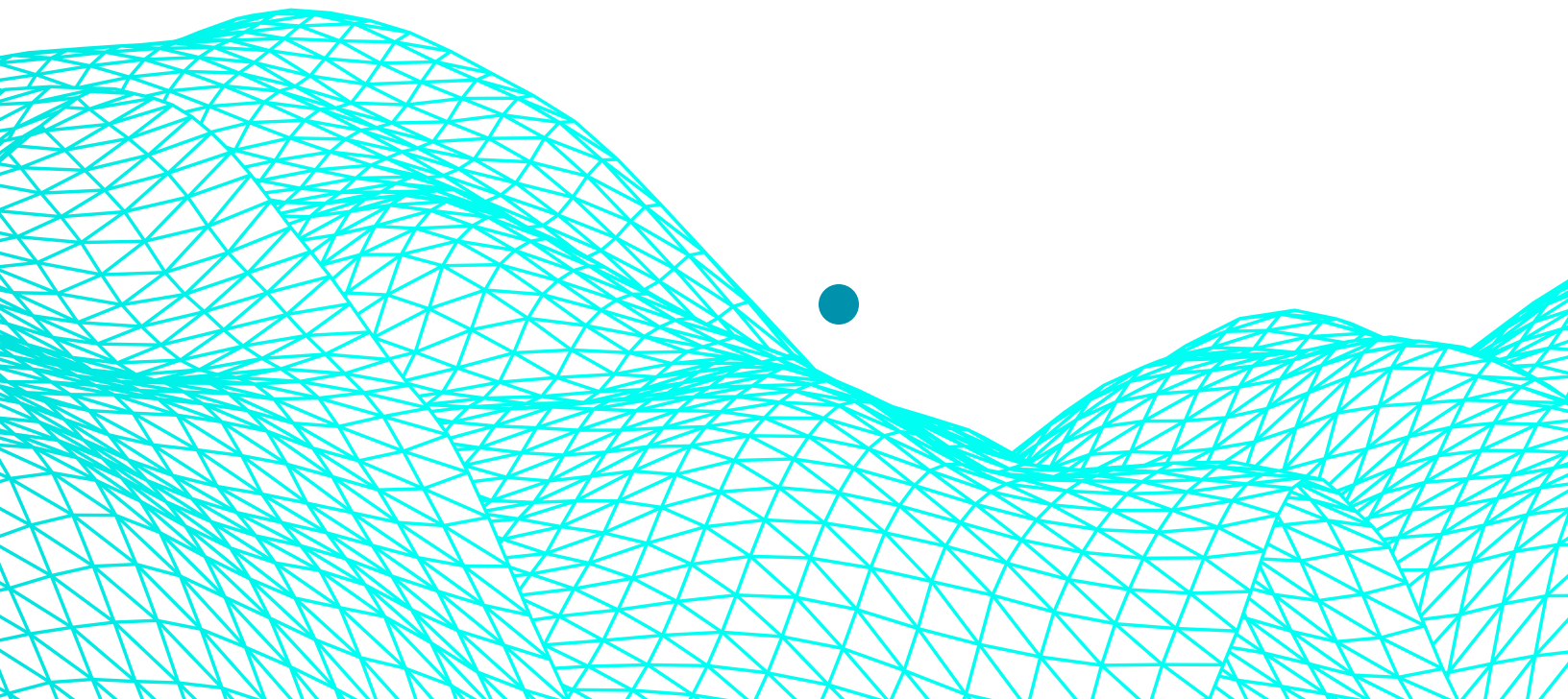
TRAIN

Postgraduate Education

The **Postgraduate Education program (PGE)** provides training and support to researchers from Harvard University's schools and affiliate academic healthcare centers, and to those outside of Harvard.

The program works to enhance clinical and translational research education across the training spectrum by:

+ Providing courses and resources at the introductory and advanced levels in a variety of content areas, including:
    — boundary-crossing skills (e.g. communication, leadership)
    — research methodologies
    — translational domains

+ Offering longitudinal programs that strengthen mentor networks while skill building (e.g. Grant Review and Support Program and Career Catalyst)

+ Connecting with Harvard-affiliated education programs to ensure integration and comprehensive support of the research community

+ Customizing learning experiences for groups to supplement their independent programs

TRAIN

Postgraduate Education

Number of PGE Courses Offered

Courses fall into the reporting period based on the date the course ends.

TYPE OF COURSE	2018	2019	2020	2021
Face-to-Face (Live)	13	18	1	0
Online	14	16	26	24
Hybrid	1	1	1	0
Webinar	0	0	13	11
Total	**28**	**35**	**41**	**35**

Number of Enrolled Participants in PGE Courses

Due to the COVID-19 shut down in early 2020, many participants turned to PGE's enhanced online offerings.

TYPE OF COURSE	2018	2019	2020	2021
Face-to-Face (Live)	562	812	30	0
Online	1,348	1,518	2,708	2,014
Hybrid	22	31	20	0
Webinar	0	0	1,844	1,038
Total	**1,932**	**2,361**	**4,602**	**3,052**

Note: Considering the pandemic, online courses continued to be the dominant offering.

Note: There was a sharp increase in 2020 because of the pandemic. In 2021, we saw increased enrollment compared to 2019.

Course Enrollment by Position

Positions are categorized as follows:

+ **Faculty:** Professor, Associate Professor, Assistant Professor, Instructor, Lecturer
+ **Fellows:** Research Fellow, Postdoctoral Fellow, Clinical Fellow, Fellow
+ **Research Staff:** Research Scientist, Research Associate, Research Assistant, Nurse Researcher
+ **Students:** Medical Student, Graduate Student, Resident
+ **Other:** Other, Blank/None

POSITION	2018	2019	2020	2021
Faculty	582	506	1,036	785
Fellows	1,289	1,274	2,140	1,136
Research Staff	158	208	513	284
Students	105	116	450	178
Other	68	136	345	295
TOTAL	**2,202**	**2,240**	**4,484**	**2,678**

While the total number of those enrolled increased from year to year, there may be some fluctuations in the distribution of individual positions.

PGE Individual Course Satisfaction

According to satisfaction survey results for PGE courses the average satisfaction rate was 99% for 2018, 2019, 2020, and 2021.

TRAIN

Career Catalyst

Career Catalyst (formerly Mentee-Mentor Matching Program) is a one-year program that matches early-stage investigators with senior faculty who serve as developmental mentors for the duration of the program. Participants in the program learn about the importance of establishing successful mentoring relationships that promote personal and professional satisfaction.

+ **2018:** A total of 15 individuals participated
+ **2019:** A total of 29 individuals participated
+ **2020:** A total of 30 individuals participated
+ **2021:** A total of 44 individuals participated

TRAIN

Clinical and Translational (C/T) Research Academy

Clinical and Translational (C/T) Research Academy is a two-year certificate program for early-career clinicians and researchers seeking to strengthen their knowledge in clinical and translational research via a structured didactic curriculum and a mentored research experience with a Harvard Medical School faculty member. Trainees pursue mentor-based research projects at their home institutions, and the program provides additional external mentoring to each trainee to help further their career and scientific development goals. C/T Research Academy focuses on the following key areas: clinical trial and study design; computational/statistical sciences; epidemiology; drug development; biomedical ethics; genetics and omics technology; and commercializing innovations.

Number of Awardees

Number of individuals that were **admitted** into the program within the reporting period. *Note: C/T Research Academy commences in July of each year.*

+ **2018:** 14 individuals were admitted
+ **2019:** 18 individuals were admitted
+ **2020:** 12 individuals were admitted
+ **2021:** 13 individuals were admitted

Number of Graduates

Number of individuals that **graduated** from the program within the reporting period. *Note: C/T Research Academy awardees graduate in June.*

+ **2018:** 17 individuals graduated
+ **2019:** 16 individuals graduated
+ **2020:** 11 individuals graduated
+ **2021:** 14 individuals graduated

KL2/Catalyst Medical Research Investigator Training (CMeRIT)

The **KL2/Catalyst Medical Research Investigator Training (CMeRIT)** program provides senior fellows and junior faculty advanced training in clinical and translational research. Trainees participate in a mentored research project in their area of expertise and receive support to apply for an independent NIH award (e.g., K23, K08, R01). Awardees also pursue an educational program that fulfills the mission of the program and provides optimal training in their chosen career objectives.

Number of KL2/CMeRIT Awardees

Number of individuals who were admitted into the **KL2/CMeRIT** program within the reporting period. The program begins each year in October.
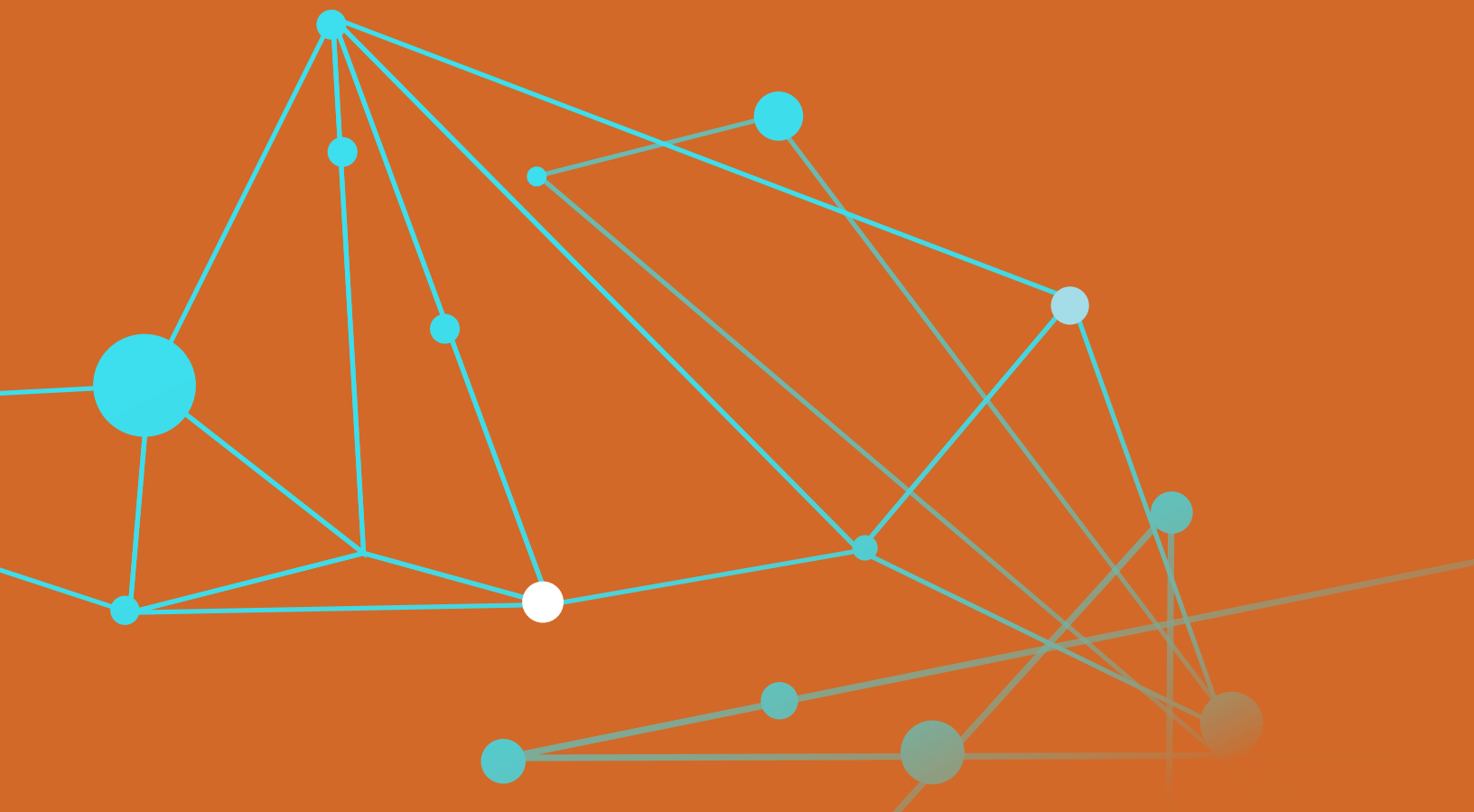
+ **2018:** 13 individuals were admitted

+ **2019:** 12 individuals were admitted

+ **2020:** 9 individuals were admitted

+ **2021:** 11 individuals were admitted

Connect

Harvard Catalyst provides tools and platforms to facilitate connections among thousands of researchers and trainees across the university and affiliated academic healthcare centers, fostering new collaborations and nurturing innovation and groundbreaking discoveries. This model promotes faculty diversity as study team members collaborate across multiple institutions and networks. Harvard Catalyst also connects clinical and translational researchers to resources, consulting guidance, funding opportunities, and other forms of support.

Our Connector, Bioinformatics, and Translational Innovator programs lead the center's efforts in this area.

CONNECT

Connector

The **Connector** program offers essential guidance and support at all phases of clinical research, from protocol development to dissemination of results, for clinical investigators across all of Harvard's schools and affiliated academic healthcare centers. The goal of this program is to facilitate high-quality research, particularly for early-stage investigators. Connector convenes clinical leaders from each of the largest affiliated academic healthcare centers to share ideas and solutions, consolidate resources, and coordinate efforts.

Number of Studies Reviewed in Protocol Review by PI Home Institution

The **Connector Protocol Review Application** is a web-based tool that allows investigators to submit requests for services to support the start-up and conduct of both inpatient and outpatient studies which are conducted in the Clinical Research Center (CRC) or elsewhere in the hospital. Services are provided by the institution's Connector-supported Translational Navigation Teams and may be free or fee-based, depending on the service and the investigator's funding status.

Services may be consultative (e.g., advice on recruitment or data safety plans, troubleshooting study challenges) or instrumental (e.g., preparation of IRB applications, creation of study documents or workflows, help with recruitment or consent). Investigators from any of the participating Harvard-affiliated institutions may apply for services at their institution. Investigators from any non-participating Harvard-affiliated institution may request consultative, but not instrumental, services from the participating institutions. All developed studies must go through Protocol Review to use Connector services. These numbers represent demand/volume for the program.

+ **2018:** 276 new studies from partner institutions were supported by the Connector program

+ **2019:** 300 new studies from partner institutions were supported by the Connector program

+ **2020:** 298 new studies from partner institutions were supported by the Connector program

+ **2021:** 315 new studies from partner institutions were supported by the Connector program

Number of Total Active Connector Studies

"Active" is defined as a study that has seen at least one study subject in the specified reporting period either on the CRC or elsewhere in the hospital. This reflects visits recorded in our scheduling software (called Scheduler) or otherwise reported by the site's Translational Navigation Team. Because a study can be active over multiple reporting periods, these numbers are not independent across years. The primary support provided is coordination of scheduling visits, but may also include, for example, consenting or data management.

+ **2018:** 526 active Connector studies took place
+ **2019:** 789 active Connector studies took place
+ **2020:** 838 active Connector studies took place
+ **2021:** 932 active Connector studies took place

COVID-19 Research

INDICATOR	2020	2021
Studies Reviewed	426	83
Studies Supported	107	112
Investigator-Initiated	61	62
Industry-Sponsored	46	50

Number of Inpatient Days

This data tracks and monitors capacity and usage for active inpatient studies that utilize Connector services. This data is reported by the sites' Translational Navigation Teams and "inpatient" is defined as "in a bed at midnight."

+ **2018:** 1,901 total inpatient days
+ **2019:** 1,789 total inpatient days
+ **2020:** 863 total inpatient days
+ **2021:** 1,554 total inpatient days

Number of Outpatient Visits

This data tracks and monitors capacity and usage for active outpatient studies that utilize Connector services. "Outpatient" is defined as a "non-overnight research visit on the CRC unit or elsewhere in the hospital." This data is reported by the sites' Translational Navigation Teams.

+ **2018:** 23,350 total outpatient visits
+ **2019:** 21,556 total outpatient visits
+ **2020:** 20,683 total outpatient visits
+ **2021:** 25,521 total outpatient visits

Number of Studies Using the Joint Contract with Quest

In 2018, Harvard Catalyst negotiated a joint laboratory contract between Quest Diagnostics and seven of Harvard's affiliated healthcare centers for the purpose of providing cost savings to individual studies through larger bulk pricing. In examining the actual lab tests run under this contract, and comparing the Quest bulk price for those tests to the average best research price available at the participating institutions, we estimated that participating studies saved approximately **$548,534** in lab fees in **2019**, **$275,188** in **2020**, and **$361,997** in **2021**.

+ **2019:** The total number of studies using the joint contract with Quest for all institutions was 96

+ **2020:** The total number of studies using the joint contract with Quest for all institutions was 99

+ **2021:** The total number of studies using the joint contract with Quest for all institutions was 134

CONNECT

Biomedical Informatics

The **Biomedical Informatics program** creates and manages platforms, informatics software services, applications, and networks that are devoted to serving C/T researchers at Harvard University and its affiliates, and our research partners in the CTSA Consortium, a network of approximately 60 centers throughout the U.S. funded by the NIH's National Center for Advancing Translational Sciences (NCATS). The program provides ways for researchers to find collaborators and resources that match their needs and interests; study populations across multiple Harvard affiliates; receive state-of-the-art education in the use of computational tools; and increase the cohesion of our research community across multiple institutional boundaries.

CONNECT

Harvard Catalyst Profiles

Harvard Catalyst Profiles is a research discovery search tool for finding publications authored by faculty at Harvard Medical School, Harvard School of Dental Medicine, and the Harvard T.H. Chan School of Public Health. In searching by topic or faculty name, networks of connections are displayed to demonstrate geographic and topical proximity, along with publication lists and other relevant background. Several features of this tool allow faculty to connect, collaborate, and network with other faculty who specialize in similar and overlapping research domains. Profiles are automatically generated for faculty who can update and enhance their profiles with photos, social medial links, awards, and other relevant content.
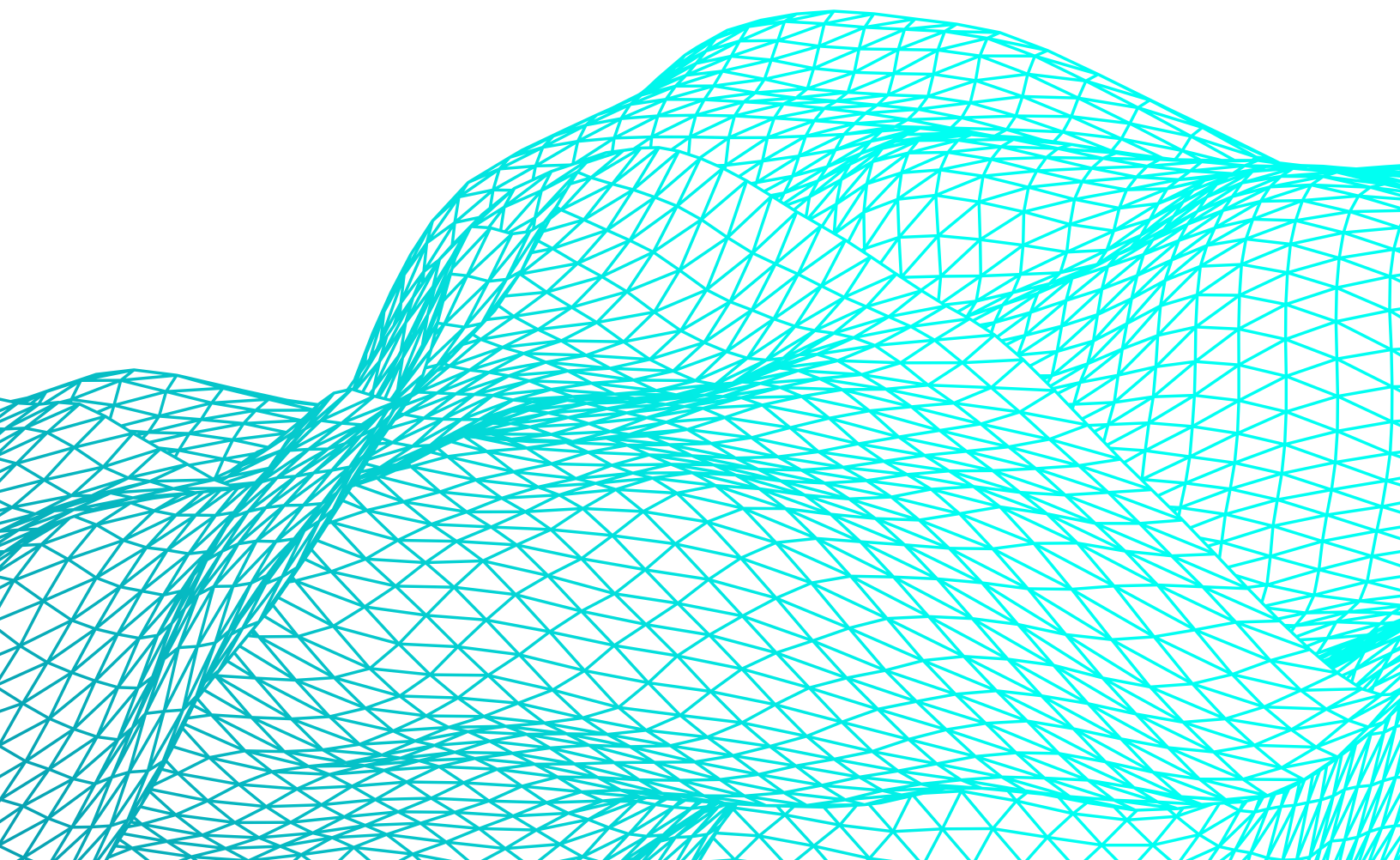
Unique Page Views

+ 2,128,786 unique Harvard Catalyst Profiles page views in 2018

+ 2,268,141 unique Harvard Catalyst Profiles page views in 2019

+ 2,527,084 unique Harvard Catalyst Profiles page views in 2020

+ 2,662,136 unique Harvard Catalyst Profiles page views in 2021

Engagement and Content Curation

+ 3,394 user-curated profiles in 2018

+ 3,970 user-curated profiles in 2019

+ 4,620 user-curated profiles in 2020

+ 4,858 user-curated profiles in 2021

Note: The total number of Profiles automatically generated reflects the number of faculty at the three schools represented (approximately 24,000). Users can curate the content to enhance the information displayed.
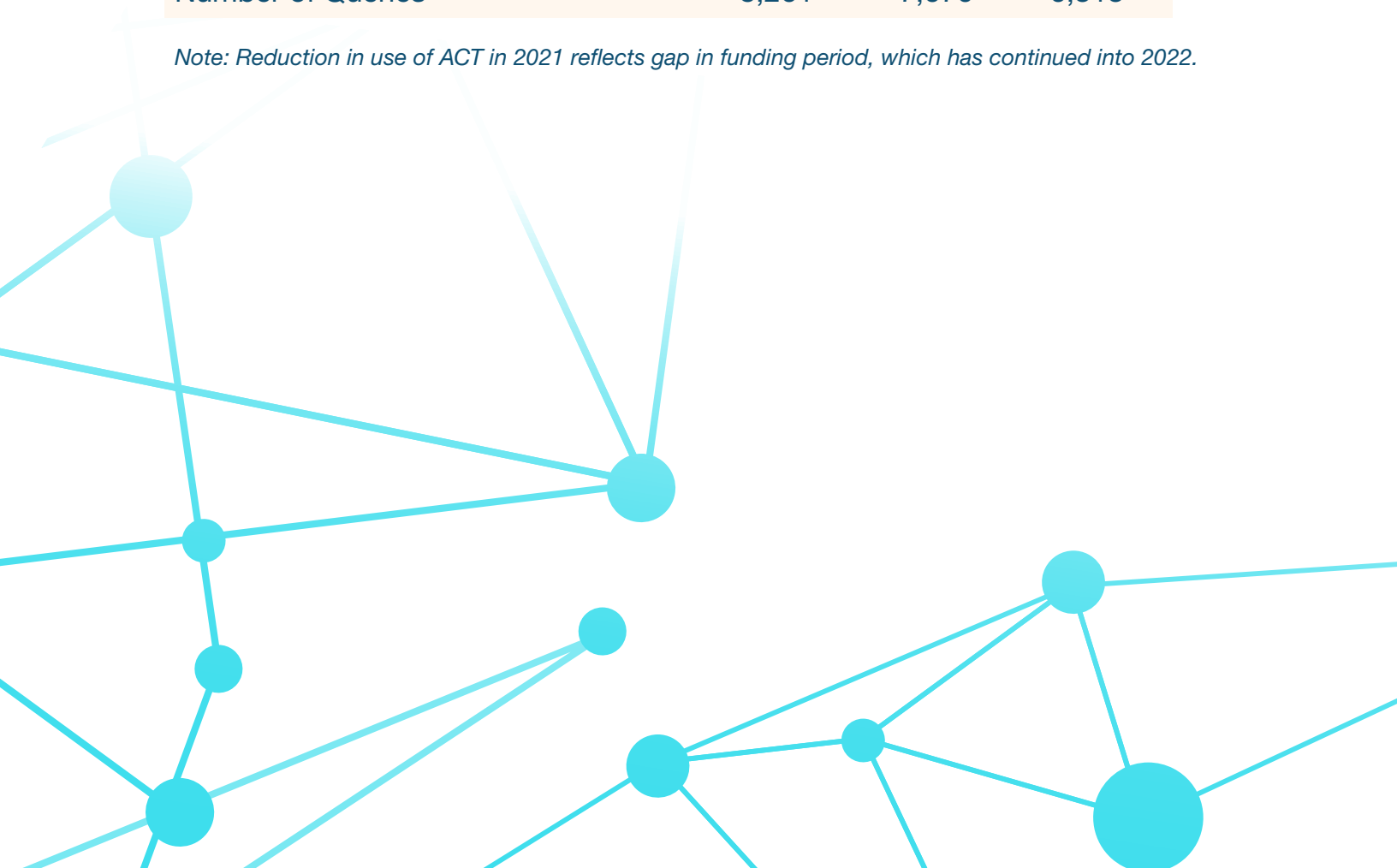
ACT (Accrual to Clinical Trials) Network

The **Accrual to Clinical Trials (ACT) Network** is a real-time platform allowing researchers to explore and validate feasibility for clinical studies across the CTSA Consortium from their desktops. ACT helps researchers design and complete clinical studies, and is secure, HIPAA-compliant, and IRB-approved. Many Harvard-affiliated researchers have access to the ACT Network, which is the largest national Shared Health Research Informatics Network (SHRINE network) to date. In 2019, the Harvard Catalyst Informatics team added more sites to the network, growing to more than 40 sites in total with more than 12,000 queries run and over 125 million patient records across all sites.

INDICATOR	2019	2020	2021
Total Number of Registered Users	5,036	5,341	5,181
Number of Query Topics (e.g. Projects)	117	294	232
Number of Queries	8,261	7,670	6,313

Note: Reduction in use of ACT in 2021 reflects gap in funding period, which has continued into 2022.

Scheduler

Scheduler is an application that allows study coordinators to schedule complex study visits with all the people, physical spaces, and equipment they need in real time. It gives flexibility to both study and CRC staff to model complex research visits in templates, and then schedule visits using an algorithm. Data on these visits can be aggregated into report queries, providing flexibility for administrators to analyze resource utilization in their units. The Informatics team recently made and released several new upgrades to Scheduler. Version 4.2.0 is an upgrade using Java 11, Tomcat 9, and MySQL8, with some additional feature enhancements.

REDCap

REDCap is a free, secure, web-based application designed to support data capture for research studies. The system was developed by a multi-institutional consortium initiated at Vanderbilt University. Data collection is customized for each study or clinical trial by the research team with guidance from Harvard Catalyst.

Most recently, Harvard Catalyst's Informatics team implemented a new functionality allowing REDCap users to quickly schedule online support appointments (15, 30, and 60-minute sessions). Streamlining the process of allowing users to set up online support meetings has made it easier and more efficient for REDCap users to access customized support. One-to-one support has increased immensely, particularly during the COVID-19 pandemic. The Informatics team also assisted in rapidly setting up a COVID-19 case tracking tool using REDCap, perhaps the first in the nation.

Total Number of Projects in Production

+ **2018:** 12,317 total projects in production, of which 2,063 were launched
+ **2019:** 14,244 total projects in production, of which 2,713 were launched
+ **2020:** 18,267 total projects in production, of which 3,617 were launched
+ **2021:** 21,955 total projects in production, of which 4,965 were launched

Translational Innovator

The **Translational Innovator program** leverages partnerships and collaborations within and outside of Harvard by offering the research community new platforms and experimental processes to examine both the conduct of research and the potential applications for these solutions. Working in partnership with the research community, the program helps to:

+ Develop novel technologies and methodologies to assist investigators with clinical implementation, while creating opportunities for cross-disciplinary investigators to enter collaborations and form teams

+ Bridge the chasm between discovery of basic biomedical observations and their clinical applications through the provision of resources, mentoring, and expertise

+ Reach throughout and beyond Harvard to identify collaborators, tools, technologies, and funding to help support promising initiatives

Note: Translational Innovator supports several, but not all, of the pilot projects noted on the following pages.

Pilot Funding

Harvard Catalyst funded a total of $1,520,349 in pilot awards during calendar years 2018-2021.

Big Ideas, Small Features: Utilizing Advanced Microscopic and Nanoscale Technologies to Further Human Healthcare
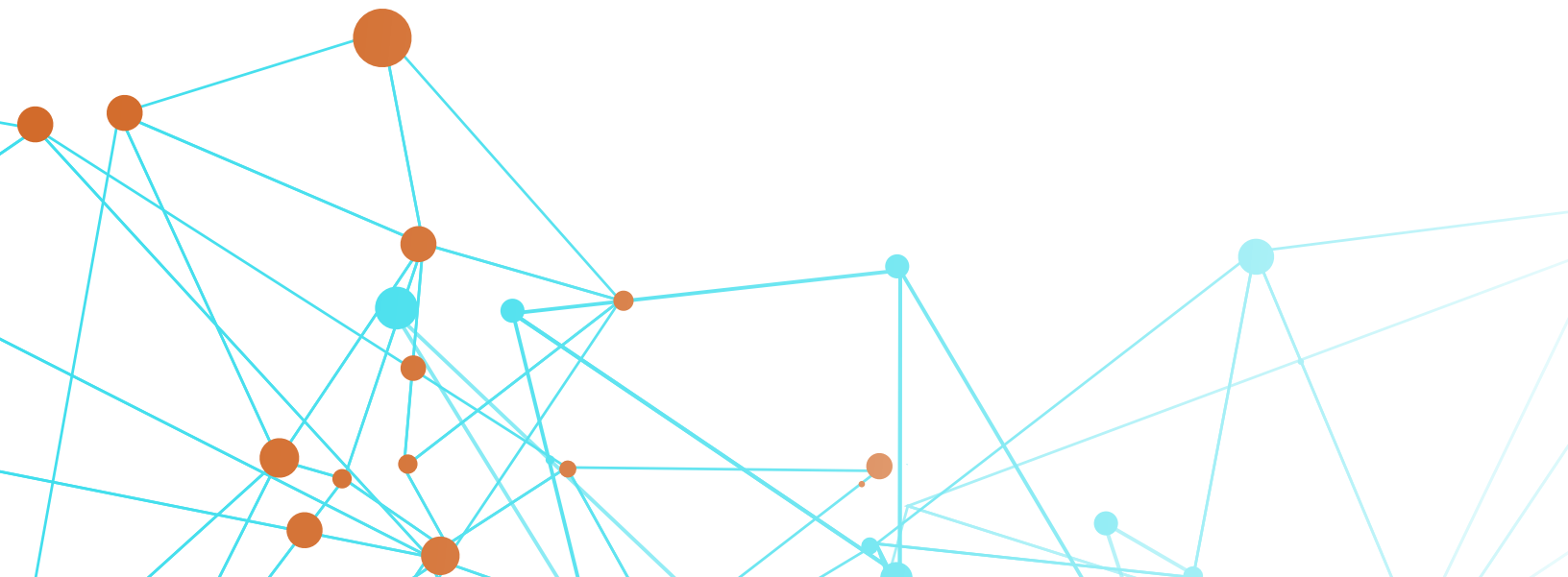
This initiative promoted funding and access to the Harvard Center for Biological Imaging (HCBI), which features advanced Zeiss microscopes, or the Center for Nanoscale Systems (CNS), that offers electron microscopy, nanoscale fabrication, and nanoscale analysis capabilities, or access to both. Funding supported the innovative application of light and electron microscopy, nanoscale fabrication, and nanoscale analysis technologies for big ideas that will advance clinical healthcare.

+ 4 pilots were funded in 2018

Targeted Secretion Inhibition: Applications in Oncology, Endocrinology, and Neurology/Pain (TSI)

This pilot grant opportunity promoted the design, development, and evaluation of novel TSIs for their potential clinical application in cancer, endocrine, neurological disorders, or pain. A critical feature of this research program was Ipsen's commitment to provide any awardees, who may require it, with scientific and technical support to design and develop project-related TSIs. Successful applicants did not necessarily need to be able to generate the TSI molecular constructs for their proposed work.

+ 5 pilots were funded in 2018

Primary and Secondary Prevention of Eating Disorders

Projects focused on novel research partnerships with the potential to generate new evidence or methodologies that foster deeper understanding of the primary or secondary prevention of eating disorders or disordered eating, and/or evaluate promising interventions that address the primary and secondary prevention of eating disorders or disordered eating.

+   3 pilots were funded in 2019

Advancing Uptake of Evidence & Community Engagement for Healthy Child Weight

Projects supported research to advance the uptake of evidence-based practices and policies related to healthy child weight through dissemination and implementation science, while increasing academic-community collaboration by supporting teams of investigators and community practitioners or policymakers that can be sustained beyond the grant period.

+   2 pilots were funded in 2019

Microbiome in Human Health and Disease

Projects promoted a greater understanding of the role(s) microbiomes play in the maintenance of normal human physiology and in the manifestation and treatment of human disease.

+   5 pilots were funded in 2019

Sight & Science: Vision Research from Diverse Fields

Projects supported broad areas of vision-related translational research ranging from investigating how mechanical and signal transduction processes give rise to sight, to examining how humans synthesize spatial and descriptive information about our external environment, to improving visual performance under limiting conditions.

+   5 pilots were funded in 2020

Everyday Exposures: Toxins and Health

Projects addressed environmental toxins that show clear translational connections to human health. The RFA was released in 2020 with funding starting in mid-2021.

+ 5 pilots were funded in May 2021

Innovations & Interventions: GI Surgical Leaks

Harvard Catalyst, in conjunction with Johnson & Johnson Innovation and its affiliates, has launched a funding opportunity seeking highly innovative proposals directed at reducing the complications resulting from post-surgery gastrointestinal (GI) leaks. Our goal is to reduce complications and improve outcomes; therefore, intervention can be done anywhere along the treatment continuum, from the pre-surgical, through surgical intervention, to post-surgical stages.
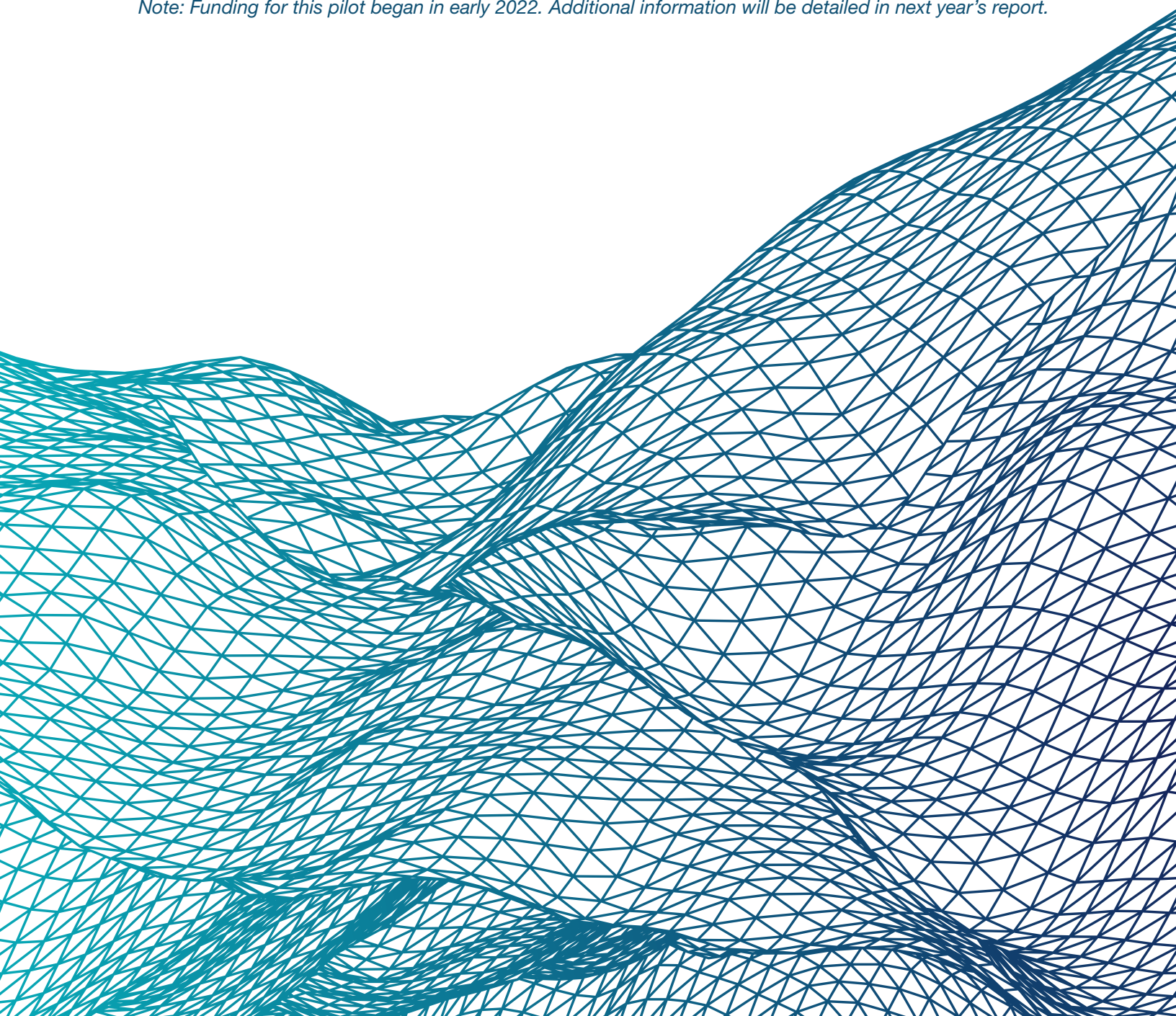
Pilot Initiatives Developed in 2021
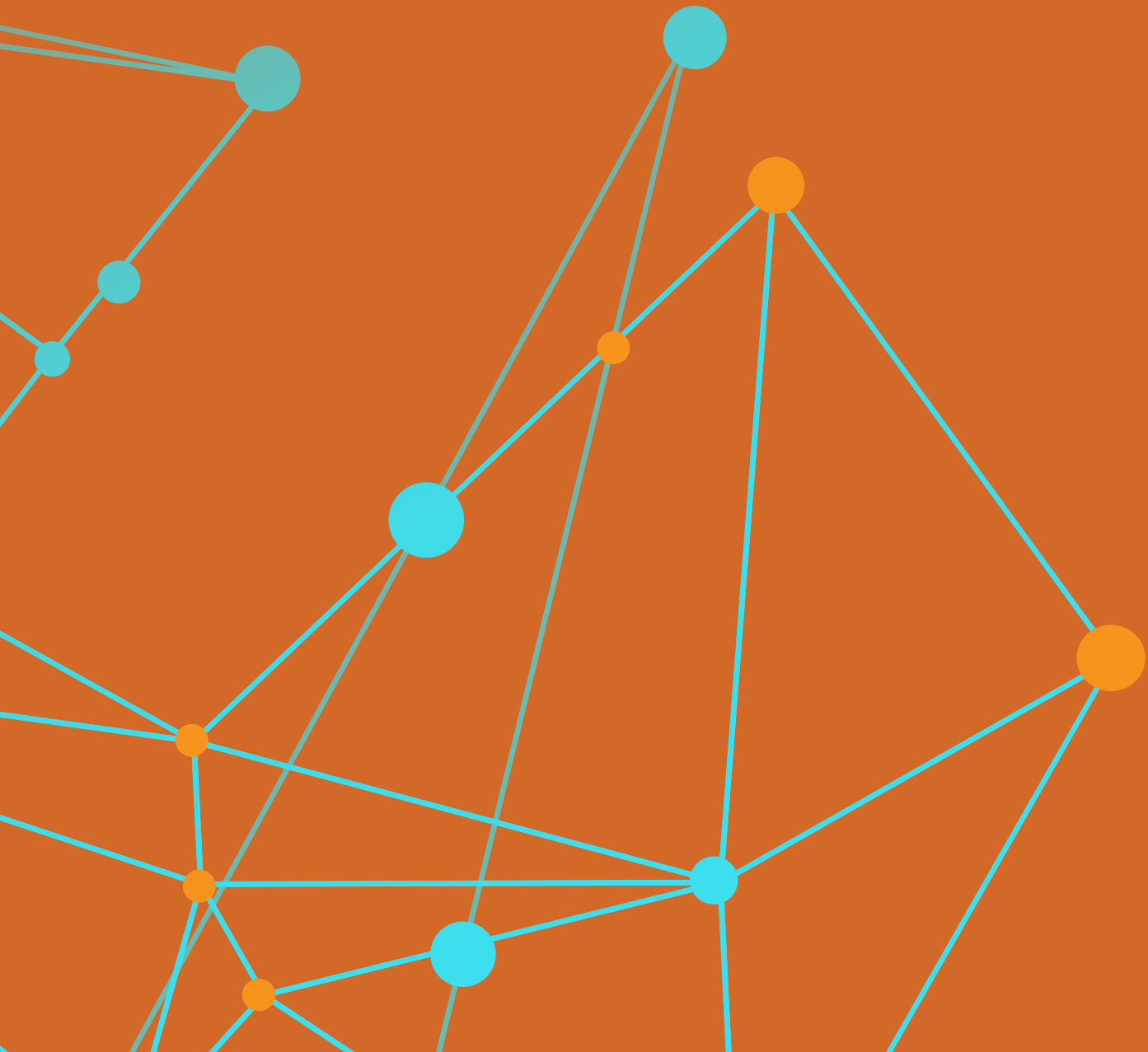
The Five Senses: Input and Response

This funding opportunity sponsored investigations on any aspect of human sensory systems or systems enabling sensory perception in human health or disease. Although traditional sensory systems (sight, sound, smell, taste, and touch) gather, organize, and integrate external stimuli, proposals for internal sensory systems (vestibular, spatial orientation, pain, and others) were also welcome.

Note: Funding for this pilot began in early 2022. Additional information will be detailed in next year's report.

Support

In addition to pilot grant funding, we provide a broad range of support and research resources to Harvard-affiliated faculty, early-career clinical investigators, fellows, researchers, and students. These include, but are not limited to, biostatistics consulting, open-source informatics tools, and regulatory guidance.
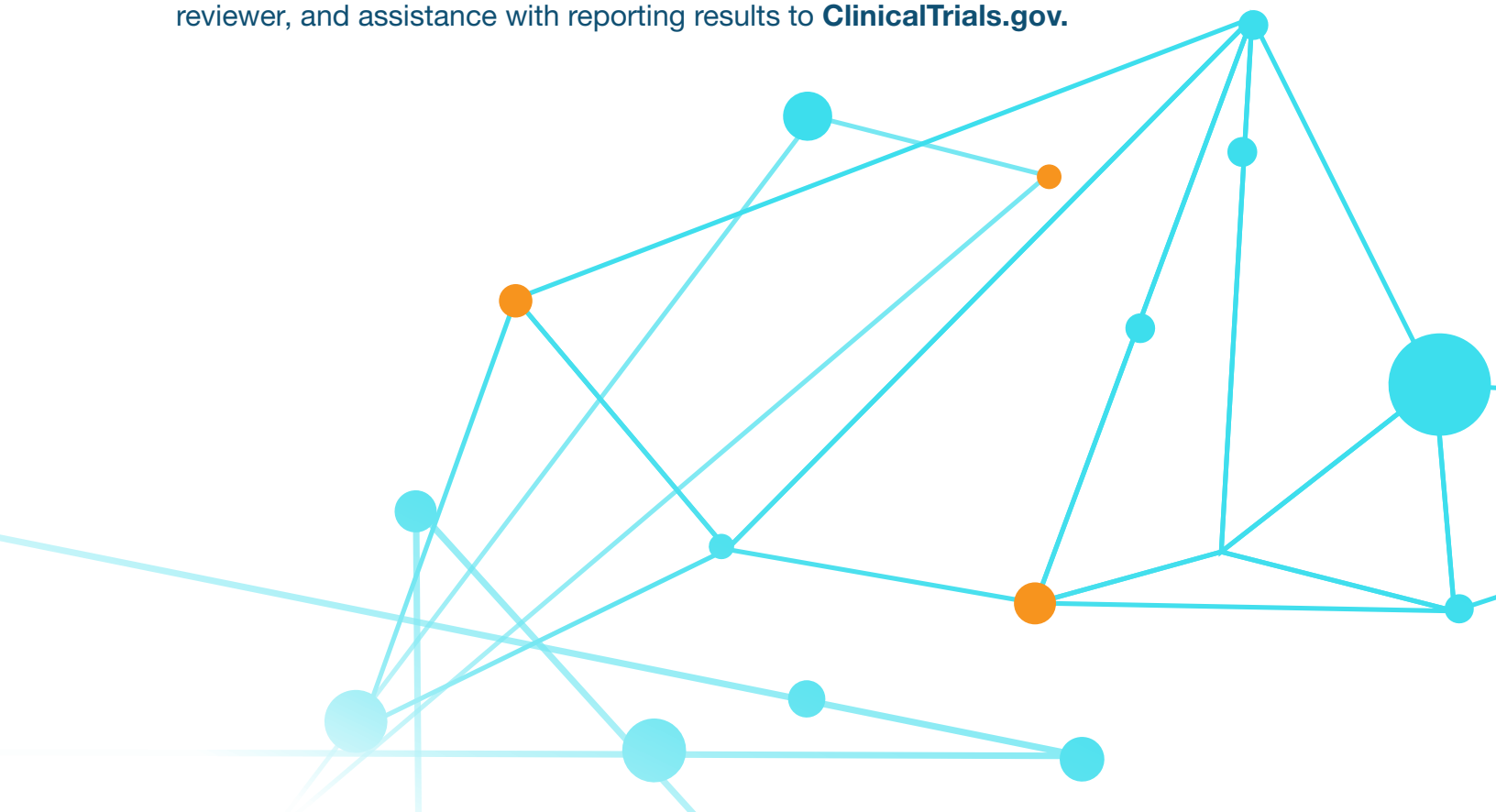
Biostatistics

The **Biostatistics program** supports Harvard clinical and translational investigators through providing consultations on a range of biostatistical and methodological topics, software tools for researchers as they design new studies, as well as training through seminars, lectures, journal clubs, and workshops.

Biostatistics Consulting

Biostatistics consulting services are geared toward clinical and translational projects in the early stages of development, including grant submission/resubmission, IRB submission, protocol review, design for non-grant project/feasibility consultation, analysis planning and advice, assistance with response to a manuscript/journal reviewer, and assistance with reporting results to **ClinicalTrials.gov.**

Number of Biostatistics Consultations Requested

+ **2018:** 936 biostatistics consults were requested
+ **2019:** 871 biostatistics consults were requested
+ **2020:** 857 biostatistics consults were requested
+ **2021:** 695 biostatistics consults were requested

Number of Biostatistics Consulting Hours Utilized

+ **2018:** 3,667 biostatistics consulting hours
+ **2019:** 4,090 biostatistics consulting hours
+ **2020:** 4,403 biostatistics consulting hours
+ **2021:** 2,858 biostatistics consulting hours

Number of Biostatistics Consulting Hours: COVID-Related Projects

As COVID-19 emerged and researchers pivoted, as did our consulting services to meet their needs.

+ **2020:** 415 biostatistics consulting hours were utilized for COVID-related projects
+ **2021:** 368 biostatistics consulting hours were utilized for COVID-related projects

According to satisfaction survey results, the average satisfaction rate was 96% for 2018, 2019, 2020, and 2021.
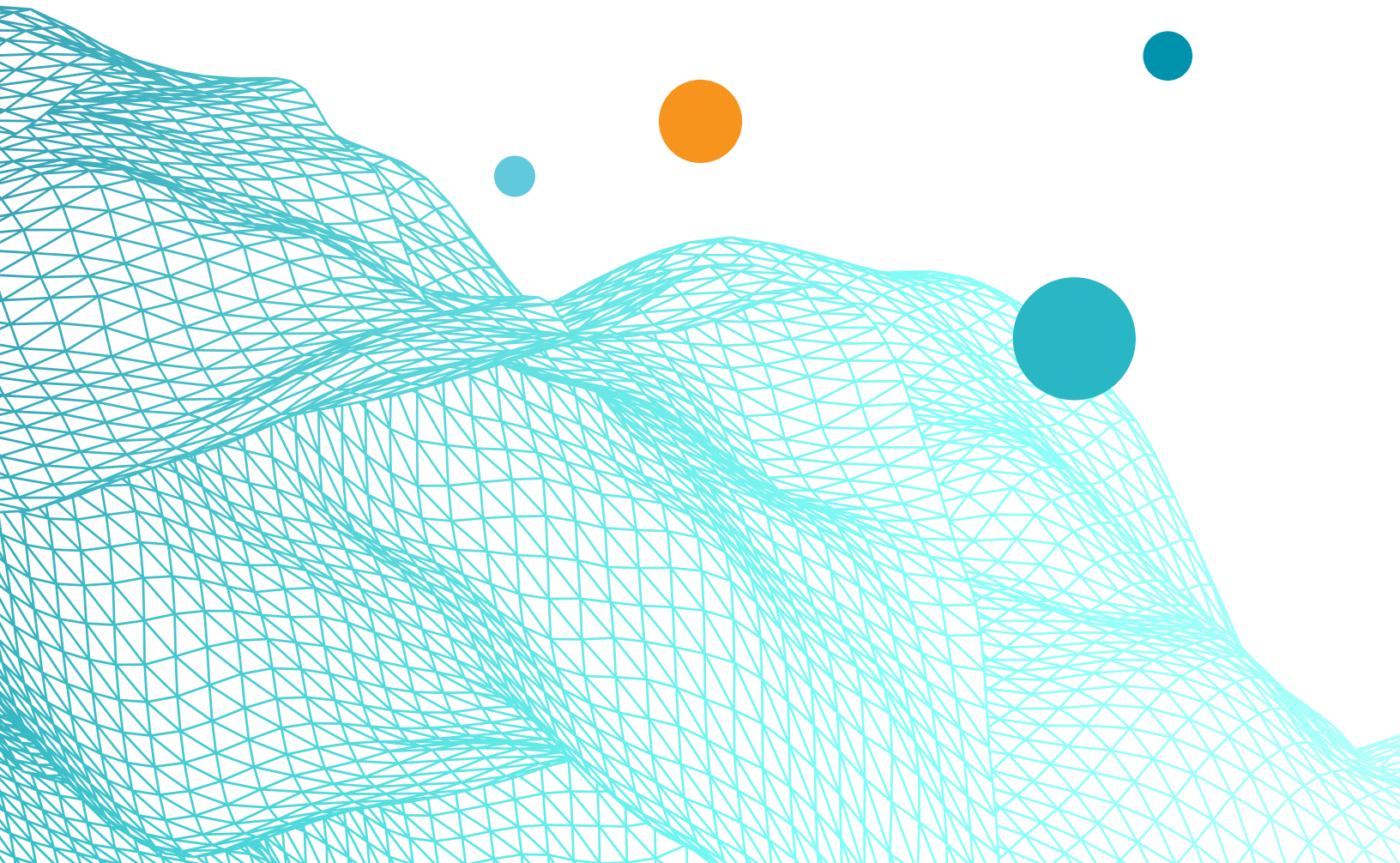
SUPPORT

Bioinformatics Consulting

Bioinformatics consulting services are supported through the Harvard Chan Bioinformatics Core at the Harvard T.H. Chan School of Public Health and the Countway Library of Medicine at Harvard Medical School. Bioinformatics consultants possess strong expertise in research computing that includes data management, analysis, and dissemination of high-throughput biomedical data.

Bioinformatics consulting services offered by Harvard Catalyst focus on the early stages of research project development. These services include study design for next generation sequencing (NGS) projects/feasibility consultation; bioinformatics analysis planning (e.g., Seq, Methylation-Seq, ChIP-Seq, Exome/WG-Sequencing), grant submission/resubmission, training advice for researchers/education on a bioinformatics topic, and assistance with response to manuscript/journal reviews.

Number of Bioinformatics Consultations Requested

+ **2018:** 99 bioinformatics consults were requested
+ **2019:** 145 bioinformatics consults were requested
+ **2020:** 130 bioinformatics consults were requested
+ **2021:** 114 bioinformatics consults were requested

Number of Bioinformatics Consultations Hours Utilized

+ **2018:** 282 bioinformatics consulting hours were utilized
+ **2019:** 483 bioinformatics consulting hours were utilized
+ **2020:** 361 bioinformatics consulting hours were utilized
+ **2021:** 298 bioinformatics consulting hours were utilized

According to satisfaction survey results, the average satisfaction rate was 90% for 2018, 2019, and 2020, and 94% for 2021.
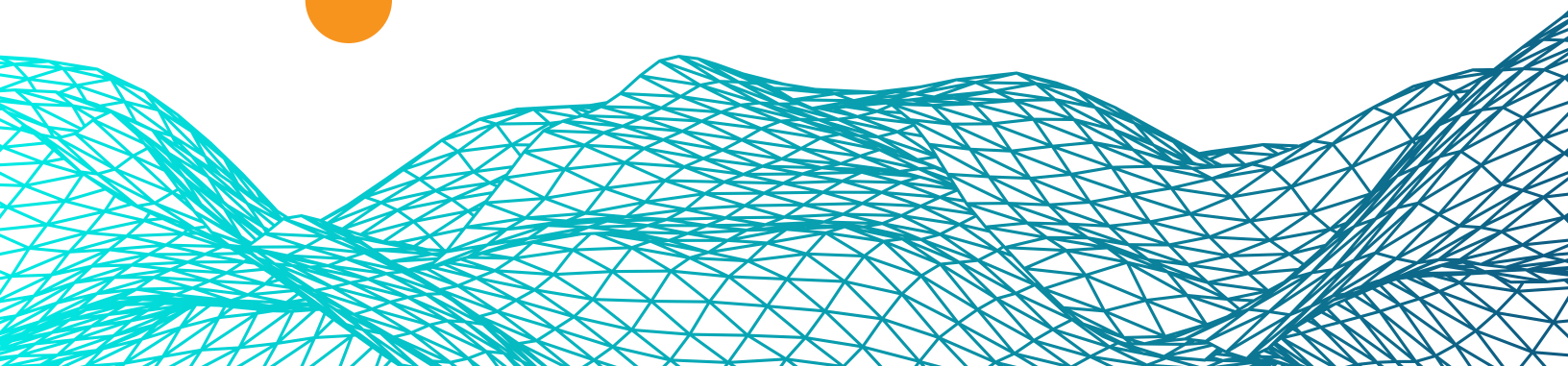
SUPPORT

Regulatory Foundations, Ethics, and Law

The **Regulatory Foundations, Ethics, and Law program** serves as a resource to the C/T research community to help minimize regulatory burdens while ensuring that research is conducted with the highest standards of scientific design. The program convenes several committees and working groups, which are composed of human research protections leadership, compliance officers, and other content experts from academic healthcare centers to explore and address issues that pose special challenges, risks, or opportunities to institutions and investigators. Each committee meets consistently to share strategies and develop guidance that advance human research protections and compliance with regulatory requirements. The program's section on the Harvard Catalyst website houses hundreds of case studies, materials for research participants and study teams, and guidance documents.

Current committees and working groups include:

+ Clinical Trials Registration & Results Reporting (CTR3)
+ Collaborative Quality Improvement Program (CQIP)
+ Emerging Technologies, Ethics, and Research Data (E-Tech)
+ Quality Assurance/Quality Improvement (QAQI)
+ Social, Behavioral, and Education Research (SBER)

Number of Downloads of Regulatory Resources and Materials

+ **2018:** 152,712 resources were downloaded

+ **2019:** 133,125 resources were downloaded

+ **2020:** 157,452 resources were downloaded

+ **2021:** 104,546 resources were downloaded

Note: 2021's decrease in downloads is attributed to technical issues associated with the development of Harvard Catalyst's new website.

These resources include case studies, guidance documents, checklists, downloadable information sheets, and articles on the following topics that require regulatory guidance:

+ Research Participant Resources Brochures (17 Languages)

+ Emerging Technologies

+ Data & Safety Monitoring for Clinical Trials

+ Investigational New Drug (IND) / Investigational Device Exemption (IDE) Resources

+ Quality Assurance (QA) / Quality Improvement (QI)

+ Social, Behavioral, and Education Research (SBER) Case Studies

+ Clinical Trials Registration & Results Reporting (CTR3)

+ Community-Engaged Research (CEnR) Resources

+ E-Tech Case Studies

+ IND/IDE Case Studies

+ International Research

+ SBER

+ Collaborative Quality Improvement Program (CQIP)

Human Subjects Training

This downloadable training resource includes all materials to present a small or large training on human research subjects for study teams.

SUPPORT

SMART IRB
Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance Platform

Harvard Catalyst developed and provides administrative support for **SMART IRB**, a national platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system, called the Online Reliance System (ORS). Together, these provide a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements. Investigators and their study teams, together with institutional and HRPP/IRB offices, use the SMART IRB platform to initiate single IRB review of a study.

SMART IRB also makes available essential education as well as flexible tools and resources designed to support the adoption and implementation of single IRB review for a range of studies. These efforts help to reduce the complexity of the IRB review process for multisite research.

Number of institutions newly signed on to the SMART IRB agreement
in the reporting period

2018: 167   **2019:** 166   **2020:** 141   **2021:** 118

Total number of institutions signed on to the SMART IRB agreement at the end
of the reporting period

2018: 510   **2019:** 676   **2020:** 817   **2021:** 934

Total number of users of the Online Reliance System

2018: 1,653   **2019:** 3,112   **2020:** 4,660   **2021:** 7,835

Total number of reliance requests processed by the Online Reliance System

2018: 1,014   **2019:** 1,328   **2020:** 1,705   **2021:** 1,459

Include

In collaboration with Harvard Medical School's Office of Diversity Inclusion and Community Partnership, our Diversity Inclusion program supports institutional efforts to increase diversity and support underrepresented in medicine faculty and trainees. Our Community Engagement program (CEP) supports open collaboration and opportunities for Harvard University researchers to partner and train with community development leaders and researchers across our city, region, and state.

INCLUDE

Diversity Inclusion

Diversity Inclusion supports Harvard Medical School faculty and trainees through:

+ Lectures and workshops aimed at addressing key career development issues

+ Education, mentoring, and community-building events geared towards improving the promotion and retention rates among diverse faculty who are conducting clinical and translational research

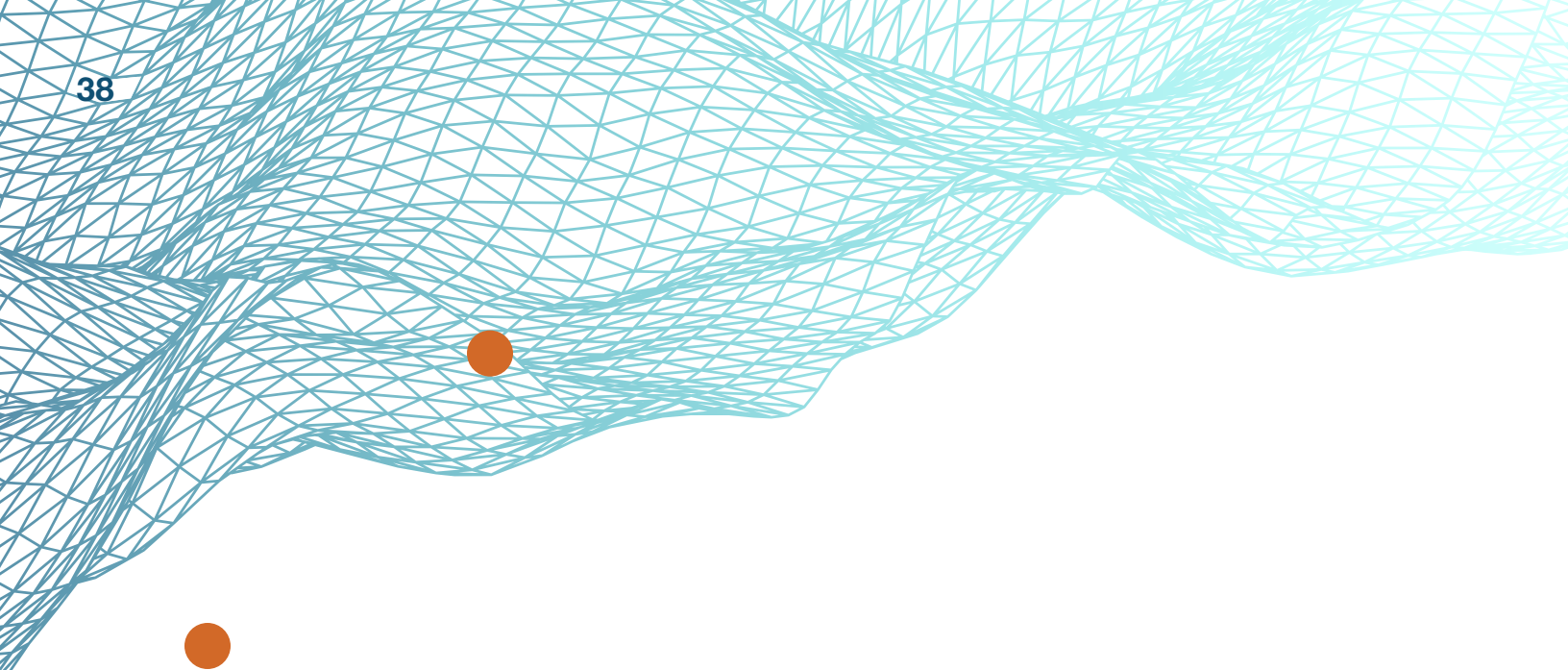+ Promotion and enrichment of cultural competence of all Harvard faculty

INCLUDE

Diversity Inclusion Faculty Fellowship

The **Diversity Inclusion Faculty Fellowship** is a two-year fellowship for outstanding junior faculty. The fellowships are designed to address the need for additional support to conduct C/T research and to free time from clinical and teaching demands at a key point in an investigator's career development. Each faculty fellow receives $100,000 over a two-year period to support their scholarly efforts. They are required to devote appropriate time toward the development of their academic career, meet regularly with their mentors, and present at the annual Minority Health Policy Meeting.

Diversity Inclusion Faculty Fellowship Awardees 2018-2021

2018 Awardee: Steven Rodriguez, PhD, Instructor, Massachusetts General Hospital, Department of Biological Chemistry and Molecular Pharmacology

Project Title: Preclinical Identification and Validation of a Novel Inflammatory Signature as Biomarkers for the Treatment of ALS

In 2019 the fellowship was not offered.

2020 Awardee: Hermioni Amonoo, MD, MPP, Assistant Professor of Psychiatry, Brigham and Women's Hospital

Project Title: Development of a Positive Psychology Intervention to Improve Mood and Health Related Quality of Life in Patients Post Hematopoietic Stem Cell Transplantation – Proof of Concept Trial

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2020 Awardee: Randy Miles, MD, PhD, Assistant Professor of Radiology, Massachusetts General Hospital

Project Title: External Validation of Clinical Assessment of a Deep Learning Risk Prediction Model for Mammography Interpretation

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2021 Awardee: Dennis Spencer, MD, PhD, Instructor in Pediatrics, Harvard Medical School, Boston Children's Hospital

Project Title: Modification of Gut Microbiome Antibiotic Resistance through Dietary Glycans

"**I hope to leverage my training and future collaborations to effectively translate research findings to implement sustainable initiatives that promote health equity and necessary public health/policy change.**"

– **ARIANA MORA,** 2021
Emory University

" **I'm really grateful that Harvard Catalyst believed in us enough to create and embrace this very unconventional program style.**"

– **VICTORIA SANCHEZ**, 2020
Indiana University School of Medicine

INCLUDE

Visiting Research Internship Program

Our **Visiting Research Internship Program (VRIP)** is an eight-week mentored, summer research experience designed to engage diverse, non-HMS medical students in clinical and translational research and health-related careers. Participants engage in weekly seminars with Harvard faculty, focusing on topics such as research methodology, health disparities, ethics, and career development, as well as participate in other Harvard Medical School programs such as career seminars and networking events.

+ **2018:** 6 students participated in VRIP
+ **2019:** 6 students participated in VRIP
+ **2020:** 6 students participated in VRIP
+ **2021:** 12 students participated in VRIP

The average satisfaction rate from participants and mentors between 2018 to 2021 is 98%.

Many VRIP participants take part in the New England Science Symposium (NESS), also supported by Harvard Catalyst, which provides a forum for underrepresented in medicine postdoctoral fellows, medical, dental, graduate, and college students to present their biomedical and health-related research activities.

Pipeline Survey

This mixed methods, exploratory, sequential study is designed to understand the influence of medical school teaching and learning environment on the training choices and outcomes of medical students, since these early decisions can influence career directions, including interest in academic research.

This longitudinal study is designed to characterize the individual, institutional, and sociocultural factors involved in career choice, particularly academic research, among medical students, with particular attention to the experiences of students who are underrepresented in medicine.

The two-stage design began with qualitative focus groups, followed by a quantitative survey. The research team has coded the data from the focus groups, used a reflexive thematic analysis to inform the results, and has written a manuscript. The research team has also completed the baseline and a quantitative survey of years 1 to 2 of Harvard Medical School first-year students.

INCLUDE

Community Engagement

Harvard Catalyst's **Community Engagement program (CEP)** supports open collaboration and opportunities for Harvard University researchers to partner and learn with community leaders and researchers across our city, region, and state. The program aims to provide robust training and collaboration opportunities to increase the pace of adoption of evidence-based programs and policies to promote community health and eliminate disparities by:

+ Creating mechanisms for high-quality engagement with community and policy stakeholders

+ Identifying key areas with potential for accelerating population-level outcomes and launch pilots

+ Leveraging resources to support evidence-based community translation

In alignment with areas of critical research evidence and community need, CEP and the Harvard Catalyst Community Advisory Board (CAB) prioritizes child health, cancer prevention/control, and emerging public health issues as its primary areas of focus. The emerging issues addressed by the CEP reflect areas of opportunity, critical mass among our researchers, and community priorities, and currently include housing and homelessness and COVID-19 response. Underscoring each of these priority areas is a focus on the translation of evidence-based practice and policy to improve community health and achieve health equity.

Engage Community and Build Capacity

The **Longitudinal Student Practice Placement Program** is designed to build sustained, bi-directional collaborations with community organizations via student practice placements. Community partners and students learn from one another. The program also increases the capacity of community partners to conduct needs assessments, evaluations, prepare for accreditation, and translate evidence to programs and policies. To date, 20 students have participated in projects which support work at 10 partner organizations. Feedback from students and community partners has been outstanding.
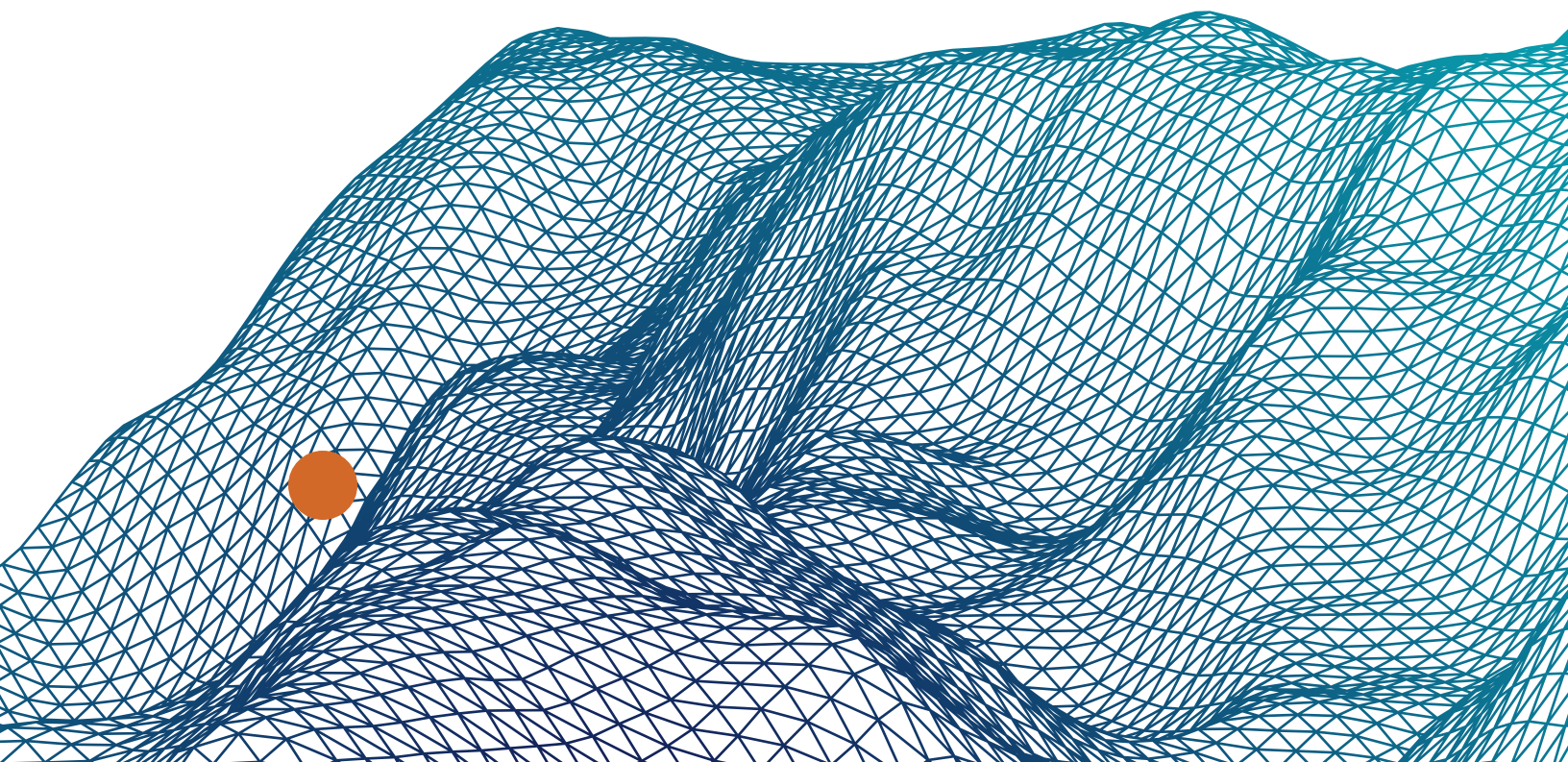
Build Researcher Skill and Capacity

In 2018, the CEP created an Implementation Science Working Group for Harvard researchers, which has grown its mailing list to nearly 329. The monthly seminar in 2021 was attended by an average of 42 individuals from across Harvard institutions and academic rank. Under the leadership of Howard Koh, MD, MPH, the program has also conducted a number of activities to address health and homelessness.

Consultations & Trainings for Community Impact: Launched in January 2020, this service focuses on providing one-on-one and small group expertise and training on implementation science, mixed methods, and community-engaged research.

In 2021, the CEP provided 50 consultations and 6 training sessions to researchers from Harvard-affiliated institutions.

Overall, our consultation service has supported 45 grant submissions, including 19 in 2021. Notably, we provided consults on the outreach core proposals for 2 major center renewals awarded in the past year: The Dana-Farber / Harvard Cancer Center Community Outreach and Engagement Core and the Harvard T.H. Chan School of Public Health Center for Work, Health and Wellbeing. We also hosted 7 small group trainings focused on community engagement and implementation science.

Stimulate Community-Engaged Research

In fall 2021, we launched an online course on Community-Engaged Research in collaboration with the Postgraduate Education Program. The course covered methods and principles of community-engaged research, how to cultivate effective collaboration between community members and researchers, and how to incorporate community-engaged concepts into research studies and practice settings.

+ We had 162 registrants for the course and 34 individuals who identified themselves as community health practitioners or community members.

Building Platforms: Community Engagement Studios

Community Engagement Studios are an important way for researchers to share their methods with community stakeholders and receive direct feedback via a facilitated conversation. Integrated into the CEP's pilot grant process, the studios consist of a panel of community experts who specialize in a specific content area that come together to advise researchers. In the past year, community engagement studios have also been conducted to support pilots focused on environmental toxins and the five senses in collaboration with the Translational Innovator program.

+ For these pilot opportunities, 18 investigators participated in a community engagement studio. Both the panelists and investigators responded favorably to this process.

Community Coalition for Equity in Research

In 2021, we launched a standing, trained community coalition to provide feedback on research protocols to increase their equity and use of community-engaged research principles. The 14-member coalition provides feedback on research to promote equity and use of community-engaged research principles. To date, the coalition has reviewed 9 research projects. All researchers have rated their experience excellent, or very good and reported that the coalition included relevant stakeholder experts, that study review will improve their research, and that coalition member feedback was provided in a respectful and appropriate manner.

Community Engaged ThinkResearch Podcast Series

This special podcast series highlights the work of our community partners and researchers as they advance important initiatives in community engagement.

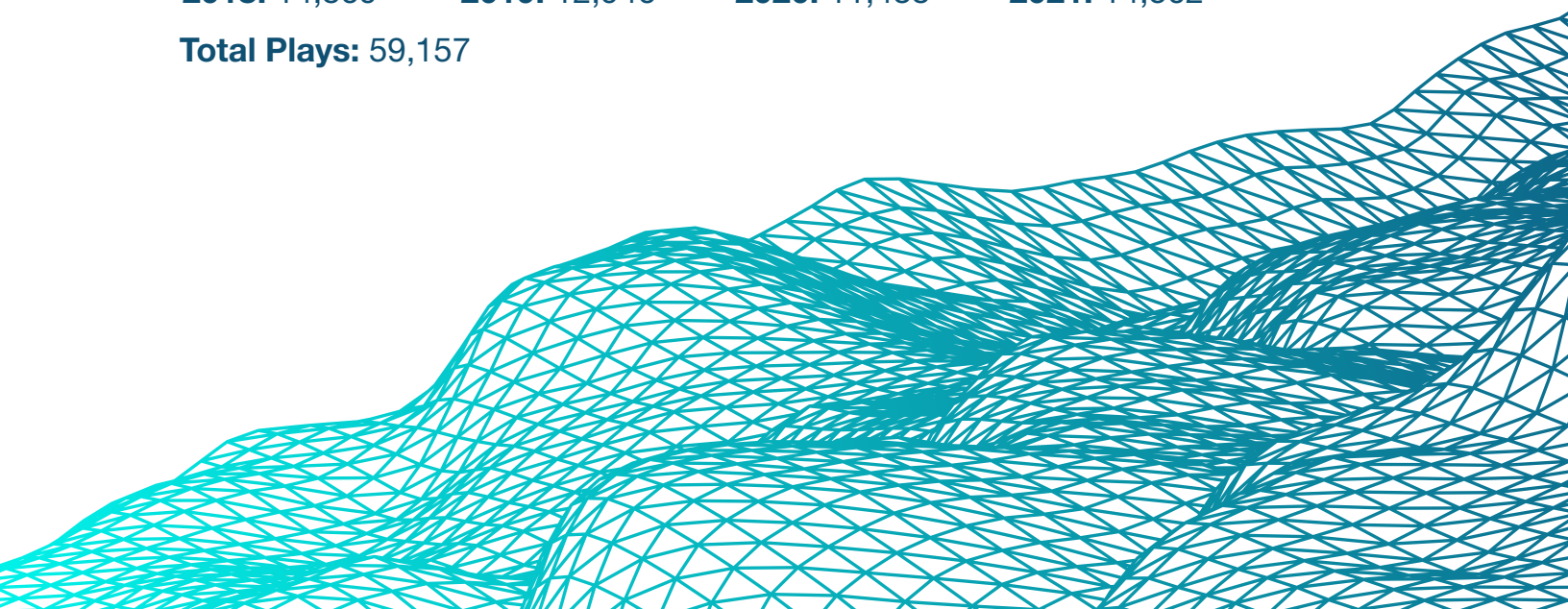## Recent podcast episodes include

+ Community Engaged: Machine Learning and Health Equity

+ Community Engaged: How Laws Impact Health Disparities

+ Community Engaged: Self Reporting and Data Collection in Trans Health Outcomes

+ Community Engaged: Combating Bullying at School for LGBTQ Youth

+ Community Engaged: Student Practice Placement Initiative

+ Community Engaged: Making an Impact on COVID-19 Vaccination Efforts

+ Community Engaged: Understanding WIC & Factors Driving Its Utilization in Massachusetts

About ThinkResearch

Produced by the Postgraduate Education program, this podcast was launched in 2016 to highlight the behind-the-scene stories of biomedical research that impacts human health. The podcast is geared towards educating both the Harvard community and a diverse public audience about the research developments and discoveries at the university and affiliates.
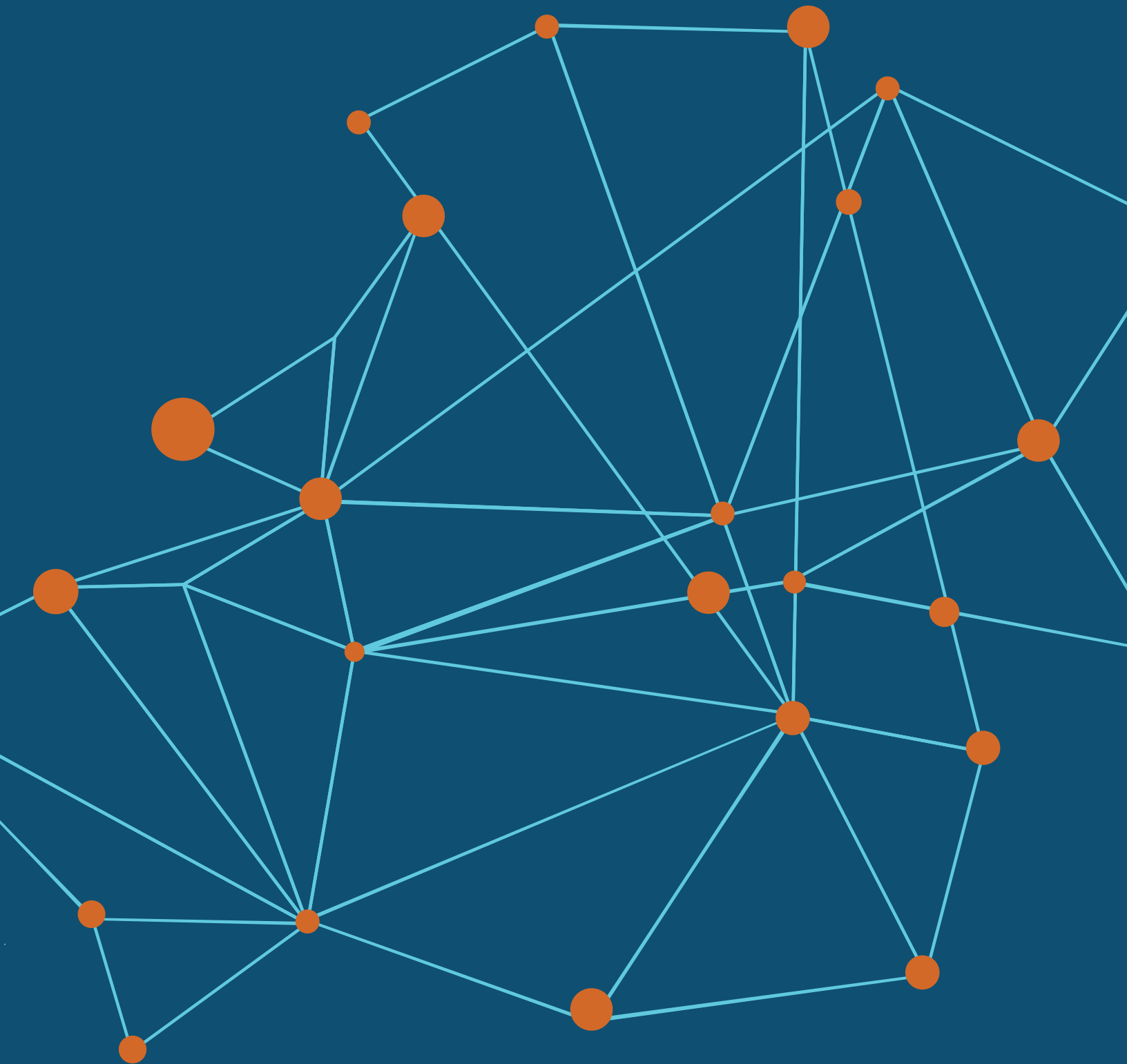
Number of Plays

2018: 14,869 **2019:** 12,946 **2020:** 11,438 **2021:** 14,502

Total Plays: 59,157

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