A Decade of Impactful Research

2025

Stanford MEDICINE Center for Clinical Research

SCCR

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Introduction

*At the Stanford Center for Clinical Research (SCCR), our mission is to **advance impactful clinical research through education and quality operations**. We conduct innovative clinical research to transform human health. During the past decade, we have built strong partnerships with research staff, trainees, faculty, industry collaborators, foundation leaders and federal sponsors to stimulate innovation and enhance the quality of our research initiatives. By trailblazing new research methodologies, we have established efficient operations that prioritize participant-centered research and ensure individuals are essential partners in the journey toward transformative health solutions. As we reflect on our achievements, **we remain dedicated to fostering a culture of inquiry and discovery as the foundation for our continued success.***

Our collaborative approach has positioned SCCR as a leading Academic Research Organization, enabling us to fully support a diverse array of studies that address critical health challenges. Our commitment to operational excellence is reflected in our robust infrastructure, which supports traditional site-based, multisite, and decentralized clinical trials. Our focus on education and training has empowered our staff and faculty, ensuring they are equipped with the necessary skills to excel in a rapidly evolving research landscape.

Looking ahead, our 2024 strategic plan, built on clear Objectives and Key Results (OKRs), will guide us toward our vision of transforming human health through innovative clinical research. We invite new and existing faculty, partners, and sponsors to join us on this journey as we continue to push the boundaries of what is possible in clinical research and improve health outcomes for communities worldwide.

Leadership

Kenneth W. Mahaffey, MD
Director

Toni Nunes, MA, MPH
Director of Operations & Strategy

Rhonda Larsen, MHS, PA-C
Senior Advisor

Nadia Elkarra, MD
Director of Clinical Research Operations

Kiera Davis, MS, RN
Associate Director of Education & Training

Kris Anderberg, RN
Associate Director of Quality & Compliance

Nicole Ventre, MS
Associate Director of Administration & Operations

Michael Ellsworth, MBA
Senior Manager of Research Finance

Sumana Shashidhar, MA, MS
Associate Director of Clinical Research Operations

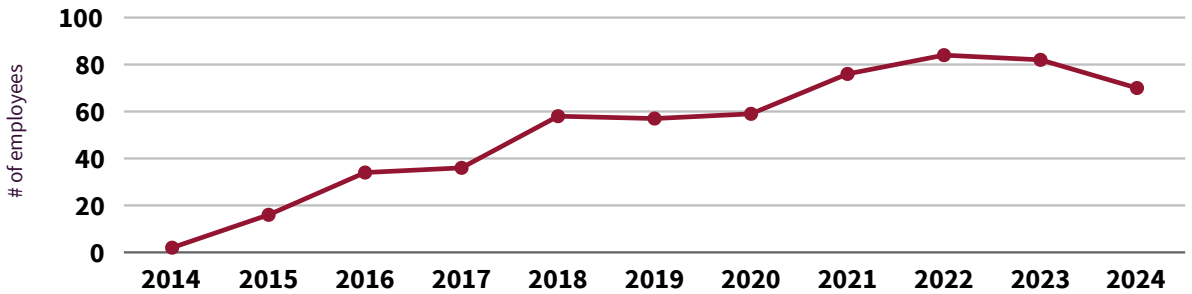
Aruna Subramanian, MD
Faculty Associate Director of Infectious Diseases

Kevin Alexander, MD
Faculty Associate Director of Clinical Events Classification (CEC)

Robson Capasso, MD
Faculty Associate Director of Mobile Digital Technology

Marco Perez, MD
Faculty Associate Director of Cardiovascular Medicine

Growth in Staff



Core Values

Who We Are

Our approach prioritizes participants and communities and views them as essential partners in the whole research process. We foster collaboration with Stanford faculty and research groups, industry partners, government entities, foundations, and other academic research organizations to ensure our research is rigorous and impactful. We believe collaboration is vital to drive innovation, design and conduct rigorous clinical research, and achieve shared goals.

We are committed to operational excellence. We have developed robust infrastructure and formed compliance-focused teams to uphold the highest standards of quality and efficiency. Our adoption of digitally-driven solutions streamlines processes and enhances productivity. We are also dedicated to educating and training the next generation of clinical research leaders at Stanford and beyond.

We embody our core values by positioning people first and ensuring participant experiences are central to our research. Our commitment to operational excellence drives us to develop evidence-based practices that generate impactful data, while our collaborative spirit strengthens relationships. ***Together, we are shaping the future of clinical research, ensuring every study we conduct meets the highest standards of integrity, quality, and compliance.***

What We Do

We collaborate with trainees, faculty and sponsors to enhance the quality and impact of clinical research. Our teams specialize in all aspects of clinical research and trials.

By the Numbers

200+
Staff, Faculty & Data Science Partners

500k
Participants Enrolled

28
University Partnerships

12
Investigational New Drug Applications

13
External Academic Partners

115k
Endpoints Adjudicated

27
Industry & Federal Partners

280+
Publications

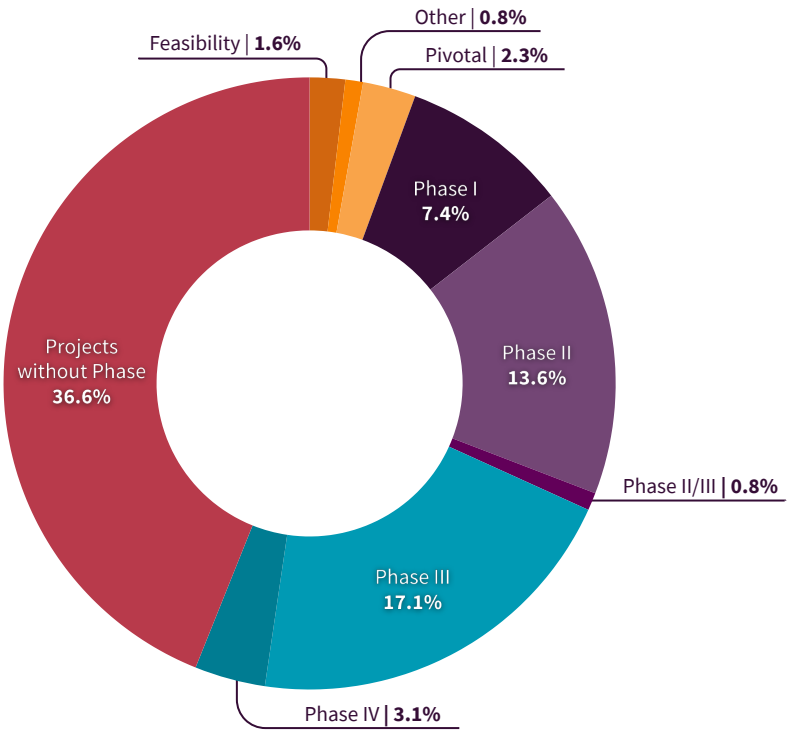
250+
Research Projects

260+
Education Programs Completed

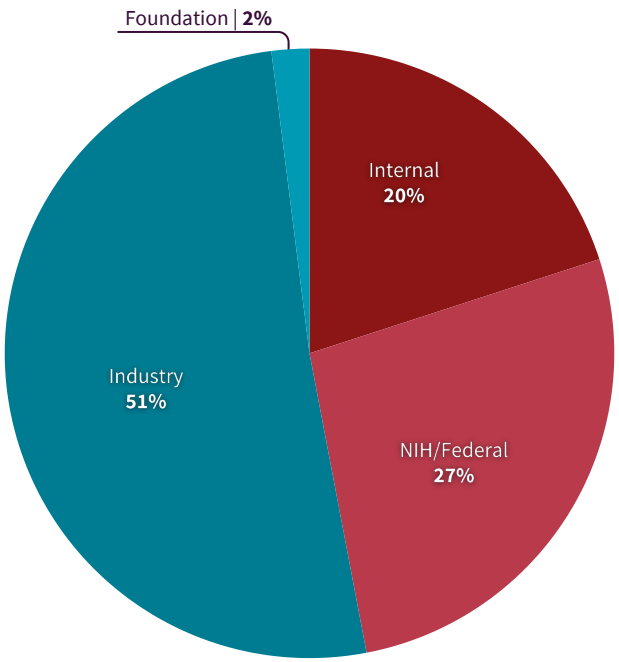
Supported Projects

*The majority of SCCR-supported projects (64%) conducted over the past 10 years are **categorized as treatment trials**. Of the treatment trials, most were testing a **drug or biologic intervention** and were Phase 3 (41%) or Phase 2 (32%).*

SCCR Projects by Phase



Funding Sources



Trial Operations Expertise

Our Clinical Coordinating Center (CCC) group has substantial expertise coordinating complex logistics, facilitating seamless collaboration across partners and sites, and optimizing operational efficiencies. We also manage traditional site-based research (SBR) for adult, single-site studies at Stanford and ensure each trial is executed with precision and adherence to the highest standards.

Clinical Coordinating Center

OFFERINGS

- Scientific Trial Leadership
- Project Management
- Project and Quality Management Plan Development
- Study Design and Protocol Development
- Budget and Scope of Work Development
- Resource Management
- Study Site Feasibility and Selection
- Study Site Management from Start-up to Close-out
- Participant Recruitment and Retention, with a focus on targeted plans for diverse populations
- Vendor Oversight and Management
- Clinical Endpoint Adjudication
- Regulatory Affairs Support

STUDY DOCUMENTATION

- Electronic Trial Master File Management

EDUCATION AND TRAINING

- Development and support of investigators' meetings
- Tailored training of site investigators and staff

DATA AND SAFETY MONITORING

- Pharmacovigilance (Safety Desk)
- Data and Safety Monitoring Board/Data Monitoring Committee Management
- Study monitoring

Site-Based Research

STUDY PORTFOLIO DEVELOPMENT

Facilitate strategic growth and management of clinical research portfolios to meet research program goals

FEASIBILITY ASSESSMENTS

Assess all new studies for operational and financial feasibility

PRE-AWARD/STUDY START-UP

Provides support and management of regulatory compliance, budget and scope of work creation, contract negotiations and grant proposals

END-TO-END STUDY CONDUCT SUPPORT AND SURVEILLANCE

Develop and maintain efficient systems, processes and workflows enabling the successful execution of studies

Quality and Compliance

The conduct of high quality, compliant clinical research is imperative for SCCR and our partners. With this critical focus, we maintain an experienced and highly skilled Quality Assurance, Regulatory Affairs and Monitoring team. Our team offers comprehensive monitoring and auditing, regulatory affairs support, FDA IND/IDE submissions and preparation for FDA, industry, or NIH audits. We create and maintain our organization-wide quality systems that provide the foundation for compliant clinical research.

Clinical Endpoint Classification

Our Clinical Endpoint Classification (CEC) team has over 10 years of experience in clinical endpoint adjudication and operations, managing a diverse portfolio of studies across various therapeutic areas in collaboration with industry, government, and academic partners. Currently, our team is involved in research trials expecting over 10,000 clinical event adjudications in the following therapeutic areas:

- High-risk cardiac patients utilizing wearable devices
- ATTR Cardiac amyloidosis
- Diabetes, Chronic kidney disease
- Acute Myocardial Infarction
- Oral Factor XI inhibitor for cardiovascular disease

CEC adjudicates key safety and efficiency outcomes including the following events:

We have a large group of trained Stanford and non-Stanford faculty that have extensive adjudication and clinical trial expertise.

FDA and Regulatory Experience in Endpoint Adjudication

Dr. Kevin Alexander serves as Faculty Associate Director for the CEC team and Dr. Ken Mahaffey oversees the SCCR CEC efforts.

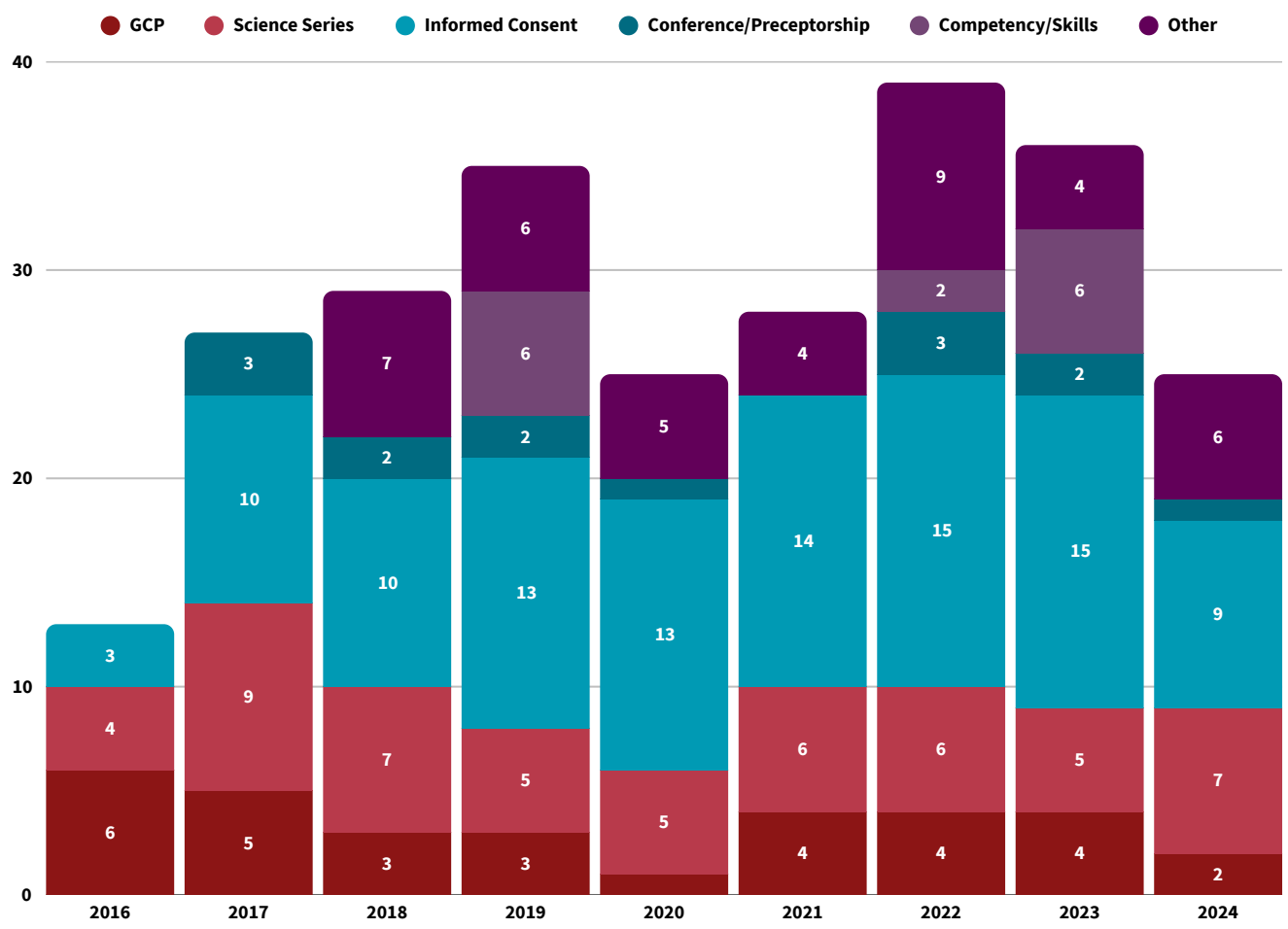
Dr. Mahaffey has extensive experience collaborating with industry in FDA interactions. He has supported regulatory filing and sponsored presentations at FDA Cardiorenal Advisory Committee meetings. Dr. Alexander also has experience with the FDA in his roles as CEC Chair and trial investigator on a number of FDA regulated trials. Through our endeavors, we have refined CEC practices, integrated technological advancements, and promoted standardization to improve the reliability and efficiency of event adjudication.

Selected Publications

- Innovation in Event Adjudication-Human vs Machine
- Clinical events classification (CEC) in clinical trials: Report on the current landscape and future directions - proceedings from the CEC Summit 2018

Education and Training

Our Education and Training initiatives are designed to augment existing resources at Stanford, providing staff and faculty with ***the tools they need to excel****. We offer onboarding programs and intensive training sessions that cover essential topics in clinical trial management and have* ***completed over 260 educational programs****. Additionally, our immersion programs with industry partners provide invaluable hands-on experience,* ***bridging the gap between academic research and industry practices.***



SCCR's Education and Training team offers tailored education and training for members of the clinical research team. Opportunities include Good Clinical Practice workshops, education on clinical topics, a comprehensive onboarding program, competency-based training, and mentorship. We partner with Stanford's world-renowned scientists, clinical researchers, and clinical specialists to provide these training sessions.

The above bar chart represents the number and type of education and training events SCCR has hosted since 2016 including GCP workshops, informed consent training, clinical education, conferences and preceptorships, and competency and technical skills training.

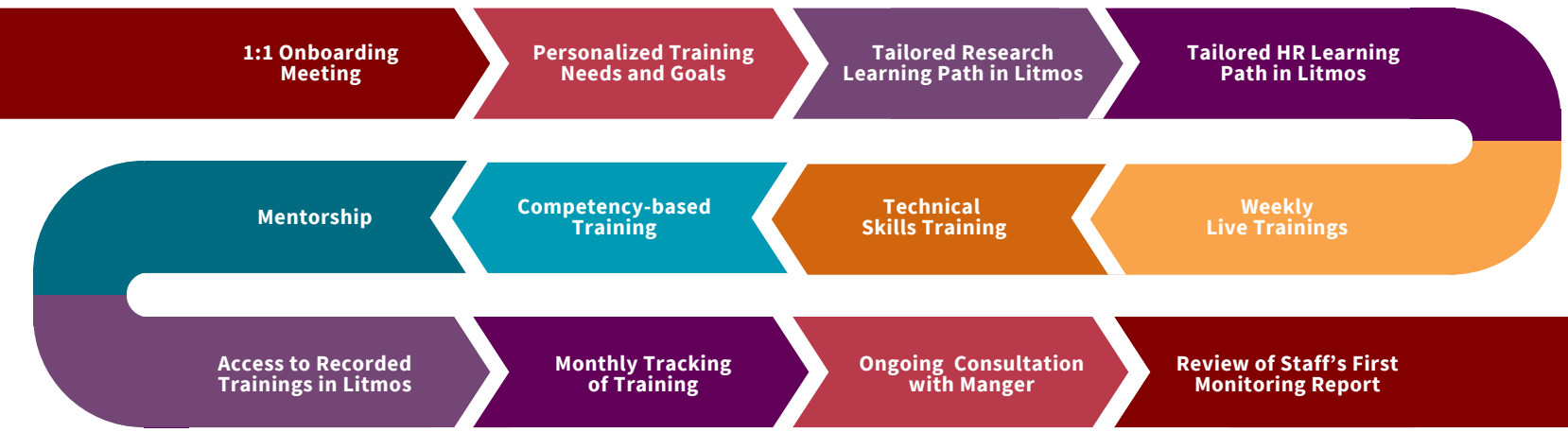
Onboarding

SCCR Onboarding Program: *Enhancing Study Success, Quality, and Retention*

We have a robust and tailored onboarding and re-boarding program for the clinical research coordinator (CRC) job family. Reports show an investment in education, training, and onboarding builds an effective, successful, and engaged workforce.

Purpose and Results

- Improve **research quality** and ensure participant safety
- Improve **study success, staff engagement,** and **retention**
- **Welcome new hires** in the CRC job family across the School of Medicine and promote cultural fit
- Provide a standard and comprehensive **onboarding program**
- **Educate, train,** and **prepare** new staff for their research roles
- Support new staff within the **first 6 months** of hire
- Save the School of Medicine **time and money**
- Add considerable value to Stanford's **research talent**



Target Audience and Benefits

The target audience for this program includes Stanford faculty looking to grow their research groups, and for divisions and departments expanding their CRC staff. Potential benefits include reducing the time faculty spend on training their staff, allowing faculty to focus on their academic responsibilities. Comprehensive onboarding empowers staff to enhance their knowledge, leading to higher-quality research outputs and innovation.

Achievements

*SCCR teams have completed over **250 projects in the past 10 years**. These have included **observational registries, implementation science projects, population health programs, and randomized trials**. Studies have included decentralized or virtual programs as well as FDA regulated drug and device studies. Projects have included **phase 1 thru phase 4 studies**. Below is an example of selected programs that are ongoing or completed.*

Cellular Immune Tolerance Program

The Cellular Immune Tolerance (CIT) program, led by Drs. Everett Meyer and Stephan Busque, has launched 16 clinical trials, including 8 investigator-initiated trials (IITs) with INDs, to advance cell therapy for non-cancer patients. SCCR provides critical research infrastructure to support these efforts. The program has brought together 35+ Stanford faculty across 14 divisions or departments.

Key Achievements:

- First U.S. patient with multiple sclerosis treated with anti-CD19 CAR T therapy
- 10 patients treated with anti-CD19 CAR T therapy
- Complete immunosuppression withdrawal achieved in several kidney + hematopoietic stem cell transplant patients
- Early results were presented at AAAS and awarded a 2024 Science Breakthrough designation

35+ Stanford Faculty	**14** Divisions Collaborating	**16** Clinical Trials	**8** IITs with INDs	**10** Patients Treated with Anti-CD19 CAR T

Publications

- Combined kidney and hematopoeitic cell transplantation to induce mixed chimerism and tolerance
- Establishment of Chimerism and Organ Transplant Tolerance in Laboratory Animals: Safety and Efficacy of Adaptation to Humans
- Macrochimerism and clinical transplant tolerance

Innovative Medicines Accelerator/Chemistry, Engineering and Medicine for Human Health

Our collaboration with Innovative Medicines Accelerator/Chemistry, Engineering and Medicine for Human Health (IMA/ChEM-H) and Gastrointestinal and Hepatology, is led by Drs. Stephan Rogalla, Alice Bertaina, Sean Spencer, Natalie Torok, Nielsen Fernandez Becker, and Konstantina Stankovic. It is at the **intersection of Immunology and Microbial Adaptation** and focuses on understanding the complex interactions between the immune system, gut microbiome, and liver health. This collaborative and innovative research aims to elucidate how the gut microbiome influences immune responses and contributes to gastrointestinal and liver diseases. By investigating these relationships, **researchers seek to identify novel therapeutic targets and develop innovative treatment strategies** for conditions such as inflammatory bowel disease, liver fibrosis, and other related disorders. This IMA/ChEM-H-SCCR effort is fostering collaboration among researchers in these fields and aims to translate findings into clinical applications that can improve patient outcomes and enhance our understanding of disease mechanisms.

Multi-site Oncology

SCCR has advanced **multi-site oncology research** through key trials, including the TrioMBM trial, led by Dr. Allison Betof Warner, which evaluates a novel immunotherapy for melanoma brain metastases. SCCR also serves as the CCC for the Bright Pink Preventive Risk Outreach and Cascade Testing (PROACT) Program with the University of Michigan. Funded by Bright Pink, this initiative enhances breast and ovarian cancer prevention and early detection, exploring the role of digital tools in improving cancer education and genetic testing access.

Johnson and Johnson / Librexia-AF

The LIBREXIA program, a global Factor XIa Phase 3 clinical development program sponsored by Bristol Myers Squibb and Janssen Research and Development, LLC, will evaluate the efficacy and safety of milvexian, an oral factor XIa inhibitory drug, in three Phase 3, randomized, and double-blind clinical trials (LIBREXIA Stroke, LIBREXIA Acute Coronary Syndrome, and LIBREXIA Atrial Fibrillation). The program will assess whether milvexian can enhance the benefit-risk profile associated with treating patients with these three conditions by reducing thrombotic events with no increased risk of bleeding. The studies, co-led by SCCR Director, Dr. Mahaffey and Dr. Caroly Lam from Singapore, **enrolled over 20,000 patients globally at over 1,000 study sites** and boasts novel advancements in study design that focus on patient perspectives and insights.

Publication and Presentation

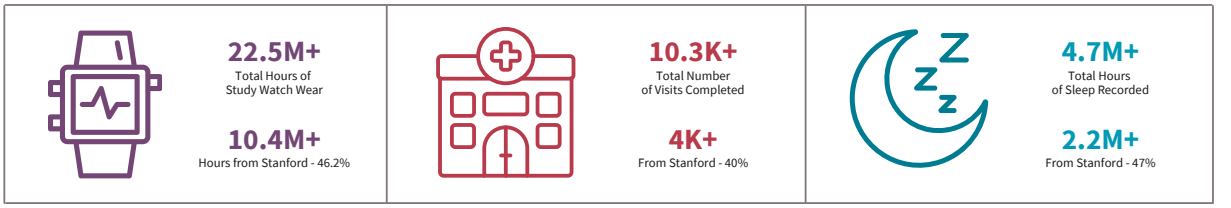
- Milvexian vs apixaban for stroke prevention in atrial fibrillation: The LIBREXIA atrial fibrillation trial rationale and design
- Librexia AF Protocol

The Stanford Heartbeat Study

The Stanford Heartbeat Study is a digital platform designed for clinical trial recruitment to identify eligible patients with atrial fibrillation (AF) for the Librexia-AF trial, led by Drs. Marco Perez and Co-I Sneha Jain. The study aimed to **increase the number of participants enrolled from underrepresented groups** and understand the characteristics of participants who do not qualify for or declined participation in the Librexia AF trial.

The heart of this study was the use of online and mobile technologies for participant identification, screening, enrollment, consent, and data collection. The Heartbeat Study database may serve as a source for future clinical trials, including data from wearables and electronic medical records. The mobile application also has the potential to become an educational resource for AFib patients about their condition. The Heartbeat Study can serve as a pathway to help us build a community of individuals eager to contribute to research and advance science through clinical trial participation.

Project Baseline



The Project Baseline Health Study (PBHS), led by Dr. Ken Mahaffey and the late Dr. Sam Gambhir, was a novel, multi-site, longitudinal observational study that explored **long-term health outcomes in over 2,500 participants nationwide**. A collaboration between Stanford, Duke University, and Verily Life Sciences, the study aimed to understand the factors influencing transitions between health and disease—and to map an integrated understanding of human health.

Overall, 2,502 participants were enrolled with 1,002 adult participants (ages 18 and older) at Stanford. The participants represent a spectrum of health statuses, from healthy volunteers to those with prior cancer or cardiovascular disease. Enrollment was designed to reflect national demographic percentages, beginning in June 2017 and concluding in June 2023, with an impressive **retention rate of 85%**, given it was conducted during the pandemic. Notably, 80% of participants expressed interest in participating in additional studies at Stanford. Our Stanford collaborations for this large project included Radiology, Oncology, Ophthalmology, Cardiovascular Medicine, Pulmonary Medicine, Sleep Medicine, Diabetology, Quantitative Scientists, as well the Clinical Translational Research Unit, Stanford Health Care, and the Veterans Affairs. SCCR was also the CCC at Stanford.

Publications

- Relationship between body mass index and cardiometabolic health in a multi-ethnic population: A project baseline health study
- Multi-dimensional characterization of prediabetes in the Project Baseline Health Study
- The Project Baseline Health Study: a step towards a broader mission to map human health

Apple Heart Study

The Apple Heart Study, led by Drs. Marco Perez, Mintu Turakhia, Manisha Desai, and Ken Mahaffey, was a decentralized, prospective study assessing the effectiveness of an irregular pulse notification algorithm (IPNA) in **identifying atrial fibrillation via an Apple Watch app**.

During just eight months, **419,297 participants** were recruited from **all 50 states and the District of Columbia**. While the probability of receiving a notification for an irregular pulse was low, over one-third of those notified were subsequently found to have atrial fibrillation confirmed by an ECG patch monitor. The algorithm demonstrated an **84% concordance rate**, leading to FDA clearance for use in Apple Watches.

Stanford served as the CCC, overseeing all aspects of the trial, including study design, safety desk, and operations management.

News and Publications

- Stanford Medicine announces results of unprecedented Apple Heart Study
- Apple Heart Study demonstrates ability of wearable technology to detect atrial fibrillation
- Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation
- Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study
- Lessons learned in the Apple Heart Study and implications for the data management of future digital clinical trials

smartADHERE

SmartADHERE, led by Dr. Mintu Turakhia, was a randomized trial evaluating a **personalized digital and human intervention for adherence to direct oral anticoagulants (DOACs)** in patients newly prescribed rivaroxaban for AFib.

The study aimed to enroll **378 participants** across **25 U.S. sites** but was terminated early with **139 enrolled**. Despite this, the trial demonstrated the feasibility of a centralized adherence intervention across multiple sites, revealing higher-than-expected adherence rates among at-risk individuals.

SCCR functioned as the CCC managing site selection, training, recruitment, and intervention implementation.

Publication

- Efficacy of a centralized, blended electronic, and human intervention to improve direct oral anticoagulant adherence: Smartphones to improve rivaroxaban ADHEREnce in atrial fibrillation (SmartADHERE) a randomized clinical trial

NIH REACT

The Rhythm Evaluation for AntiCoagulaTion with Continuous Monitoring of Atrial Fibrillation (REACT-AF) study, funded by the NIH, and in collaboration with Northwestern University and Johns Hopkins University, led by Dr. Marco Perez, investigates the **integration of smart technology for medication management** in patients with paroxysmal AFib.

This innovative **"pill-in-pocket" strategy** involves continuous heart rhythm monitoring through a smartwatch and a novel application, advising participants to administer their DOAC during qualifying AFib episodes. The study aims to enroll over **5,000 participants** across the anticipated **100 sites**, with nearly **2,000 already consented**.

SCCR serves as a CCC, managing clinical sites, co-leading recruitment and retention, and leading the Clinical Events Adjudication and the safety desk—ensuring rigorous oversight.

NIH RECOVER/COVID

Established in early 2020, the SCCR- Innovative Medicines Accelerator-Infectious Disease (SCCR-IMA-ID) Treat COVID team rapidly launched **10 clinical trials**, enrolling **500 participants** and facilitating **3,500 visits**. Our trials explored various therapeutic approaches, leading to the Emergency Use Authorization process for several promising therapies and approval of multiple Investigational New Drug applications.

The RECOVER study is a nationwide observational study examining Long COVID across **85 sites**. Our team at SCCR and SHC TriValley, led by Drs. Upi Singh, PJ Utz, Andre Kumar, and Minjoung Go, enrolled **1,020 adult participants**, conducting extensive biospecimen sampling and clinical assessments to understand the varying impacts of Long COVID.

RECOVER sub-studies our site has participated in include **RECOVER NEURO** (interventions for cognitive dysfunction), led by Drs. Upi Singh and Linda Geng, **RECOVER VITAL** (evaluate safety of Paxlovid), led by Drs. Andre Kumar and Alfredo Urdaneta, **RECOVER AUTONOMIC** (interventions for autonomic dysfunction symptoms), led by Dr. Linda Geng, and **RECOVER ENERGIZE** (improving exercise intolerance and post-exertional malaise) led by Dr. Andre Kumar.

News and Publications

- RECOVER Stanford
- RECOVER
- Development of a Definition of Postacute Sequelae of SARS-CoV-2 Infection

A Heartfelt Thank You to Our Collaborators

As we reflect on the past decade, we extend our gratitude to those who have joined us on this remarkable journey toward improving human health. Your support and collaboration have been instrumental in our progress and achievements.

Research Participants: To the individuals who entrusted us with their health journeys, thank you for your courage and commitment. Your participation has been the cornerstone of our research and innovation.

Stanford Department of Medicine, Faculty, Administration, Operations Teams, and Research Partners: We are grateful to the Department of Medicine and our leadership for their strategic investments and support; and for our Stanford colleagues whose insights and feedback have strengthened our infrastructure and processes. Your dedication to excellence has propelled us forward.

Thank you to our Stanford collaborators and partners:

- Abdominal Transplantation
- Anesthesia
- Biomedical Informatics Research
- Blood and Marrow Transplantation & Cellular Therapy
- Cardiovascular Medicine
- Center for Digital Health
- Clinical Excellence Research Center
- Chemistry, Engineering, and Medicine for Human Health
- Clinical Trials Office
- Department of Genetics
- Dermatology
- Emergency Medicine
- Gastroenterology & Hepatology
- Health Policy
- Hematology
- Hospital Medicine
- Human Centered Artificial Intelligence
- Immunology & Rheumatology
- Infectious Diseases
- Innovative Medicines Accelerator
- Institute for Immunity, Transplantation and Infection
- Stanford Institutional Review Board
- Microbiome Therapies Initiative
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- Neurology
- Neurosurgery
- Oncology
- Orthopedic Surgery
- Otolaryngology/Head & Neck
- Otology & Neurotology
- Pediatrics
- Pediatric Disease Prevention
- Pediatric Hematology/Oncology
- Pediatric Infectious Diseases
- Pediatric Stem Cell Transplantation
- Population Health
- Primary Care and Outcomes Research
- Pulmonary, Allergy and Critical Care Medicine
- Quantitative Sciences Unit
- Radiology
- Research Management Group
- Stanford Center for Innovative Study Design
- Stanford Department of Medicine
- Stanford School of Medicine
- SPARK
- Spectrum
- Stanford Prevention Research Center
- Technology and Digital Solutions
- Translational Research and Applied Medicine
- University Information Technology
- Vascular Medicine
- Vascular Surgery
- Veterans Affairs Cooperative Studies Program

Industry, Federal, Foundation and Internal Sponsors: Thank you to our sponsors for your generous support and belief in our mission. Your investment has enabled us to make significant strides towards health improvement.

SCCR Staff: To each member of our team, past and present, your hard work and passion have made a profound impact. Thank you for your meaningful contributions and commitment to our collective aims.

Academic Partners: Thank you to our academic partners, we appreciate your collaboration. Together, we have been able to design and conduct rigorous programs with scientific and data integrity.

A Special Thank You to:

- The Quantitative Sciences Unit team for their partnership on many of our projects as the Data Coordinating Center
- The Stanford Center for Innovative Study Design for being the coordinating center for a number of our projects, including the LIMIT trial
- The Veterans Affairs Cooperative Studies Program for their partnership on the AMP trial

Academic Partners

Baim Institute for Clinical Research
TIMI Study Group
George Clinical
CRF Clinical Trials Center
St. Jude Medical
CPC Clinical Research
Canadian VIGOUR Centre Bridging Hearts and Minds
Northwestern University
BCRI
UCSF
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Johns Hopkins University
Duke Clinical Research Institute
UCRO

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NOVARTIS
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SOCAR RESEARCH
Bristol-Myers Squibb
PRAHealthSciences

Together, we have made a significant impact, thank you for being an integral part of our mission.

Looking Forward

Discover how our new strategic plan will propel us toward our vision for the future. Click or scan here to explore the exciting initiatives that will shape our journey ahead!

SCCR Executive Report

DoM Annual Report 2024

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