

May 18, 2026

NINDS Funding for Clinical Trials: The Therapeutic Research Pipeline

Clinton Wright, MD, MS

Director, Division of Clinical Research, NINDS

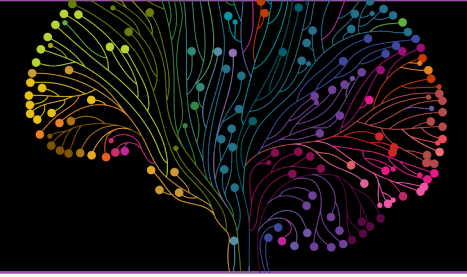
Member, Stroke Branch, Division of Intramural Research, NINDS



National Institute of
Neurological Disorders
and Stroke



Mission of NINDS

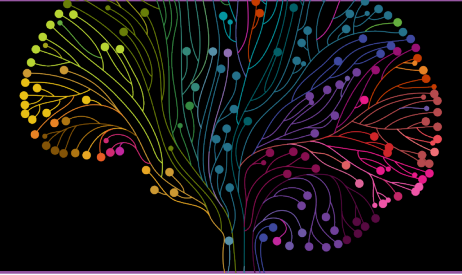


*The mission of NINDS is to seek **fundamental knowledge** about the brain and nervous system and to use that knowledge to **reduce the burden of neurological disease** for all*

- ✓ Support and perform basic, translational, and clinical neuroscience research
- ✓ Fund and conduct research training and career development programs and ensure a vibrant, talented, and diverse workforce
- ✓ Promotes the timely dissemination of scientific discoveries and their implications for neurological health to the public



NINDS Approach to Funding Neuroscience Research in 2026



Key Updates for FY 2026

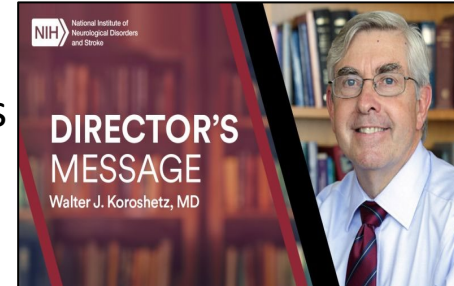
- **CSR now reviews all applications** - NINDS no longer runs study sections
- **Grants.gov** - Single official source for funding opportunities
- Reducing specific NOFOs, encouraging broader use of Parent NOFOs
- New "**Highlighted Topics**" to communicate priority areas
- New requirements for foreign components (PF5/UF5 Activity Codes)

! Major Change: No Strict Paylines

- NINDS will **NOT publish percentile-based paylines**
- Funding decisions based on: scientific merit, portfolio balance, investigator effort, and rigor

No Major Changes: Funding Priorities & Policies

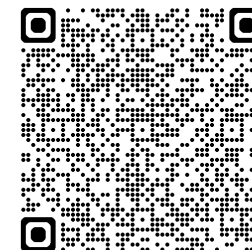
- Fund as many investigators as possible, will continue to employ greater stringency in funding investigator-initiated grants to investigators for:
 - Those with >\$1.5 million in NIH funds,
 - Parent R01s with total costs greater than ~\$750,000 per year."
- Special consideration for **Early-Stage Investigators**
- NINDS continues to consider bridge funding for certain circumstances"



NINDS's Approach to Funding Neuroscience Research in 2026

Wednesday, November 26, 2025

Thanks to the herculean efforts of our dedicated staff, we successfully and fully obligated our Fiscal Year (FY) 2025 NINDS appropriation of \$2.69 billion. Superb scientists supported by NINDS continue to advance our mission to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people.



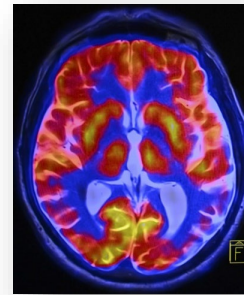
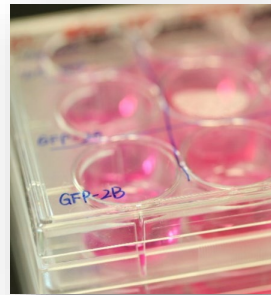
NINDS Organization: Investing Across the Research Spectrum

Division of
Neuroscience

Division of
Translational
Research

Division of Clinical
Research

Division of
Extramural Activities
*includes training
programs*

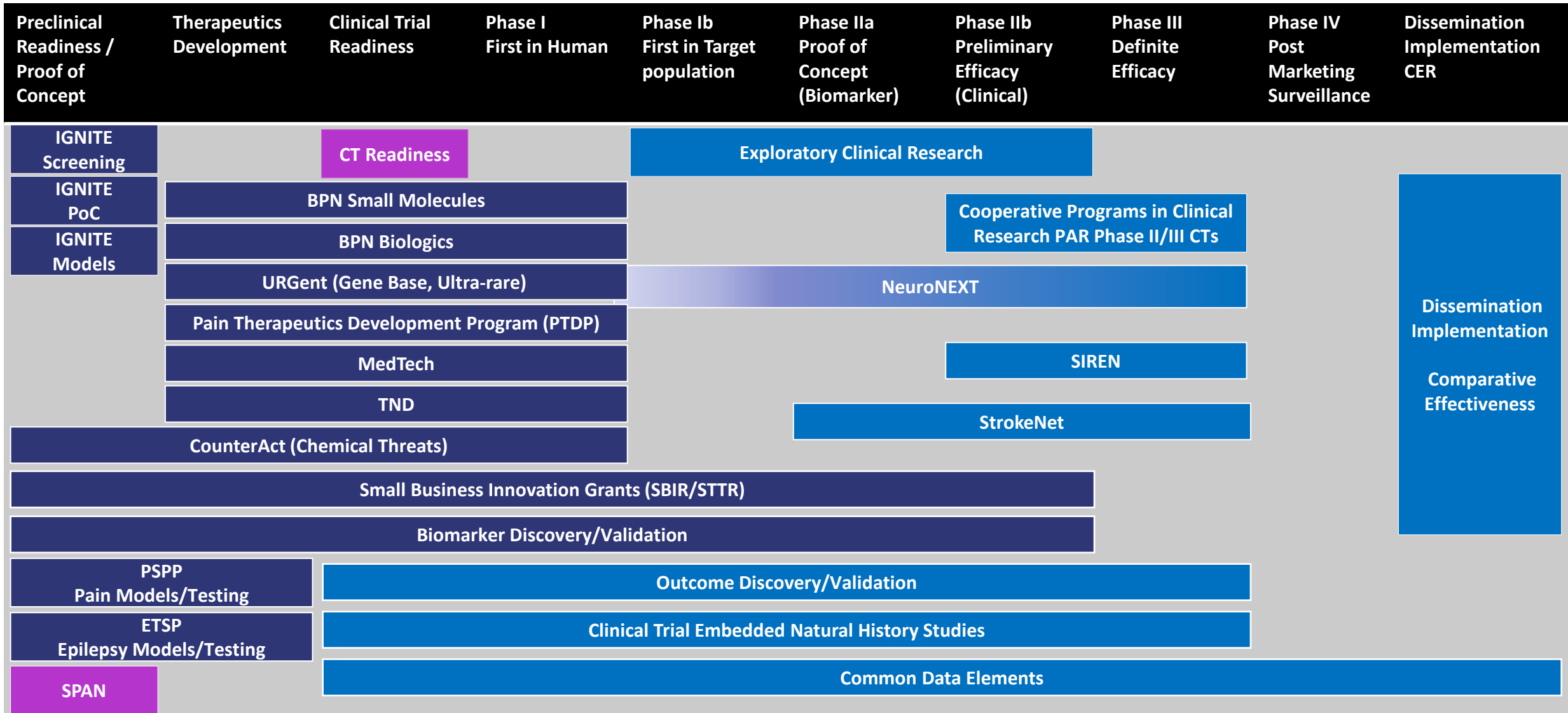
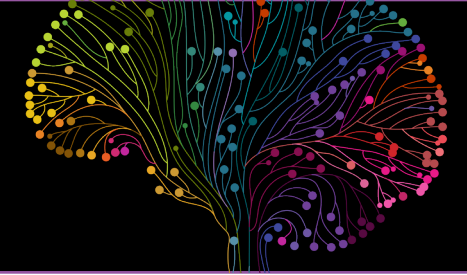


BASIC
*Fundamental Neuroscience
Disease-Focused Research*

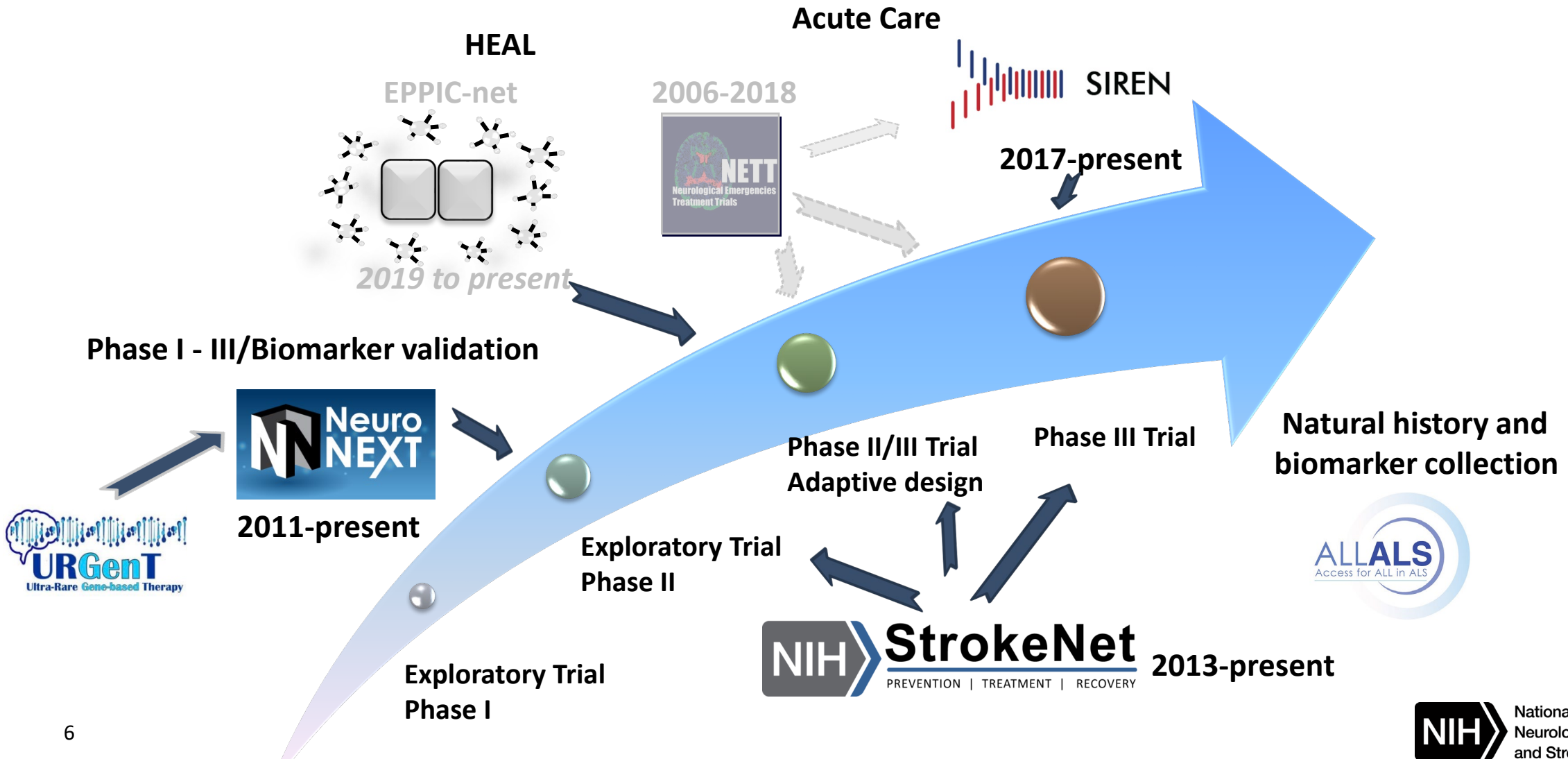
TRANSLATIONAL
*Pipeline through to
FDA IND/IDE*

CLINICAL
*Phase I, II, III Trials
FDA Review*

NINDS Clinical Trial Pipeline



NINDS Funds Standing Clinical Research Networks



StrokeNet: NINDS Stroke Clinical Trial Network



Overview

- 2013 - present
- 29 regional centers with 432 satellite stroke hospitals, a coordinating center, and a data coordinating center
- Phase 2 and phase 3 clinical trials and biomarker studies to advance acute stroke treatment, prevention, and recovery
- 27 active trials
 - 14 Acute Interventional
 - 8 Recovery and Rehabilitation
 - 5 Prevention

How to Apply

- [PAR- 25-052](#)
- **Contact:** Scott Janis, Program Director
janiss@ninds.nih.gov



Recent Updates

- **I-ACQUIRE** results presented at ISC 2026
 - Intensive high-dose rehabilitation significantly improved arm and hand function in infants with hemiparetic perinatal stroke
- **TRANSPORT-2** results published in Lancet March 2026
 - Adding tCDS to constraint induced movement therapy, while safe and well-tolerated, did not lead to a further reduction in motor impairment.



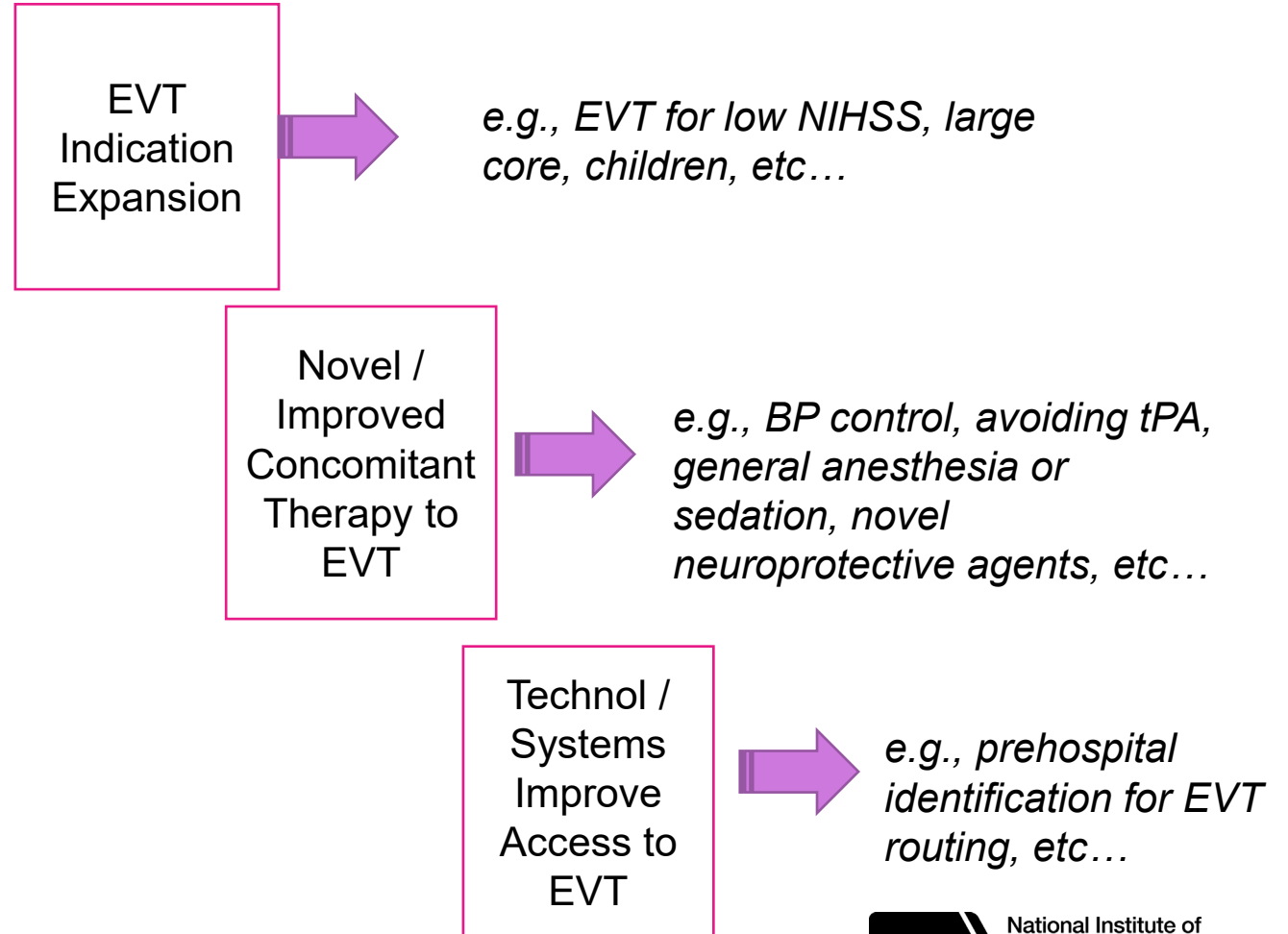
An Endovascular Thrombectomy Platform: STEP

Overview

- StrokeNet Thrombectomy Platform (STEP)
- Randomized Multifactorial Adaptive Platform (REMAP design)
- 38 StrokeNet sites across the US
- Leverages existing registries for data collection
- Domain 1: Assessing whether EVT improves the global disability outcome of AIS patient subgroups (i.e., those with low NIHSS and with median and distal occlusions)

How to Apply

- [OTA-24-009](#)
- **Contact:** Scott Janis, Program Director
8 janiss@ninds.nih.gov



NeuroNEXT: Network for Excellence in Neuroscience Clinical Trials



Overview

- 2011 - present
- Regional sites, data and clinical coordinating centers
- Designed to advance the field by accelerating biomarker and therapy development
- Links with URGenT to serve as a pipeline for NINDS-funded gene based therapies
- 2 active trials
 - NMDAR encephalitis, Prion disease



How to Apply

- [OTA- 24-013](#)
- **Contacts:**
- Lumy Sawaki-Adams, MD, PhD Director, NeuroNEXT
lumy.sawaki-adams@nih.gov
- Emily Caporello, Small Business Program Director
emily.caporello@nih.gov



Recent Updates

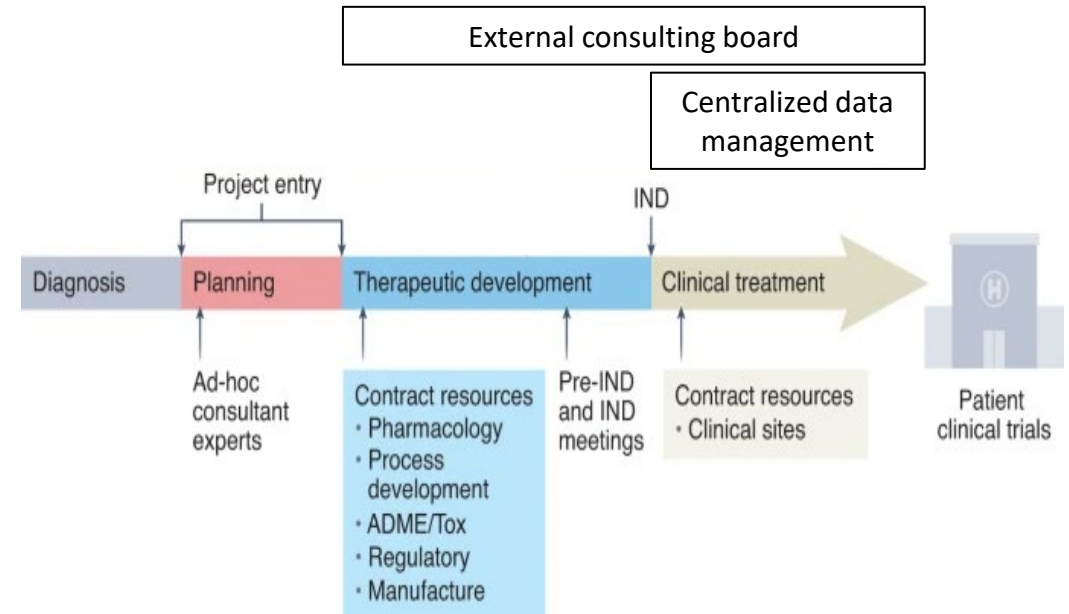
- New study PRiSM, launched first-in-human clinical trials of this divalent siRNA for prion disease in newly diagnosed symptomatic prion disease patients.



Ultra-Rare Gene Therapy (URGenT) Network

What is URGenT?

- [URGenT](#) will provide support for the development of state-of-the-art **gene-based therapies for ultra-rare neurological and neuromuscular diseases**
- Phased program with **multiple entry points**
- Funding and resources to advance gene-based therapies **from late-stage nonclinical development into clinical testing**
- Accelerated development timeline - **3 years start to finish**
- **Provides pipeline into NeuroNEXT**



Correspondence | [Published: 04 November 2021](#)

NINDS launches network to develop treatments for ultra-rare neurological diseases

[Nature Biotechnology](#) 39, 1497–1499 (2021) | [Cite this article](#)

882 Accesses | 15 Altmetric | [Metrics](#)

SIREN: Strategies to Innovate Emergency Care Clinical Trials Network



OVERVIEW

- Established in 2017 and co-funded with NHLBI
- 11 regional centers with 50 satellite ER sites, coordinating and data center
- Goal to improve outcomes of patients with neurologic, cardiac, respiratory, hematologic and traumatic emergencies by identifying effective treatments administered in the earliest stages of critical care
- 5 active trials:
 - Brain oxygen optimization in severe TBI, hyperbaric oxygen treatment in severe TBI, cooling in cardiac arrest patients (adults and pediatrics), treatment for acute hypoxemic respiratory failure (AHRF)

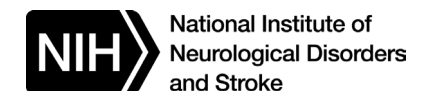
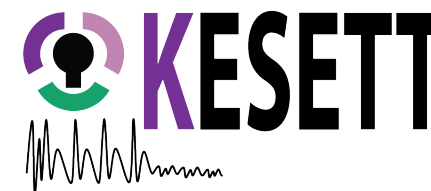
HOW TO APPLY TO SIREN

- [PAR-25-049](#)
- **Contact:** Jeremy Brown, Program Director
Jeremy.brown@nih.gov

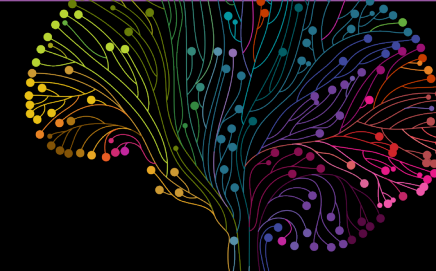


Recent Updates

- Enrollment in the KESETT clinical trial kicked off (Ketamine add-on therapy for Established Status Epilepticus Treatment Trial)
 - First patient randomized 3/6/2026



Training Opportunities in NINDS Clinical Trial Networks



Each network offers training opportunities and professional development for research fellows



NIH SIREN
Emergency
Trials
Network

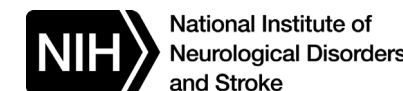
- Traineeship program
- Monthly didactics



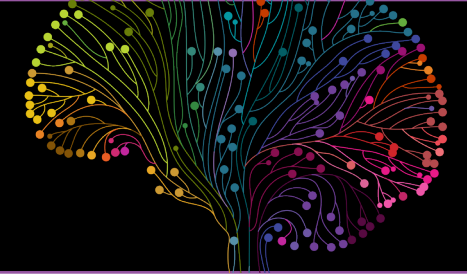
- Traineeship program
- Educational committee with networking, mentorship, webinars



- Traineeship program
- Grand rounds
- Professional development webinars
- Basic/ translational science webinars



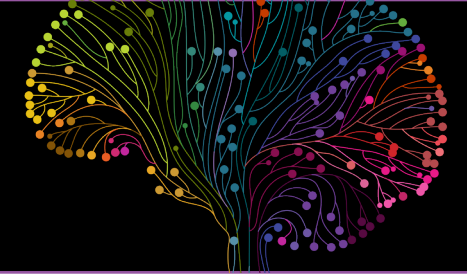
Clinical Trials Methodology Course (CTMC)



- **Identify promising junior investigators** in clinical neurosciences
- **Provide a rigorous foundation** in design, funding, conduct, monitoring/ oversight, ethical performance, reporting of patient-oriented clinical research
- **Promote ongoing professional career development** before, during, and after program
- There may be tracks: Foundations, Advanced, Biostatisticians (vary year to year)
- 2026 application window closed, keep an eye out for 2027 in December!



Future Funding Opportunities



- **NINDS Efficacy and Exploratory Clinical Trials (UG3/UH3):** PAR-26-069
 - Exploratory and efficacy clinical trials that address questions within the mission and research interests of the NINDS and may evaluate drugs, biologics, and devices, as well as surgical, behavioral and rehabilitation therapies.

Forecasted



- **Clinical Trials and Ancillary Studies Conducted within NIH-Funded Clinical Trial Research Networks (UG3/UH3):** PAR-27-007
 - Multi-center clinical trials to be conducted within an established Clinical Trial Research Network funded by one of multiple NIH Institutes and Centers.

Forecasted





Thank you!!

Clinton Wright, MD, MS
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Investigator-Initiated Clinical Trial Funding Opportunities – What Is on the Horizon for US Federal Funding Programs

NHLBI Perspective

Yves Rosenberg, M.D, M.P.H.

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Division of Cardiovascular Sciences

National Heart, Lung and Blood Institute, NIH

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Disclosures

The opinions expressed in this talk are my own and may not reflect the views of the NHLBI, the NIH, or the US Federal Government



National Heart, Lung and Blood Institute Strategic Plan Framework

NHLBI STRATEGIC GOALS

UNDERSTAND HUMAN BIOLOGY

To expand knowledge of the molecular, cellular, and physiological mechanisms governing the normal function of HLBS systems as essential elements for sustaining human health.

REDUCE HUMAN DISEASE

To extend our knowledge of the pathobiology of HLBS disorders and enable clinical investigations that advance the prediction, prevention, preemption, treatment, and cures of human diseases.

To enable essential



Objective 5: Develop and optimize novel diagnostic and therapeutic strategies to prevent, treat, and cure heart, lung, and blood diseases and sleep disorders

Enable research health impact.



Objective 6: Optimize clinical and implementation research to improve health and reduce disease

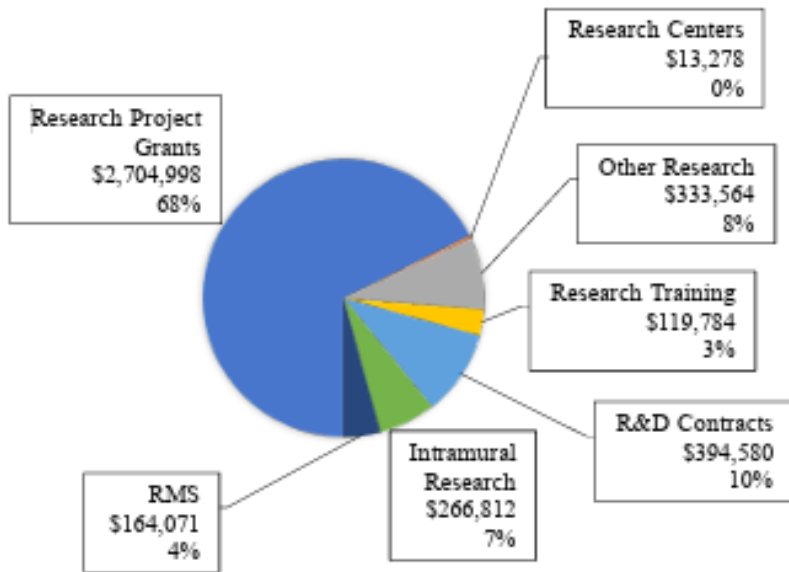
Heart, lung,

Heart and blood

- 6 Optimize clinical and implementation research to improve health and to reduce disease
- 7 Leverage emerging opportunities in data science to open new frontiers in research on heart, lung, and blood diseases and sleep disorders
- 8 Further develop and sustain a scientific workforce capable of accomplishing the NHLBI mission

National Heart, Lung, and Blood Institute Budget

FY 2025 Budget Mechanisms
(Dollars in Thousands)



BUDGET AUTHORITY BY ACTIVITY*

(Dollars in Thousands)

Activity	FY 2023 Final		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023 Final	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Extramural Research								
<u>Detail</u>	NA	NA	NA	NA	NA	NA	NA	NA
Center for Translation Research and Implementation Science	NA	\$126,856	NA	\$126,177	NA	\$126,586	NA	-\$270
Heart and Vascular Diseases	NA	\$2,137,727	NA	\$2,126,771	NA	\$2,133,478	NA	-\$4,249
Lung and Sleep Health	NA	\$815,926	NA	\$811,565	NA	\$814,193	NA	-\$1,733
Blood Diseases and Resources	NA	\$492,962	NA	\$490,370	NA	\$491,947	NA	-\$1,015
Subtotal, Extramural	NA	\$3,573,470	NA	\$3,554,884	NA	\$3,566,203	NA	-\$7,267
Intramural Research	463	\$254,255	473	\$264,706	473	\$266,812	10	\$12,557
Research Management & Support	480	\$157,433	493	\$162,755	493	\$164,071	13	\$6,638
TOTAL	943	\$3,985,158	966	\$3,982,345	966	\$3,997,086	23	\$11,928

*Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

CONGRESSIONAL JUSTIFICATION FY 2025

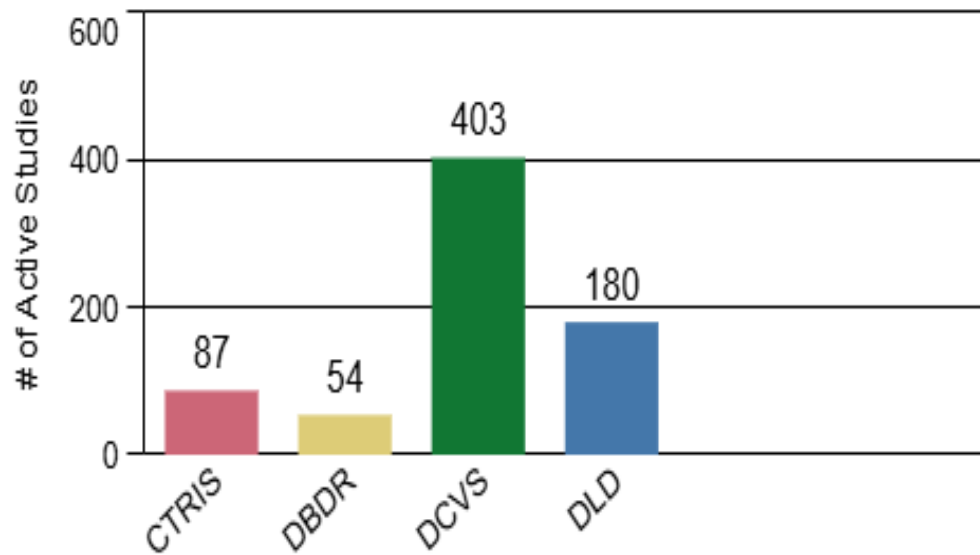
<https://www.nhlbi.nih.gov>

National Heart, Lung and Blood Institute Clinical Research Funding

Active Clinical Studies

Investigators Initiated Clinical trials NHLBI NOFOs (FY17 – FY24)

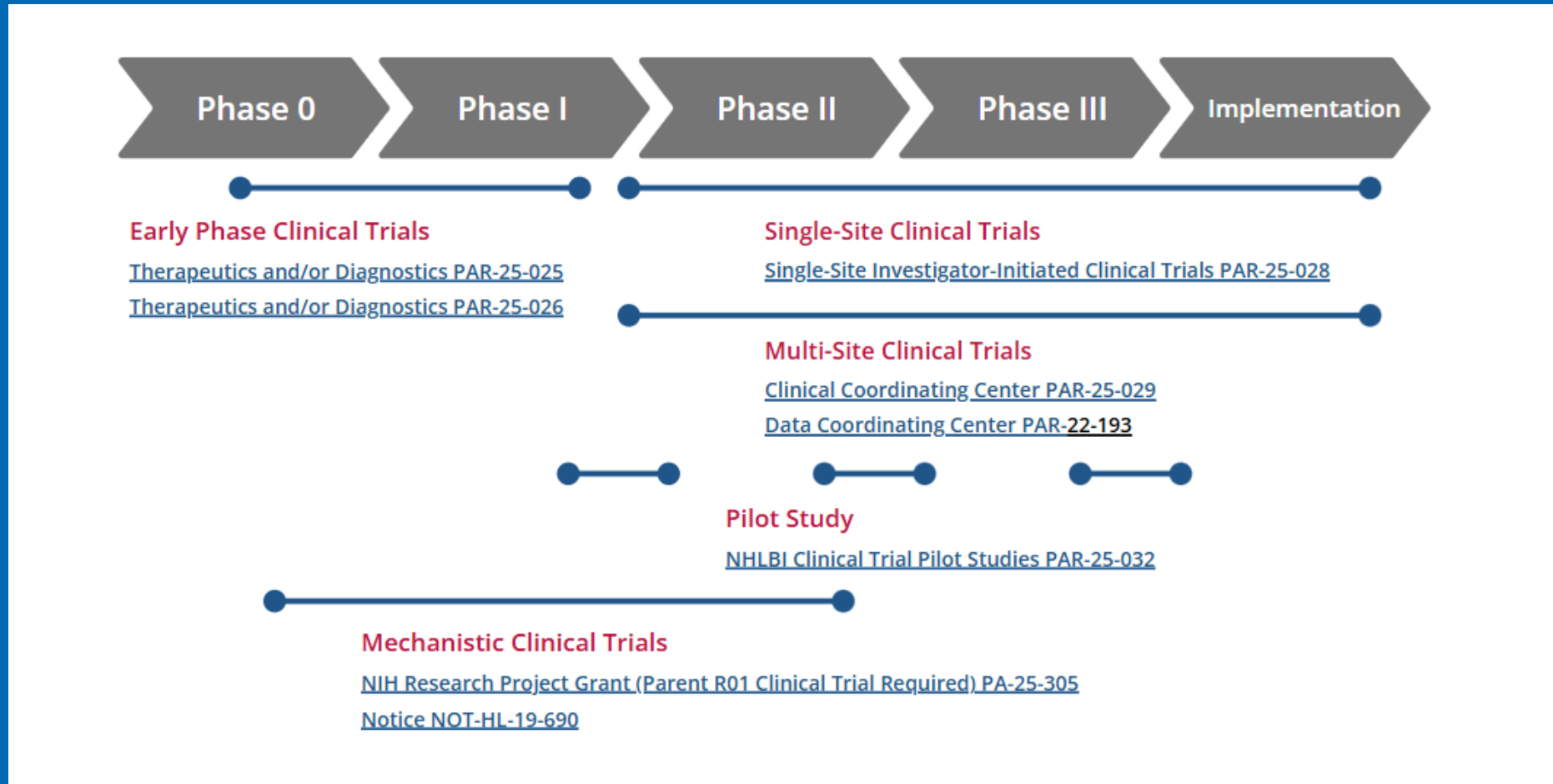
724 Studies by Division



Trial Types	N
Pilot Trials	85
Single-Site Trials	60
Multi-Site Trials	54
Early Phase Trials	19
Grand Total	218

NHLBI Clinical Trial (CT) Ecosystem

Clinical Trial Development Continuum



NHLBI Clinical Trial (CT) Ecosystem

Available Notice of Funding Opportunities (NOFOs)

Pilot CT	Mechanistic CT	Early-Phase CT	Single-Site CT	Multi-Site CT
<p>R34 PAR-25-032</p>	<p>R01 PA-25-305 NOT-HL-19-690, FAQs</p>	<p>R33 PAR-25-025 R61/R33 PAR-25-026</p>	<p>R61/R33 PAR-27-011 FAQs</p>	<p>UG3/UH3 PAR-27-012 (CCC) U24 PAR-27-013 (DCC) FAQs</p>
<p>Finalize design and test feasibility of a future full-scale CT, including intervention, site activation, trial procedures, participant availability, and other essential information for conduct of full trial</p> <p>Up to 3 years</p> <p>IND/IDE approval required prior to funding</p>	<p>Understand a biological or behavioral process, the pathophysiology of a disease/condition, or the mechanism of action of an intervention</p> <p>Does not evaluate safety, clinical efficacy, and/or clinical management</p> <p>Up to 5 years</p>	<p>Evaluate the safety, side effects, best dose, timing, and/or best administrative route for a new treatment or therapy; first in-human trials</p> <p>Can be single- or multi-site</p> <p>R61: 1-2 years R33: Up to 3 years</p>	<p>Phase II and above: efficacy, comparative effectiveness, pragmatic and/or implementation research</p> <p>R61: 1 year R33: Up to 4 years</p> <p>IND/IDE approval required prior to funding</p>	<p>Phase II and above: efficacy, comparative effectiveness, pragmatic and/or implementation research</p> <p>UG3: 1 year Total UG3/UH3: Up to 7 years</p> <p>IND/IDE approval required prior to funding</p>

NHLBI Clinical Trial (CT) Ecosystem

Clinical Trial Pilot Studies (R34)

- Supports studies that are both *necessary and sufficient* to inform the planning of a Phase II-IV clinical trial within NHLBI's mission.
- Applications will describe the planned clinical trial and in so doing demonstrate that the proposed (R34) research is scientifically necessary to design or plan the subsequent trial (without further studies)
- Examples of research topics include but are not limited to the following:
 - Refine the appropriate study population, consent, statistical methods, intervention, or outcome
 - Collect information necessary to verify available populations, attrition rate, event rate, or response rate
 - Standardize the intervention or outcome across multiple sites
 - Test the feasibility of an outcome or intervention in the field
 - Determine whether adequate adherence to a treatment is achievable
 - Standardize and validate survey instruments
 - Standardize and test effectiveness of training tools

NHLBI Clinical Trial (CT) Ecosystem

Early Phase CT for Therapeutics and/or Diagnostics (R61/R33 CT Required)

- Phase 0 and I clinical trials (including bridging studies)
- Diagnosis and therapeutic interventions (e.g., drugs, devices, and biologics, including cells and cell products) for HLBS disorders in adults and children
- Support for final stage, agent-associated preclinical activities needed for the implementation & conduct
- Bridges a gap from pre-clinical to clinical
 - R61: stability studies, final formulation, IND filing, trial development
 - R33: phase I trials

Submissions containing animal studies are NOT appropriate/permitted for this NOFO

<https://grants.nih.gov/grants/guide/pa-files/PAR-25-026.html>

NHLBI Clinical Trial (CT) Ecosystem

Single-site Clinical Trial (R61/R33) NOFOs and Multi-site Clinical Trial CCC and DCC (UG3/UH3 and U24)

Phased funding, milestone-driven and performance based to achieve successful completion of the study on-time and on budget

■ Key features

- Address HLBS scientific priorities with the potential to change clinical practice, impact health, or advance science
- Demonstrate operational feasibility:
 - Experience relevant to conducting clinical trials
 - Trial management plan including risk assessment/management plans
 - Supporting information that equipoise is present
 - Subject recruitment and retention (supporting information for accrual targets/site)
 - Performance milestones to be met, how, and when
 - IND/IDE approval by time of award
 - Timeline
 - Dissemination of results

[PAR-27-011: Single-Site Investigator-Initiated Clinical Trials \(R61/R33 Clinical Trial Required\)](#)

[PAR-27-012: Clinical Coordinating Center for Multi-Site Investigator-Initiated Clinical Trials \(Collaborative UG3/UH3 Clinical Trial Required\)](#)

[PAR-27-013: Data Coordinating Center for Multi-Site Investigator-Initiated Clinical Trials \(Collaborative U24 Clinical Trial Required\)](#)

NHLBI Clinical Trial (CT) Ecosystem

Single-site Clinical Trial (R61/R33) NOFOs and Multi-site Clinical Trial CCC and DCC (UG3/UH3 and U24)

Core Milestones (UG3/R61):

- Finalizing protocol and consent,
- Getting DSMB and IRB approvals,
- Activating 25% of the sites for a multi-site CT
- Enrolling at least 1 participant by the end of the UG3-U24/R61 phase.

Core Milestones (UH3/R33):

- Enrollment of 25%, 50%, 75% and 100% of the projected recruitment
- Study closure and completion plans
- Database lock
- Submission of primary manuscript

UG3-U24/R61 (1 year)

UH3-U24 (6 years)/**R33** (4 years)

NIH Clinical Trials: The Future is Coming!

Planned Suite of Trans-NIH Clinical Trial NOFOs:

Feasibility CT	“Other” Trials *	Multi-Site CT	Pragmatic CT	Network CT
<ul style="list-style-type: none">• R34• Early-stage trials for feasibility & acceptability• Prepare for subsequent definitive trial	<ul style="list-style-type: none">• R61/R33• Phase I and above• Single site trials	<ul style="list-style-type: none">• UG3/UH3• Phase II and above• Includes complex single-site trials & decentralized trials	<ul style="list-style-type: none">• UG3/UH3• Effectiveness & implementation in setting where health care is delivered• Must already demonstrate efficacy	<ul style="list-style-type: none">• UG3/UH3• Phase II and above utilizing an NIH-funded Network

New NOFOs to be published late 2026/early 2027?

*New working group formed to cover identified NOFO gaps

Cardiovascular Diseases Still Not Quite Evidence Based!

Figure 3. Proportion of Recommendations With Level of Evidence A by Subspecialty Area in Topic Areas Covered by Both a Current American College of Cardiology/American Heart Association and European Society of Cardiology Guideline Document

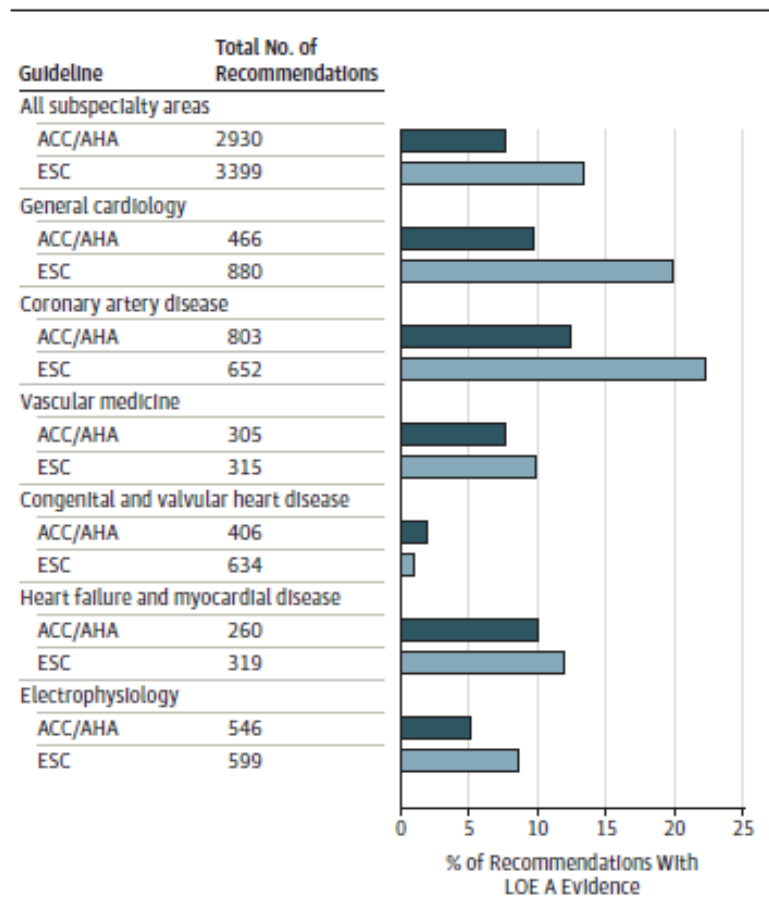
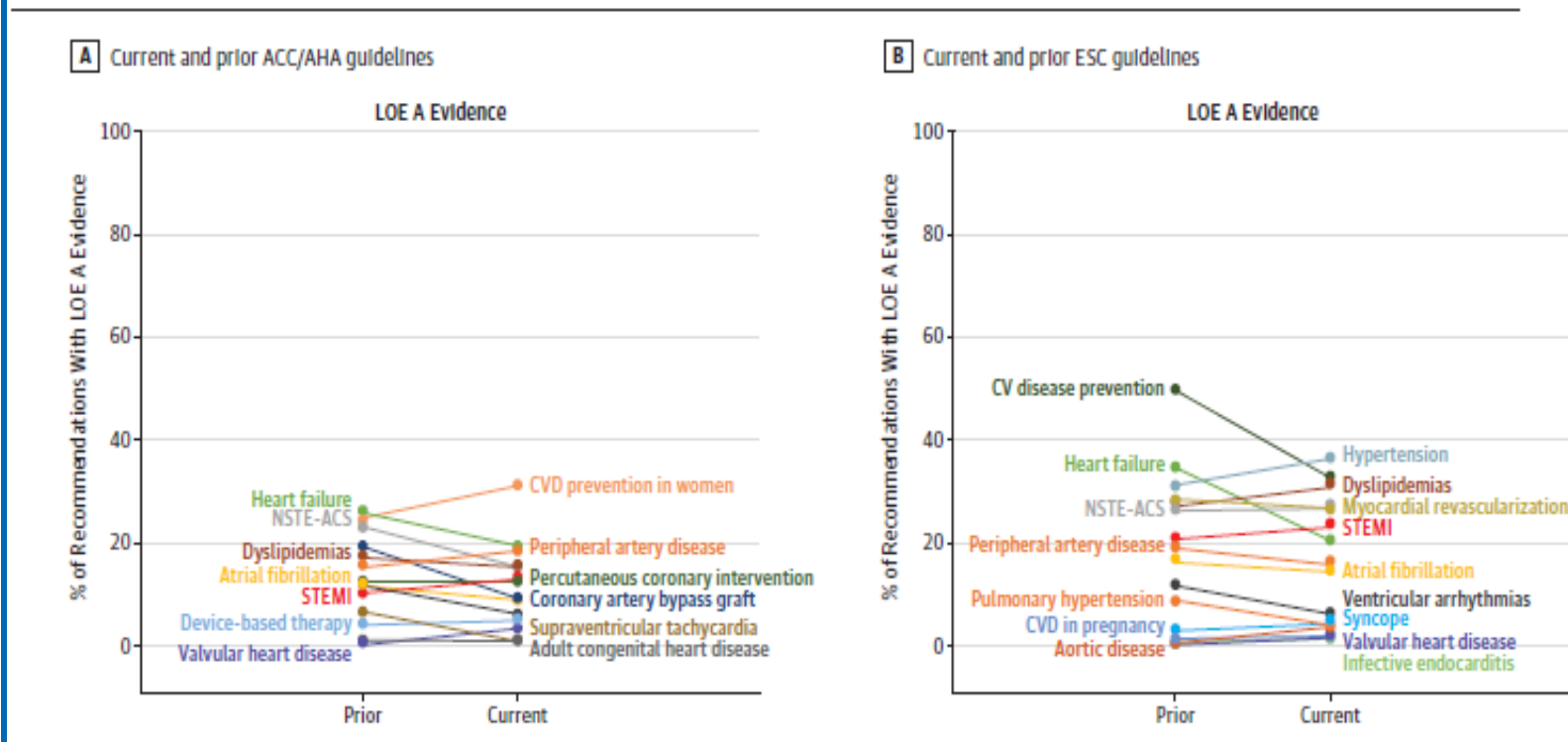


Figure 2. Proportion of Recommendations With Level of Evidence A, B, and C in Current and Prior Guideline Documents





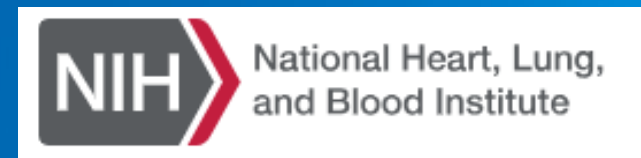
Thank You!

Yves Rosenberg, M.D, M.P.H.

E-mail: rosenbey@nhlbi.nih.gov



G



Society for Clinical Trials Meeting

NCI CTEP & CIP Overview: Research & Funding Opportunities

Pedro A. Torres-Saavedra, PhD

Mathematical Statistician

Division of Cancer Treatment and Diagnosis (DCTD)

Biometric Research Program (BRP)



pedro.torres-saavedra@nih.gov

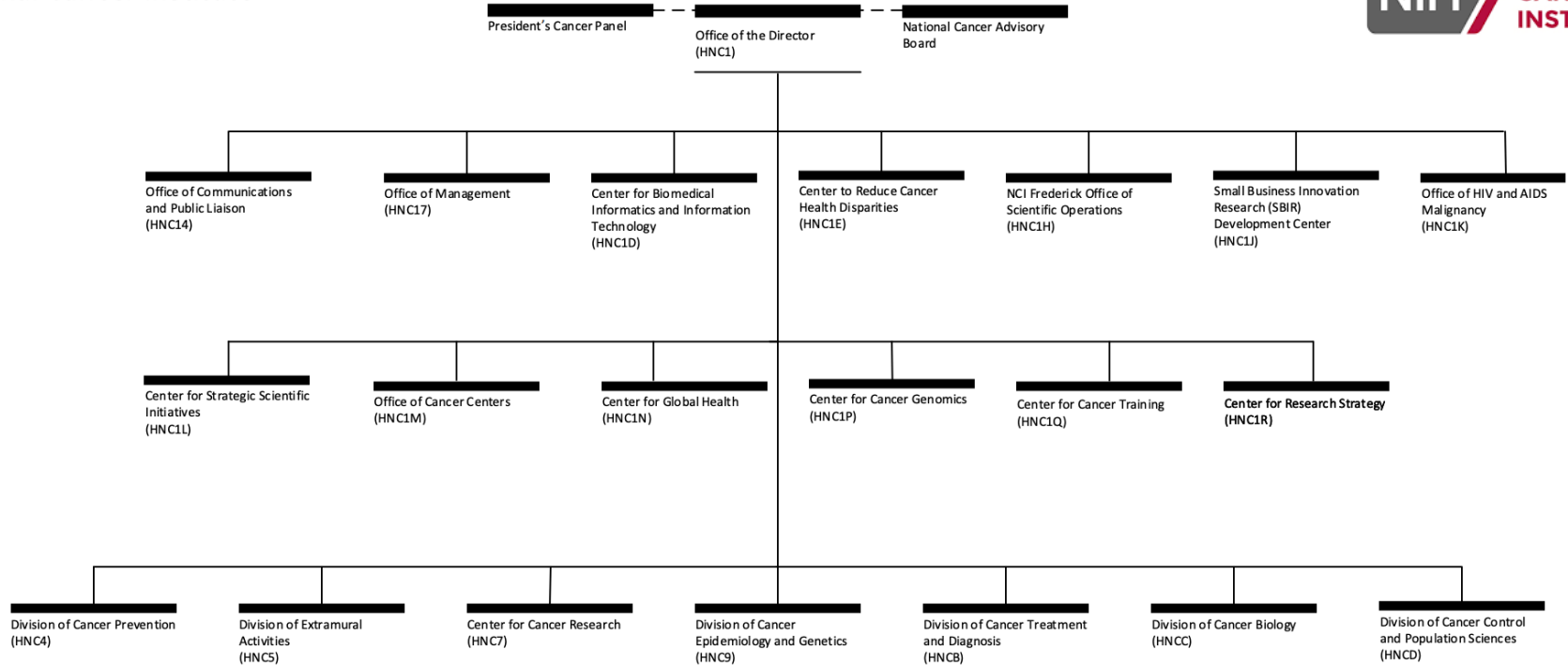


Disclaimer:

Drs. Torres-Saavedra is an employee of the National Cancer Institute. The views expressed in the paper do not necessarily represent views or policies of the National Cancer Institute, National Institutes of Health, or the U.S. Department of Health & Human Services.

NCI Structure

National Cancer Institute



DIVISION OF CANCER TREATMENT AND DIAGNOSIS (2025)

Dr. James H. Doroshow
Division Director
Dr. Toby T. Hecht
Deputy Director

Office of Cancer Clinical Proteomics Research
Dr. Henry Rodriguez
Office Director

Office of Cancer Complementary and Alternative Medicine
Dr. Jeffrey D. White
Office Director

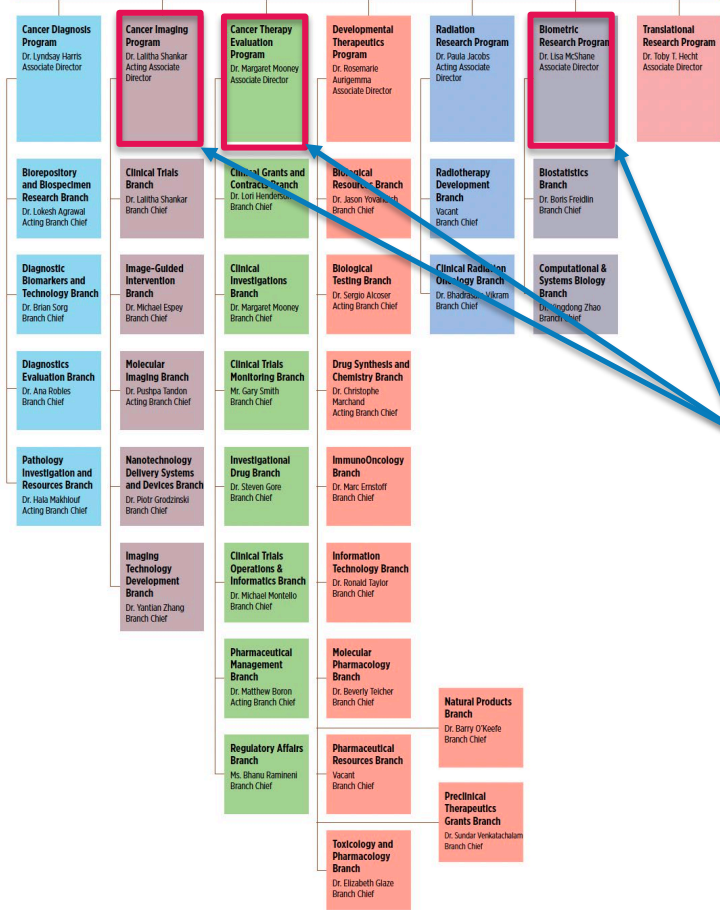
Developmental Therapeutics Clinic
Dr. Alice Chen
Clinic Head

Division of Cancer Treatment and Diagnosis (DCTD)

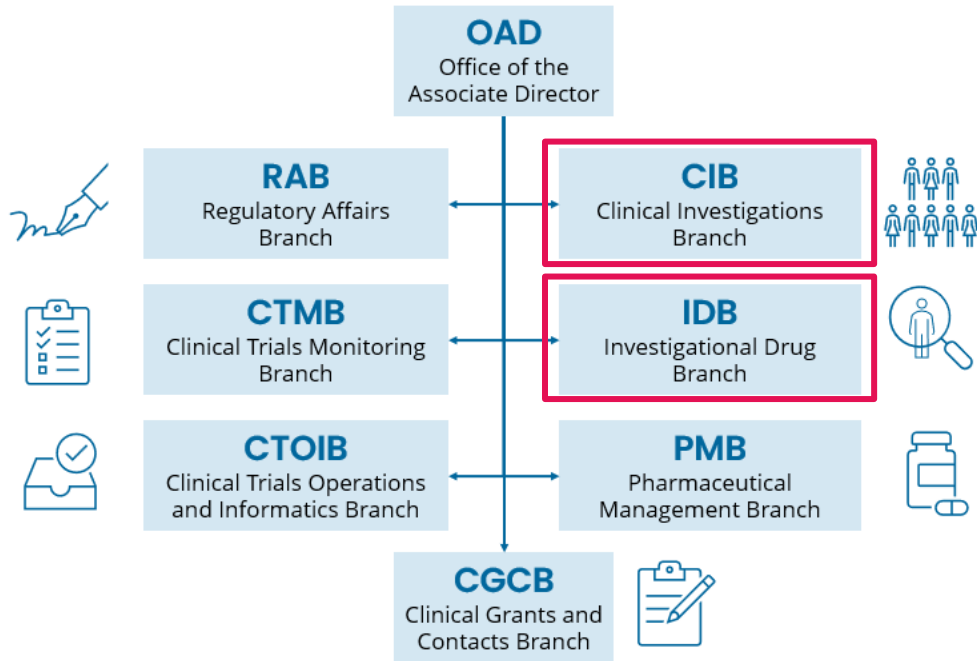
Mission Statement: The DCTD mission is to support the development of novel diagnostic and therapeutic approaches for cancer by expediting the initial and subsequent large-scale testing of new agents, biomarkers, imaging tests, and other diagnostic and therapeutic interventions (radiation, surgery, immunotherapy) in pre-clinical studies and in cancer patients.

Biometric Research Program (BRP): Provides biostatistics and computational and systems biology support for staff with the DCTD and NCI intramural investigators. This support includes:

- Statistical leadership and oversight for NCI therapeutic and diagnostic trials and translational research;
- Research in methods for the design, monitoring, and analysis of clinical trials and related studies;
- Conducting self-initiated research on topics important to cancer research.



Clinical Trial Evaluation Program (CTEP) Organization



Clinical Oversight of CTEP-Supported Network Trials

Two branches (**IDB** and **CIB**) consist primarily of physicians providing clinical oversight and direction to the development of agents under the CTEP Investigational New Drug (IND). They also oversee the design and conduct of **early** and **late-phase clinical trials** of novel cancer treatments.

Investigational Drug Branch (IDB)



IDB manages NCI's innovative [early phase experimental therapeutics program](#), which has contributed to the clinical development of anticancer agents since the early 1970s.



IDB has [scientific oversight](#) of the NCI's [Experimental Therapeutics Clinical Trials Network \(ETCTN\)](#), which performs clinical studies of promising anti-cancer agents in collaboration with the academic and pharmaceutical industry research communities.



DCTD/CTEP currently holds approximately 210 INDs for investigational oncology agents/combinations which involve about 100 collaborative agreements with pharmaceutical/biotechnology companies.



ETCTN investigators submit Letters of Intent (LOI) for clinical trials using the [Agents Available Under CTEP CRADAs \(Cooperative Research and Development Agreement\)](#).



Early-career investigators in the ETCTN are encouraged to learn about applying to the [Career-Development LOI \(CRDL\)](#) program for priority consideration.

Experimental Therapeutics Clinical Trials Network (ETCTN)

ETCTN Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs)

- 1 City of Hope Comprehensive Cancer Center LAO**
- Case Western Reserve (Cleveland, OH)
 - Stanford Cancer Institute (Stanford, CA)
 - University of California Davis Comprehensive Cancer Center (Davis, CA)
 - USC / Norris Comprehensive Cancer Center (Los Angeles, CA)
 - University of Chicago (Chicago, IL)

- 2 Dana-Farber – Harvard Cancer Center LAO**
- Beth Israel Deaconess Medical Center (Boston, MA)
 - Mayo Clinic (Rochester, MN)
 - Massachusetts General Hospital (Boston, MA)
 - NYU Langone (New York, NY)

- 3 JHU Sidney Kimmel Comprehensive Cancer Center LAO**
- Emory University (Atlanta, GA)
 - MedStar Georgetown University Hospital (Washington, DC)
 - Memorial Sloan Kettering Cancer Center (New York, NY)
 - Thomas Jefferson (Philadelphia, PA)
 - University of Colorado Hospital (Aurora, CO)
 - University of Maryland/Greenebaum Cancer Center (Baltimore, MD)
 - University of Virginia Cancer Center (Charlottesville, VA)
 - University of Wisconsin Carbone Cancer Center (Madison, WI)
 - Wake Forest University Health Sciences (Winston-Salem, NC)

- ★ LAO Headquarters (Primary Campus)
- AO Locations (Affiliated Organizations)

Note: Locations reflect primary campus/city. Map includes U.S. locations and Toronto, Canada.



- 4 Ohio State University Comprehensive Cancer Center LAO**
- Huntsman Cancer Institute/ University of Utah (Salt Lake City, UT)
 - NYP/Weill Cornell Medical Center (New York, NY)
 - University of Kentucky/Markey Cancer Center (Lexington, KY)
 - UNC Lineberger Comprehensive Cancer Center (Chapel Hill, NC)

- 5 University Health Network Princess Margaret Cancer Center LAO**
- Moffitt Cancer Center (Tampa, FL)
 - Northwestern University (Chicago, IL)
 - Rutgers Cancer Institute of New Jersey (New Brunswick, NJ)
 - University of Miami Miller School of Medicine – Sylvester Cancer Center (Miami, FL)
 - UT Southwestern/Simmons Cancer Center (Dallas, TX)
 - Virginia Commonwealth University/Massey Cancer Center (Richmond, VA)

- 6 University of Texas MD Anderson Cancer Center LAO**
- University of Texas Medical Branch (Galveston, TX)
 - University of Texas Austin (Austin, TX)
 - University of Texas Health Sciences in San Antonio (San Antonio, TX)

- 7 UPMC Hillman Cancer Center LAO**
- Montefiore Medical Center (Bronx, NY)
 - Oregon Health Sciences Center (Portland, OR)
 - UC Irvine Health/Chao Family Comprehensive Cancer Center (Irvine, CA)
 - University of Cincinnati Cancer Center (Cincinnati, OH)

- 8 Yale University Cancer Center LAO**
- Memorial Hospital East (Marlborough, MA)
 - NYP/Columbia University Medical Center/Herbert Irving Comprehensive Cancer Center (New York, NY)
 - Irving Comprehensive Cancer Center (Lake Success, NY)
 - UC San Diego Moores Cancer Center (La Jolla, CA)
 - University of Florida – Gainesville (Gainesville, FL)
 - University of Kansas Cancer Center (Kansas City, KS)
 - University of Oklahoma Health Sciences Center (Oklahoma City, OK)
 - Vanderbilt University/Ingram Cancer Center (Nashville, TN)
 - Washington University School of Medicine (St. Louis, MO)

IDB Portfolio (~80 early-phase clinical trials)

All ETCTN Trials: Updated April 15, 2026 (Includes trials that are in review, approved, and active)

CTEP Trial ID	Title	Limited/ETCTN-wide	Radiation Oncology	Disease Area(s)	ClinicalTrials.gov website (if available)
10703	A Phase I/II Trial of Sapanisertib in Combination with Cabozantinib in β -Catenin-Mutated Hepatocellular Carcinoma	Limited for escalation ; wide for Phase II	No	Gastrointestinal	https://clinicaltrials.gov/study/NCT06811116
10706	A Phase 2 Window of Opportunity Trial of Neoadjuvant Agonistic Anti-CD40 Antibody CDX-1140 and Cemiplimab in AJCC Stage III-IV Head and Neck Cancer Patients Prior to Surgery	ETCTN-wide	No	Head and Neck	https://clinicaltrials.gov/study/NCT06980038
10708	A Phase 2 Pilot Study of Mirdametinib in Relapsed Refractory Chronic Lymphocytic Leukemia	ETCTN-wide	No	Leukemia	https://clinicaltrials.gov/study/NCT07061951
10713	A Phase I Trial of 225Ac-anti-CD33 and PD1-Inhibitor in Recurrent Glioblastoma	Limited	No	Brain	https://clinicaltrials.gov/study/NCT07422363
10716	A Phase 1 and Randomized Phase 2 Trial of CX-5461 (Pidnarulex) and Cemiplimab (REGN2810) in Refractory Microsatellite Stable Colorectal Cancer	ETCTN-wide	No	Gastrointestinal	https://clinicaltrials.gov/study/NCT07147231
10717	Phase 1b/2 Trial of Pidnarulex in MYC Aberrant Lymphoma	ETCTN-wide	No	Lymphoma	https://clinicaltrials.gov/study/NCT07069699
10720	Phase 1b Study of Pidnarulex and Trastuzumab Deruxtecan in Patients with HER2 Expressing Solid Tumors	ETCTN-wide	No	Breast, Solid tumors (mutations)	https://clinicaltrials.gov/study/NCT07137416
10721	Phase II Trial of Neoadjuvant Chemoimmunotherapy vs Chemotherapy in Sinonasal Squamous Cell Carcinoma	Limited	No	Head and Neck	https://clinicaltrials.gov/study/NCT07281417

National Clinical Trial Network (NCTN) History & Goals

NCTN was established in 2014 to transform the former Cooperative Group Trial Program into a network & establish a programmatic infrastructure to:

1. Harmonize processes & promote collaborations
2. Focus on questions **not well supported in the commercial environment**:
 - Radiotherapy, surgery, and multimodality treatment trials
 - De-escalation trials; Evaluate sequencing of different agents/treatments & agent combinations
3. Prioritize trials & incorporate innovative science and design
4. Provide large-scale testing of molecularly-defined cancers: Adult & Pediatric MATCH—ComboMATCH—myeloMATCH in AML
5. Conduct trials with a broad national representation of patients and special populations, including children, adolescents & young adults, and patients with rare cancers

NCI NCTN Organizational Structure

The 11 former Cooperative Groups were consolidated into 6 Groups in 2014 with the following network structure



LEGEND

- Centralized Functions:
 - Centralized Institutional Review Board
 - Cancer Trials Support Unit
 - Imaging and Radiation Oncology Core (IROC) Group
 - Common Data Management System
 - Central Hosting
- 32 Lead Academic Participating Sites (LAPS)
- Operations
- Statistics & Data Management
- Tissue Banks
- Member Sites

Distinct RFAs under Cooperative Agreements

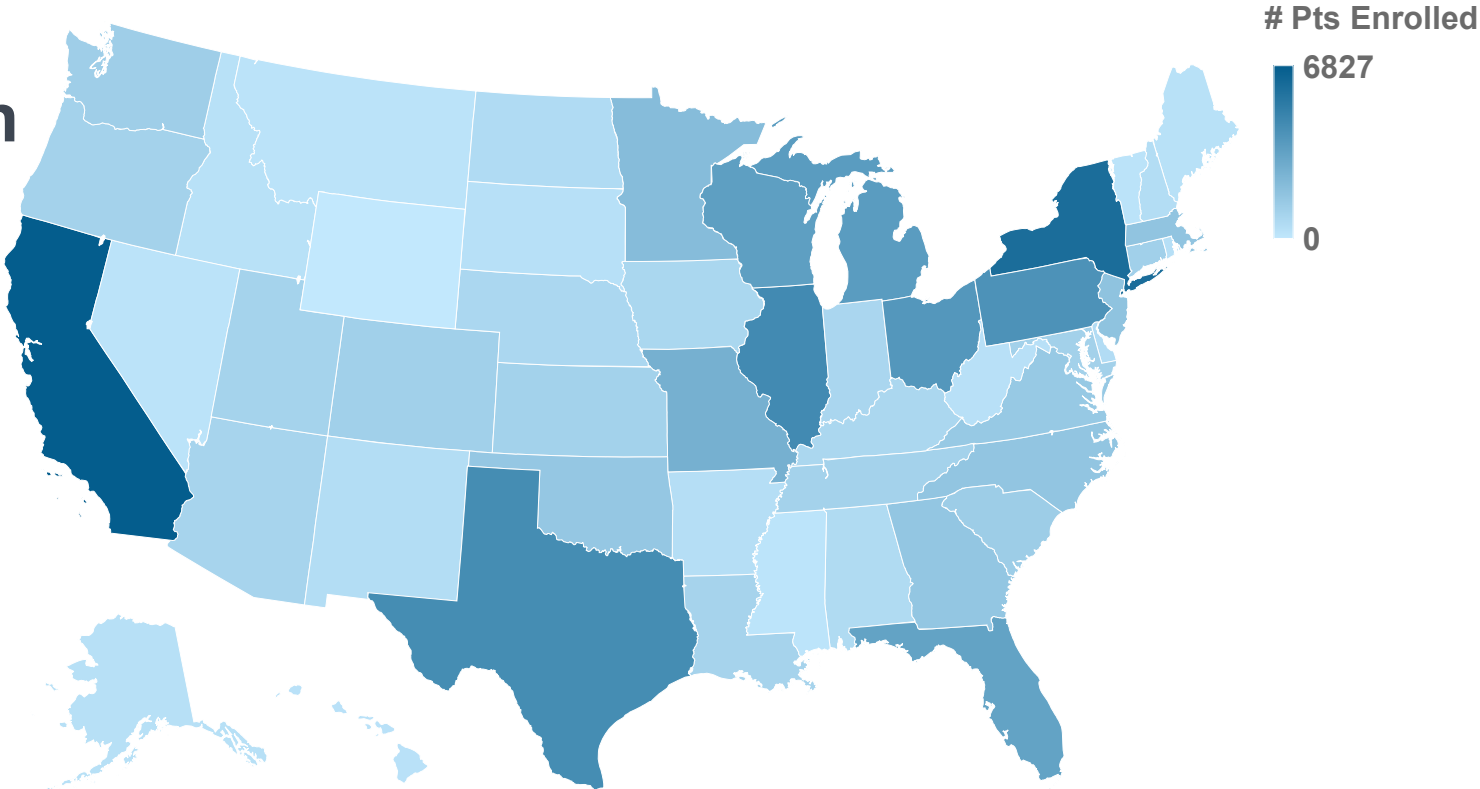
- 5 US Group Operations Ctrs (U10)
- 5 US Group Stats/Data Mgt Ctrs (U10)
- Canadian Collaborating Grp (U10)
- Imaging/RT Core Services Ctr (U24))
- Multiple Adult Lead Academic Participating Sites (UG1)

PLUS: Tumor Banks (U24) funded under separate grants for each US NCTN Group overseen by DCTD Cancer Diagnosis Program

Enrollment to Intervention Step of NCTN Cancer Treatment Trials

March 1, 2019 to January 3, 2026

**Broad
National
Participation
Across
the US**

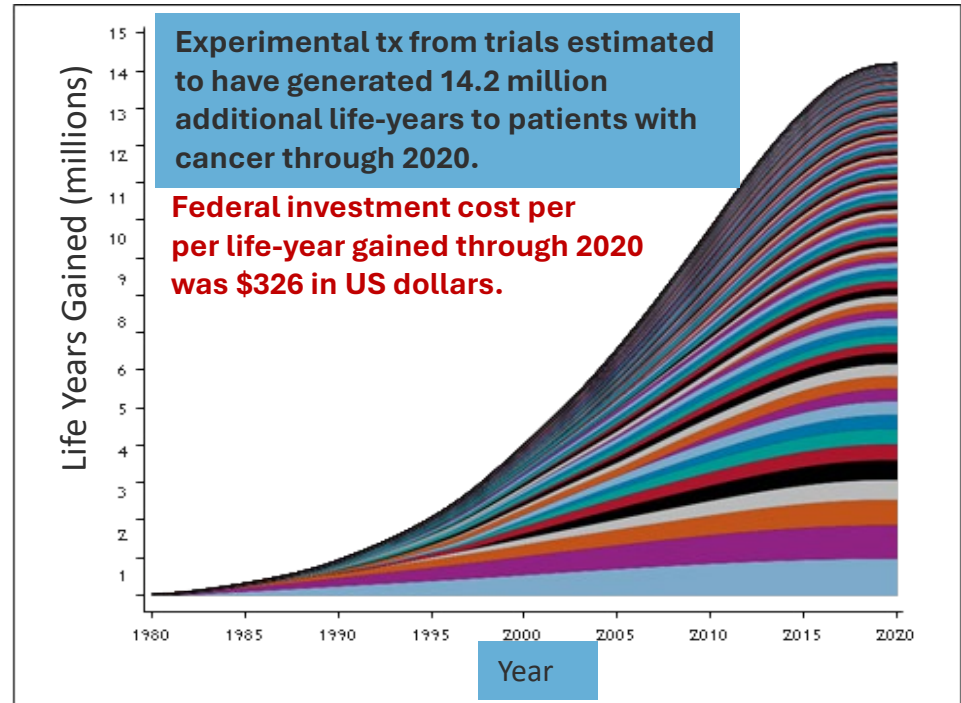


Benefit of Network: Population, Clinical, & Scientific Impact of NCI's National Clinical Trials Network Treatment Studies

162 Adult NCTN positive, randomized trials since 1980 analyzed comprising 108,334 patients. Trials cited 165,336 times thru 2020, with 87.7% cited in cancer care guidelines favoring recommended treatment.

Relevance: Impact of US NCTN trials on adult cancer outcomes cannot be overstated; this evidence should compel sustained financial investment and continued academic contributions to this valuable resource.*

*Relevance section written by JCO Editor-in-Chief Jonathan W. Friedberg, MD.



Cumulative life-years gained through 2020 by Study

Practice-Changing Trials

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Blinatumomab in Standard-Risk B-Cell Acute Lymphoblastic Leukemia in Children

July 2024 Print Publication:
Blinatumomab improves OS

June 2024 FDA Approval: For adult and pediatric patients one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (Ph-negative BCP ALL) in the consolidation phase of multiphase chemotherapy

Feb 2025 Publication of COG trial showed blinatumomab increased 3-year disease-free survival from 90% to 96% in children

Selected by the Society for Clinical Trials as the 2024 Trial of the Year

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Prospective Validation of a 21-Gene Expression Assay in Breast Cancer

The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812

JULY 12, 2018

VOL. 379 NO. 2

Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer

CONCLUSIONS

Adjuvant endocrine therapy and chemoendocrine therapy had similar efficacy in women with hormone-receptor-positive, HER2-negative, axillary node-negative breast cancer who had a midrange 21-gene recurrence score, although some benefit of chemotherapy was found in some women 50 years of age or younger. (Funded by the National Cancer Institute and others; TAILORx ClinicalTrials.gov number, NCT00310180.)

ORIGINAL ARTICLE

21-Gene Assay to Inform Chemotherapy Benefit in Node-Positive Breast Cancer

CONCLUSIONS

Among premenopausal women with one to three positive lymph nodes and a recurrence score of 25 or lower, those who received chemoendocrine therapy had longer invasive disease-free survival and distant relapse-free survival than those who received endocrine-only therapy, whereas postmenopausal women with similar characteristics did not benefit from adjuvant chemotherapy. (Funded by the National Cancer Institute and others; RxPONDER ClinicalTrials.gov number, NCT01272037.)

CTEP Funds & Grants Distribution (2023)

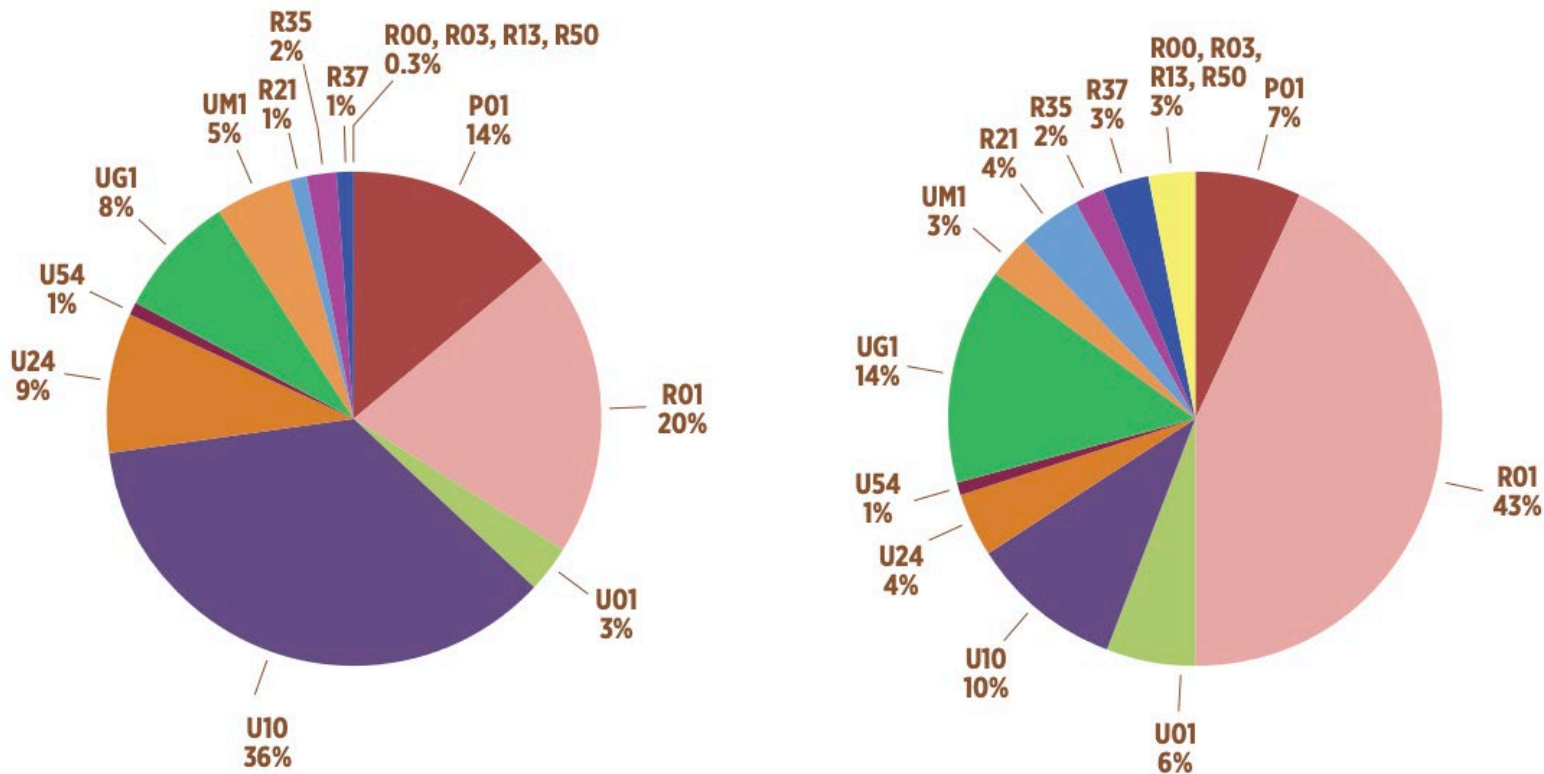


FIGURE 45: DISTRIBUTION OF CTEP 2023 GRANT FUNDS (LEFT) AND NUMBERS OF GRANTS (RIGHT) BY MECHANISM.

Additional Resources: NCTN Clinical Trial Specimens



NCTN Clinical Trial Specimen Sharing

- Investigators can access an inventory of over 2 million clinical trial biospecimens with detailed clinical and outcome data through NCI's [NCTN Navigator](#).
- Proposals to use these specimens are reviewed and approved by the [Core Correlative Sciences Committee \(CCSC\)](#).
- Investigators interested in accessing specimens from completed NCTN trials that are not listed in Navigator can contact the NCTN Group that led the trial to find out if specimens are available.



Inventory



299

Trials



193657

Patients



2967742

Specimens

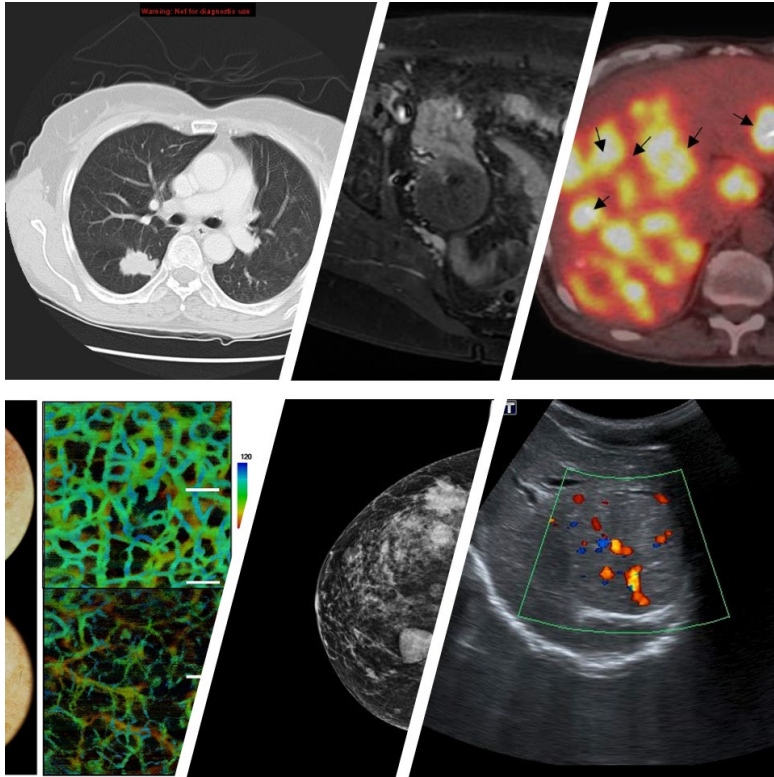
Additional Resources: NCTN/NCORP Data Archive

- Data from NCTN phase 2/3 and 3 clinical trials that have been completed and reported out are available through the [NCTN/NCORP Data Archive](#).
- NCTN and NCORP data will include clinical datasets, a data dictionary, and limited metadata fields. Datasets are patient-level, de-identified, and include data for all variables used in the analyses presented in each corresponding publication (with minor exceptions).
- Investigators interested in data from completed NCTN trials that are not listed in the Data Archive can contact the NCTN Group that led the trial to find out how to submit a data request.



Data Access Transition in Progress: Ability to access Archive data from NCTN & NCORP trials is being transferred to dbGaP.

Cancer Imaging Program (CIP)



The NCI Cancer Imaging Program fosters advances in *in vivo* medical imaging sciences through support of basic and applied research in cancer imaging as well as promotion of imaging in clinical trials in order to gain greater understanding of the pathways of cancer biology for the benefit of cancer patients and people at cancer risk.



Cancer Imaging Program (CIP)



Molecular Imaging Branch: To encourage the development of molecular imaging from basic discovery of methods and agents to their development as preclinical tools and into clinical use in the service of diagnosis and therapy of cancer patients and those at risk.



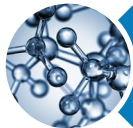
Imaging Technology Branch: To encourage and nurture the development and translation of medical imaging instrumentation and technology for the diagnosis and therapy of cancer.



Clinical Trials Branch: To promote the study of the efficacy of diagnostic imaging techniques through clinical trials in order to diagnose and treat cancer more effectively and at an earlier stage.



Image-Guided Intervention Branch: To promote the use of imaging techniques in the performance of diagnostic and therapeutic procedures for the diagnosis and treatment of cancer.



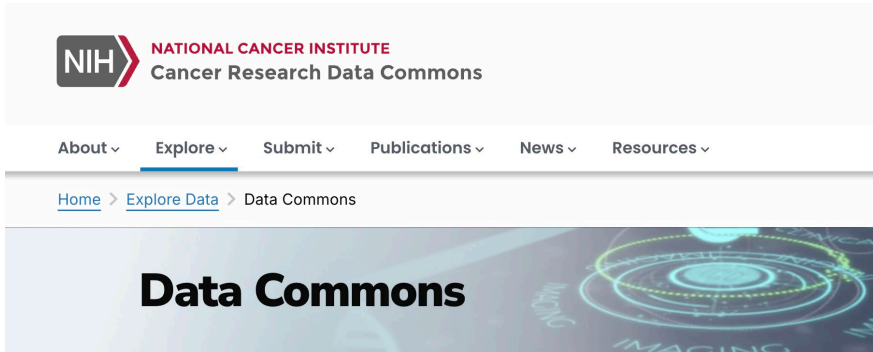
Nanodelivery Systems and Devices Branch: To promote the use of nanotechnologies in fundamental studies of cancer biology and in the development of new cancer interventions related to in vitro diagnosis, imaging and treatment of cancer.



Additional Resources: The Cancer Imaging Archive (TCIA) & CRDC's




TCIA is a service that de-identifies and hosts a large archive of medical images (MRI, CT, digital histopathology, etc) of cancer accessible for public download. Supporting data related to the images such as patient outcomes, treatment details, genomics and expert analyses are also provided when available.



CRDC's house NCI-funded research data, including genomic, proteomic, imaging, epidemiology, and clinical and translational studies data, as well as canine biomedical data for comparative research. This data comes from select external programs and large NCI-funded research projects.

Current CTEP/CIP-Related Funding Opportunities

Funding Opportunity	Example
Molecular Imaging of Inflammation in Cancer PAR-24-311, R01 Not Clinical Trial; Expires Jan 7, 2028	Expanding imaging tools to detect and monitor inflammation and immune-related adverse events in cancer immunotherapy.
Integration of imaging and fluid-based tumor monitoring in cancer therapy PAR-25-175, R01 Clinical Trial Optional; Expires Jan. 7, 2028	How do imaging and liquid biopsy based tumor monitoring results correlate within each cancer type prior to, during therapy or after treatment?
Academic Industrial Partnership (AIP) to translate and validate In vivo Imaging systems PAR-25-079, R01 Clinical Trial Optional; Expires Jan. 7, 2027	Methods for prospectively annotating imaging data to be 'Artificial Intelligence' ready and subsequent validation; Validation and correlation studies
 NCI Investigator Initiated Early Phase clinical trials for Cancer Treatment and Diagnosis PAR-25-081 R01 Clinical Trial Required; Expires Jan. 7, 2028	Tests approved agents and combinations for new indications
Towards Translation of Nanotechnology of Cancer Interventions PAR-25-336 R01 Not Clinical Trial; Expires Nov. 15, 2027	Develop tools to understand and minimize immune-related adverse effects (irAEs)

Career Development LOI (CRDL) Program for Early-Career ETCTN Investigators

- The ETCTN Career Development Letter of Intent (LOI) (CRDL) is intended to increase the success rate for LOI submissions from early-career investigators and to provide critical opportunities for investigators to develop and succeed in clinical research careers.
- Becoming a principal investigator (PI) on a clinical trial is an important career development step for junior investigators.
- It permits the investigator to acquire experience in trial design and execution, provides an opportunity to achieve recognition within the research community, and provides credibility when applying for grant funding.
- Findings from NCI-supported early phase studies are presented at scientific meetings and are published in peer-reviewed journals, both of which are important for successful career advancement.



Related Funding Opportunities

The NCI intends to issue a notice of funding opportunity (NOFO) for the **NCI Research Specialist (Clinician Scientist) Award (R50)** specifically for clinician scientists supporting NCI-funded clinical trials research. The Research Specialists Award is designed to encourage the development of stable research career opportunities for exceptional clinician scientists who want to continue to participate in the NCI clinical trials networks through leadership in the 1) development of clinical trials, 2) implementation of NCI clinical trials in their institutions, and 3) national service to the NCI clinical trials networks through participation in the scientific review committees, monitoring committees and other activities, but not serve as principal investigator of research project grants.

The NOFO (**PAR-27-089**) is expected to be published in late summer 2026 with the **first expected application due date on November 2, 2026**. The Forecasted Opportunity is available here: <https://www.grants.gov/search-results-detail/362277>.



Take-Home Messages

- Build connections with institutions that are members of the NCI clinical trials networks (ETCTN, NCTN, and others). Many clinicians and biostatisticians across the US participate in NCI-supported research groups.
- Early-phase clinical trials may be conducted outside the NCI-funded networks (it depends on the funding mechanism).
- NCI-sponsored clinical trials not only generate primary findings but also support research and resources in areas such as correlative science (e.g., molecular and imaging biomarkers) and patient-reported outcomes (NCORP), with some substudies embedded within the trials themselves.
- Take advantage of resources from NCI-funded trials for grant applications (e.g., R01s) and for conducting and publishing research (e.g., TCIA, Navigator, NCTN/NCORP Archives).
- Explore NCI program websites (e.g., CTEP, CIP) to learn about funding opportunities and ways to engage in NCI-sponsored research. For current and forecasted opportunities, refer to:
 - <https://grants.nih.gov/funding/explore-nih-opportunities>
 - simpler.grants.gov
 - <https://dctd.cancer.gov/funding/announcements>

We're Hiring

The Biostatistics Branch (BB) within the **Biometric Research Program (BRP)** of the Division of Cancer Treatment and Diagnosis (DCTD) (<https://dctd.cancer.gov>) of the National Cancer Institute (NCI) is seeking candidates with preferably a **Ph.D. in Statistics, Biostatistics or equivalent**.

The candidate will be a member of the Biometric Research Program (BRP) and will collaborate with NCI investigators in the DCTD Cancer Therapy Evaluation Program (CTEP), Cancer Imaging Program (CIP), Cancer Diagnosis Program (CDP), and potentially other NCI programs, including the NCI Center for Cancer Research. The candidate's responsibilities may include coordination with DCTD senior staff in the development and review of national clinical trials evaluating new therapeutics and diagnostics. The candidate will conduct research on statistical issues arising in clinical and translational science, including clinical trial design, management and analysis, diagnostics development, and other important topics related to cancer research. Candidates with an interest in clinical trial design and molecular/imaging characterization of cancer are especially encouraged to apply.

This is an exploratory ad to gauge interest and a possible candidate pool. Vacancy Announcements (VAs) to fill the positions will be posted on WWW.USAJOBS.GOV at a later date.

Thank You!



**NATIONAL
CANCER
INSTITUTE**

cancer.gov

cancer.gov/espanol



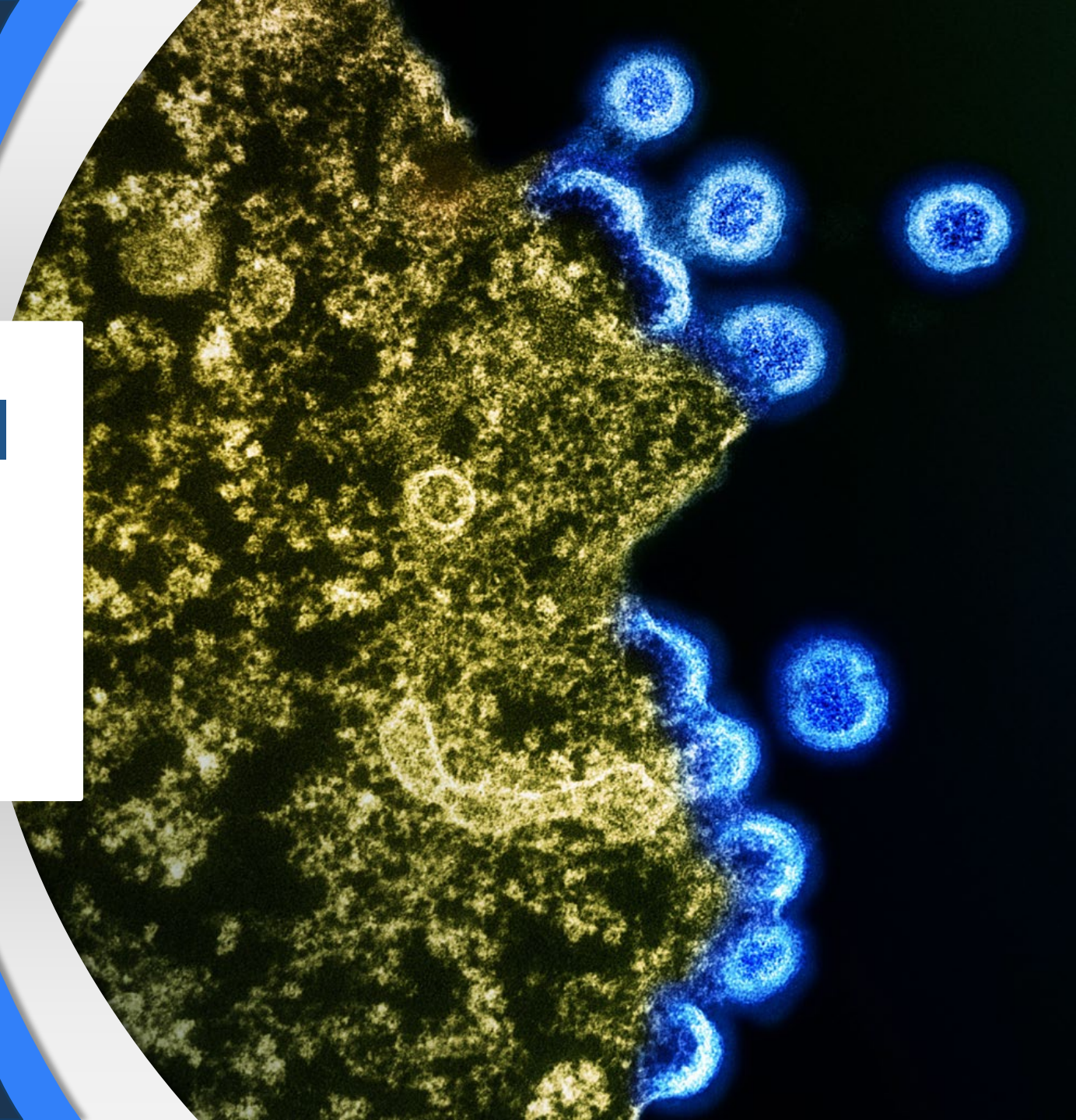
National Institute of
Allergy and
Infectious Diseases

NIAID Clinical Trial Networks

Society for Clinical Trials
Annual Meeting
May 18, 2026

Seema Nayak, M.D.
Director

Office of Clinical Research Resources
Division of Microbiology and
Infectious Diseases



The National Institute of Allergy and Infectious Diseases (NIAID)

- Conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

NIH Research Project
Grant (Parent R01 Clinical
Trial Required)
PA-25-305

Application budgets are not limited but need to reflect the actual needs of the proposed project.

<https://grants.nih.gov/grants/guide/pa-files/PA-25-305.html>

NIH Exploratory/
Developmental Research
Project Grant (Parent R21
Clinical Trial Required)
PA-25-306

The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

<https://grants.nih.gov/grants/guide/pa-files/PA-25-306.html>

Supporting research in:

- the causes, diagnosis, prevention, and cure of human diseases;
- the processes of human growth and development;
- the biological effects of environmental contaminants;
- the understanding of mental, addictive and physical disorders; and
- directing programs for the collection, dissemination, and exchange of information including the development and support of medical libraries and the training of medical librarians and other health information specialists.

Investigator-Initiated Clinical Trials



The screenshot shows a Grants.gov listing for an investigator-initiated clinical trial. The header includes the SIMPLER logo and the text 'Grants.gov'. Navigation links for Home, Search, About, Community, and Sign in are visible. The main title is 'NIAID Clinical Trial Implementation Cooperative Agreement'. Below the title is a 'Save' button with a star icon. The agency is listed as 'National Institutes of Health'. A 'Forecasted' status is shown in a grey box. The 'Estimated Post Date' is 'December 5, 2025'. Additional information includes 'Assistance Listings: 93.855--Allergy and Infectious Diseases Research' and 'Last Updated: June 27, 2025'. A link to 'View version history on Grants.gov' is also present.

Grants.gov Home Search About Community Sign in

NIAID Clinical Trial Implementation Cooperative Agreement

☆ Save

Agency: National Institutes of Health

Forecasted

Assistance Listings: 93.855--Allergy and Infectious Diseases Research

Estimated Post Date:
December 5, 2025

Last Updated: June 27, 2025 [View version history on Grants.gov](#)

<https://simpler.grants.gov/opportunity/81895450-caf7-48ab-bab4-b80f0d74e3b1>

- This program would support the implementation of investigator-initiated, milestone driven, high-risk clinical trials including mechanistic studies associated with these clinical trials.
- Includes support for the conduct, completion, and analysis of the clinical trial.

Collaborative International Research Project (PF5)



SIMPLER Grants.gov Home Search About Community Sign in

NIH Collaborative International Research Project (Parent PF5 Clinical Trial Optional)

★ Save

Agency: National Institutes of Health

Closing: May 7, 2029

[Assistance Listings: 93.310--Trans-NIH Research Support](#)

<https://simpler.grants.gov/opportunity/3df028f3-f97a-4cdf-9359-1c6515d091ce>

- NIH no longer accepts applications that request funds for foreign components using the traditional grant subaward/consortium structure.
- The PF5 activity code facilitates an application and award structure that allows NIH to track the expenditure of federal funds at foreign components and meet federal reporting and oversight needs.

Grant Opportunity Forecast: PAR-28-011

Feasibility Studies to Inform the Design of Future Clinical Trials

The National Institutes of Health intends to publish a Notice of Funding Opportunity (NOFO) to solicit applications that propose feasibility studies that could inform the design and conduct of subsequent definitive clinical trials. Applications to this NOFO should demonstrate that the proposed feasibility research is scientifically necessary to design or plan the subsequent definitive clinical trial. Applications are not being solicited at this time. This notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects.

Estimated Post Date: November 24, 2026

Grantor Contact:

NCCIH Division of Extramural Research Program Officer: NCCIHDERFunding@nih.gov

<https://www.grants.gov/search-results-detail/362101>

Grant Opportunity Forecast: PAR-28-010

NIH Pragmatic Trials Conducted in Health Care Systems

The National Institutes of Health intends to publish a Notice of Funding Opportunity (NOFO), Pragmatic and Implementation Trials Conducted in Health Care Settings. This funding opportunity will support large-scale pragmatic trials that test intervention effectiveness in routine clinical care and/or implementation trials that evaluate strategies for delivering interventions within health care settings. This phased award will use a milestone-driven cooperative agreement mechanism, supporting a planning phase and a phase for full trial execution. Applications are not being solicited at this time. Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects.

Estimated Post Date: November 24, 2026

Grantor Contact:

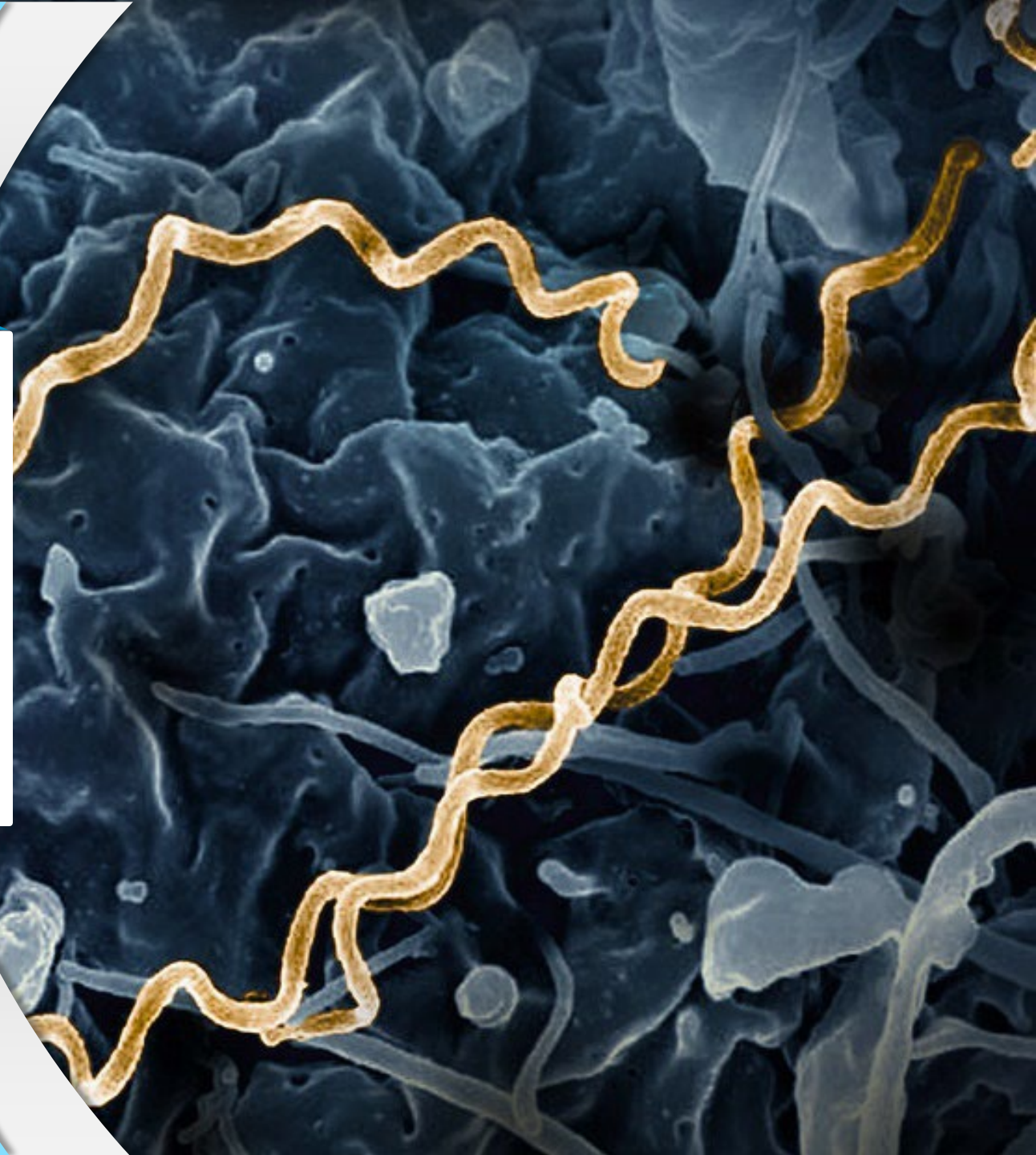
NCCIH Division of Extramural Research Program Officer: NCCIHDERFunding@nih.gov

<https://www.grants.gov/search-results-detail/362108>

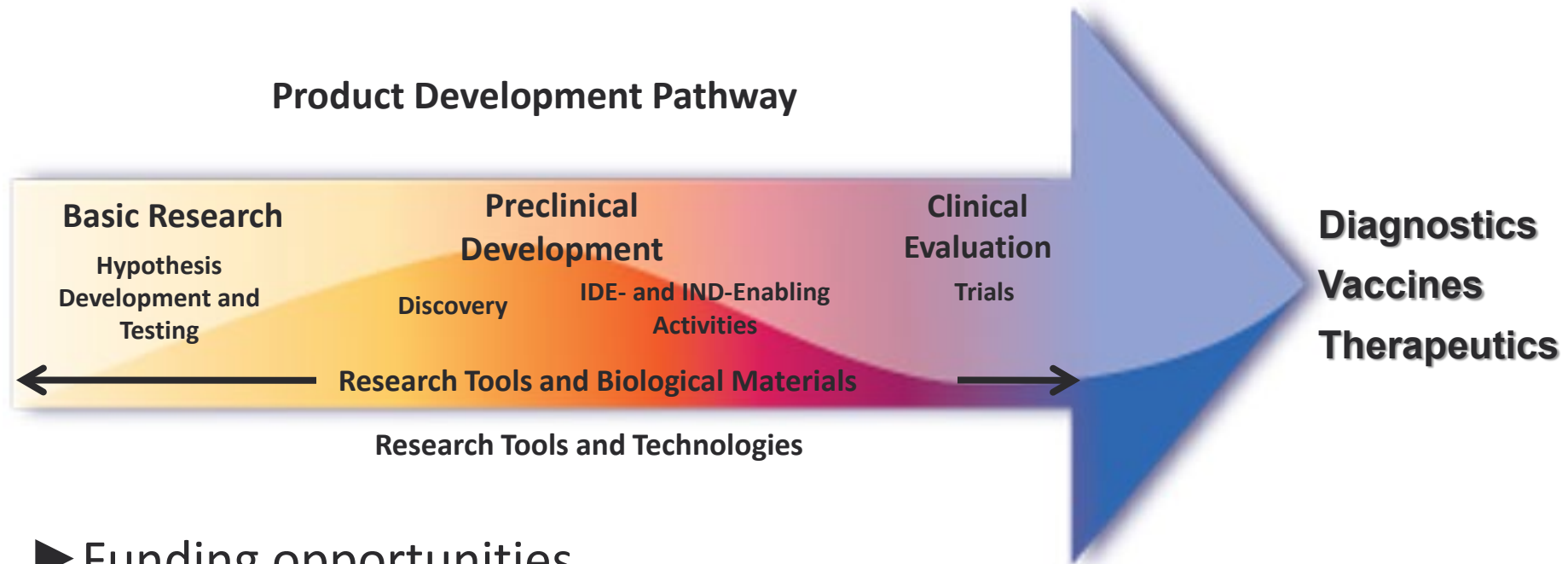


National Institute of
Allergy and
Infectious Diseases

DMID Clinical Trial Support



Resources for Researchers



- ▶ Funding opportunities
 - ▶ Research tools and biological materials
 - ▶ Preclinical and clinical servicesto facilitate product development

Clinical Resources

- Purpose
 - Provide a ready resource for the conduct of interventional trials and clinical research studies for vaccines and other preventive biologics, therapeutics, diagnostics, and devices for all infectious diseases except HIV
- Emphasis and Scope
 - Public health
 - Product development
 - Responding to emerging infectious diseases
 - These contracts provide services, not direct funding, for all aspects of the clinical trial

DMID Clinical Trial Infrastructure

Clinical Trial Implementation

Extramural Networks

- **Focus:** Phase 1 to Phase 4 vaccine and treatment trials
- **Sites:** 25



- **Focus:** Antimicrobial resistance
- **Sites:** 130



- **Focus:** Influenza
- **Sites:** 3



Early Phase Clinical Trial Units (EPCTUs)

- **Focus:** Phase 0 to Phase 2 clinical trials important to DMID

Other Mechanisms

- Investigator Initiated Clinical Trials (IICT)
- OTIPD Product Development

Clinical Trial Support

Support Services

- **Role:** Data and stats
- **Role:** Monitoring, safety, quality
- **Role:** Study product, biospecimens
- **Role:** Regulatory support
- **Role:** Central laboratory
- **Role:** sIRB

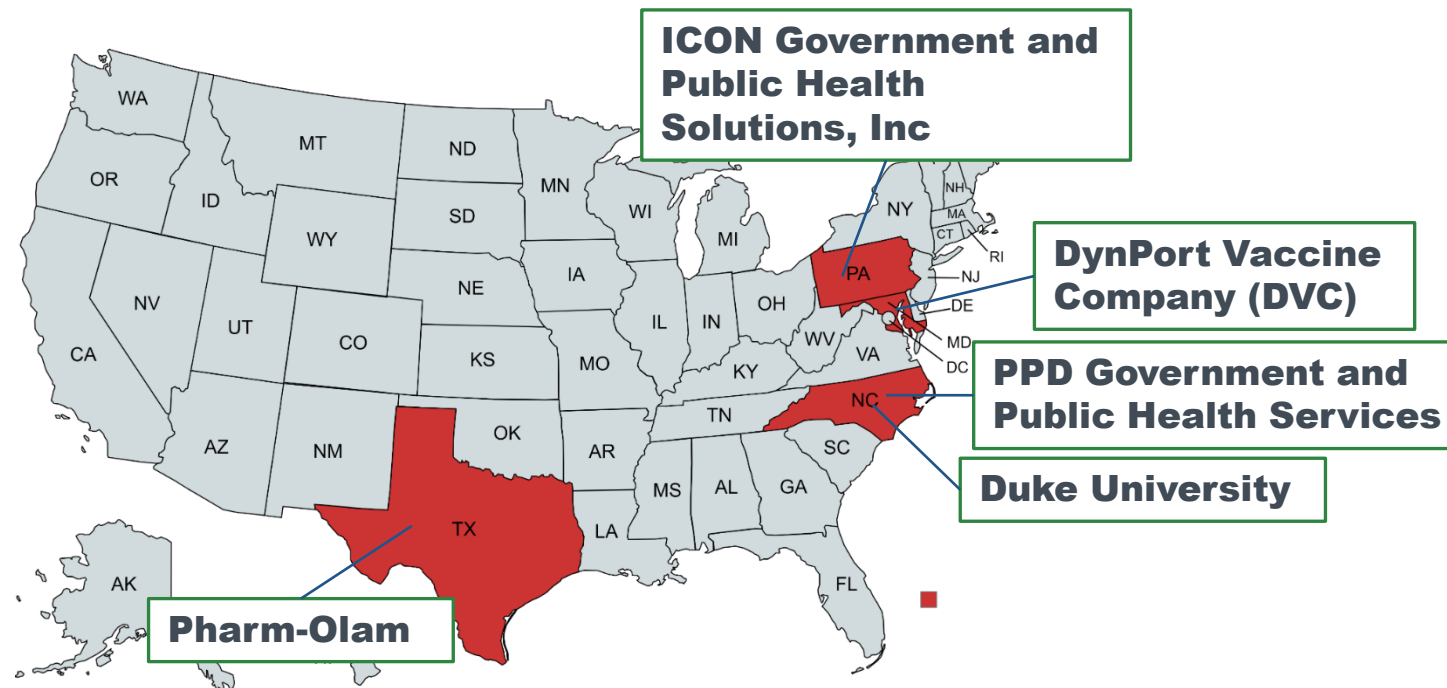


Early Phase Clinical Trial Units: EPCTUs

Support Ph0, Ph1, Ph1/2
and small Ph2 studies –
IDIQ mechanism

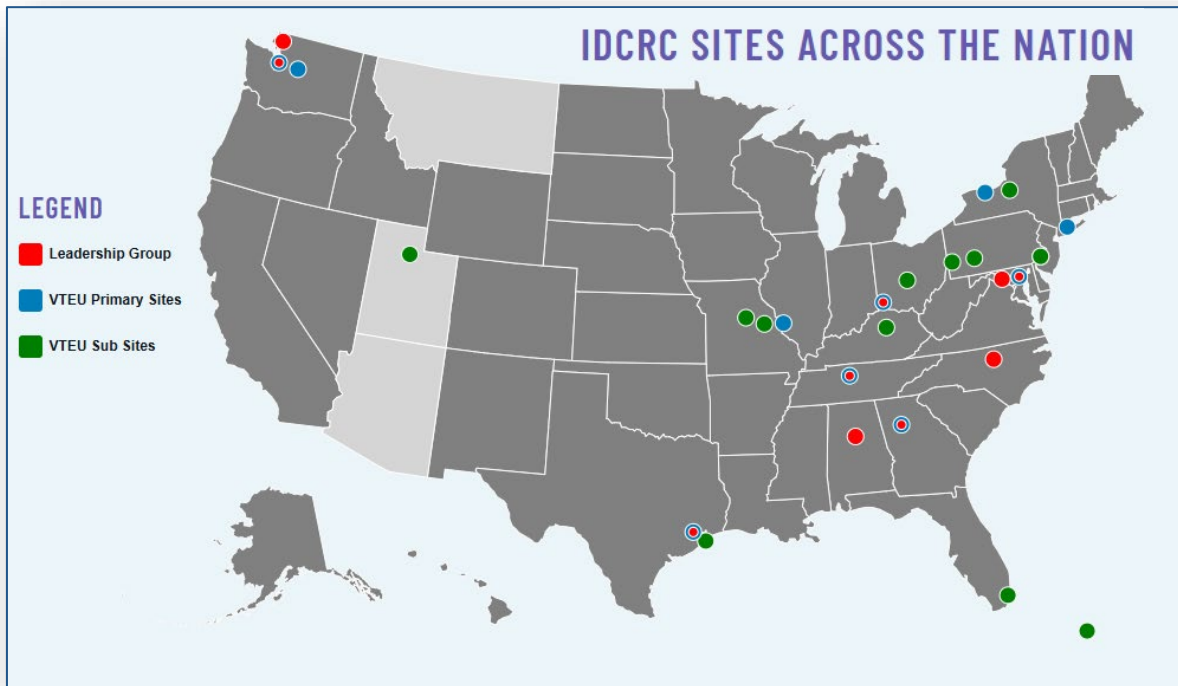
Healthy volunteers, special
populations, target disease
populations

Includes bioanalysis
capabilities



www.niaid.nih.gov/research/early-phase-clinical-trial-units

The Infectious Diseases Clinical Research Consortium (IDCRC) and Vaccine and Treatment Evaluation Units (VTEUs) work in tandem with the National Institute of Allergy and Infectious Diseases (NIAID) as a coordinated national and global network of scientific experts working to develop and test vaccines and other therapies to combat infectious diseases.



www.niaid.nih.gov/research/idcrc

Proposing a Study Concept for the Network

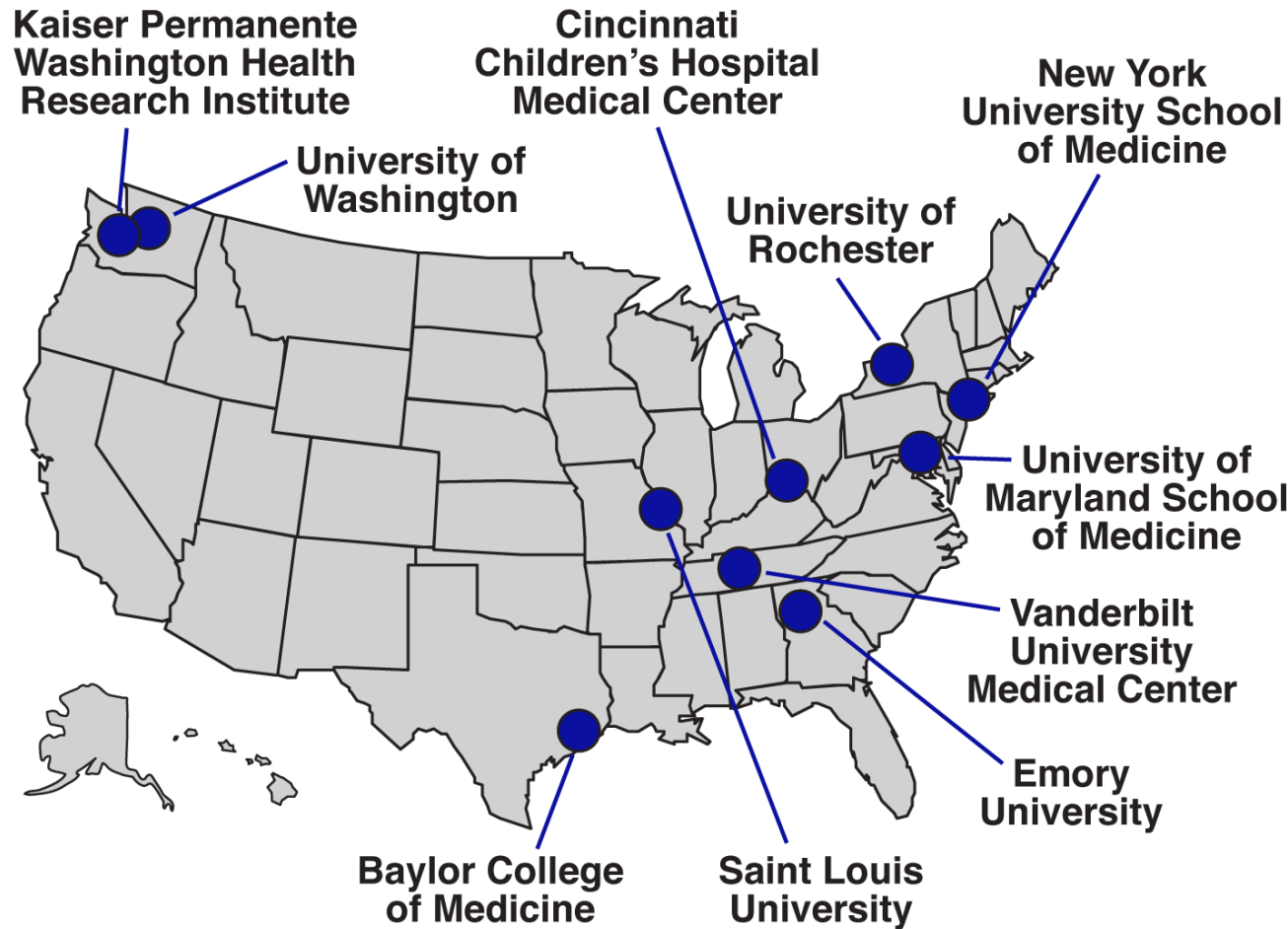
INITIAL CONCEPT PROPOSAL FORM

Proposals for IDCRC studies may be submitted through the Initial Concept proposal (ICP) available above. Key information about the process and eligibility is as follows:

- ICPs are welcome from investigators who are affiliated with the IDCRC/VTEU network as well as investigators external to this network. Investigators external to the network are advised to seek a partner within the established network or at DMID prior to concept submission. The IDCRC will facilitate finding a partner if requested.
- ICPs may be submitted at any time throughout the calendar year.
- The ICP form will be submitted to the IDCRC Expert Working Group (EWG) Liaisons, Executive Management Team (EMT), appropriate EWG Co-Chairs and DMID representatives, and the appropriate EWG. EWG Liaisons may request a review from the [Statistics and Data Science Unit \(SDSU\)](#) and may provide preliminary feedback and/or request additional information if needed to make an initial determination. The EWG Co-Chairs and DMID representatives will review the ICP using the standardized criteria listed below, solicit input from EWG members, and submit a summary/recommendations to the EMT for their further review.

<https://idcrc.org/concept/index.html>

NIAID Vaccine and Treatment Evaluation Units (VTEUs)

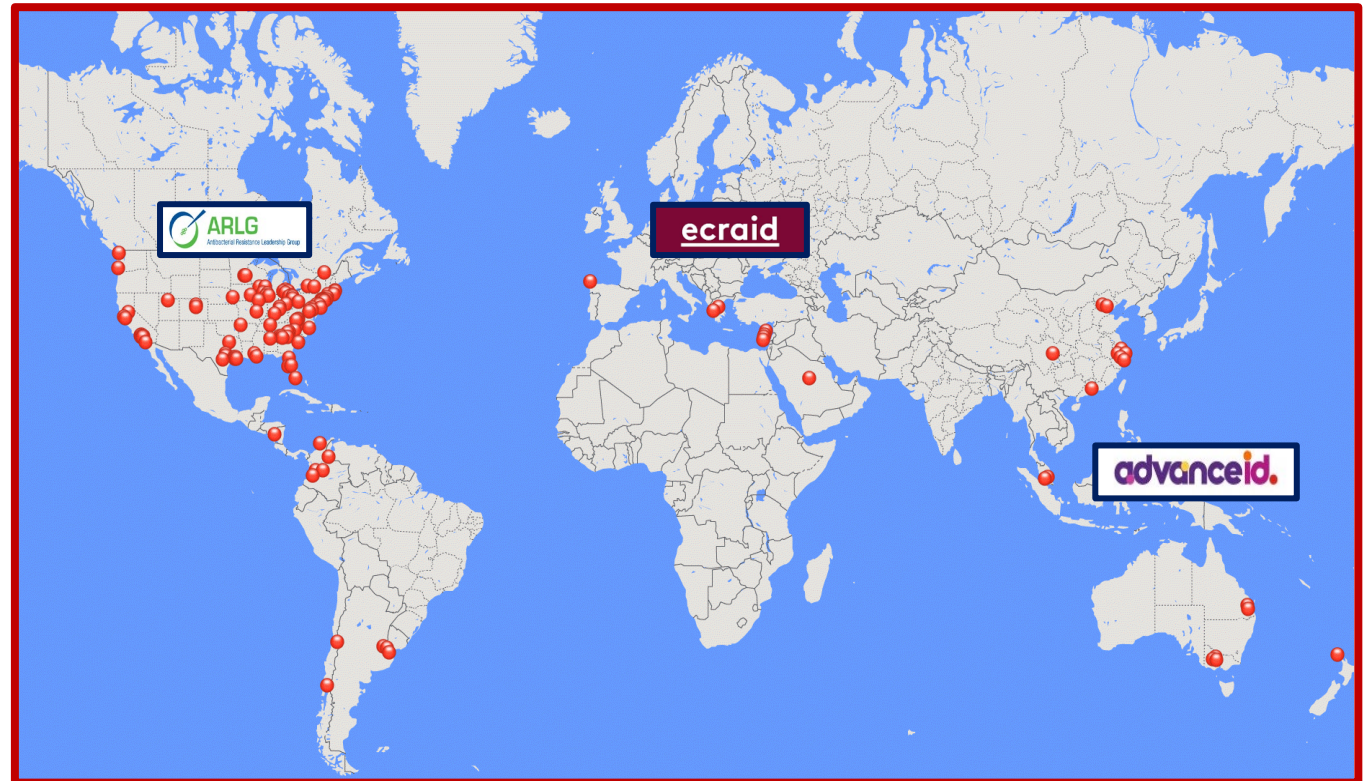


- Established in 1962
- Phase 1-4 clinical trials for vaccines, therapeutics and devices
- Epidemiologic and sample collection studies
- International trials
- Access to diverse populations (e.g., pediatric, elderly)

Antibacterial Resistance Leadership Group (ARLG)

Established in 2013 to **develop, prioritize, and implement** a clinical research agenda to impact antibacterial resistance

- Reviewed > 195 proposals
- Initiated >65 clinical studies
 - > 160 clinical sites
 - > 28K subjects
- 10K strains in repositories
- Updated 2 treatment guidelines
- Obtained 2 FDA approvals for Dx
- >330 manuscripts
- Work with > 70 mentees
- Established a global AMR clinical partnership

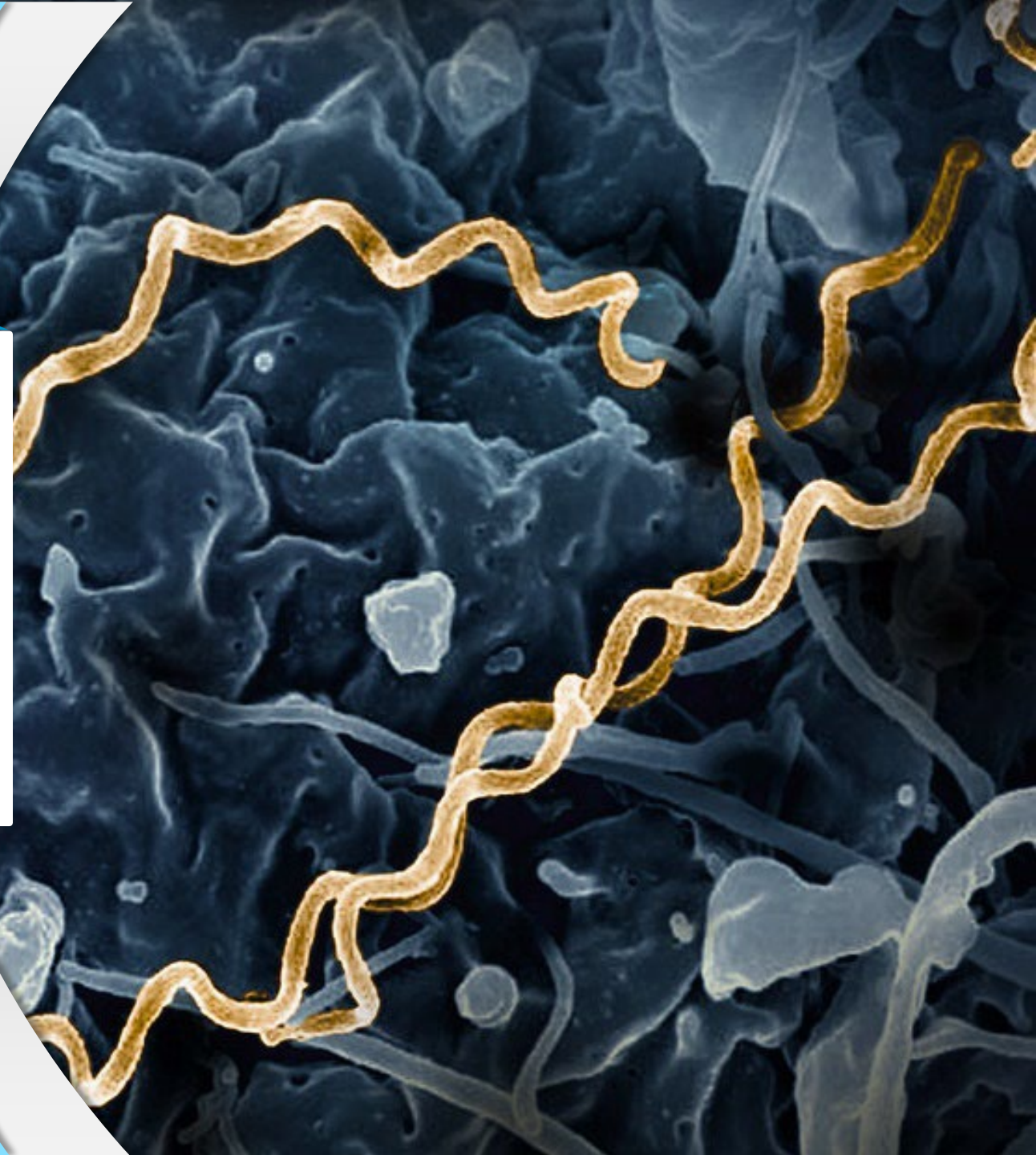


www.arlg.org



National Institute of
Allergy and
Infectious Diseases

DAIT Clinical Trial Support



Immune Tolerance Network (ITN)



Mission:

- To advance the clinical application of immune tolerance by performing high quality clinical trials of emerging therapeutics integrated with mechanism-based research.

In particular, the network aims to:

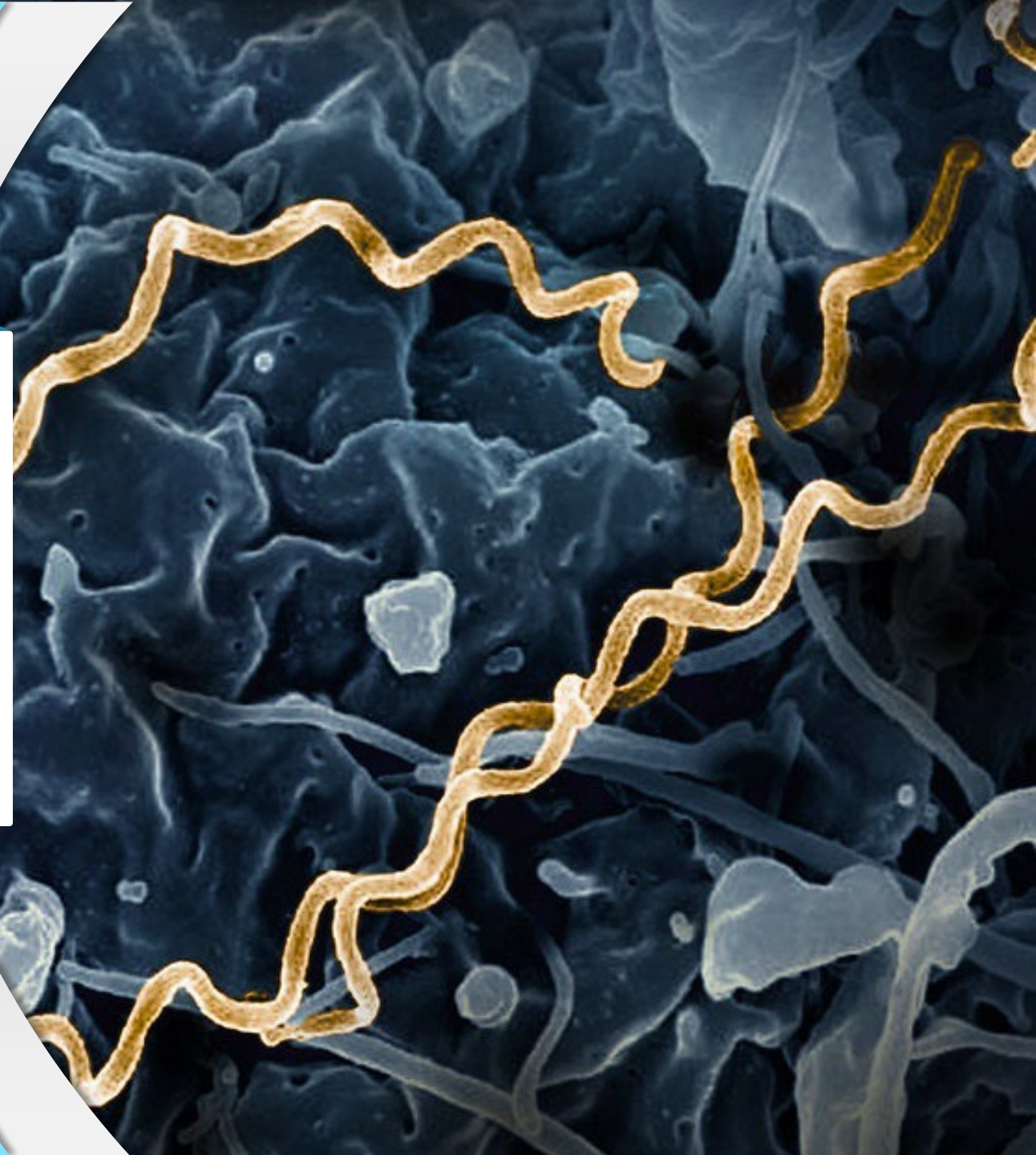
- Establish new tolerance therapeutics
- Develop a better understanding of the mechanisms of immune function and disease pathogenesis
- Identify new biomarkers of tolerance and disease

ITN accepts applications for novel clinical trials from all interested scientists from academia, industry and government. Please see: <https://www.immunetolerance.org/for-researchers/proposals>



National Institute of
Allergy and
Infectious Diseases

DAIDS Clinical Trial Support



HIV/AIDS Clinical Trials Networks

- AIDS Clinical Trials Group (ACTG)
- HIV Prevention Trials Network (HPTN)
- International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)
- HIV Vaccine Trials Network (HVTN)
- HIV/AIDS Network Coordination (HANC)





Submit a Proposal

The ACTG welcomes investigators from outside our funded Clinical Research Sites to engage with the network. There are many ways to get involved based on your interests and goals and participation in site activity is not required. Opportunities include applying to join scientific committees, submitting new research concepts for potential protocol development, and requesting access to our robust sample and data repositories.

Early-career investigators, fellows, postdoctoral researchers, and new faculty are strongly encouraged to get involved and learn how the ACTG can help support your research goals.

<https://actgnetwork.org/submit-a-proposal-2>



Research Proposals

The HPTN is open to receiving research proposals at any time.

Submit a Research Idea

Please review Section 9 of the [HPTN Manual of Procedures \(MOP\)](#) to best understand the concept & protocol development process. HPTN leadership will assess the needs and resources of the network when considering the idea and will invite submission of a full study concept (see below) if there is potential for support.

To submit a research idea, send a Letter of Intent to concepts@hptn.org.

[Letter of Intent Template](#)

<https://www.hptn.org/resources/proposals>

Submit a Research Proposal



PROPOSING AN IMPAACT STUDY

Proposals for new IMPAACT studies may be submitted by internal or external investigators in the form of a study concept any time. Concepts are first reviewed through the relevant Scientific Committee (SC). Those approved by the SC will move forward for review and prioritization by the Scientific Leadership Group (SLG). The SLG will determine if development into a full study protocol is warranted. See the [IMPAACT Network Manual of Procedures](#) for further details; Section 9 describes the protocol development process and Section 15 describes ancillary studies, including Data Analysis Concept Sheets (DACS), New Works Concept Sheets (NWCS), and Data Requests (DR). The Ancillary Studies overview presentation summarizes MOP guidance for DACS, NWCS, and DR.

<https://www.impaactnetwork.org/studies/submit-research-proposal>



HIV VACCINE
TRIALS NETWORK

Submitting an Auxiliary Studies Proposal

To submit a proposal, please review all information on this page prior to completing the [proposal template](#). Once completed, email your proposal to vtn.research@hvtn.org. The proposal template requests the information needed for the approval process. To ensure a timely response, please provide all the information it requests and contact us at vtn.research@hvtn.org with any questions. [General timeframe and approval process steps](#) are outlined below.

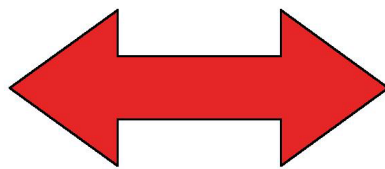
We acknowledge receipt of all submitted proposals in a timely manner and will let you know if we require additional information.

[DOWNLOAD PROPOSAL TEMPLATE](#)

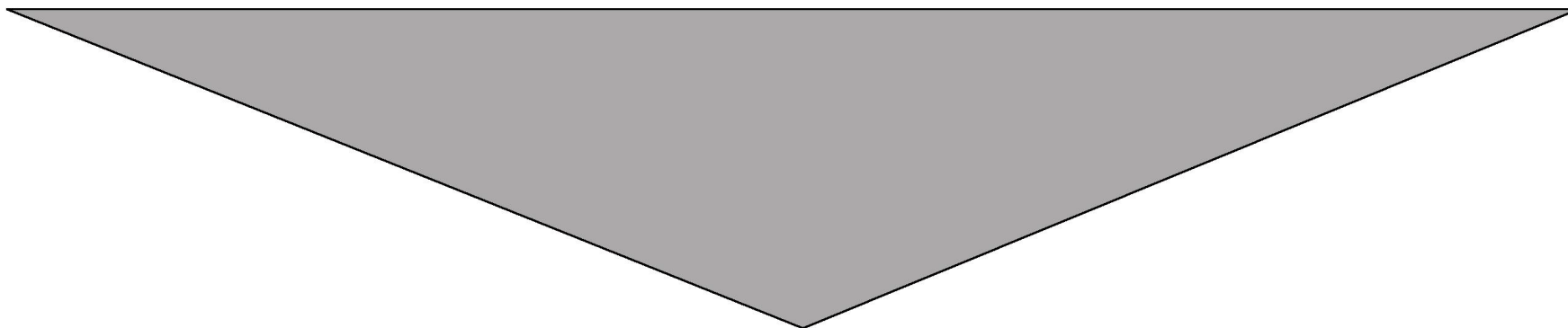
<https://www.hvtn.org/scientific-programs/scientific-programs-overview/auxiliary-studies.html#submit>

NIAID Research: A Dual Mandate

Maintain and “grow” a robust basic and applied research portfolio in microbiology, infectious diseases, immunology and immune-mediated diseases



Respond rapidly to new and emerging disease threats



New/Improved Interventions