

INDIANA CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE

WELCOME TO INDIANA CTSI

A STRONG INDIANA PARTNERSHIP FOCUSED ON
IMPROVING THE HEALTH OF THE INDIANA POPULATION



Indiana CTSI programs that facilitate research include:

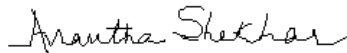
- Novel Translational Methodologies and Pilot Studies Program, **Project Development Teams (PDTs)**
- Biomedical **Informatics** Program
- Design and **Biostatistics** Program (DBP)
- **Regulatory** Knowledge and Support (RKS)
- **Clinical Research** Resource Center (CRRC)
- **Community Health** Engagement Program (CHEP)
- Translational Technologies and Resources (TTR) **Cores** Program
- Research **Education**, Training and Career Development
- **Bioethics** and Subject Advocacy Program (BSAP)
- Disease and **Therapeutic Modeling** Program
- **Biomedical Engineering** and Bionanotechnology Program
- **Indiana CTSI HUB** (<http://www.indianactsi.org>)

Dear Colleague,

Thank you for your interest in the Indiana Clinical and Translational Sciences Institute (Indiana CTSI). The Indiana CTSI is a statewide laboratory created to transform health sciences research and health care delivery. The institute is part of the new initiative by the National Institutes of Health (NIH) to create regional “homes” for clinical and translational life sciences.

Indiana CTSI is led by Indiana University, Purdue University, and the University of Notre Dame along with key community partners across the state of Indiana. Please review the enclosed summaries of Indiana CTSI’s programs that have been created to enhance translational research. I look forward to you joining the Indiana CTSI in its efforts to accelerate biomedical discoveries and to improve the health of the people of Indiana.

Sincerely,



Anantha Shekhar, MD, PhD
Director, Indiana CTSI

Indiana CTSI Funding Opportunities

More information: ICTIS HUB (<http://www.indianactsi.org/>);

E-mail: ICTSI@iupui.edu

Award	Summary of program	Eligibility and Guidelines	Schedule for Awards	Institutions
<p>K Scholar awards</p> <p>Contact: Kurt Kroenke, MD, Director; (317.630.7447, E-mail: kkroenke@iupui.edu)</p>	<p>The K12 program focuses on junior faculty pursuing clinical or translational research. Mentors work with K12 Scholars.</p>	<p>Clinical doctoral degree (e.g., MD, DDS, PharmD, OD, DPT, PhD clinical psychologist, etc.)</p>	<p><u>RFA: December</u></p> <p><u>Applications Due: Feb. 1</u></p> <p><u>Awards Announced: April</u></p>	<p>All</p>
<p>T Trainee awards</p> <p>Contact: Jon Story, PhD, Director; (765.494.6843, E-mail: jastory@purdue.edu)</p>	<p>The T32 focuses on pre-doctoral training in translational research. Mentors work with T32 trainees.</p>	<p>Enrollment in clinical doctoral degree program (e.g., medical, dental, pharmacy, etc.) or in PhD program in basic, social, or other sciences with a focus on translational research.</p>	<p><u>RFA: December</u></p> <p><u>Applications Due: Feb. 1</u></p> <p><u>Awards Announced: April</u></p>	<p>All</p>
<p>K Basic Science Scholar awards</p> <p>Contact: Rose Fife, MD, MPH, Director; (317.274-2754, E-mail: rfife@iupui.edu)</p>	<p>The K12 program focuses on junior faculty pursuing Basic Science research. Mentors work with K12 Scholars.</p>	<p>Non-clinical doctoral degree (e.g., PhD basic science).</p>	<p><u>RFA: January</u></p> <p><u>Applications Due: March 1</u></p> <p><u>Awards Announced: April</u></p>	<p>IUSM</p>
<p>CBR/CTR grants</p> <p>Contact: Lisa Dinsmore (317.274.4404, E-mail: ldinsmo@iupui.edu)</p>	<p>This award is to foster collaborations between investigators at IUB, Purdue, ND, IUSM, and IUPUI in translational research projects with strong potential to develop into externally funded programs or IP.</p>	<p>Awards are considered seed grants with a maximum limit of \$75,000 for a one (1) year duration. Projects must have participation by two (or more) principal investigators representing at least two CTSI partner institutions.</p>	<p><u>RFA: December</u></p> <p><u>Applications Due: March 1</u></p> <p><u>Awards Announced: May</u></p>	<p>All</p>
<p>PDT pilot funding</p> <p>Contact: Tammy Sajdyk, PhD (317.2787488, E-mail: tsajdyk@iupui.edu)</p>	<p>Provides funding to support development of preliminary data for external grant submissions.</p>	<p>Researchers in translational basic and clinical research at all ICTSI institutions are eligible to apply for PDT pilot funding,</p>	<p>On-going (Application is made to home institution except IU-B, which is made to IUSM)</p>	<p>All</p>
<p>Pilot Core Funding</p> <p>Contact: Liliith Reeves (317.278.6930, E-mail: lreeves@iupui.edu)</p>	<p>Promotes use of CTSI cores across CTSI partner institutions and supports science with a high potential for external funding or IP.</p>	<p>Faculty may apply for a maximum of \$10,000 in CTSI Designated Core services. The core need NOT be from the faculty home institution.</p>	<p><u>RFA: August</u></p> <p><u>Applications Due: October 15</u></p> <p><u>Awards Announced: Jan.</u></p>	<p>All</p>
<p>Research Inventions and Scientific Commercialization (RISC)</p> <p>Contact: Rose Fife, MD, MPH (317.274.2754, E-mail: rfife@iupui.edu)</p>	<p>Pilot program to support potential gaps in research that leads to IP generation at IU in collaboration with IUETC.</p>	<p>Researchers in translational basic and clinical research identified by IUETC.</p>	<p>On-going</p>	<p>IUSM IUPUI</p>
<p>Innovation Postdoc</p> <p>Contact: Gregory Crawford, PhD (574.631.6456, E-mail: gregory_crawford@nd.edu)</p>	<p>Post-doc funding to facilitate movement of research inventions/concepts to commercialization.</p>	<p>Faculty at Notre Dame in the College of Science</p>	<p>On-going</p>	<p>Notre Dame</p>
<p>Purdue's Verne A. and Ramoth H. Trask Venture Fund. <i>The "Trask fund"</i></p> <p>Contact: Ms. Jeni Martin, (765.588.3470, E-mail: jjmartin@prf.org)</p> <p>Alfred Mann Institute at Purdue</p> <p>Contact: Steve Mogensen (765.494.8316, E-mail: smogensen@amipurdue.org)</p>	<p>A mechanism to assist faculty to further commercial potential of IP disclosed to the Office of Technology Commercialization (OTC).</p> <p>Key elements include a statement of the clinical issue and proposed solution, scope of work, development goals and plan, timeline and budget,. A confidentiality agreement is required.</p>	<p>Investigators actively engaged with their assigned case manager from the OTC regarding their disclosed technology. The Fund objective is to support short-term projects that will enhance commercial value of Purdue University intellectual property assets</p> <p>Projects that involve disclosed innovation from Purdue Univ.</p>	<p><u>Applications Due: Twice Annually</u></p> <p>On-going</p>	<p>Purdue</p> <p>Purdue</p>

How do the Project Development Teams (PDT) benefit research?

The Project Development Teams (PDT) serves as a “one-stop shop” for study development by providing investigators access to multidisciplinary research expertise, biostatistics, IRB/regulatory services, nursing support, and pilot funds. These teams are not simply review groups but experienced researchers who discuss ideas and concepts with investigators to assist in developing high quality, feasible, fundable clinical/translational research projects.

Why would I want to learn more and/or use this program?

Eight PDTs address a broad spectrum of research focuses:

- The *Preclinical PDT* (TRAC1) focuses on translational studies in animal and cellular models.
- The *Pediatric PDT* (PRAT) facilitates research in children with emphasis on interactions with basic scientists to design and implement bench-to-bedside studies.
- The *Adult PDT* (TRAC2) focuses on early translational studies related to adult medicine.
- The *Behavioral/Population Science PDT* (BEHV) helps investigators design and implement epidemiological and behavioral research.
- The *Purdue PDT* has particular strengths in assisting investigators with a special emphasis on bioengineering, nutritional, and veterinary medicine.
- The *Translating Research into Practice PDT* (TRIP) focuses on projects that evaluate and implement evidence-based practice and other health services research.
- The *Notre Dame PDT* provides access to broad biomedical expertise particularly in basic research.
- The *Imaging PDT* provides expertise in the application of anatomical, functional, and molecular imaging methodologies and technologies.

Projects are submitted by investigators via personal referral or the ICTSI HUB website:

(<https://www.indianactsi.org/programs/pdt>).

What is this program doing to support research efforts?

- Actively reviewing projects and assisting in design to accelerate translational research
- Providing funding to support development of preliminary data for external grant submissions
- Following interactions with the PDTs, investigators have submitted successful proposals for external funding
- Facilitating enrollment of human subjects, including children, in pilot projects

Where do I find more information?

Preclinical PDT: Mark R. Kelly, PhD, (317-274-2755, E-mail: mkelley@iupui.edu)

Pediatric PDT: Scott Denne, MD, (317-274-4920, E-mail: sdenne@iupui.edu)

Adult PDT: Sharon Moe, MD, (317-278-2868, E-mail: smoe@iupui.edu)

Behavioral/Population Science PDT: Victoria Champion, DNS, (317-274-4187, E-mail: vchampion@iupui.edu)

Purdue PDT: Connie Weaver, PhD, (765-494-8231, E-mail: weavercm@purdue.edu)

Translating Research Into Practice (TRIP) PDT: Bradley Doebbeling MD, MSc, (317-423-5504, E-mail: bdoebbel@iupui.edu)

Notre Dame PDT: Mayland Chang, (574-631-2965, E-mail: mchang@nd.edu)

Imaging PDT: Gary Hutchins, PhD, (317-274-3687, E-mail: gdhutchi@iupui.edu)

<https://www.indianactsi.org/programs/pdt>

How does the Biomedical Informatics program benefit research?

The Biomedical Informatics Program (BIP) increases the effective utilization of data and knowledge resources by improving investigators' awareness and understanding of how to access information, use the software tools available, and expanding and refining the data available to researchers, including linkages that allow biospecimen and derivative data to be shared.

Why would I want to learn more and/or use this program?

The BIP services include:

- Identification of sources for relevant clinical data
- Secure access, for allowable purposes, to integrated, longitudinal, population-based patient data and health information for the support of patient care, research, quality improvement, and public health
- Outreach to data sources and improved processes for creating interfaces and normalizing the data
- Implementation of and improvements in specimen management software and coordinating sample management with clinical annotations
- Processes for high-throughput experimental data management for capture, storage, management, analysis, and integration with the clinical data repository
- Tools to facilitate utilization of data and integration into study design processes through the Design and Biostatistics Program

What is this program doing to support research efforts?

- Increasing utilization through better communication and processes and expanding the data
- Supporting significant progress through the specimen management developmental projects

Where do I find more information?

Director, J. Marc Overhage, MD, PhD, (317-423-5579, E-mail: joverhag@iupui.edu)

Co-director, William Tierney, MD, (317-423-5579, E-mail: wtierney@iupui.edu)

Gunther Schadow, MD, (317-423-5521, E-mail: gschadow@iupui.edu)

Rosenman, Marc, MD, (317-423-5500, E-mail: mrosenma@iupui.edu)

<http://www.indianactsi.org/programs/biomedinfo>

How does the Design and Biostatistics program benefit research?

The Design and Biostatistics Program (DBP) provides support in study design and analysis planning for developing new research projects. It also offers enhanced educational and training opportunities for researchers. Biostatistics expertise is available from IU and Purdue as well as the University of Notre Dame.

Why would I want to learn more and/or use this program?

The DBP provides:

- A wide range of expertise in study design, biostatistics, statistical genetics, and computational biology
- Optimal study design and development for research projects
- State-of-the-art data management and analyses for funded projects
- Connections to potential collaborators
- Educational and training opportunities at various levels of statistical sophistication

What is this program doing to support research efforts?

- Providing a consortium of statisticians at IU, Purdue, and Notre Dame, who can be accessed through the ICTSI
- Providing biostatistics support for research development leading to funded projects
- Providing data management and statistical analyses for funded projects
- Offering continuing medical education (CME) courses in biostatistics and bioinformatics

Where do I find more information?

Siu Hui, PhD (IUPUI), (317-423-5589, E-mail: shui@iupui.edu)

George McCabe, PhD (Purdue), (765-496-8378, E-mail: george.p.mccabe.1@purdue.edu)

Steven Buechler, PhD (Notre Dame), (574-631-6233, E-mail: Steven.A.Buechler.1@nd.edu)

<http://www.indianactsi.org/programs/dbp>

How does the Regulatory Knowledge and Support program benefit research?

The Regulatory Knowledge and Support (RKS) Program provides support for addressing federal, state, and local regulations, as well as assistance in streamlining the process of protocol submission and review.

Why would I want to learn more and/or use this program?

The RKS Program services that benefit faculty and trainees include:

- Education and assistance on regulatory compliance
- Regulatory input on study designs
- Human subjects consultation
- IRB process information

What is this program doing to support research efforts?

- Consulting and providing regulatory support to ICTSI researchers and staff individually and via the PDTs
- Conducting educational programs on human subjects regulatory issues for researchers and research staff
- Supporting the Regulatory Advisory Council (RAC)

Where do I find more information?

Jody Harland, MS, CIP, Lead Regulatory Advisor, (317-274-2115, E-mail: harlandj@iupui.edu)

<http://www.indianactsi.org/programs/regknowsupprog>

How does the Clinical Research Resource Center benefit research?

The Clinical Research Resource Center (CRRC) provides research coordinator support, space, nursing, and sample processing support to conduct academic and industry sponsored clinical research studies for both inpatient and outpatient visits.

Why would I want to learn more and/or use this program?

- The CRRC supports:
 - NIH and other externally funded studies
 - Industry sponsored studies
 - Investigator initiated pilot projects
 - Inpatient and outpatient adult and pediatric protocols including rooms, research nurses, and sample processing
- The Purdue Clinical Research Center (PCRC):
 - NIH and other externally funded studies
 - Investigator initiated pilot projects
 - Industry sponsored studies
 - Outpatient adult and pediatric protocols including rooms and sample processing
 - Provides specialized facilities for metabolic and body composition studies

What is this program doing to support research efforts?

- Providing a streamlined submission and approval process and independent advisory committee for the CRRC
- Improving the CRRC protocols support capabilities for a large number of diverse investigators and protocols

Where do I find more information?

Scott Denne, MD, Director, (317-274-4920, E-mail: sdenne@iupui.edu)

Munro Peacock, MD, Co-director, (317-274-4356, E-mail: mpeacock@iupui.edu)

<http://www.indianactsi.org/programs/icrc>

How does the Community Health Engagement program benefit research?

The Community Health Engagement Program (CHEP) is committed to enhancing statewide community participation and engaging community healthcare providers as collaborators in research, agents of health systems change, and liaisons to diverse Indiana populations.

Why would I want to learn more and/or use this program?

The CHEP supports research through:

- Identifying and recruiting practitioners to participate in Practice-based Research Networks
- Identifying and recruiting study participants
- Conducting community-based health research, design, and evaluation of novel approaches to community engagement, network design, and education of collaborating practitioners
- Coordinating with the Cooperative Extension Service to encourage community engagement
- Developing and pilot testing new data management tools, resource sharing, and regulatory strategies
- Supporting research education (in collaboration with the Research Training Program)
- Working with community leaders to provide better ways to conduct and disseminate research about health to Indiana's communities and citizens

What is this program doing to support research efforts?

- Developing a multidisciplinary planning committee spanning the CTSI member institutions and community-based participatory research
- Involving over 100 stakeholder organizations statewide for involvement in the CHEP network
- Providing ongoing development of outreach materials to encourage community partners to play an active role in the ICTSI's ongoing development

Where do I find more information?

Ronald T. Ackermann, MD, MPH, (317-278-0906, E-mail: rtackerm@iupui.edu)

David G. Marrero, PhD, (317-278-0905, E-mail: dgmarrer@iupui.edu)

Brenda Hudson, MA, (317-278-0913, E-mail: brlhudso@iupui.edu)

Carol Boushey, PhD, (765-496-6569, E-mail: boushey@purdue.edu)

<http://www.indianactsi.org/chep>

How does the Translational Technologies and Resources program benefit research?

The Translational Technologies and Resources Program (TTR) facilitates use of core technologies within CTSI member institutions including IU, Purdue and University of Notre Dame. The cores service investigators in both basic and clinical research.

Why would I want to learn more and/or use this program?

The TTR services that benefit research include:

- A Core Pilot Grant Program to support pilot studies
- TTR Liaisons to advise investigators on core services to enhance their studies
- A Specimen Storage Facility to support biorepository storage and processing
- Participates in Project Development Teams to build applicable core services into projects

What is this program doing to support research efforts?

- Providing a searchable website to locate core services at <http://www.indianactsi.org/research/cores>
- Maintaining ICTSI core designation standards
- Providing a Specimen Storage Facility (SSF) that leases space for investigator freezers or storage space in a CTSI SSF freezer
- Providing links to educational materials about core technologies through the search function at <http://www.indianactsi.org/research/cores>

Where do I find more information?

TTR Director: Kenneth Cornetta, MD, (317-274-2240, E-mail: kcornett@iupui.edu)

TTR Manager: Lilith Reeves, MS, MT(ASCP)SH, (317-278-6930, E-mail: lreeves@iupui.edu)

<http://www.indianactsi.org/research/programs/ttr>

How does the Research Education, Training and Career Development program benefit research?

The Research Education, Training and Career Development Program serves to provide pre-doctoral and young investigator training awards and create new courses and career development opportunities for translational research training.

Why would I want to learn more and/or use this program?

Research Education, Training and Career Development services:

- Provides Masters degree, Graduate Certificate and/or selected coursework in Clinical Research
- Supports candidates for young investigator (K award) and pre-doctoral (T award) education programs
- Recruits and supports mentors to new researchers
- Assesses the education and training needs for new researchers
- Tracks student performance to assure education and training needs are met

What is this program doing to support research efforts?

- Funding faculty young investigator positions with NCRR and institutional funds
- Funding pre-doctoral trainee positions with NCRR and institutional funds
- Implementing a new track in Translational Research

Where do I find more information?

Kurt Kroenke, MD, Director of Research Education, Director of Young Investigator Program, (317-630-7447, E-mail: kkroenke@iupui.edu)

Jon Story, PhD, Director of Pre-Doctoral Program, (765-494-6843, E-mail: jastory@purdue.edu)

Mark Payne, MD, Director of Translational Research Education, (317-278-6239, E-mail: rpayne@iupui.edu)

<http://www.indianactsi.org/programs/retcd>

How does the Bioethics and Subject Advocacy program benefit research?

The Bioethics and Subject Advocacy Program (BSAP) promotes bioethics as a central theme to all research in Indiana and to enable the Indiana CTSI to anticipate and address ethical and policy issues that arise in the design, conduct, and dissemination of clinical translational research.

Why would I want to learn more and/or use this program?

The BSAP services include:

- comprehensive education, consultation, and policy programs for responsible conduct of research
- design and implementation of Web-based training modules
- small group learning programs and formal classroom instruction
- user-friendly access to bioethics experts
- comprehensive “out-reach” bioethics initiative to support the education, research, and policy needs of diverse external groups
- dynamic online gathering place for bioethics education, research collaboration, and information sharing (Bioethics Digital Gateway)

What is this program doing to support research efforts?

- Providing consultation services on bioethics and subject advocacy
- Providing the Bioethics Digital Gateway as a fully integrated component of the ICTSI HUB and have populated it with links to existing research ethics information resources
- Representing the Indiana CTSI research environment to the broad Indianapolis community as well as at national and regional meetings of professional organizations

Where do I find more information?

Eric M. Meslin, PhD, (317-278-4040, E-mail: emeslin@iupui.edu)

Indiana Center for Bioethics (317-278-4034)

<http://www.indianactsi.org/programs/bsap>

How does the Disease and Therapeutic Modeling program benefit research?

The ICTSI Disease and Therapeutic Response Modeling Program is designed to generate quantitative models of disease and drug effect as well as drug exposure that can be used to catalyze the movement of new diagnostics and therapies along the translational continuum.

The program involves a full partnership with (and significant contribution of resources and expertise from) Eli Lilly and Company, based in Indianapolis, and the ICTSI.

Why would I want to learn more and/or use this program?

The collaboration provides researcher support in three major areas:

- Provides substantial salary support for post-doctoral level training positions
- Increases the capability of disease-state and disease progression modeling by training individuals in specific competencies
- Develops major disease-state and disease-progression models
- Makes the models publicly available through the CTSA network

What is this program doing to support research efforts?

- Supporting six new training positions (three per year each for two years) within the ICTSI under a master agreement with Eli Lilly

Where do I find more information?

David Flockhart, MD, PhD, (317-630-8795, E-mail: dflockha@iupui.edu)

Robert Bies, Pharm.D, PhD, (317-630-7868, E-mail: rbies@iupui.edu)

Jamie Dananberg, MD, PhD, (Eli Lilly & Co., E-mail: DANANBERG_JAMIE@LILLY.COM)

<http://www.indianactsi.org/programs/dtrmp>

How does the Biomedical Engineering and Bionanotechnology program benefit research?

The Biomedical Engineering and Bionanotechnology program provides a seamless blend of technical, pre-clinical, clinical, and industrial expertise to enhance projects and expedite their progress towards clinical implementation. This networking effort, in concert with the unique facilities and capabilities this program area brings to bear, will buoy many projects towards commercialization.

Why would I want to learn more and/or use this program?

The Biomedical Engineering and Bionanotechnology Program uses the ICTSI framework to tightly link Purdue's biomedical device development and bionanotechnology capabilities with pre-clinical resources in Purdue's School of Veterinary Medicine and, in turn, with the clinical resources of the IU School of Medicine in order to increase the number and scope of substantive technologies that are translated into patient care. The program's goal is to create a regional backbone that, when partnered with Indiana's burgeoning medical device industry, will form a highly functional technology translation pipeline with substantial and unique productivity.

What is this program doing to support research efforts?

- Facilitating access critical capabilities in biomedical engineering and bionanotechnology at Purdue
- Providing a common translational research/project development pipeline template that allows for staging and progress monitoring of each project
- Mapping projects onto the template and assisting with achieving pertinent short-term objectives of each project

Where do I find more information?

George R. Wodicka, PhD, (765-494-2998, E-mail: wodicka@purdue.edu)

James F. Leary, PhD, (765-494-7280, E-mail: jfleary@purdue.edu)

<https://www.indianactsi.org/research/programs/bioeng>

How does the Indiana CTSI HUB benefit research?

The Indiana CTSI HUB (<http://www.indianactsi.org>) is the face and gateway for translational research activities for the statewide consortium, including T1 and T2 translational efforts. It is built on the research virtual organization Web 2.0 framework for ease of use and provides an environment for interactive research applications.

Why would I want to learn more and/or use the Indiana CTSI HUB?

- **Project Development Team (PDT)** application (<http://www.indianactsi.org/programs/pdt>)
- **Clinical Trial assistance** from the ICRC (formerly GCRC) (<http://www.indianactsi.org/recruitment>)
- **Funding opportunities** and on-line grant review system (<http://www.indianactsi.org/research/funding>)
- **Subject Recruitment Assistance** (<http://www.indianactsi.org/recruitment>)
- **Search for core services** including all ICTSI member institutions (<http://www.indianactsi.org/research/cores>)
- **Search for Clinical Trials** (<http://www.indianactsi.org/clinicaltrial>)
- **Compliance Services** information and key links (<http://www.indianactsi.org/research/humansubjects>)
- **Research Coordinator** help page (<http://www.indianactsi.org/research/coordinators>)
- **Research Networking** (<http://www.indianactsi.org/research/members>)
- **Faculty Publications** (<http://www.indianactsi.org/research/facultypub>)
- Additional sites for the public, education and training, and Indiana CTSI resources

What is this program doing to support research efforts?

- Providing federated identities to allow researchers in Indiana the ability to log in securely to the NIH and many other sites across the country using their institutional log-ins
- Supporting customized program web sites and online services
- Providing a platform for cross institutional group collaboration
- Providing a simulation environment for interactive research applications

Where do I find more information?

Bill Barnett, PhD, (812-856-3038, E-mail: barnettw@iu.edu)
Indiana CTSI Administrative Office (317-278-2874, E-mail: ictsi@iupui.edu)

<http://www.indianactsi.org/>

INDIANA CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE

CREATING A STRONG PARTNERSHIP IN INDIANA FOCUSED ON IMPROVING THE HEALTH (AND ECONOMY) OF THE INDIANA POPULATION

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