



UW ICTR Learning Health System Demonstration Project 2023-2024 Program Announcement

A Learning Health System (LHS) helps bring research into healthcare practice, providing necessary evidence at moments when stakeholders see an opportunity to make healthcare more efficient and effective. The establishment of a Learning Health System aligns with the goals of the Agency for Healthcare Research and Quality (AHRQ), as the LHS uses data to track changes in healthcare and applies proven strategies to enhance patient safety and care. An integral component of this system is the Plan-Do-Check-Act (PDCA) cycle. This cycle helps transform data into knowledge, apply that knowledge, and feed information on results back into the data pool. This process is key to fostering an LHS, encouraging culture shifts that support real-world clinical trials, and ultimately accelerating the delivery of precise, evidence-based care to improve patient health outcomes.

However, implementation of these LHS principles has been sluggish, leading to growing health inequalities and soaring healthcare costs. The slow uptake of evidence-based practices in everyday care has resulted in notable delays in enhancing health outcomes. Achieving the LHS's promise of clinical and operational improvements and widely applicable knowledge requires a culture shift and process overhaul. This shift begins by creating a cooperative environment where health systems, clinicians, researchers, patients, payors, vendors, government, and other important stakeholders can work together. This environment needs to be disciplined but adaptable, using real-time clinical data to drive PDCA cycles and continuously test and improve patient care quality and safety.

The University of Wisconsin has been active in LHS activities since 2013, beginning with evidence-based quality improvement programs. In 2022, UW Health bolstered its partnership with the University of Wisconsin-Madison's Institute for Clinical and Translational Research (ICTR) to advance the LHS. The focus of ICTR LHS is on data-driven technologies and acute/inpatient care delivery, aiming to unite our ICTR experts in team science, implementation science, biostatistics, and other consultants with the operational teams in our health system. This Program Announcement invites teams to identify significant questions and care gaps that could be addressed using an informatics, data-driven workflow with a focus on healthcare outcomes. The goal is to demonstrate an implementation-focused and data-driven LHS that uses patient experiences and care information to iteratively inform decisions and interventions at the point of care.

The Program Announcement introduces support for the development of ICTR's LHS initiative by funding a large-scale, pragmatic healthcare demonstration project that is a priority for UW Health. The project must include a clinical champion as the Principal Investigator, and a detailed plan for rapid and effective implementation into clinical practice of a patient intervention. Pragmatic comparative effectiveness trials are preferred but quasi-experimental quality improvement projects are also encouraged.

The successful grantee will use the results of this award to demonstrate a data-driven and collaborative Learning Health System that improves healthcare delivery and grows the LHS infrastructure in a sustainable manner. The following criteria must be met:

- **Continuous Quality Improvement in the Quintuple Aims.** The National Academy of Medicine¹ and AHRQ acknowledged the need for continuous improvement in health outcomes and healthcare delivery by proposing an LHS. An LHS aims to progress healthcare delivery to rapidly "Learn from

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What We Do and Do What We Learn." Stakeholders and researchers in the LHS should work closely with health systems operations to allocate the resources for collecting real-world data that may be analyzed to provide real-world evidence that serves the quintuple aims of any health system: (1) addressing health inequity and justice gaps and advancing health equity; (2) reducing costs; (3) improving patient health; (4) enhancing the patient care experience; (5) and reducing clinician burnout.

- **Data-Driven Decision-Making** is used, drawing upon methods in data science. The National Institutes of Health (NIH) defines data science as “the interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are developed and used to extract knowledge and insights from increasingly large and/or complex sets of data.” The proposed team and computing infrastructure should provide the resources to collect real-world data on UW Health patients and follow its LHS governance workflow and required collaborators to collect real-world evidence to inform operational decisions that can lead to process redesign and change management in clinical practice. The strategic goal of a *data-driven* LHS is to improve health outcomes by leveraging data science to incorporate rapid methods needed for process redesign and overcome the delays in implementation that currently plague healthcare. Experts in implementation science and systems engineering should work closely with the health system’s enterprise analytics team and ICTR’s Clinical and Health Informatics Institute (CHI²).
- **Integration of UW Health Key Strategic Areas into the Demonstration Project:** Proposals should align with a key strategic initiative based on the UW Health Strategic Priorities or the 2023 corporate plan of UW Health to design a single Demonstration Project. Current UW Health strategic imperatives include: 1) design our future work and workforce; 2) excel in value-based care; and 3) be the destination for specialty care. Additionally, project scale is a major consideration; ideally, demonstration projects should involve many patients that impact the health system. These include projects that examine the comparative effectiveness of two interventions that are already available in clinical practice (i.e., clinical equipoise), and should include sustainable infrastructure built into the budget for the LHS.

Note: If your research question involves an intervention that is novel and has not demonstrated efficacy, or an intervention lacking data on efficacy, or if you are in the early stages of developing an intervention, please consider the ICTR Pilot Awards Program opportunities described in its Funding Opportunities website. Projects that involve large community populations and/or focus on outpatient population care settings should consider exploring opportunities with the Health Innovations Program.

AWARD

Each award provides **up to \$150,000** for up to **12 months** of direct cost support.

ELIGIBILITY OF CLINICAL CHAMPION (Demonstration Project Principal Investigator)

- The Clinical Champion must be employed by UW-Madison (*either sole appointment, or joint-appointment with VA Hospital, UW Milwaukee*) and have the title of:
 - Assistant, Associate or Full Professor (tenure track, CHS, or clinical) with clinical effort in a UW Health Department/Division
 - Whereas residents, fellows, post-doctoral associates are **NOT** eligible to serve, they are eligible to serve as co-Investigators.

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- 20% salary support (up to NIH annual salary cap: \$199,300 + fringe per year) must be included in the budget for the Clinical Champion as the Principal Investigator (PI). The sponsoring Department/Division Chair must provide a letter of support agreeing to the 20% buyout from this award for the PI's effort.
- *If awarded*, research teams will be required to participate in a 90-minute facilitated Collaboration Planning process as part of the [ICTR Team Science](#) initiative. In addition, the PI will serve as one partner in a dyad working relationship with a health operations leader/executive with corresponding content/operational expertise. **These roles will need to be identified and delineated in the Letter of Intent.**

KEY DATES AND DEADLINES

Program Announcement	October 27, 2023
LOI Due	December 8, 2023
IRB Consult Due (for accepted LOIs)*	January 8-March 10, 2024
Full Application Due	June 2, 2024
Peer-Review and LHS Steering Committee Review Period	June 12-August 18, 2024
Demonstration Projects Announced	August 25, 2024
Demonstration Project Start Date	September 1, 2024
LHS Component Consultations	September 8, 2024 – October 31, 2025

*ICTR Dissemination and Implementation Consultation recommended. See contact details in post-award requirements below.

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LETTER OF INTENT (mandatory)

Due December 8, 2023. Letters of Intent (LOIs) must be submitted as a **single PDF/Word document** to lhs@ictr.wisc.edu. Note: The LOI will be reviewed by Director (Majid Afshar) and Associate Director (Anne Gravel Sullivan) of the LHS to ensure alignment with the health system priorities, LHS focus in acute/inpatient care delivery, and clear delineation of clinical champion and operational lead prior to an invitation for a full application.

The Letter of Intent - please include the following:

1. Clinical Champion/PI Name, contact information, and department/division
2. Title of your proposal.
3. Names and roles of key personnel.
4. Specific aims and *brief* overview of UW Health LHS Demonstration Project should include enough detail to identify **both** scientific and design/methods reviewers.
5. Please indicate all contributors, collaborators and/or invested groups for this demonstration project and how they will be involved in this project. We strongly encourage the clinical champion to identify a dyad partner with a UW Health operations leader/manager. The clinical champion must have some affiliation with UW Health to be considered for the LHS award.
6. Identify the **Learning Health System components and Quintuple Aims** your Demonstration Project will address.

Select proposals that are determined to meet the criteria for a UW Health-based LHS demonstration project will be encouraged to submit a full application. Prior to submission of a full application, project PIs will be required to hold consultations with the IRB and D&I Launchpad. The purpose of these consultations is to assess and provide feedback on the demonstration project's design to proactively identify facilitators that can help mitigate barriers to swift IRB approval/exemption, as well as optimize project scalability, impact and sustainability. Questions about the application process may be directed to the LHS Leadership at lhs@ictr.wisc.edu.

APPLICATION REQUIREMENTS

The full application is due on **June 2, 2024**

Please note the application instructions:

- A complete application includes **items 1-11** below
- Please insert page numbers on the full application
- Templates for the Face Page, Abstracts and Budget are within the *2023 Application Forms* on the [ICTR Funding Opportunities page](#).
- Narrative: Maximum length of 6 pages, 11-point Arial font with ½" margins
- **Submit the full application as a single PDF/Word document** to lhs@ictr.wisc.edu by 5 pm on June 2, 2024

Full Application Components (1-10):

1. **Face Page**
2. **Scientific Abstract:** Provide a concise description of the proposed demonstration project written for scientific audiences. 500 word maximum. Your scientific abstract must include:

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- Scientific rationale supporting your proposed demonstration project meeting the criteria of data-driven decision-making strategy, and alignment with UW Health key strategic areas.
 - Scientific aims and demonstration project design. The investigator should describe the need for the project by the participating health system (UW Health), and how they will leverage ICTR resources in CHI², Team Science, Protocol Development, D&I Launchpad, and BERD. Also describe how completion of the project will be achieved using a rapid PDCA cycle (consult with D&I to help).
- 3. Quintuple Aims Abstract:** The abstract is an opportunity to express to our *LHS Steering Committee* how you anticipate that this project can, in the long-term, impact the health of patients and serve the need of the following Quintuple Aims: (1) advancing health equity; (2) reducing costs; (3) improving patient health; (4) enhancing the patient care experience; and (5) reducing clinician burnout. It should **not** be a reiteration of the Scientific Abstract but **instead** should *tell a story* that addresses the importance of how the demonstration project will enhance healthcare efficiency to achieve the Quintuple Aims as a framework from the Institute for Healthcare Improvement for achieving value-based care (500 word maximum). The Quintuple Aims abstract should describe:
- The magnitude of the health problem: how many individuals are affected and the scope of the issue locally and nationally? How will the project, in the context of the health system, improve health and advance health equity and enter our digital era of healthcare?
 - How the costs of healthcare are impacted and whether/how this project addresses health inequities and advance health equity. Identify at least two of the Quintuple Aims on which the project focuses and detail what questions the project will address.
 - The longer-term policy implications of your LHS project. How might your LHS project inform and improve the LHS workflow for the health system?
- 4. Health System/Community Engagement:** Provide a concise description of the primary patient audience(s) targeted by the demonstration project and how the project will improve acute/inpatient care in that community. 500 word maximum. The application must include:
- A description of your plans for Collaboration/Engagement.
 - Describe your healthcare partners/invested groups/stakeholders. Stakeholders include all entities that are engaged in the production, implementation, or dissemination of the demonstration project as well as the committee groups that approve the clinical operations integration and workflow.
 - Describe your relationship with your partners/stakeholder(s) and describe their role in the program evaluation and adoption, and in advising and/or collaborating on the LHS project. When writing this section, applicants should address each of the following:
 - A description of how health system members and/or partners will be included (e.g., provide input into) in the project design, testing, and/or execution (e.g., during a specific phase of the PDCA cycle)
 - A list of patient/stakeholder collaborators. Who are the intended beneficiaries of this project and how will patient members, contributors and/or invested stakeholders be involved; what roles will they play? Are the experiences of the patient and provider included in the outcomes?
- 5. Biosketches for Key Personnel:** Please use the new NIH Biosketch format as described here: <https://grants.nih.gov/grants/forms/biosketch.htm>

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- **Special note for Clinical Champion/PI applicant:** The Personal Statement of the NIH Biosketch must include detail on how the proposed research represents an independent area of investigation for the applicant and integration with the health care system. Letters from the faculty supervisor and department chair or dean expressing support for the 20% buyout with funds from this award with an outline of the PI's proposed role with healthcare operations and clinical workflow should be included.

6. Budget (\$150,000 for 12 months of direct support) Requirements:

- Use the budget template which is bundled with the face page in the application materials.
- Budget Justification is required (maximum 2 pages).

When creating your budget, please note the following parameters:

- **Indirect costs are *not* allowed.**
- Investigator salary support is allowed for the required 20% FTE.

7. Narrative Requirements: The narrative should not exceed 6 pages and should address each of the following components (**sections a-f below**).

- Specific Aims.** Each proposal should include LHS aims that align with the Quintuple Aims.
- Background and Significance.** When writing this section, applicants should address the following:
 - What is the UW Health priority the Demonstration Project will address?
 - What is the estimated hospital/health system benefit of the LHS project and how big is the impact of the planned intervention?
 - Identify the care or quality gap, e.g., do the existing data or workflow in the healthcare delivery and patient need the LHS framework?
- Investigator.** Please explain how the PI, study team, and health partners are especially suited to this project (i.e., their expertise), including clinical operations involvement
- Environment.** Will the clinical environment in which the work will be done contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? What is the sustainable infrastructure build that will result? Will any digital health advancements be invoked and what are the data-driven resources?
- Approach.** Describe the overall strategy, methodology, and analyses to accomplish the specific aims of the project. Include preliminary studies, if appropriate.
 - Identify and describe the program/ treatment/intervention to be implemented and evaluated. Be sure to provide sufficient detail on the intervention itself and the pragmatic design for the intervention with reference to the publications providing evidence on the established efficacy of the intervention and need for a quality improvement evaluation or comparative effectiveness trial.
 - Describe the pragmatic data-driven approach and evaluation framework that informs the design and the outcomes being tested (e.g., the LHS model that will be used).
 - Describe the setting for your implementation, including readiness and capacity to implement the intervention as well as hospital partners and committees involved for approvals.

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- Describe the implementation strategies you will use and your consultation results with D&I launchpad.
 - Describe any consultations or expertise input accomplished to date. A priority is for quasi-experimental or pragmatic randomized clinical trials with an EHR-embedded approach. Sample size calculations should be included.
 - Rapid Plan Do Check Act (PDCA) Cycle: Include a plan for how a rapid PDCA cycle will ensue with the project, particularly in the context of stakeholder involvement, after the intervention is deployed. When writing this section, applicants should consider the following:
 - What factors influence the timeliness of final implementation or de-implementation within the allotted 12-month period?
 - How will you match the rigors of science with the timeliness for business needs and operations of a healthcare delivery system?
 - How will the tools and materials from your project be disseminated?
- f. **Special Criteria.** Applicants must address how they will incorporate the following special criteria in their research project.
- **Investigator – Health Partner collaboration:** The project involves a partnership between a clinical champion (PI) and a UW Health operational leader. What processes and mechanisms will be used to ensure continuous alignment between the clinical champion and health operations leader over the course of the project?
 - **Interdisciplinary collaboration:** The project involves developing a collaborative planning process and mechanisms to support interdisciplinary team involvement. What results came from ICTR's Team Science consultation to ensure interdisciplinary collaboration?

The required application components below do not count against your 6-page narrative.

7. **Timeline:** Earliest start-date for the award is September 1, 2024, and projects must be completed within 12 months of the start date. IRB approval and D&I Consultation should be completed before project work involving human subjects can begin.
8. **Literature citations:** Please attach a separate reference section.
9. **Letters of collaboration/support:** Please include *signed* (can be electronic) letters of support from the division chief/department chair for clinical champion and LOS from operational leadership (attesting to their willingness to support the project, as well as its acceptability, feasibility and resources UW Health will bring to the partnership). Also consider collaborators who are associated with the special criteria that you choose.

POST-AWARD REQUIREMENTS, CONSULTATIONS AND MEETINGS

PRESENTATION: The PI (clinical champion) is REQUIRED to meet with LHS leadership to coordinate LHS components with the ICTR Team Science Collaborative Planning process; Dissemination and Implementation Consultation; ICTR Biostatistics, Epidemiology, and Research Design (BERD) Consultation; ICTR Protocols Development, and the Center for Health Informatics Institute (CHI²). LHS leadership will meet with awardee in the first month of the award with plans to complete these

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activities with the first two months of the award date with follow-up quarterly progress reports. See details below for each of these components.

MANDATORY APPROVALS: UW Health Hospital Operations Committees that are required for the Demonstration Project (i.e., Nursing, Clinical Decision Support, Center for Clinical Knowledge Management, Clinical AI and Predictive Analytics, Inpatient Providers, Epic Super-User, etc.)

MANDATORY CONSULTATIONS:

D&I Consultation: A [consultation](#) with the [Dissemination & Implementation \(D&I\) Launchpad](#) is required to ensure projects produce generalizable knowledge and address health inequities.

[Biostatistics and Epidemiology Research Design \(BERD\) Consultation](#): A consultation with BERD scientists is required to ensure projects are designed to produce data of sufficient volume and quality to be used in scientific research around the effectiveness and scalability of the project intervention(s).

[Protocols Development Consultation](#): A meeting with the Protocols Development team regarding the project IRB submission and registration with ClinicalTrials.gov is required to facilitate swift and accurate navigation of the project through the necessary protocols for approval.

[Center for Health Informatics Institute \(CHI²\)](#): Consult with the Clinical Research Data Service (CRDS) to plan data extraction query and procedures.

TEAM COLLABORATION KICKOFF: PIs are required to attend and help lead a project Team Collaboration Kickoff workshop facilitated by the Team Sciences group. The purpose of this Collaborative Planning session is to bring together all LHS partner stakeholders to discuss project roles and responsibilities, as well as project timeline, process, research, and administrative functions.

BIWEEKLY PROJECT TEAM MEETINGS: Clinical Champion PIs and their LHS Clinical Operational Lead counterparts (Dyads) are required to meet at minimum every two weeks to ensure momentum behind project progress and to address any issues identified during project implementation.

QUARTERLY PI/TEAM MEETINGS WITH ICTR LHS DIRECTOR/TEAM: Quarterly meetings between the PI, Operational Co-lead/team and the ICTR LHS Director/Associate Director (Drs. Majid Afshar and Anne Gravel) are required to ensure project activities, progress and outcomes are documented effectively for reporting purposes. More frequent check-ins may be required depending on the project progress and timeline. **Quarterly reports** of those activities and outcomes, as well as a **Summative Report** to be shared by the project team at each quarterly meeting.

1. Summary W. *The Learning Healthcare System*. Washington, DC: National Academies Press; 2007.

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