

HICOR Expanding Clinical Trials Initiative

2025 Report

About Us

The Hutchinson Institute for Cancer Outcomes Research (HICOR), a multidisciplinary research institute at Fred Hutchinson Cancer Center, is led by health economist Scott D. Ramsey, MD, PhD, and medical oncologist Veena Shankaran, MD, MS. Our mission is to reduce the human and economic burden of cancer through stakeholder-informed research and the Value in Cancer Care Initiative, which engages providers, payers, policymakers and patients to improve cancer care delivery in WA state.

Acknowledgements

This work is the result of ongoing collaboration with community oncology clinics throughout the state of Washington who took the time to share their perspectives and research priorities with our team. We would like to thank the individuals at Fred Hutch departments for helping us connect with oncology practices and patient communities, and for providing advice and support towards this effort: Office of Community Outreach and Education (OCOE), Seattle Translational Tumor Research (STTR), Strategy, and Clinical Research Support.

We would like to sincerely thank the Fred Hutch Cancer Center for program funding.

To read this report online, visit FredHutch.org/HICOR

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The Expanding Clinical Trials Initiative



In 2023 HICOR launched a Fred Hutch funded program to expand cancer trial enrollment in Washington State. Our goal is to develop and deploy sustainable strategies that engage diverse communities in cancer research and accelerate statewide trial enrollment.

Building on HICOR's Value in Cancer Care (VCC) infrastructure and longstanding partnerships with Washington's oncology community, our program strategy is to:

- Reimagine clinical trials in our state by expanding their focus to include care delivery and survivorship studies.
- Enable all community oncology clinics in Washington to participate in this new trial infrastructure.
- Advance statewide enrollment through targeted strategies that resolve institutional barriers to research collaboration reported by community oncology sites.

Why Clinical Trials Matter

Cancer clinical trial participation improves patient outcomes and lowers costs for payers, yet fewer than 1 in 20 cancer patients in Washington enroll in a trial. Barriers are complex and include both patient and clinic-level challenges. Patients cite time and financial constraints, uncertainty about the experience, and limited opportunities from providers. Community oncology clinics may face significant administrative and financial hurdles, as well as concerns about study relevance to their practice and patient populations.

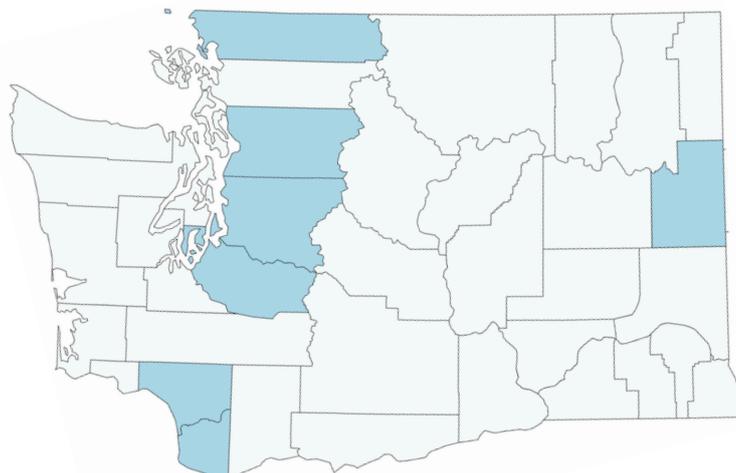
Executive Summary

Established in 2023, the Trials Expansion Initiative has launched six pilot studies and enrolled over 100 patients, addressing oncology clinic priorities while enhancing Fred Hutch’s research infrastructure to support streamlined clinical trial implementation across community sites.

Pilot Studies

Title	PI	Overview	Partnering Clinic(s)	Status
 DISCOVER*	Scott Ramsey	Assess the relationship between insurance status, health-related social needs, and symptoms during chemotherapy.		Accrual complete
 PAYMENT*	Veena Shankaran	Test a randomized intervention of unrestricted payments to cancer patients following diagnosis to improve outcomes.		Near activation
 PRO-ACTIVE	Erin Gillespie	Assess if virtual fitness program reduces cancer-related fatigue in patients undergoing radiation for breast cancer.		Accrual complete
 Talking About Cancer	Megan Shen	Assess if a remote training intervention helps patients with advanced cancer and their informal caregivers with advanced care planning.		Near activation
 REGENT	Hiba Khan	Assess feasibility, uptake, and patient/provider satisfaction of a remote, comprehensive germline genetic testing program.		In start up
 FLoC	Allison Cole	Assess the impact of a social prescribing intervention on cancer survivor loneliness, quality of life, and receipt of guideline-concordant survivorship care.		Enrolling

*Study supported by external funding



Studies active or opening in 7 counties

How We Work



Program Impact



Clinic-Investigator Matching

- Conversations with 11 oncology health systems revealed their top care delivery research priorities: care coordination, health equity, palliative and end-of-life care and patient navigation
- Launched targeted funding opportunities and successfully paired clinics with Fred Hutch (FH) investigators to conduct pilot studies



Strengthen Care Delivery Trial Infrastructure

- Worked with Finance department to increase options for participant payments
- Co-developed new protocol templates for observational and non-treatment interventional trials
- Partnered with Fred Hutch departments on Client Relationship Management Software launch to track research contacts at community clinics



Launch Trials

- Activated pilot studies at 11 community partner sites outside UW Medicine, improving geographic and demographic representation in FH clinical trials
- 108 participants enrolled across WA and AK
- Provided tailored study support for protocol development, regulatory submission, training, and pragmatic trial design to minimize clinic and participant burden

Future Opportunities

- Fund 2 new cancer care delivery (CCD) pilots in the catchment area each year
- Prioritize efforts to engage clinics and open more pilot studies in Alaska
- Conduct listening sessions with clinics in each region to refresh priority areas, match clinics with FH investigators, and co-develop 1–2 new study concepts
- Complete recruitment for all active pilots; convert successful pilot studies into R01s
- Partner with Philanthropy to sustain the program and engage local sponsors committed to improving cancer care in their communities

Project Implementation

HICOR leveraged more than a decade of partnerships with clinics and community stakeholders across Washington State to support the Trials Expansion program. To identify barriers to trial participation, our team engaged clinics individually, through the Value in Cancer Care (VCC) Summit, and via HICOR’s statewide VCC network. These connections enabled us to reach oncologists, nurses, coordinators, social workers, and others in nearly every oncology practice in the state. In-depth conversations with nine clinics highlighted key challenges, clinician and patient pain points, and research priorities.

We also hosted interactive sessions at the 2024 and 2025 VCC Summit to gather further community insights on cancer care delivery (CCD) obstacles and opportunities. Across these engagements, the team documented feedback and identified 8 recurring themes (see **Appendix A: Priority Areas**). These themes informed outreach to Fred Hutch investigators and guided the pilot study review process, helping us to assess proposed studies for alignment with community needs, develop clinic-investigator partnerships, identify opportunities to expand trial access, especially in rural or underserved communities across the catchment area.

To advance this work, HICOR partnered with Fred Hutch colleagues in provider outreach and research operations to ensure clinics could access the institutional resources needed to open trials (see page 5 for more details.)

**Community Clinic
Research Priority Areas:**

- Care Coordination
- Symptom Management
- Patient Navigation
- End of Life Care
- Cost of Care
- Health Equity
- Survivorship Care
- Organizational Challenges
- Palliative Care

Six pilot studies have been funded to date, with capacity for more in fiscal year 2026. For each study, HICOR collaborates with clinics to assess their operational needs, and with Fred Hutch investigators to deliver tailored research support. Depending on the project, HICOR may lead IRB submissions, contracting, site communications, and consenting - or provide targeted assistance while investigators and their research teams manage these tasks independently. This flexible approach has made pilot study participation accessible to a broad pool of researchers, especially those who are junior or new to Fred Hutch.

“We are getting ready to start enrolling patients in the Talking About Cancer study in the next few weeks! I wanted to reach out and ask if there are any other opportunities for other trials we could open here this year.”

— Krystal Hartman, BSN, RN,
Clinical Research Nurse, Skagit Regional Cancer Care Center

Our Impact

Key Accomplishments

- **Clinic–Investigator Matching:** Successfully paired interested clinics with FH researchers
- **Hands-On Study Enablement:** Supported CCD study design, protocol development, IRB preparation, contracting, site training, and pragmatic recruitment strategies that minimize clinic burden
- **Statewide Reach & Non-UW Sites:** Activated community partners at 10 clinics within 5 health systems beyond UW Medicine, improving geographic and demographic representation
- **Operational Agility:** Adapted support for clinics from light-touch regulatory guidance to full project coordination based on each site’s infrastructure and needs

Organizational Success

HICOR has worked collaboratively with Fred Hutch departments to identify and solve operational barriers to implementing cancer care delivery research in community clinics.

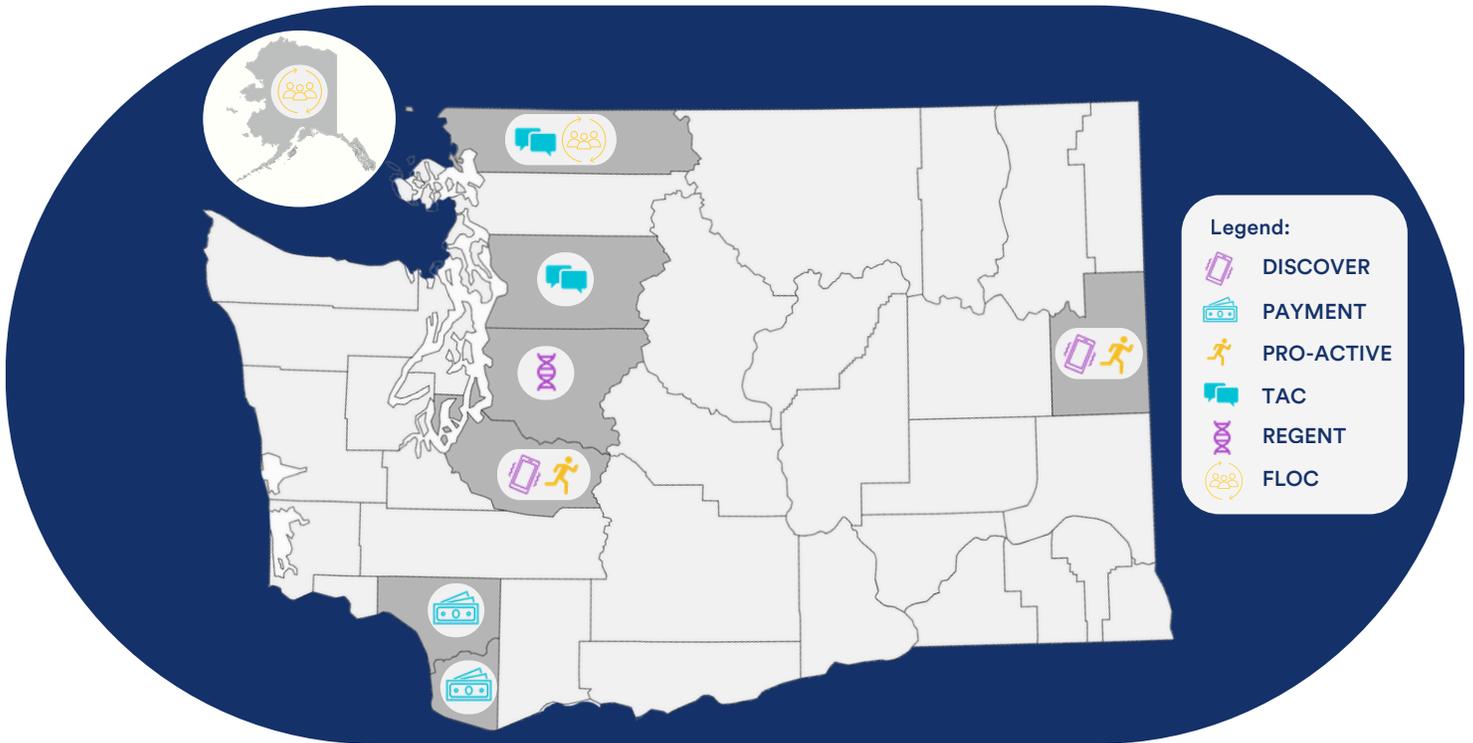
Barrier	Solution
Limited options for participant payments	<ul style="list-style-type: none"> • Worked with finance to get approval for a reloadable debit card option that allows for more flexibility in providing and managing study payments
Scientific review process not optimized for non-treatment studies	<ul style="list-style-type: none"> • Co-developed protocol templates for observational and non-treatment interventional trials
CCD data collection methods and options	<ul style="list-style-type: none"> • Leveraged REDCap builds and qualitative research support via CDS
Relationship management	<ul style="list-style-type: none"> • Launched Client Relationship Management (CRM) software to track clinic contacts and study opportunities
Contracting with community sites	<ul style="list-style-type: none"> • Worked with the Office of General Counsel (OGC) to develop a performance site agreement template for community partners
Coordinating across multiple internal workstreams	<ul style="list-style-type: none"> • Participated in the development of the enterprise CRM • Collaborated on clinic outreach efforts with Strategy, Network & Outreach (SNO) • Distributed Request for Applications (RFA) for pilot study funding opportunities

Key Accomplishments

The HICOR team provides start up support to pilot award recipients, meeting early with awardees to identify how to speed study launch. Support ranges from light-touch regulatory and administrative guidance to full project coordination for sites or investigators with limited research infrastructure. Our team assists with tasks such as contracting, IRB submissions and site training, drawing on deep experience in CCD research to help address common barriers and advise on budgeting and recruitment strategies that minimize clinic burden, such as having Fred Hutch staff carry out intervention and follow up activities remotely. We leverage our VCC network connections to facilitate clinic buy-in and communication. Our efforts to pair Fred Hutch study teams with interested clinics in Eastern WA and other remote parts of the catchment area have directly contributed to patient recruitment in these regions.

- 6** pilot studies launched
- 2** completed studies with > 95% enrollment target met
- 108** participants enrolled across 3 open studies since 2024
- 25%** of participants enrolled from sites serving majority rural populations in Eastern WA and on the peninsula

Below: Map of recruiting clinic locations. As per the legend, some clinics operate multiple locations.



- 1** R01 under review based on pilot study data
- \$300,000** in pilot funding awarded
- 2** abstracts in development
- \$574,998** in external research funding awarded
- 11** community oncology clinics participating across WA and AK
- 3** studies scheduled to begin recruiting in 2026

Reflections and Road Ahead

What We Have Learned

- Clinics favor **readymade studies** aligned to their priority areas
- Investigators benefit from **startup support** (IRB, contracting, budgets, recruitment)
- Remote/centralized interventions (e.g., monitoring, telehealth) help to **reduce the clinic workload** while reaching rural patients, critical for catchment-wide equity and Cancer Center Support Grant (CCSG) aims

Future Opportunities

In the coming year we plan to build on our success expanding access to clinical trials for Washington State’s community clinics and patients through collaborative community-driven research projects. HICOR will continue to provide support to research teams that includes contracting, protocol development, IRB preparation, and the operational infrastructure needed to bring the research to life. Below are some specific activities planned for the next year of the Initiative.



Clinic-Investigator Matching

- Conduct listening sessions with clinics in each region to **refresh priority areas** and co-develop 1–2 **new study concepts**



Strengthen Care Delivery Trial Infrastructure

- Apply blueprint established in WA to build connections with community clinics and **explore research opportunities in Alaska**
- Partner with Philanthropy to sustain the program and **engage local sponsors** committed to improving cancer care in their communities
- Continue enterprise collaborations that **remove process friction**



Launch Trials

- Complete recruitment for all active pilots; **convert successful pilots into R01s**
- **Fund 2 new CCD pilots** in the catchment area
- Leverage opportunities to **scale studies nationally** within SWOG/NCORP



Appendix A: Priority Areas

This table outlines the research priority areas identified through interactive sessions with 11 community clinics.

Coordination of Care

Challenge	Example	Potential care delivery research focus
Delays from referral to oncology	Primary Care Providers (PCPs) refer to non-cancer specialists before oncology consult, prolonging time to diagnosis	Test interventions to streamline referral pathways
Missed incidental findings	Incidental findings from Emergency Department (ED) or pre-op not consistently captured in the Electronic Health Record (EHR)	Develop and evaluate EHR-based prompts or workflows to ensure follow-up of incidental findings
Limited availability of real-time clinical data	Reduces opportunities for risk analysis or triage for treatment side effects	Pilot remote symptoms and risk monitoring tools that could be integrated into clinic workflows
Fragmented coordination across systems	Inconsistent after-hours coverage with unclear roles for care managers and pharmacists	Assess models of shared after-hours coverage and navigation support
Lack of adherence to clinical pathways	None provided by clinics	Explore evidence-based clinic-level interventions to improve adherence

Symptom Management

Challenge	Example	Potential care delivery research focus
Monitoring symptoms	No remote monitoring for bio specific in immunotherapy	Develop and test remote monitoring interventions
ED overuse	Uncontrolled symptoms contribute to potentially avoidable ED visits during treatment	Remote symptom monitoring and targeted patient education

Patient Navigation

Challenge	Example	Potential care delivery research focus
Mental health support	Patients cannot reach providers in time to discuss symptoms and receive care	Telehealth programs to increase timely access to mental health services
Lack of knowledge about what tests to order	Providers may not know which genetic tests to order, when to order them, or how to act on the results	Physician education and training on appropriate test ordering and result interpretation
Vaccine navigation	Clinics cannot always administer the HPV vaccine when and where patients need it	Partner with community pharmacies to expand access

End of Life Care

Example

Challenge	Example	Potential care delivery research focus
Lack of palliative care uptake	Patients and families lack awareness of palliative care or associate it with “giving up”	Develop and test patient-facing educational tools and approaches
Provider not equipped to offer services	Providers are reluctant or feel unprepared to initiate early conversations with patients and families	Develop and test provider-facing, culturally competent educational tools and training
Palliative care offered too late	Patients do not have access to palliative care early in the treatment course	Evaluate models that integrate palliative care earlier in the care pathway

Cost of Care

Challenge	Example	Potential care delivery research focus
Frequency of ED visits	Prior authorization rules for growth factors and generic drugs limit providers’ ability to prevent ED visits during treatment	Track denials and compare outcomes in a small cohort of patients with and without prior authorization requirements
Limited access to germline testing	Insurance coverage restrictions and requirements create cost barriers	Test interventions to improve cancer patients’ access to germline testing

Health Equity

Challenge	Example	Potential care delivery research focus
Data collection	Missing race and ethnicity data limits the clinic’s ability to assess equity of care	Test strategies to improve completion of demographic surveys and explore alternative methods to capture these data
Caring for rural patients	Patients in remote areas have difficulty accessing care	Telehealth and remote monitoring interventions

Survivorship Care

Challenge	Example	Potential care delivery research focus
Management of side effects	Limited options for addressing long term side effects	Assess and compare approaches for managing long-term side effects

Organizational Challenges

Challenge	Example	Potential care delivery research focus
Specialty staffing	Limited access to specialists leads to delays in screening, treatment, diagnostic workup, and managing death-with-dignity requests	Telehealth programs to expand access to high-demand specialties

Appendix B: Pilot Studies

Title	PI	Overview	Enrollment	Partnering Clinic(s)
<p>DISCOVER*</p>  <p>Use of an app and biosensor to address disparities during chemotherapy for unplanned visits to the emergency department</p>	Scott Ramsey	<p>Assess the relationship between insurance status, health-related social needs, and symptoms during chemotherapy.</p> <p>Coordination of Care, Symptom Management</p>	62/60 Complete	<p>MultiCare </p> <p>Spokane and Puget Sound</p>
<p>PAYMENT*</p>  <p>Preventing financial Adversity among Early-stage cancer patients through unrestricted cash</p>	Veena Shankaran	<p>Test a randomized intervention of unrestricted payments to cancer patients following diagnosis to improve outcomes.</p> <p>Cost of Care</p>	Target: 20	<p> PeaceHealth</p> <p>Vancouver and Longview</p>
<p>PRO-ACTIVE</p>  <p>Leveraging digital health to promote evidence-based physical activity to improve symptoms among patients undergoing radiation for breast cancer</p>	Erin Gillespie	<p>Assess if virtual fitness program reduces cancer-related fatigue in patients undergoing radiation for breast cancer.</p> <p>Symptom Management</p>	40/40 Complete	<p>MultiCare </p> <p>Spokane and Puget Sound</p>
<p>Talking About Cancer</p>  <p>Community-Engaged Development of Talking About Cancer (TAC) to Improve Engagement in Advance Care Planning</p>	Megan Shen	<p>Assess if a remote training intervention helps patients with advanced cancer and their informal caregivers with advanced care planning.</p> <p>Coordination of Care, End of Life Care</p>	Target: 40	<p> Skagit Regional Health</p> <p>Mount Vernon</p> <p> Providence</p> <p>Everett</p>
<p>REGENT</p>  <p>Remote comprehensive Germline Genetic Testing – Prostate</p>	Hiba Khan	<p>Assess feasibility, uptake, and patient/provider satisfaction of a remote, comprehensive germline genetic testing program.</p> <p>Patient Navigation/Coordination of Care, Provider/Staff Scarcity</p>	Target: 50	<p> Virginia Mason Franciscan Health</p> <p>Burien</p>
<p>FLoC</p>  <p>Fred Hutch study of Loneliness in Cancer Survivors</p>	Allison Cole	<p>Assess the impact of a social prescribing intervention on cancer survivor loneliness, quality of life, and receipt of guideline-concordant survivorship care.</p> <p>Survivorship Care</p>	6/26 Open	<p> Skagit Regional Health</p> <p>Mount Vernon</p> <p> PeaceHealth</p> <p>Ketchikan, AK</p>

* DISCOVER is funded by the Andy Hill Care Fund, PAYMENT is funded by SWOG

Advisory Board

Our Advisory Board members provide strategic input to the initiative by troubleshooting key challenges and offering feedback on pilot proposals and emerging research ideas. They also help develop strategies to engage researchers and ensure the program's work remains relevant and impactful for community oncology settings.



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HICOR extends gratitude to all of the community clinics participating in Trials Expansion pilot studies:



Virginia Mason
Franciscan Health

Burien



PeaceHealth

Vancouver, Longview, Ketchikan



Providence

Everett



Skagit Regional Health

Mt. Vernon



Downtown Tacoma, Auburn, Gig Harbor,
Puyallup, Cancer Institute Spokane



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