



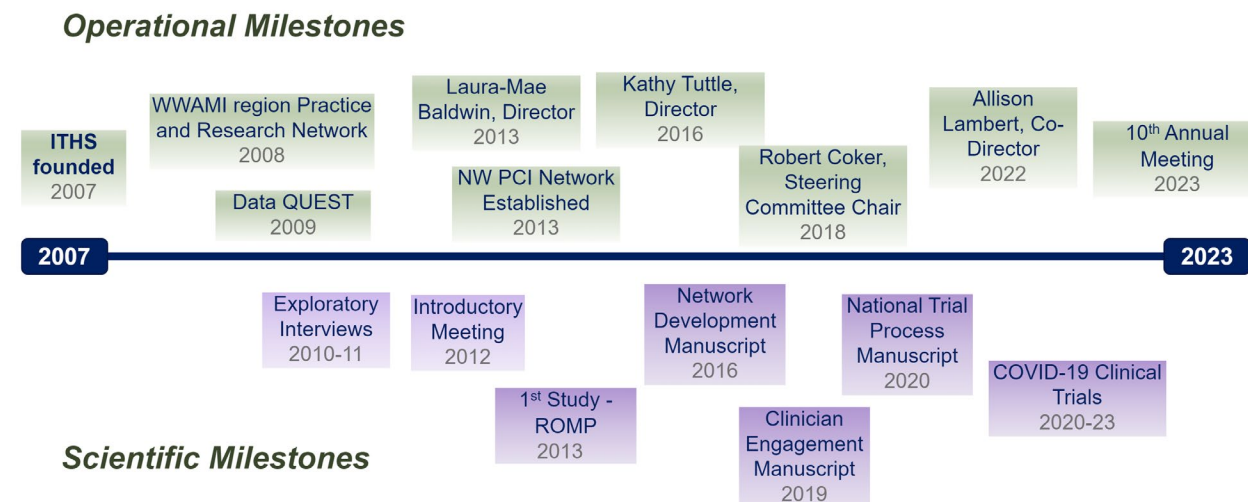
Expanding Access to High Quality Clinical and Translational Research:

A Summary of Northwest Participant and Clinical Interactions Network Efforts and Impacts 2013-2023

Background

The Northwest Participant & Clinical Interactions (NW PCI) Network is a collaborative group of seventeen clinical and translational research centers, affiliated with medical centers, health systems and universities dedicated to connecting diverse populations with local high-quality research. Founded in 2013, the NW PCI Network began with a desire to bring together research organizations to collaborate on the translation of health innovations for the benefit of patients across Washington, Wyoming, Alaska, Montana and Idaho (WWAMI). Beginning with interviews among research administrators and investigators to understand more about regional research needs and resources, an introductory meeting of several sites to describe their research, and a deep understanding of and extensive experience with clinical research, a common interest in conducting more grant-funded, investigator-initiated research emerged.¹ The timeline below in Figure 1 describes key network milestones.

Figure 1: NW PCI Network Milestones



The Institute of Translational Health Sciences, funded by a Clinical and Translational Science Award from the National Institutes of Health (NIH),^{2,3} supported establishment and ongoing network administration. The NW PCI Network is unique among other research networks in that it is disease agnostic, without a focus on a specific disease or condition, and there is no contractual arrangement between the coordinating center and the member sites. NW PCI sites are dedicated to research, and collaborate in good faith, even across member sites that are business competitors.

Network success can be attributed in large part to the governance of the Steering Committee and Network leadership, consisting of regional research experts in clinical and translational science from member sites. Together, the NW PCI Network Steering Committee, regional leaders, coordinating center staff and Network members have developed trusting and collaborative relationships which have enabled the expansion of research capacity, the inclusion of rural and remote populations, and the conduct of highest quality research across the WWAMI region.

Introducing the Bonnie Ramsey Northwest Participant and Clinical Interactions Network Keynote Lectureship

Dr. Bonnie Ramsey, a dedicated and distinguished pediatric pulmonologist is a co-founder of the NW PCI Network. The highly successful Cystic Fibrosis Therapeutics Development Network, directed by Dr. Ramsey served as an important model for development of the NW PCI Network. Founders relied heavily on Dr. Ramsey's experience and expertise. Dr. Ramsey fully understands the importance of equal, multidirectional partnerships and the NW PCI Network policies and procedures reflect this vision. The NW PCI Network benefits daily from Dr. Ramsey's advocacy and representation at the ITHS Executive Committee as the Network has become an integral part of the ITHS.

In honor of Dr. Ramsey's many contributions, the NW PCI Network is pleased to announce the Bonnie Ramsey Northwest Participant and Clinical Interactions Network Keynote Lectureship. Beginning this year, all future keynote lectures at the NW PCI Annual Meeting will honor Dr. Ramsey's legacy and serve as a reminder of the importance of "meeting people where they are." Congratulations on your retirement, Bonnie! You have our gratitude and best wishes!



Building Successful Research Collaborations

Much of the work of the NW PCI Network involves collaborating with investigators across the WWAMI region and nationally. Beginning with the Research on Medical Process or ROMP study in 2013, 165 matches between NW PCI Network sites and other collaborators have been created; 47% of which involve NW PCI sites serving large rural populations. The submission of 62 grant applications were supported by the NW PCI sites and coordinating center, resulting in 28 funded awards for a total of \$96 million.

Network sites also collaborated with each other to conduct original research on the engagement of regional clinicians in research⁴ and develop new procedures to enable NW PCI sites to participate in and gain access for their patients to large multisite clinical trials emanating from the National Institutes of Health.⁵ A significant outcome of this work is the criteria through which other ITHS partners can assess

new study opportunities for feasibility within NW PCI sites and relevance to regional patient populations. These criteria are used by members of the ITHS Hub Liaison Team to triage new opportunities before distribution of study information to site champions. A summary of national multisite trial activity is shown in Table 1.

Table 1: Summary of National Multisite Trial Activities 2019-2022
23 national multisite trial opportunities*
17 studies matched with 37 sites (40% serving significant rural patient populations) ^
3 studies have pending site selection
10 studies are onboarding, ongoing or complete
3 studies were matched but funding was not awarded
1 study was distributed with no interested NW PCI sites
7 studies did not meet criteria for site distribution

* Through the ITHS Hub Liaison Team and other Contacts

^ Three non-NW PCI sites onboarded to 3 studies with NW PCI coordinating center support

Expanding Research Capacity

The COVID-19 pandemic had immediate and catastrophic impacts on research across the WWAMI region and the world. NW PCI sites quickly mobilized to hold working sessions to discuss procedures for pausing studies, notifying research volunteers, and defining infection control protocols for study procedures that could not be halted. NW PCI Network sites, coordinating center and infrastructure (e.g., policies, procedures) were tested as never before, resulting in innovations improving study startup speed⁶, and standardized use of remote technologies in research.

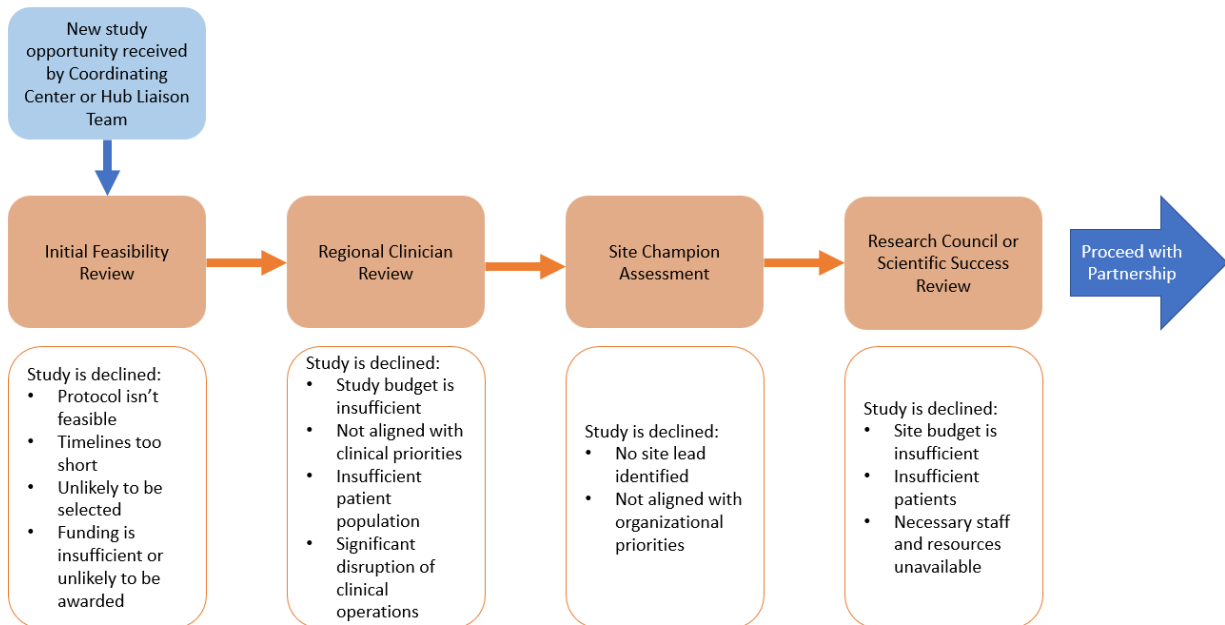
Infrastructure developed for assessment of national multisite clinical trials was critical to the rapid dissemination of the NIH COVID-19 platform trials to the NW PCI Network sites. The ITHS Hub Liaison Team collaborated with the national coordinating centers to disseminate consolidated information, adapt electronic health record queries and submissions to be both feasible and time-efficient for NW PCI Network sites, and submitted feasibility questionnaires and other start-up materials on behalf of the Network. Distribution of these trials afforded patient access to scarce study drugs and were critical to the development of the novel therapies that are now standard of care for treating patients with SARS-CoV-2. Through this process, twelve NW PCI sites were matched to eight COVID-19 studies, including an ongoing “long COVID” study and two others that have extended beyond COVID-19 to address other causes of severe viral pneumonia.

Ensuring High Quality, Accessible Research

The NW PCI Network employs a 3 to 4-tiered assessment process with each new study opportunity involving 1) initial feasibility review by coordinating center or Hub Liaison Team staff using study feasibility assessment criteria co-developed with NW PCI sites, 2) review by regional clinicians to ensure clinical relevance, 3) assessment by site champions to determine interest and site-specific relevance, and 4) review by on-site research councils or “Scientific Success Committees” (Figure 2).⁴ Scientific Success Committees and research councils are operated by many NW PCI sites and typically focus on alignment with organizational priorities, availability of the patient population, budget, and necessary internal resources (e.g., staffing, study drug management). This rigorous vetting process occurs prior to sites’

commitments to collaborate on any study and is an efficient and effective method of filtering out potentially problematic studies.

Figure 2: Vetting Process for New Study Opportunities



NW PCI Network Annual Meetings are also an integral part of ensuring high quality, accessible research and provide opportunities for professional development and networking. All Annual Meeting participants serve as both teachers and learners by sharing best practices, identifying and addressing emerging issues impacting sites, working together to solve problems, and providing opportunities for professional development. Thematic foci provide structure and continuity of topics from keynote lectures to panel discussions to small group sessions and have addressed areas such as racism and diversity, research as a driver of health care, and climate change impacts on health. Working sessions, called Learning Laboratories, are focused on specific issues requiring the diverse perspectives of Network members. Topics have included development of new projects or research infrastructure, engaging patients in research, remote research technologies, improving study startup, increasing diversity in research, training research staff, and predicting financial outcomes of new study opportunities.

Current and Future Initiatives

Collaborative Quality Improvement Initiative is a NW PCI Network-wide initiative to partner on multisite quality improvement (QI) initiatives to strengthen research operations across the WWAMI region. This initiative involves an environmental scan to identify opportunities for quality improvement, development of a data dashboard to enable tracking of QI metrics, data governance, and dissemination of results.

Increasing the Diversity of the Research Workforce brings together Network sites, the Coordinating Center, and new partners within the ITHS and across the region. The ITHS is developing curricula to build awareness about research careers and training research coordinators. Collaborations with state and regional networks involved in workforce development (e.g., IDEA Networks for Biomedical Research Excellence, Area Health Education Centers) will establish a pipeline of diverse trained research personnel

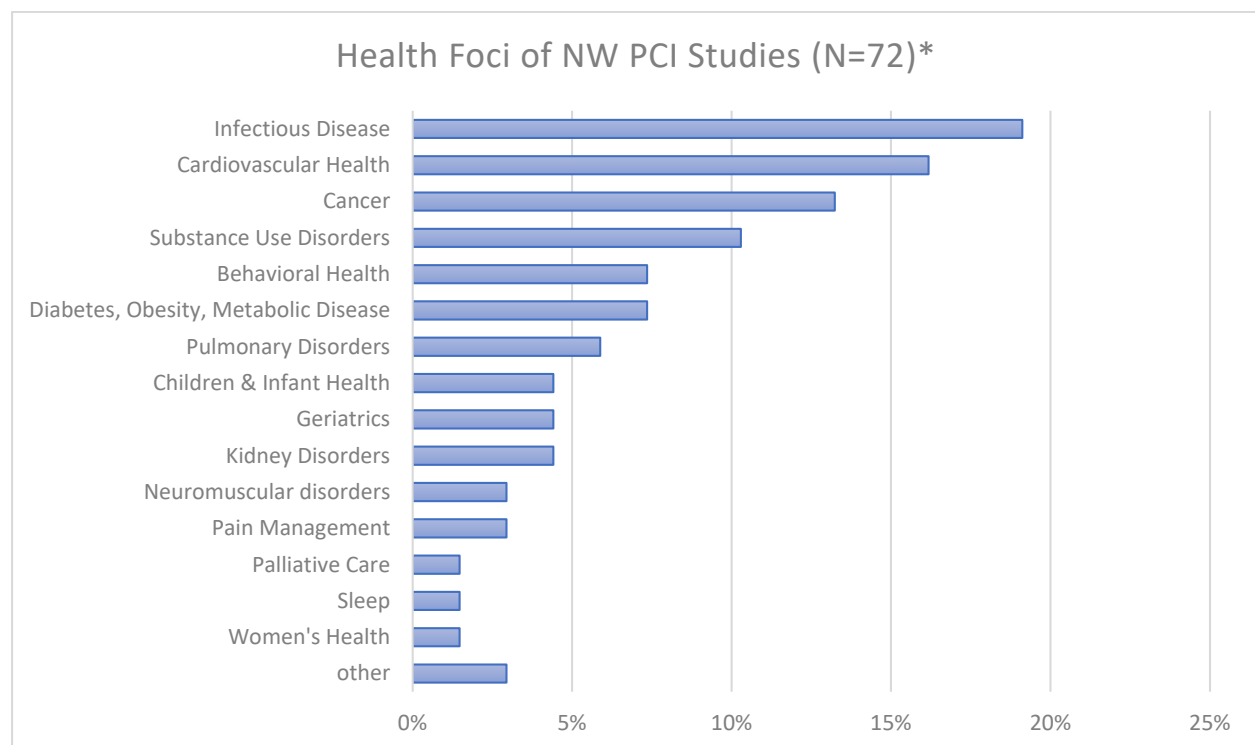
and meet a critical staffing need at many NW PCI sites. We are working with ITHS administration to increase awareness of and access to NIH Diversity Supplement Funding for NW PCI Network investigators.

Patients as Partners is an ongoing effort to integrate patients and research volunteers into the NW PCI Network to ensure research efforts include and are informed by diverse communities, especially those experiencing health disparities and systemic racism and are underrepresented in research. This work involves training of community members and investigators, supporting funding opportunities for NW PCI site investigators (e.g., diversity supplements), facilitating development of community-academic partnerships, and integration of patients into the NW PCI Network Annual Meeting, Steering Committee and Scientific Success Committees.

Summary

The last decade has been eventful. The NW PCI Network has consistently worked together to enable local populations to participate in high quality research across the WWAMI region, through building collaborative research partnerships addressing a wide spectrum of health concerns (Figure 3), gaining access to national multisite clinical trials, and enabling rapid access to study medication during the worst of the pandemic. The NW PCI Network improves the quality of research across the continuum from training investigators to develop feasible and relevant protocols, reviewing new study opportunities and collaborating across the Network on best practices and quality improvement.

FIGURE 3: Primary Health Foci of NW PCI Studies



*Included are NW PCI supported studies with a primary health focus. Some studies may have additional health foci. Other studies (e.g., health information technology, workforce development) are not included.

The foundation built over the last 10 years has well prepared the NW PCI Network for the future. Efforts to collaborate on quality improvement initiatives are expected to continue well into the next decade. Similarly, creating a pipeline of trained and experienced research staff and fully integrating patients into all aspects of Network operations and research are long-term endeavors. All the while, research will continue to happen and the NW PCI Network will be at the forefront, ensuring patients and communities have access to and confidence in the WWAMI region research enterprise.

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