Expanding Diversity through Innovation: Development of the I-SPY ACCESS Initiative for the I-SPY2.2 and DCIS RECAST Clinical Trials

Sara Horton, MD[1]; Dame Idossa, MD[3]; Kelly Hewitt, MD[2]; Laura J. Esserman, MD, MBA[4]

[1] Quantum Leap Healthcare Collaborative, San Francisco, CA; [2] Huntsman Cancer Institute, University of Utah, Salt Lake City, UT; [3] Mayo Clinic, Rochester, MN; [4] UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA



Abstract

Since its inception, the I-SPY adaptive platform has prioritized diversity. The I-SPY ACCESS initiative advances inclusion by supporting nontraditional sites through tailored feasibility/readiness assessments, streamlined regulatory process, discipline-specific training (pharmacy, imaging, pathology/RCB). provision of multilingual materials, and remote coordination capacity (virtual CRCs).

Introduction

Underrepresentation of racial/ethnic minorities, lower-socioeconomic groups, and rural patients limits the generalizability and equity of oncology trials.[1] The **I-SPY** platform uses serial MRI and biomarkers to adapt therapy in early breast cancer, providing infrastructure to test operational solutions that reduce participation barriers.[2-4] **I-SPY 2.2** advances this adaptive approach, while **DCIS RECAST** evaluates personalized, lower-burden strategies for DCIS (endocrine therapy with long-term monitoring/active surveillance).[5–7]

The **ACCESS** initiative enables safety-net, community, and rural sites to participate through feasibility/readiness assessments, tailored supports (virtual CRCs; central-IRB templates; pharmacy, imaging, and pathology/RCB training), multilingual education, and advocate peer support—establishing process metrics now and positioning evaluation of activation speed, accrual diversity, retention, and data quality as sites mature.

Methods and Materials

The ISPY ACCESS program selects candidate sites and guides them through a structured activation process. Gaps and identified barriers trigger tailored support, followed by onboarding and early-operations coaching.

Site Selection Feasibility and Readiness:

Identify institutions serving underrepresented communities"

- Assess demographics and research commitment
- Confirm operational readiness in alignment with I-SPY standards.

Tailored Support Package:

Satellite Site Model: Pair with established I-SPY sites to access capabilities (e.g., MRI workflows) that may be cost-prohibitive to build locally.

Enhancements: Targeted support for facilities, technology, and equipment to meet trial specifications and protect patient safety.

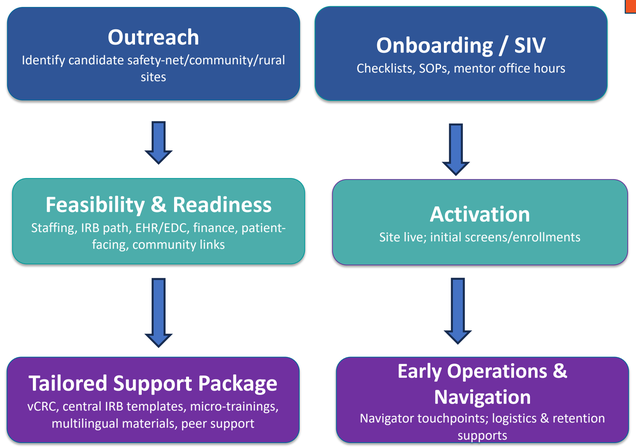
Training & Education: Focused training for investigators, research staff, and coordinators to ensure protocol adherence and quality.

Patient Barrier Mitigation (standardized toolkit).

Transportation: Partnerships or vouchers for reliable, affordable transport

Financial Evaluation: Systematic review of potential out-of-pocket or unforeseen costs; connect sites/patients to assistance resources.

Patient Support: Facilitate navigation for language, cultural, and educational needs through curated materials



Results

I-SPY 2.2: 7 ACCESS sites have been identified of which 2 are activated & enrolling.

DCIS RECAST: 1 ACCESS site activated; 11 additional sites in onboarding.

Discussion

Early implementation of this process highlights staffing/coordination and patient-facing domains as frequent feasibility gaps.

ACCESS addresses these with virtual CRC coverage, central IRB templates, discipline-specific training (pharmacy, imaging, pathology/RCB), and advocate-supported patient engagement.

This process-first model strengthens readiness now and enables later evaluation of accrual diversity and retention.

Conclusions

The ISY ACCESS program confirms that opening complex and innovative clinical trials at safety net, rural, and/or low resourced health care systems is feasible.

To promote equity and accessibility in clinical trials, it is essential that these trials are offered to patients within the settings where they receive their care.

Contact

Sara Horton, MD
Quantum Leap Healthcare Collaborative
Email: s.horton@quantumleaphealth.org
Website: quantumleaphealth.org
Phone: 202-276-2488

This presentation is the intellectual property of the author/presenter. Contact them at <<your email address>> for permission to reprint and/or distribute.

1. AACR Cancer Disparities Progress Report: https://cancerprogressreport.aacr.org/disparities/
2. I-SPY overview (QLHC): https://www.quantumleaphealth.org/for-patients/i-spy-trials/about-i-spy-2/
3. I-SPY 2 imaging collection (TCIA): https://www.cancerimagingarchive.net/collection/ispy2/
4. Adaptive platform design background: https://pubmed.ncbi.nlm.nih.gov/19440188/
5. DCIS RECAST (QLHC—investigators): https://www.quantumleaphealth.org/for-investigators/recast-dcis/
6. DCIS RECAST (ClinicalTrials.gov): https://clinicaltrials.gov/study/NCT06075953
7. DCIS RECAST (QLHC—patients): https://www.quantumleaphealth.org/for-patients/i-spy-recast-dcis-patient

© POSTER TEMPLATE BY GENIGRAPHICS® 1.800.790.4001 WWW.GENIGRAPHICS.COM