

Deploying the Enterprise-Wide Project Manager:

Disease Group-Driven Clinical Trial Expansion to Regional Research Sites

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Background

Health System Expansion

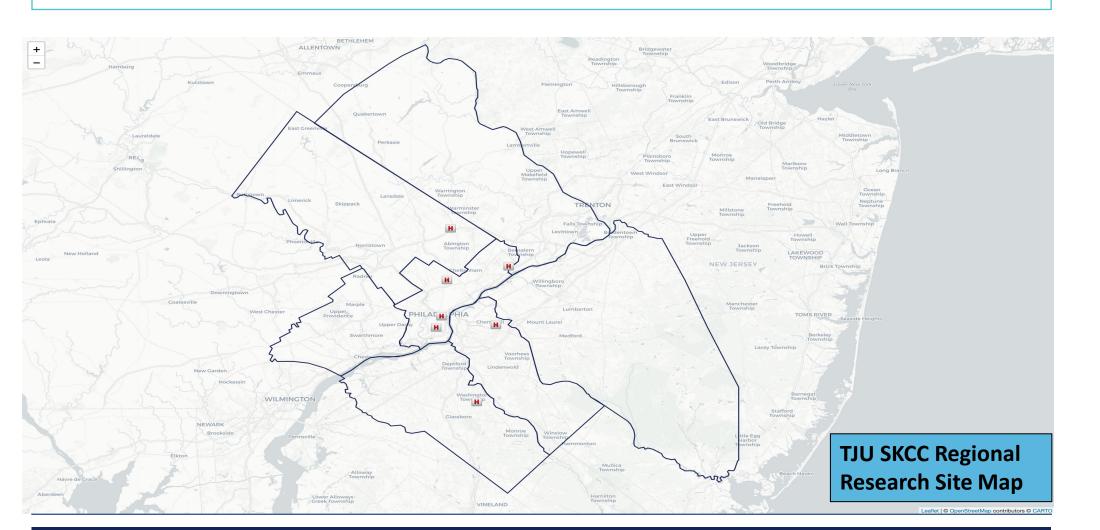
- Rapid expansion of Jefferson Health to 17 hospitals
- Sidney Kimmel Cancer Center (SKCC) expands clinical trial access across the enterprise & out into the community

Enterprise-Wide (E-W) Pilot

- 4 community clinical trial sites across Jefferson enterprise
- Began with pilot of E-W Breast and Gynecological multidisciplinary disease groups (MDGs)
- Pilot successful but model now expanding to 10 MDGs

Regional Research Sites (RRS)

- 4 community locations where clinical trials occur across SKCC catchment area beyond central hub (Center City)
- Potential for increased accrual & improved patient access



Goals

Review successes and barriers to E-W MDG expansion

Develop standardized toolkit to support MDG PM in moving E-W

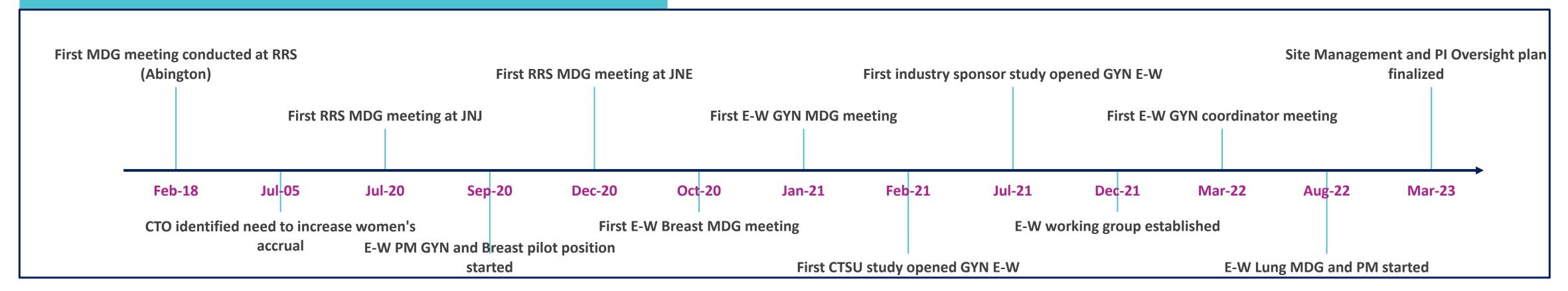
Track E-W clinical expansion by MDG

Solutions and Methods

- 1. Standardization of process documents to reflect E-W involvement (e.g., PI Oversight Plan, start-up checklists)
- 2. E-W MDG and staff meeting participation
- 3. REDCap survey to assess physician and PM buy-in
- 4. Trial database analysis of E-W trial activation and accrual by MDG

Outcomes

E-W PM Role Development Timeline

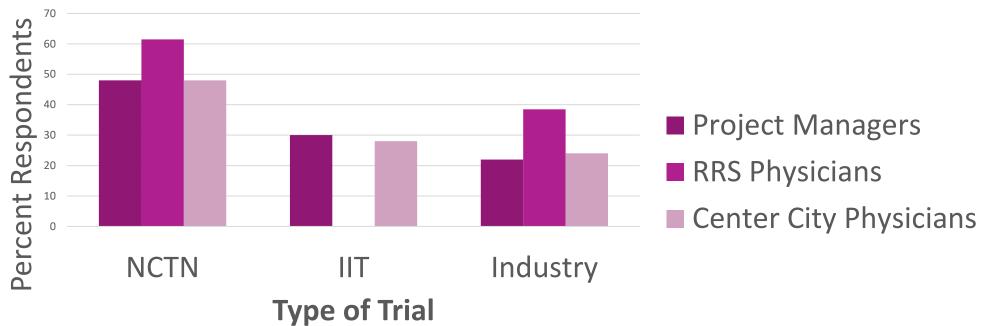


Physician and PM Survey Results

Current Challenges to Opening E-W Trials

Stakeholder	Key Challenges
Research PMs	 Staffing bandwidth RRS capacity for complex trials Sponsor support Nursing coverage for long PK days
RRS Physicians	 Lack of dedicated academic time Staffing bandwidth Need for streamlined study start-up
Center City Physicians	 Staffing bandwidth RRS capacity for complex trials Lack of RRS physician engagement Need for streamlined study start-up

Type of Trial Best Situated to Open at RRS



E-W Feasibility Packet

- Tool for increasing efficiency and decreasing timelines for clinical trial feasibility and study start up
- Reduce start-up burden for all SKCC sites and sponsors

Current Trial Activity Across Regional Research Sites

New Trials Opened by Sites per Year *As of May 3, 2024	2021	2022	2023	2024
Center City	57	69	78	33
Abington	13	13	21	10
Einstein	0	0	2	1
New Jersey	3	3	4	4
Northeast	10	12	4	0

Lessons Learned and Future Directions

Lessons Learned

- Expansion to community sites is a multi-year journey
- Requires process standardization at enterprise-level
- Physician buy-in is key, but contrasting physician priorities between central hub and community sites
- Enhanced staffing capacity key to supporting E-W shift
- Importance of E-W education and buy-in
- NCTN and institutional trials best situated for initial trial expansion to community sites

Future Directions

- Partnering with physician leadership to create engagement plans tailored to community and central hub physicians
- Systematic Sponsor engagement
- Continued rollout of successful E-W pilot to all MDGs

