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

**Outcomes**

**E-W PM Role Development Timeline**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Dates</th>
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<tbody>
<tr>
<td>First MDG meeting conducted at RRS (Abington)</td>
<td>Feb-18</td>
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<tr>
<td>First RRS MDG meeting at JNU</td>
<td>Jul-05</td>
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<tr>
<td>First RRS MDG meeting at JNE</td>
<td>Jul-20</td>
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<tr>
<td>First E-W GYN MDG meeting</td>
<td>Sep-20</td>
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<tr>
<td>First E-W Breast MDG meeting</td>
<td>Dec-20</td>
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<tr>
<td>First industry sponsor study opened GYN E-W</td>
<td>Oct-20</td>
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<tr>
<td>Site Management and PI Oversight plan finalized</td>
<td>Jan-21</td>
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<tr>
<td>First E-W GYN coordinator meeting</td>
<td>Feb-21</td>
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<tr>
<td>First RRS MDG meeting at JNE</td>
<td>Jul-21</td>
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<tr>
<td>First E-W working group established</td>
<td>Dec-21</td>
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<tr>
<td>First CTSU study opened GYN E-W</td>
<td>Mar-21</td>
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<tr>
<td>E-W working group established</td>
<td>Aug-22</td>
</tr>
<tr>
<td>First E-W GYN coordinator meeting</td>
<td>Mar-23</td>
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**Physician and PM Survey Results**

**Current Challenges to Opening E-W Trials**

<table>
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<tr>
<th>Stakeholder</th>
<th>Key Challenges</th>
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</table>
| 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**

- NCTN
- IIT
- Industry

- 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

**Lessons Learned and Future Directions**

- 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
- 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

**Current Trial Activity Across Regional Research Sites**

<table>
<thead>
<tr>
<th>Site</th>
<th>New Trials Opened per Year</th>
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| Center City | 2021: 57  
2022: 69  
2023: 78  
2024: 33 |
| Abington | 2021: 13  
2022: 13  
2023: 21  
2024: 10 |
| Einstein | 2021: 0  
2022: 0  
2023: 2  
2024: 1 |
| New Jersey | 2021: 3  
2022: 3  
2023: 4  
2024: 4 |
| Northeast | 2021: 10  
2022: 12  
2023: 14  
2024: 0 |

**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