Category: Cross-cutting Innovation and Collaboration – Completed project

Decentralizing Oncology Treatment Trials at Local Safety Net Hospital to Increase Under-Represented Minority Enrollment with Hub and Spoke Model

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1. Background
Under-Represented Minority (URM) recruitment in oncology treatment trials remains problematic despite vested interest by involved parties (industry, academic, patients, providers, government). These patients face limited access due to proximity of centers offering trials, low socio-economic status and insurance. Ingalls (local safety net hospital) service area includes 73.6 percent African American/Black, 4.0 percent biracial, and 7.8 percent Hispanic with a median household income of $52,563 and poverty rate of 18.7 percent.

2. Goals
Ingalls conducted a small number of clinical trials as an independent site prior to a merger with University of Chicago Medicine (UCM) in 2016, but the goal (maximize accrual, increase access and streamline effort) of offering broad clinical trial access through a decentralized academic partnership would require engagement, commitment, and resources.

3. Solutions and Methods
Numerous stakeholders were engaged at both institutions to integrate Ingalls – legal, finance, regulatory, pharmacy, operations, leadership, data management and more. The majority of legacy Ingall's infrastructure was retired and UCM's centralized services were utilized. UCM's robust clinical trial network was leveraged and this eliminated duplication of efforts (memorandum of understanding (MOU) enacted to waive secondary legal review, local IRB relies on UCM IRB, centralization of pharmacy and data management, etc.). Patient facing staff were retained and trained under UCM policies. In 2019 our investigator-initiated trials were opened under this model, in 2020 Ingalls became a UCM cooperative group component, and in 2022 we had full integration (all solid tumor/ chronic hematology industry and Phase I trials at this site).

4. Outcomes
Accrual, and specifically URM accrual, to oncology treatment trials has increased at UCM as a direct result of the Ingalls collaboration. In FY22, 23 and 24 the number of open treatment trials was 48, 69 and 82. FY22 treatment accrual at Ingalls was n=22 (59.1% AA/B, 4.5% Hispanic), FY23 = 27 (48.1% AA/B and 0% Hispanic), FY24 = 63 (58.7% AA/B and 1.6% Hispanic). Anticipated volume for FY25 is over 80 patients. Results do not include screen failures, non-treatment, biobank/registry, and referral to main campus for studies not available locally. In addition to unique enrollment, 304 (FY24) services were completed at Ingalls for patients enrolled at our main campus.

5. Learned and Future Directions
Thoughtful consideration and collaboration by impacted departments is critical, but effort was rewarded over time. Increasing access, via local enrollment and retention, has a positive impact on treatment accrual of URMs. While the Ingalls and UCM partnership was formal, the processes and workflows put in place are scalable to less formal relationships. Leveraging local centers, who have already proven

trustworthy in a given URM population, to provide clinical trial care can be an innovative way to increase accrual and access.

Figure