

Background:

Brooklyn is a critical catchment area for NYU Langone Health (NYULH) due to its large, diverse population. In response to the growing need for accessible oncology care, construction was completed for Perlmutter Cancer Center – Sunset Park (PCC-SP), NYU’s 1st comprehensive NCI designated cancer center in Brooklyn, in June 2019.

Patient cases have since surged an astounding 172%, as seen in figure 1. Furthermore, since 2021, there has been a total of 61 patients referred from Brooklyn to Manhattan for clinical trial enrollment, as seen in figure 2.

The NYULH community recognized this pressing demand for accessible trial opportunities for the Brooklyn population, and addressing this need quickly became a priority.

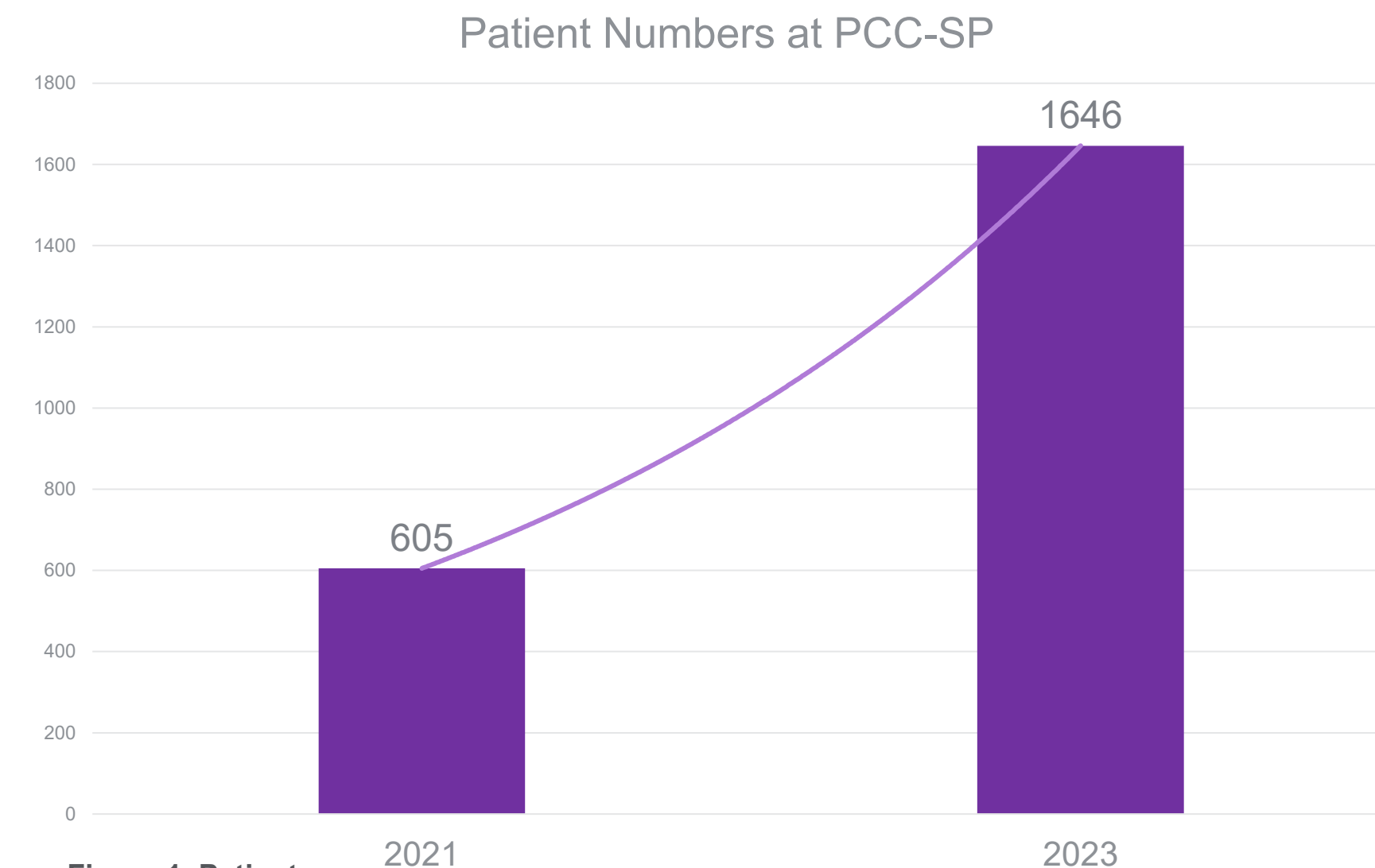


Figure 1. Patient Numbers

Year	Referral #
2021	3
2022	19
2023	39
Total:	61

Figure 2. Referral numbers

Goal:

To establish a comprehensive satellite Clinical Trials Office (CTO) in Brooklyn to augment trial enrollment in underserved areas

Lessons Learned and Future Directions:

Lessons Learned:

- Operationalizing a satellite CTO requires
 - Site Assessment
 - Multi-department collaboration
 - Buy-in from key stakeholders
 - Proper resource and budget allocation.
- Selective feasibility process and careful escalation of trial complexity proves to be a successful strategy in launching a new site.**

Future Directions:

- Collaboration and planning underway with NYULH leadership to establish a full Investigational Pharmacy and research biospecimen processing lab.

Solutions and Methods:

Formal site assessment:

- In April 2021, CTO leadership conducted a formal site assessment to determine research capabilities at PCC-SP

Key Needs Identified:

- Data, Regulatory, Business and finance operations will be centralized
- Dedicated Brooklyn CTO Staff
- Develop an Investigational pharmacy (IP)
- Space for research biospecimen equipment

Developing a Plan:

- How to activate trials despite our limitations
- Selective feasibility process**
 - Review analytic case data to determine patient population
 - First review feasibility for Investigational Pharmacy only

Escalation of Trial Complexity:

- GYN surgical trial that did not require Investigational Product.
 - Thoracic trial that utilizes all SOC therapies.
 - Activated multiple Breast trials that utilize IP.

Outcomes:

Key Needs Resolved: Dedicated CTO Staff

- Collaborative efforts resulted in two Clinical Research Coordinator positions and one Program Manager position, approved in March 2023 and filled by December 2023. Additional resources planned for upcoming fiscal year.

Key Needs Resolved: Investigational Pharmacy

- Exceptional partnership between PCC, Pharmacy, and Hospital leadership → shared space for IP in the cancer center
- Onsite investigational pharmacists capable of compounding and dispensing drugs of both hazardous and non-hazardous classes

Key Needs Resolved: Research Biospecimens

- shared space within the PCC-SP lab, with onsite research coordinators to process and ship research biospecimen samples at BSL1.
- High complex biospecimen processing will utilize CTSI until PCC has dedicated research processing lab

Accrual Outcomes:

- 10 therapeutic accruals from 2022-2024: **90% diverse accruals**
- 5 Non-Therapeutic Accruals in 2024: **60% diverse accruals**

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