



Full Integration of the Gynecologic Oncology Research Operations under the IU Simon Cancer Center Clinical Trials Office

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Background

The Clinical Trials Office continues to coordinate services, share standard operating procedures, and maintain standard of quality for clinical trials with cancer-related studies. Although the Clinical Trials Offices services are available to all departments seeking to conduct cancer related studies, some departments prefer to use their own departmental resources. The Gynecologic Oncology model poses a challenge for accrual goals, maintenance of standardization and quality of clinical research. Full integration of the Gynecologic Oncology research staff under the Clinical Trials Office with the support of the Gynecologic Leadership and new Principal Investigator allows for improvement of clinical research operations.

Goals

Fully integrate Gynecologic Oncology clinical trials operations under the direction of the Clinical Trials Office:

- Develop a trusting relationship with Gynecologic Oncology leadership and Principal Investigators.
- Provide regulatory, clinical and financial responsibilities under the Clinical Trials Office.
- Provide oversight of clinical research activity under the Gynecologic Oncology program.
- Expand Gynecologic Oncology Clinical Trials portfolio and increase clinical trial accruals
- Provide cross-coverage for staff support

Methods

- Clinical Trials Office Leadership met with Gynecologic Oncology Leadership to understand vision and future direction
- Gynecologic Oncology Principal Investigator attended training and overview of the clinical trials office operations.
- Initiated quarterly meetings with Gynecologic Oncology leadership to review current research activity and address current issues.
- Gynecologic Oncology Principal Investigators play key leadership roles within the Indiana University Simon Cancer Center clinical research management and oversight.
- Hired clinical research staff under the Clinical Trials Office and participated in our onboarding and orientations process, which allows us to rain on current standard operating procedures
- Dieses oriented teams (Principal Investigators, Clinical Research Nurses, Clinical Research Specialist, Data Coordinators, Regulatory and Finance) meet on a weekly and monthly basis to review Gynecologic Oncology portfolio.
- Share specific clinical trials metrics to Principal Investigators and Disease-oriented teams on a monthly basis.

Results

Since fully integrating the Gynecologic Oncology Research operations under the Clinical Trials Office, the clinical trial portfolio has expanded and therapeutic accruals have increased (multifactorial).

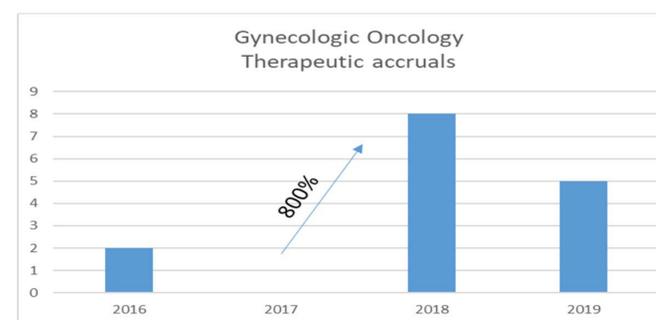


Figure 1: The total number of Gynecologic Oncology Therapeutic accruals prior to and after full integration under the clinical trials office. **Therapeutic accruals have increased 800% from CY2017-18 and projected for 90% for CY2019.**

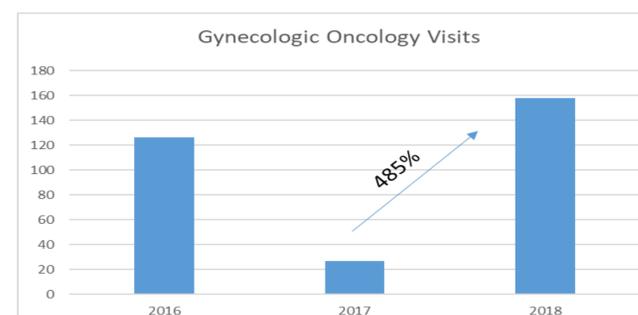


Figure 2: The total number of Gynecologic Oncology Therapeutic visits prior to and after full integration under the clinical Trials office. **Therapeutic visits have increased 485% from CY 2017-18.**

Future Direction

While we fully integrated the Gynecologic Oncology research operations under the Clinical Trials Office, we continue to monitor clinical research activity on a monthly basis to address workload and expectations. With the support of Gynecologic Oncology leadership and Principal Investigator has allowed for a smooth transition for both departments. We continue to monitor progress and are excited for two new Gynecologic Oncology physicians to join the department in CY2018 and 19 with the goal of exceeding 2018 accrual goals.

