



Memorial Sloan Kettering
Cancer Center

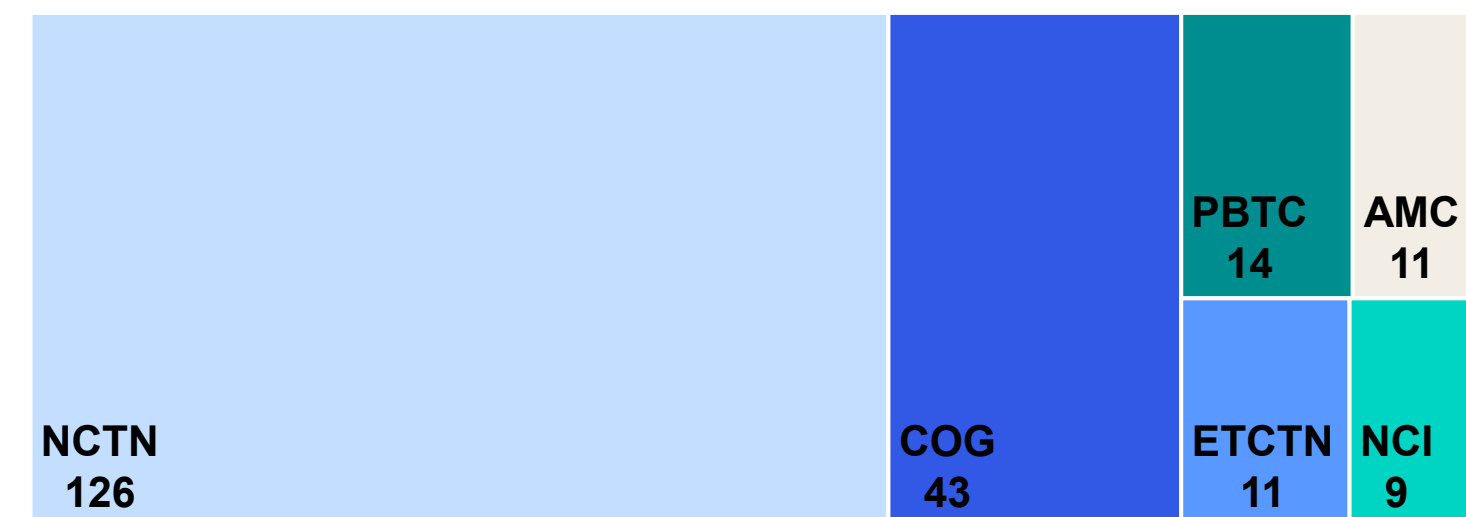
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Memorial Sloan Kettering Cancer Center (MSK)

Evolution of MSK's NCI Network Program

Introduction

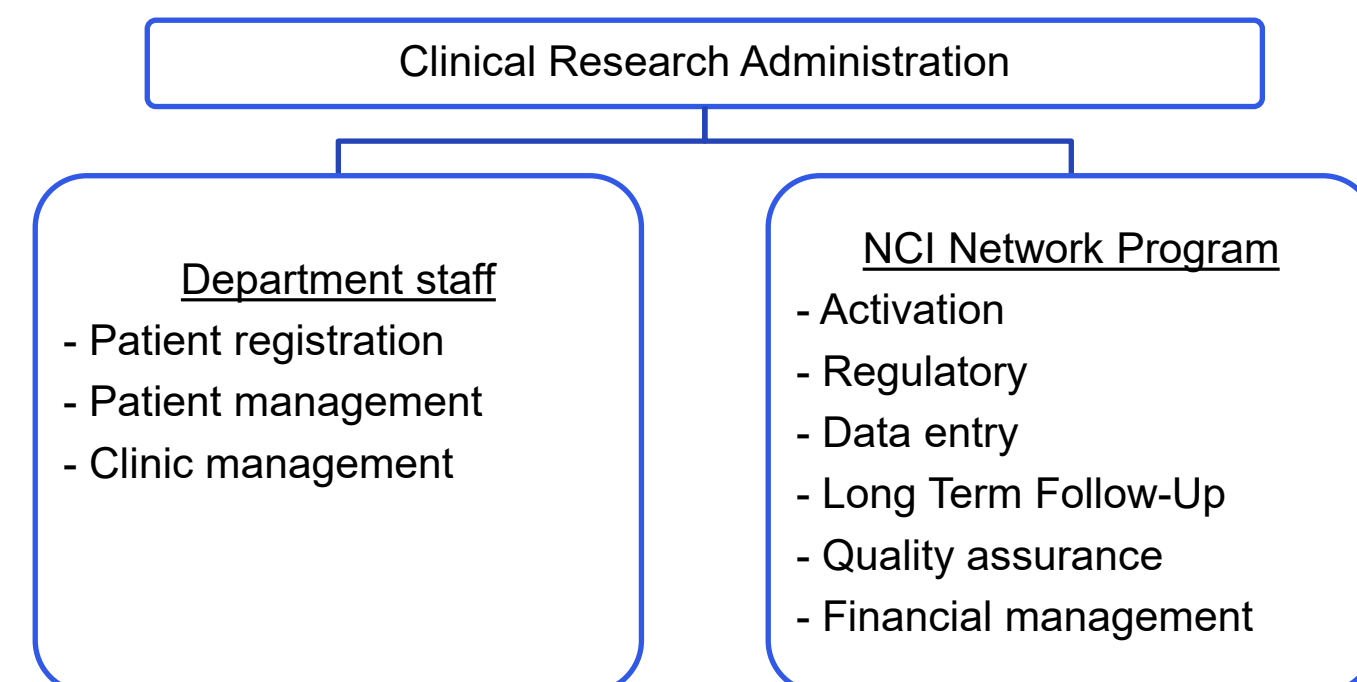
MSK's NCI Network Program (NNP) oversees all NCI-funded groups and consortiums operating at MSK.

MSK NCI Network Portfolio (n=214 studies)



The NNP structure provides central oversight and enables economies of scale and shared standard operating procedures. The staff within the NNP are subject matter experts in NCI Central Institutional Review Board (CIRB) procedures, NCI Clinical Trials Monitoring Branch audit guidelines, and the standard working procedures of the NCTN Lead Groups and NCI Consortia.

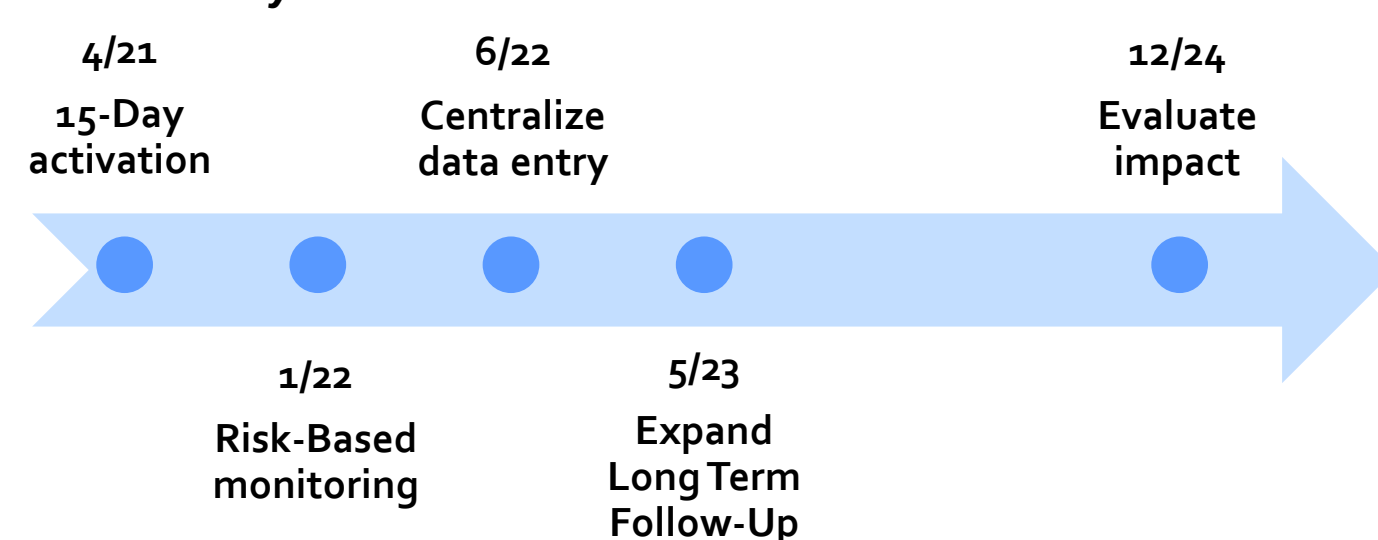
Breakdown of Responsibilities



Goals

To evaluate the impact and efficacy of key NNP initiatives.

Timeline of key initiatives

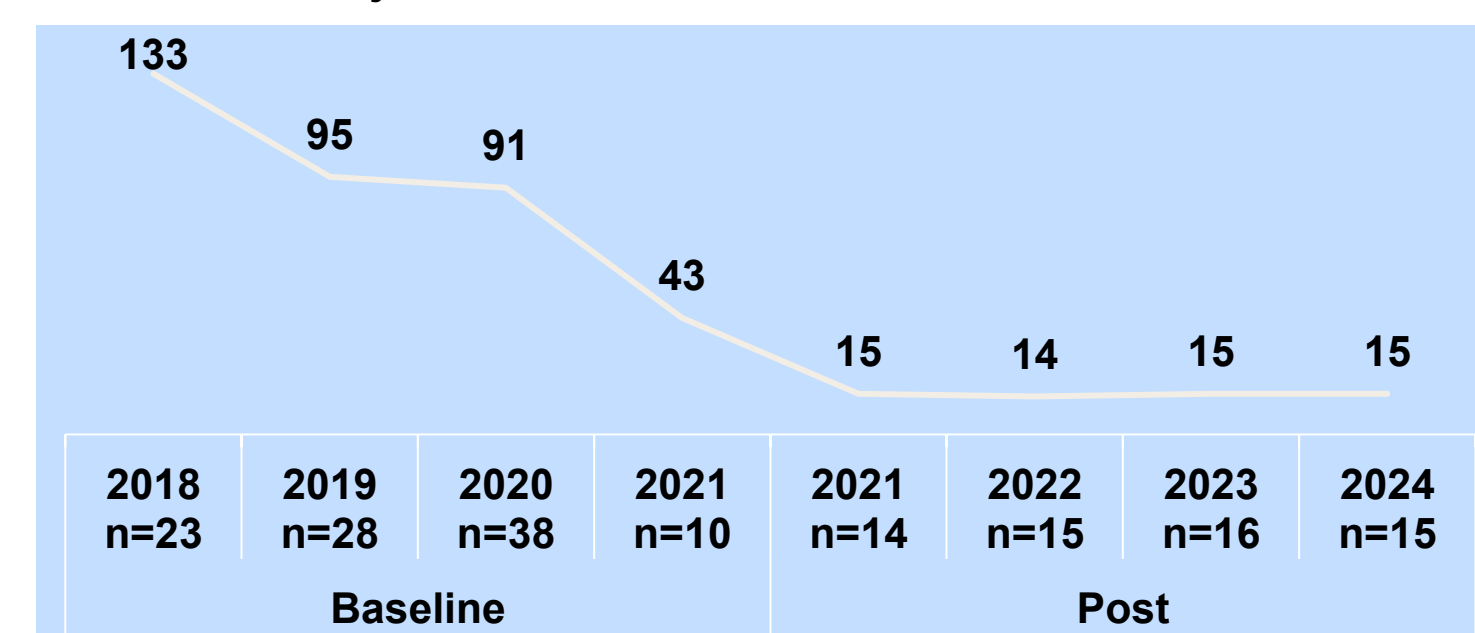


Methods & Results

15-Day Activation

We implemented an expedited review process, allowing for fast-tracked, concurrent department, committee and IRB/PB reviews. The completion of five key start-up requirements; eligibility checklist, sponsor regulatory documents, protocol training, study-specific contract, and sponsor activation are required to open to accrual. We compared overall time to activation (OTTA).

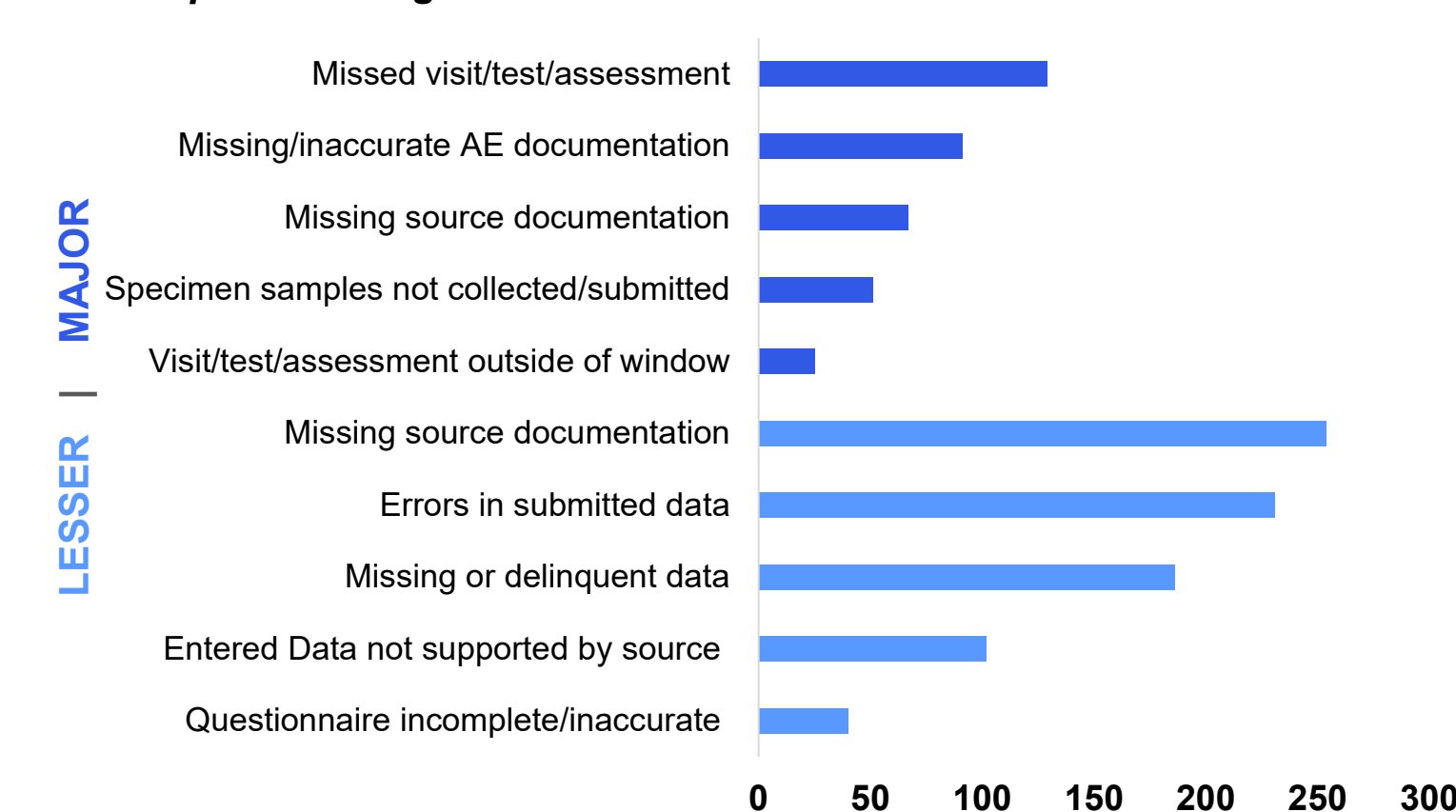
Median OTTA days



Risk-Based Monitoring

The team completes 10 visits per month. We draw on findings from external audits with a focus on the patients' baseline and active treatment timepoints and results. We have generated metrics allowing us to identify top areas of concern to drive re-education efforts and inform working groups to improve quality across MSK. Informed consent and eligibility reviews are completed as part of a separate initiative and those metrics are not included here.

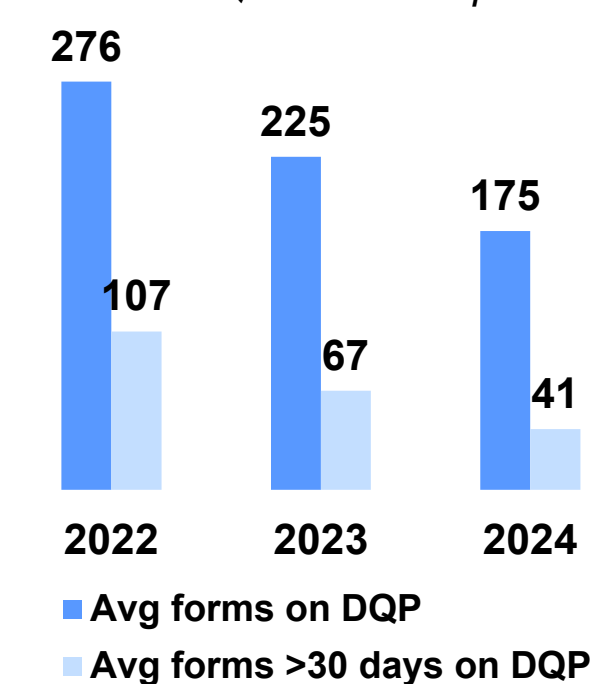
2024 Top monitoring deficiencies



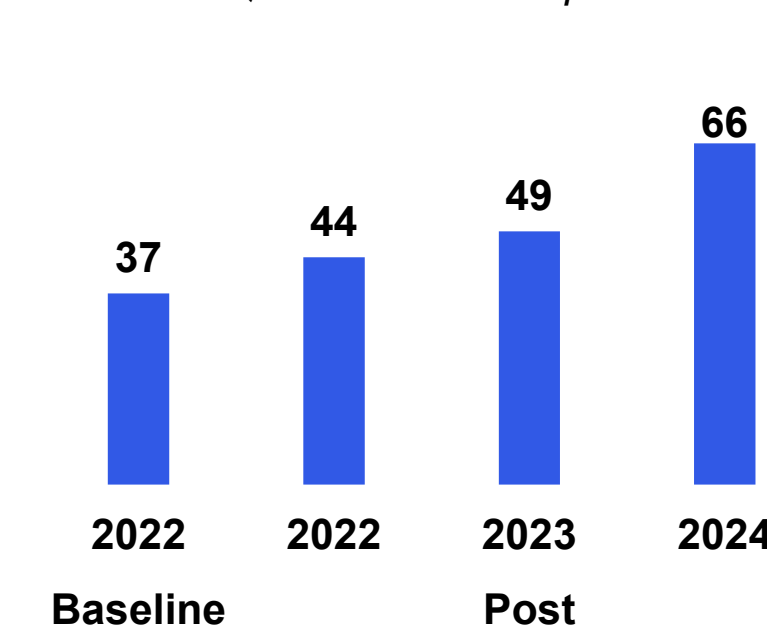
Centralize Data Entry

We recruited Clinical Research Coordinators (CRCs) at a ratio of 1 CRC for 65 patients on treatment or 80 in follow-up. Roles and responsibilities were clearly defined for the Department and NCI teams. We developed and completed general, NCI focused, and disease specific trainings. CRCs were aligned to disease groups and protocols, partnering with Department staff to support timely visits and complete source documentation. We leveraged the CTSU DQP to prioritize data entry and used monitor findings to guide re-education and reinforce key concepts.

Delinquent forms
CTSUS DQP Forms Report



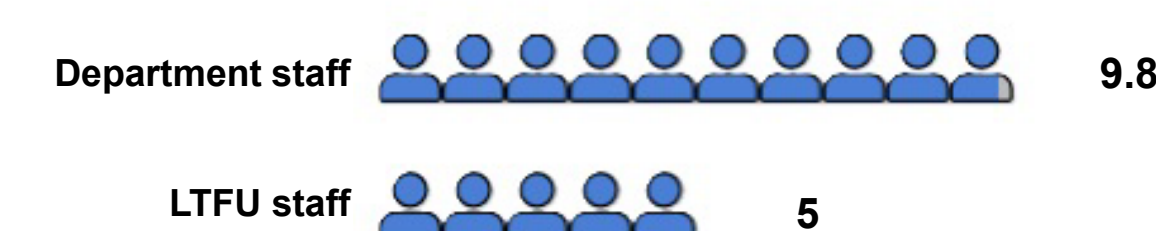
Percentage of on-time forms
CTSUS DQP Timeliness Report



Expand Long Term Follow-Up (LTFU)

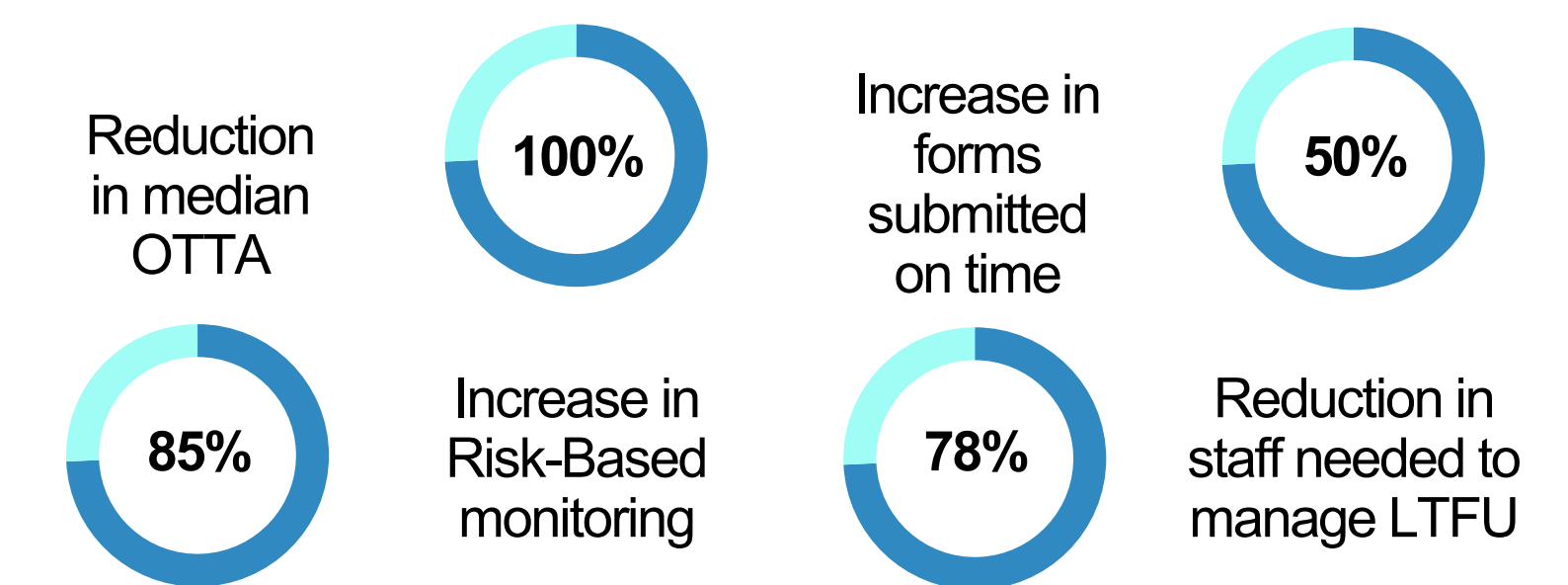
Patients in the LTFU portion of their protocol journey may not require the same time and attention that active treatment patients do. However, they do still require special attention and sometimes additional effort by the study staff to ensure they are maintaining contact. A centralized team set up to manage only LTFU patients that is trained in the methods available to keep in touch with participants can do more with less.

Full Time FTEs needed to manage LTFU patients



Conclusions

Impact



MSK is in good standing with all NCI-funded groups and consortiums in terms of data submission, data quality, and auditing reports. By centralizing key function, we've decreased our time to activation and improved data reporting timeliness. Implementing program-wide monitoring has yielded valuable data allowing us to pinpoint areas requiring reeducation and further training. We have also improved our compliance with LTFU participants while reducing the headcount.

Future Direction

This program is necessary for ensuring the focus, direction and efficient use of institutional resources while maintaining high quality research. We will look to utilize monitoring data to measure the impact of these centralized functions on data quality.

Over the past year, we have learned from other Cancer Center's across the country from monthly calls. We look forward to continued collaboration and sharing of best practices.

Acknowledgements

Thank you to the NCI Network Committee and the NCI Network Team members for all your hard work and dedication on these important trials.