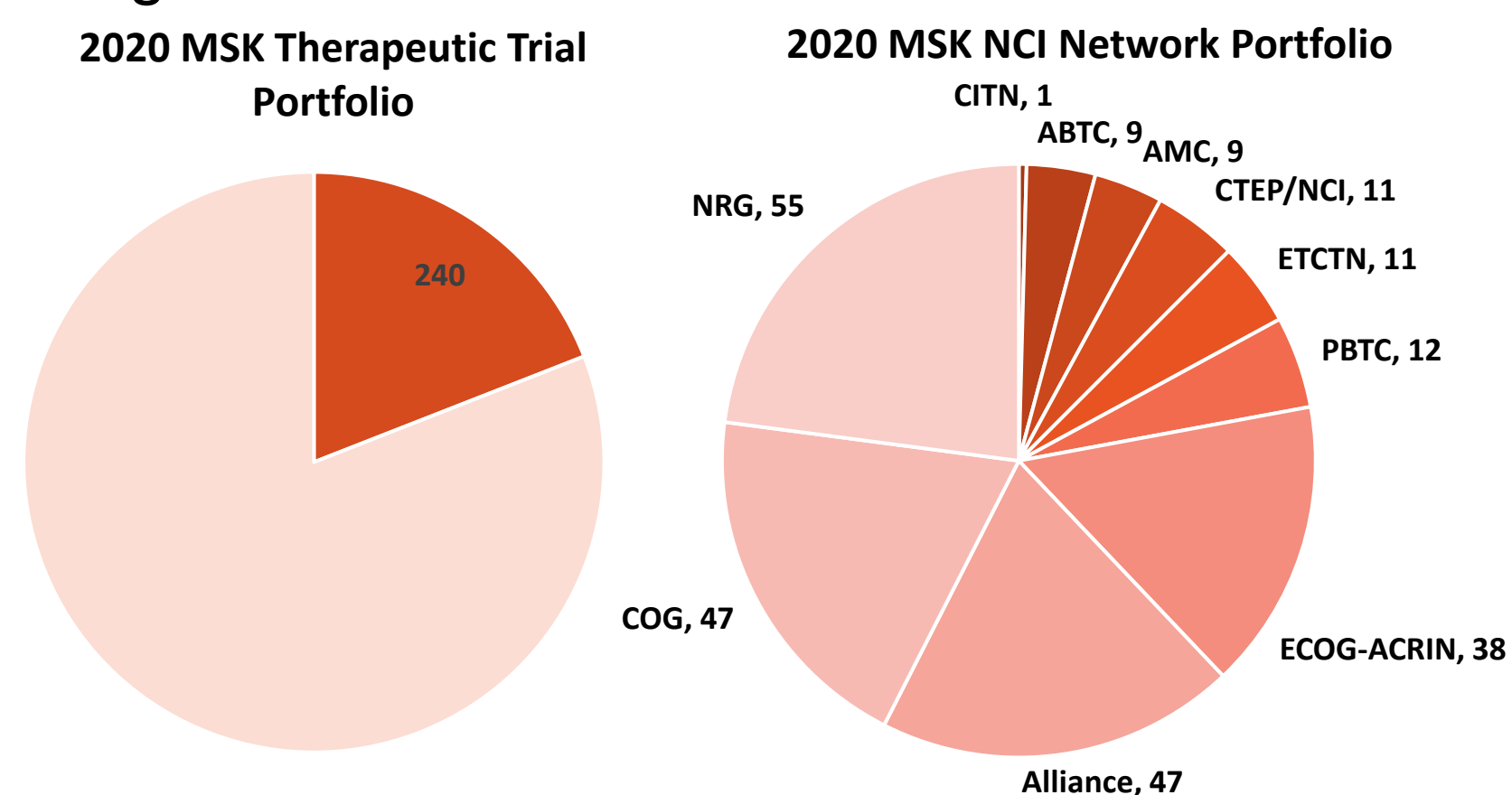


MSK's NCI Network Program

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Introduction

As an NCI-Designated Comprehensive Cancer Center, MSK receives funding via the Cancer Center Support Grant (CCSG) which requires collaboration in NCI research efforts. MSK does this through participation in and enrollment to NCI sponsored group studies. As part of the CCSG renewal process, MSK examined our NCI sponsored group portfolio and noted siloed physician leadership, quality concerns and limited financial support. At the direction of Leadership, MSK's NCI Network Program was created.



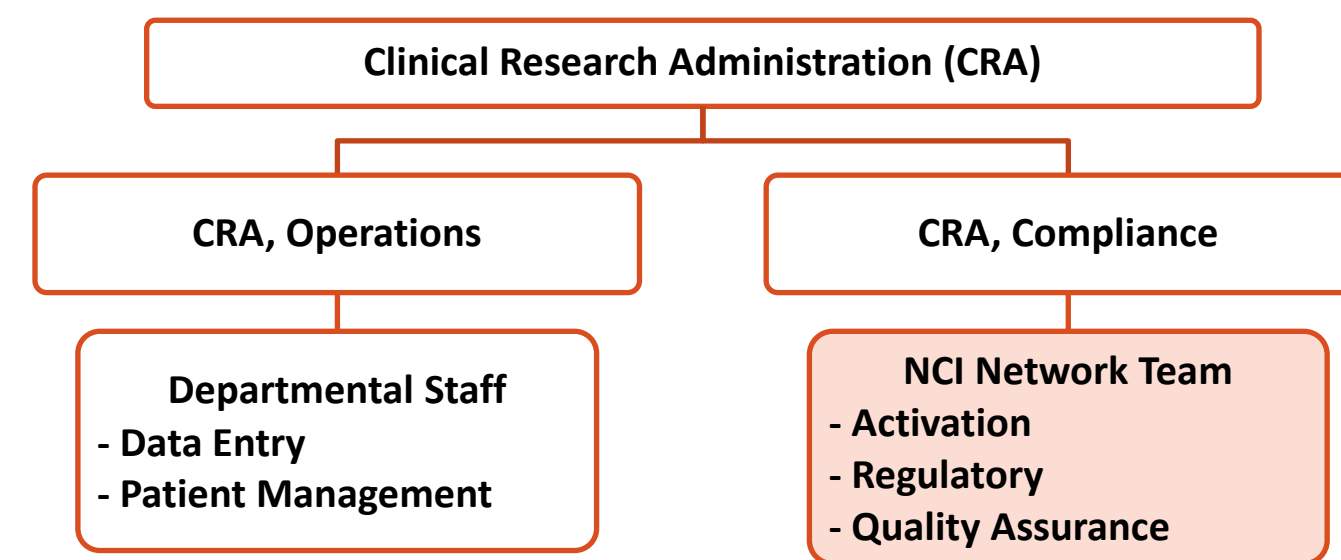
Background

NCI Network Committee (NNC)

NCI group PIs in addition to disease specific champions formed to oversee MSK's NCI sponsored trials. Members meet monthly to review protocols in the activation, accrual metrics, non-performing studies and grant and data metrics.

NCI Network Team (NNT)

NCI subject matter experts were assembled to create the NNT. The team focuses on Protocol Activation, Operations, Regulatory and QA. The team works alongside Clinical Research Operations to support all study teams participating in NCI Group protocols.



Methods

Activation

The NNT developed a strategy to solicit decisions by MSK PIs on trials to activate. We partnered with the Protocol Review and Activation Cores (PRC and PAC) to streamline activation requirements in order to open studies within 15 days. We also developed a 'Just-in-Time' or rapid activation approach for participants waiting. Decisions and timelines are recorded in a database.

Data Oversight & QA

The NNT implemented an oversight approach that assesses data status monthly and works with PIs and study teams when there are data concerns. We worked with Operations to create an escalation plan for concerns. In addition, the NNT instituted a retrospective review of eligibility (ECL) and informed consent (ICF) for 100% of all participants. Lastly, the NNT employed Risk Based Monitoring (RBM) to review high-risk trials (n=11).

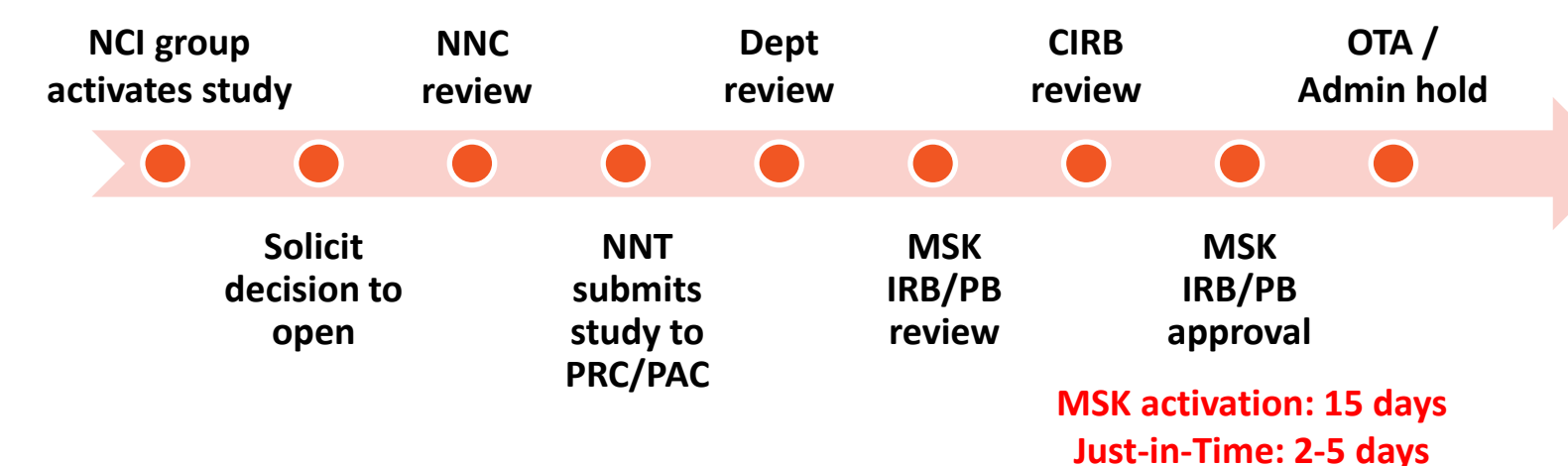
Cost Sharing

Leadership confirmed their commitment to these studies and committed to share costs. The grants/subawards are used to support the NNT and provide a pre-determined annual amount for studies. Once the annual amount identified is exhausted the expenses are transitioned to a cost share fund.

Results

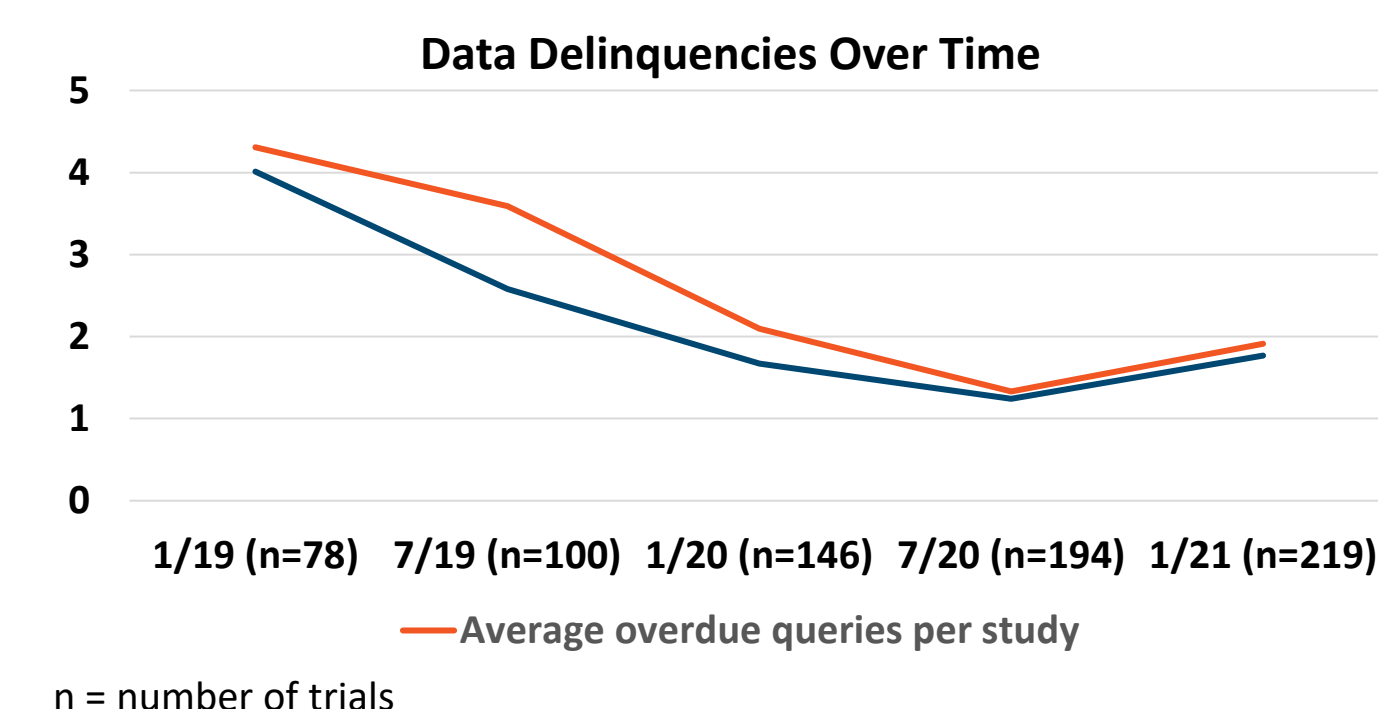
Activation Highlights

- The first two trials using the streamlined approach were activated within 15 days, compared to 101 days (2020 median).
- Used JIT approach to open a trial for pediatric patient in 4 days.



Data & QA Metrics

- Source verified 215 patients for ECL/ICF of which 139 had documentation issues highlighted for correction thus avoiding potential audit findings.
- Improved data reporting timeliness which has led to improved performance monitoring reports from Alliance and NRG.



Cost Sharing Metrics

- 2020 expense and reimbursement were tallied to determine the Program cost.
- 83% of the 2020 cost was supported by NCI. The remaining 17% was covered by MSK; 13% on Sr. Mgmt and positions deemed institutional responsibility and 4% from the cost share for Clinical & non-Clinical staff.

Conclusions

Program accruals returned to pre-COVID numbers in Q1 2021; we anticipate exhausting NCI support sooner and require an increase in institutional cost sharing. This Program is necessary for ensuring the focus, direction and efficient use of NCI and institutional resources. This investment in infrastructure allows us to support our contribution to NCI Sponsored research.

Future Plans

- Compare 2020 & 2021 activation timelines and Program cost
- Evaluate compliance of studies with streamlined activation
- Implement 'time outs' to identify potential issues in real time
- Increase NNT Monitoring staff to expand the number of studies and volume of RBM
- Continue to evaluate PI satisfaction

NCI Network Committee	
Carol Aghajanian, MD	NCTN Grant Holder, NNC Chair
Chris Barker, MD	Radiation Oncology
Christopher Comstock, MD	ECOG-ACRIN Site PI
Ira Dunkel, MD	PBTC National/Site PI
Christopher Forlenza, MD	COG Site PI
Daphna Gelblum, MD	Radiation Oncology
Julia Glade Bender, MD	COG
Nancy Lee, MD	NRG Site PI
Michael Morris, MD	Alliance Site PI
Allison Moskowitz, MD	CITN Site PI
Ariela Noy, MD	AMC Site PI
Valerie Rusch, MD	Vice Chair, Research; Surgery
Martin Tallman, MD	ECOG-ACRIN Disease Chair
William Tap, MD	ETCTN Site PI
Oliver Zivanovic, MD	NRG Site PI

Acknowledgements

Thank you to the NNC and NNT for all your hard work and dedication on these important trials.