

Perlmutter Cancer Center

An NCI-designated Comprehensive Cancer Center

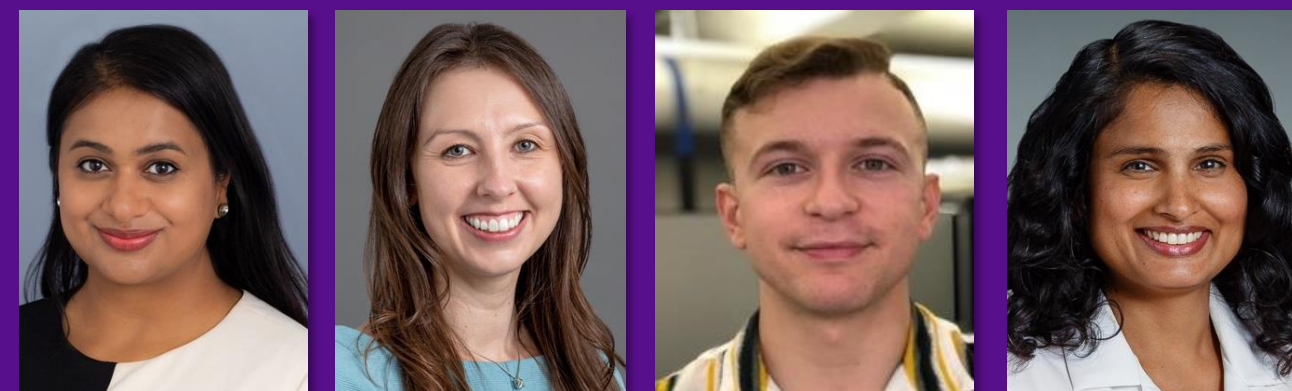
Keeping an eye on RNI:



Frequent Monitoring to Eliminate Preventable Reportable New Information



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BACKGROUND

Responsible handling of Reportable New Information (RNI) is essential to the conduct of clinical trials.

The Perlmutter Cancer Center Clinical Trials Office (CTO) has sought to eliminate preventable harm and provide the highest standard of care and safety to our patients by reducing instances of preventable RNI.

RNI reporting addresses unanticipated adverse events, protocol changes to prevent apparent immediate hazards, or additional potential risk and/or harm to which research subjects are exposed. Certain types of RNI cannot be prevented because, by their nature, trials produce experiential data that was previously unknown or cannot be predicted. Other types of RNI result from the action or inaction of members of the study team, and may have been prevented by changes to the workflow, procedures or policies of the institution conducting the trial.

GOALS



SOLUTIONS AND METHODS

-  Worked with IT to develop an RNI database where all RNI submitted in the week prior is pulled and sent to CTO leadership for review
-  Expanded and frequently revised trainings for clinical staff each year since 2019. Training sessions were an opportunity to identify trends and obtain timely feedback from staff most familiar with the workflows
-  Initiated weekly CTO high reliability organization huddles attended by the entire CTO staff. Enabled communication and explanation of urgent policies/procedure changes
-  We initiated assembly of an RNI Committee to meet regularly with a focus on eliminating preventable RNI with representation from every unit and position within the CTO.

OUTCOMES

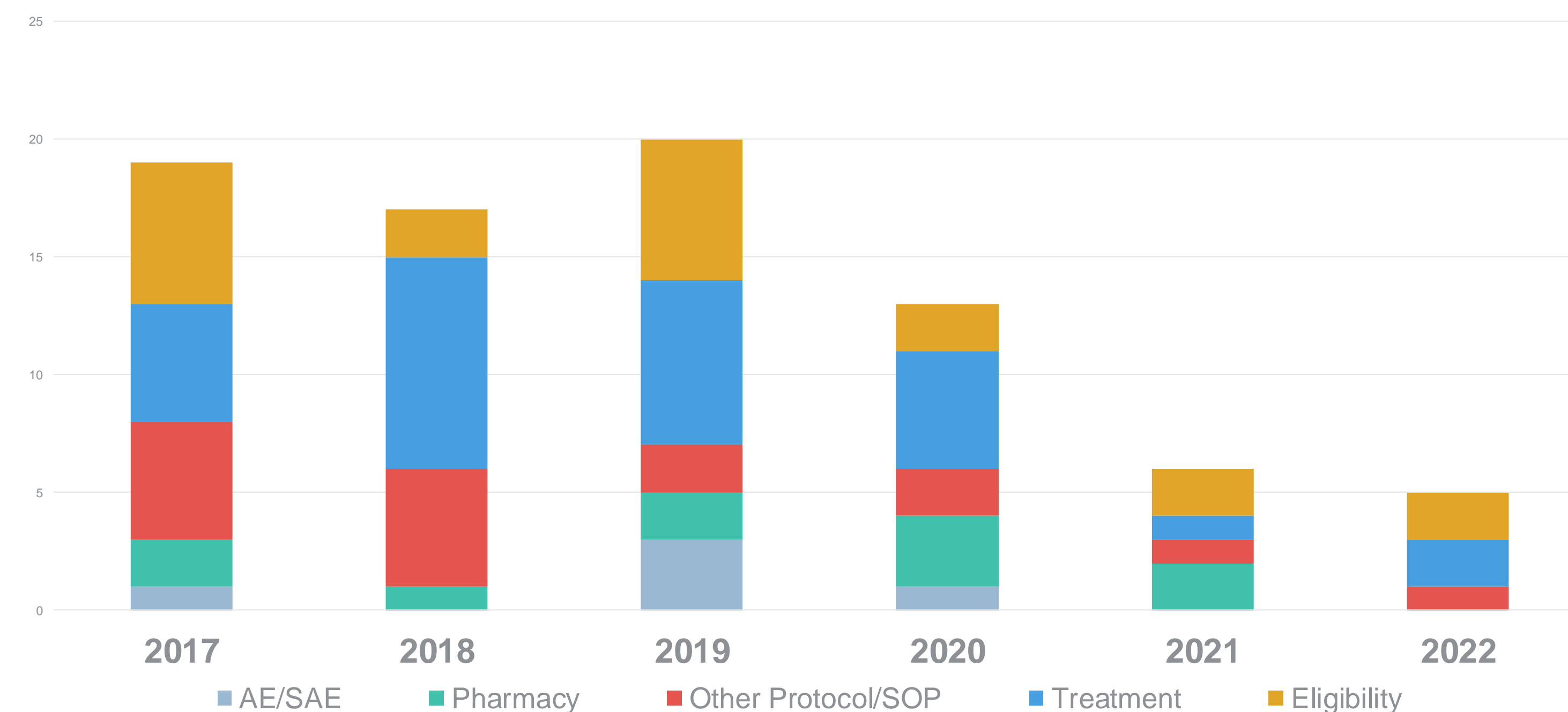
75% reduction in preventable RNI arising from our clinical care of trial patients, from 20 instances in 2019 to 5 in 2022.

Elimination of preventable RNI related to adverse event reporting and our investigational pharmacy.

During this same period we experienced an increase in the size of our portfolio:

- *Activating an average of 14% more trials year-over-year*
- *42% more subjects accrued to Phase I/II trials from 2018-2022 vs 2013-2017*

Instances of Preventable Clinical RNI



LESSONS LEARNED AND FUTURE DIRECTIONS

The centralization of RNI review has been successful and has demonstrated the potent synergy between regular oversight by leadership and collaboration with staff who have expertise on how best to close gaps in workflows and policies. There is no simple way to account for human error in all forms; no workflow or policy is impervious to inadequate execution. We will continue our weekly review of RNI indefinitely, and our diverse committee will continually refine our workflows and practices with the goal of mitigating preventable harm.



Perlmutter Cancer Center/ NYU Langone Website

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