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## Background

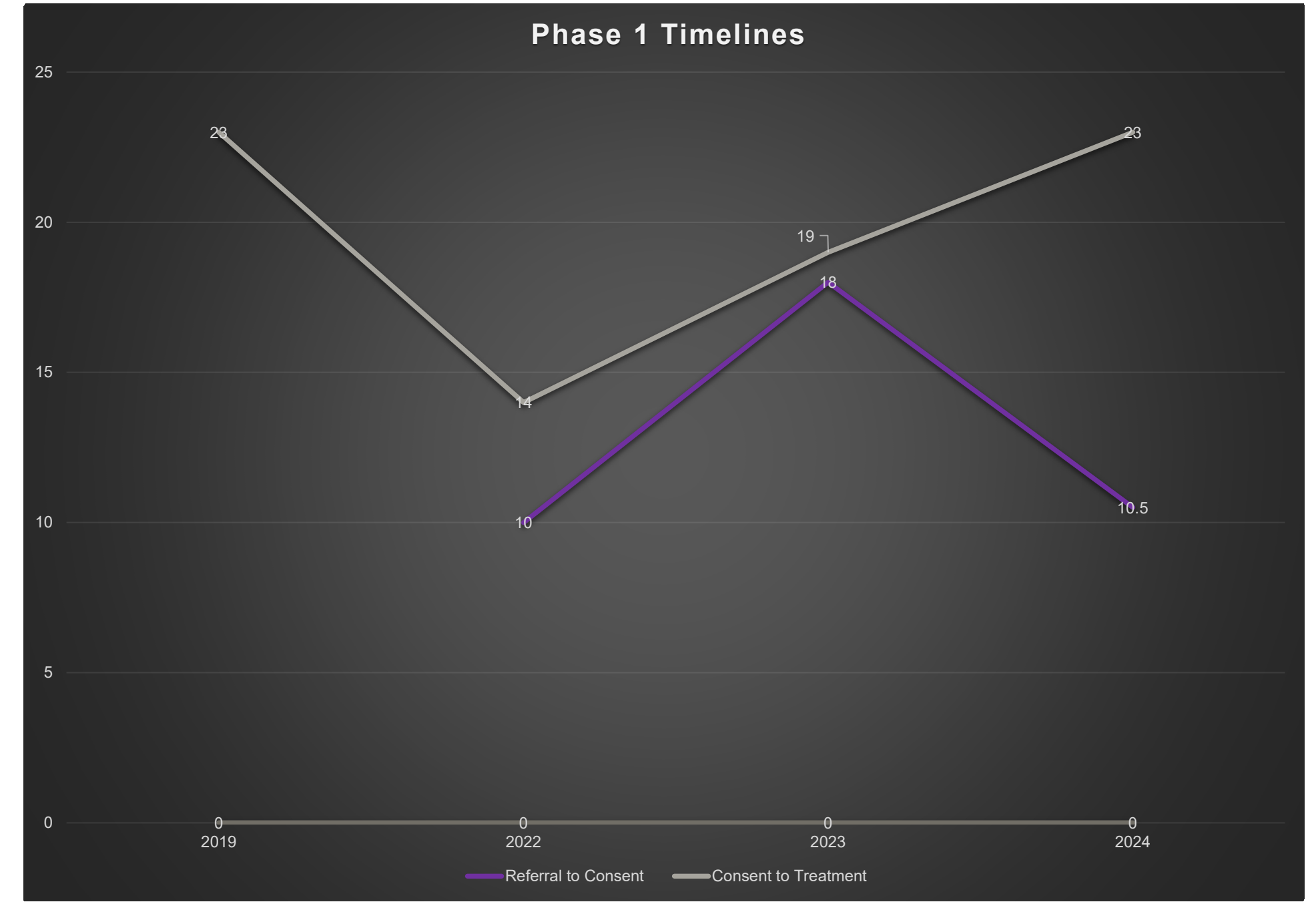
Patient recruitment is vital for the success of oncology clinical trials as is the ability to swiftly enroll patients on to trials due to patients' often critical condition. These remain persistent challenges, particularly with limited research staffing and evolving work environments. The Phase 1 and Thoracic Disease Management Groups (DMGs) at Perlmutter Cancer Center at NYU Langone implemented a referral-based prescreening workflow to address these challenges. This initiative aimed to enhance efficiency by having physicians communicate trial preferences to dedicated pre-screeners who reviewed patient records for preliminary eligibility before initiating patient contact. To evaluate the effectiveness of this workflow, the Clinical Trials Office (CTO) conducted a comprehensive review of referral data.

## Goals

Our goal was to assess the referral-based prescreening workflow's effectiveness in facilitating patient enrollment in oncology treatment trials. We aimed to analyze enrollment, evaluate process efficiency, and identify trial portfolio gaps, seeking insights into the workflow's impact on trial accrual and patient care pathways.

## Solutions and Methods

We conducted a retrospective review of data from July 2022 to April 2024, extracting information from institutional trackers documenting the referral process to screen failure or study enrollment. Data points extracted included date of referral notification, consent acquisition, initiation of treatment, and reason for screen failure, if applicable. Accrual data from 2019, 2022, 2023, and 2024 were reviewed to assess the workflow's impact on trial accrual rates, excluding 2020 and 2021 due to COVID-19 disruptions.



## Outcomes

From July of 2022 to April of 2024, the Thoracic DMG received 290 referrals, with 47.93% consenting and 36.21% accruing to a trial. The Phase 1 DMG received 694 referrals, with 25.79% consenting and 18.73% accruing to a trial.

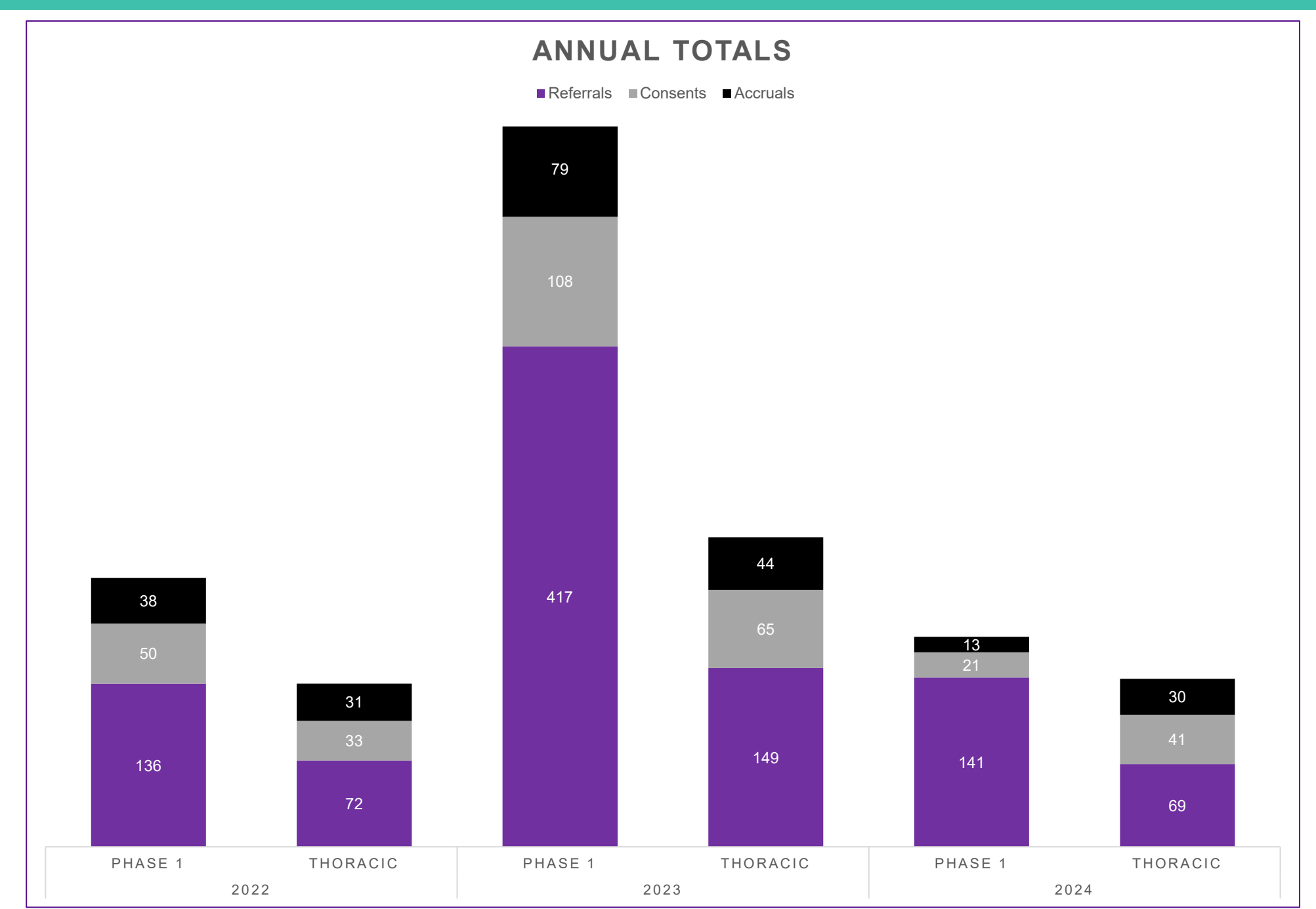
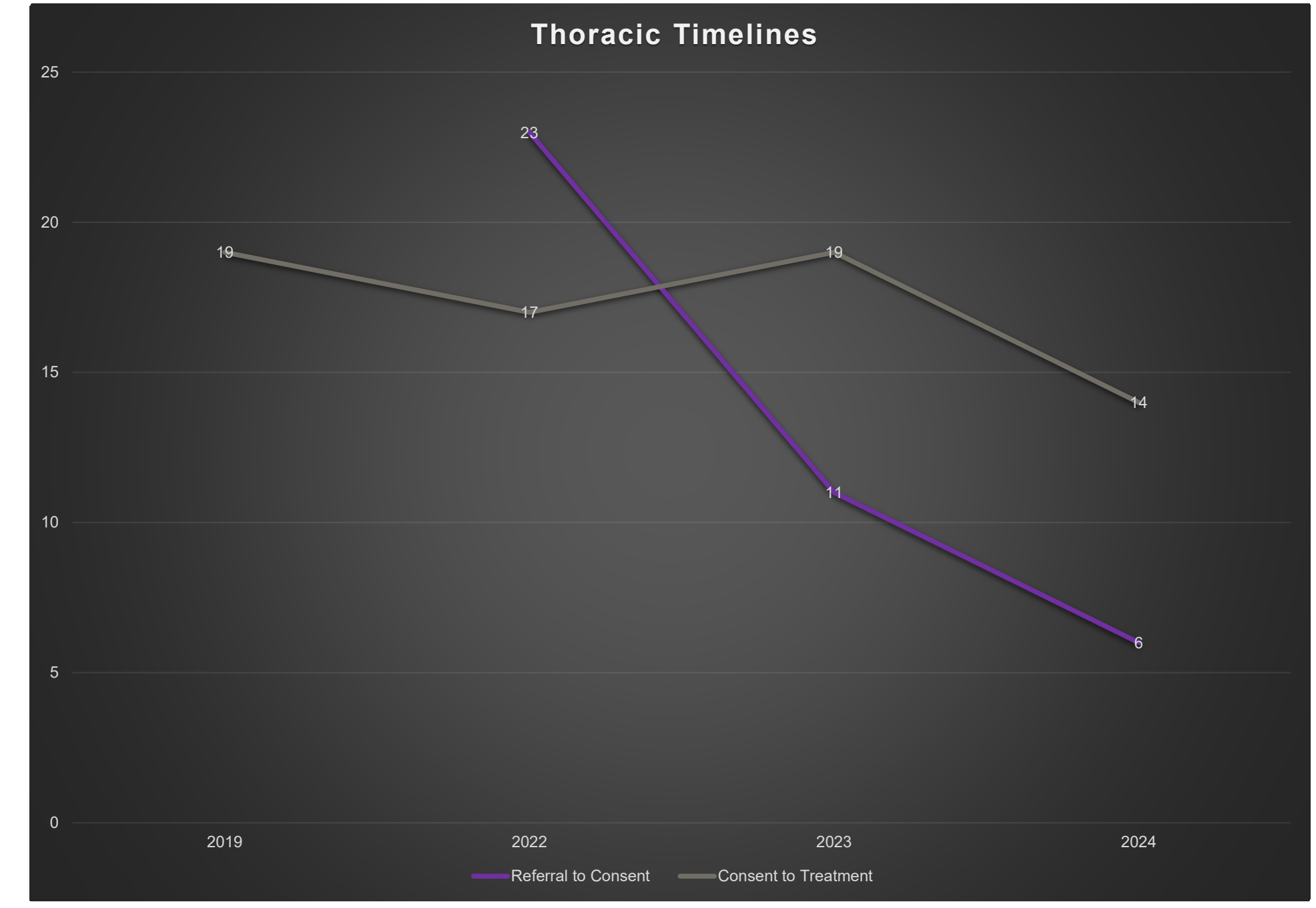
The Thoracic DMG accrued 31, 44, and 30 subjects in 2022, 2023, and 2024, respectively from referrals; and 49, 103, 103, and 54 subjects overall in 2019, 2022, 2023, and 2024, respectively. Referrals comprised 30.10%, 42.72%, and 55.56% of overall accruals between 2022-2024.

The Phase 1 DMG accrued 38, 79, and 13 subjects in 2022, 2023, and 2024, respectively from referrals; and 67, 78, 107, and 23 subjects overall in 2019, 2022, 2023, and 2024, respectively. Referrals contributed to 48.71%, 73.83%, and 56.52% of overall accruals between 2022-2024.

Thoracic data showed an average of 23, 11, and 6 days between referral notification and consent in 2022, 2023, and 2024, respectively. The average time between consent to trial start was 17, 19, and 14 days during the same period. In 2019, the average time between consent and trial start was 19 days.

In Phase 1, the average time from referral notification to consent was 10, 18, and 10.5 in 2022, 2023, and 2024, respectively. The average time from consent to trial start was 14, 22, and 23 days during this period. In 2019, the average time from consent to trial start was 23 days.

Consented patients did not proceed to trial for various reasons, including opting for standard of care treatment, failing to meet inclusion criteria, or finding alternative trial options elsewhere.



## Lessons Learned and Future Directions

The data underscores the significant role of referrals in treatment accruals for both the Thoracic and Phase 1 groups, emphasizing the need for optimized referral management and patient navigation onto treatment clinical trials.

The pre-screening workflow resulted in higher treatment accruals compared to 2019 for both Thoracic and Phase 1 groups. Dedicated pre-screeners tracked referral progress, maintained updated patient lists, and facilitated trial navigation, preventing drop-offs.

Since implementation in 2022, we've noted a consistent reduction in the time from referral/prescreening to consent signing and observed a downward trend in the time from consent to treatment initiation in the thoracic group. The workflow allowed teams to efficiently plan for and screen patients for trials as pre-screeners would often acquire necessary source documents (e.g., molecular reports) and outline variables that may contribute to delays in treatment initiation (e.g., medication washouts). Reducing the timeline from referral to receiving treatment is crucial due to patients' often critical condition, necessitating swift trial enrollment. We did not see the same consistent trend in the Phase 1 group. This could be attributed to various factors such as slot availability, a lack of a suitable trial, and limited staff resources.

Despite slight increases in consent and accrual timelines, the workflow improved overall patient navigation compared to 2019. We propose diversifying our Phase 1 portfolio, advocating for fair slot distribution, and streamlining the referral process to minimize delays in patient access to novel treatments. Dedicated pre-screeners for each DMG may further improve treatment trial accruals and timelines. Moving forward, we hope to implement dedicated pre-screeners in other DMGS to better understand the impact of this workflow at our institution overall. Data collected from this will be used for further analysis.