

Assess the Impact of Repeat Imaging and Assessments on Patient Enrollment in Oncology Clinical Trials.

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1. Background

To participate in clinical trials, patients must complete specific pre-enrollment procedures, such as laboratory assessments and imaging. While these steps are crucial for eligibility, they can sometimes be inconvenient for patients and the research coordinators when done repeatedly to fulfill protocol windows. Research indicates that unnecessary repeats can often cause a burden on the research staff to continuously screen patients, cause delay in enrolling, add additional administrative burden, and add cost. This study will provide valuable insights into the challenges faced, helping us better understand and improve the experience for research participants and coordinators.

2. Goals

This study aims to determine how many patients have required repeated scans for oncology trial enrollment. We plan to assess the impact of these repetitions on eligibility, patient management, and any notable differences in diagnostic outcomes compared to initial assessments. Also, we'll analyze the administrative and temporal burden challenges of these repeat procedures to understand how they may affect patient screening experiences.

3. Solutions and Methods

This study utilizes a web-based Clinical Trial Management System (CTMS) called OnCore to identify patients and utilize the Electronic Health Record, EPIC, from oncology clinical trials conducted at UICC over the past four and a half years (2020–2024). The research will involve a retrospective review of patient records from these Electronic Health Records. The methods will include identifying patients through the OnCore system. For each patient who has consented to participate in an interventional clinical trial, we will collect data on the timing and frequency of imaging and laboratory assessments, as well as any subsequent repeat procedures necessary to meet eligibility criteria. The collected data will be entered into a REDCap database for further analysis.

4. Outcomes

The main focus will be to determine how frequently repeat assessments occur, evaluate their impact on patient management and enrollment, assess the differences in results between the baseline assessment and the repeated assessments, and calculate the additional time and administrative resources required for these repeats.

5. Learned and Future Directions

Our aim is to consider patients participating in trials who undergo repeated scans and frequently miss the time frame, as well as to understand how this impacts their decision to enroll. We want to determine whether the new scans differ from the original ones and the extent to which the time frame is exceeded. Ultimately, we hope to advocate for more flexibility in these windows which could improve patient enrollment and reduce unnecessary procedures.