Yale CANCER CENTER

A Comprehensive Cancer Center Designated by the National Cancer Institute

Protocol Review Committee
OnCore Instructions
Dose Escalation/ Dose Expansion Studies

Table of Contents

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Determining Accrual Targets

Accrual targets are determined for studies at the time of Disease Aligned Research Team (DART) Protocol Review. The accrual information is noted in the Details Section of the Main Tab in the protocol record within the Clinical Trials Management System, OnCore and in the DART Protocol Review Form.

OnCore:

DART Protocol Review Form:

If the study includes multiple phases, indicate how many subjects you expect to enroll in each phase.

Multi-phase Studies

Multi-phase studies that include dose escalation and dose expansion will be recorded as multi-phase studies in the Details Section of the Main Tab of OnCore. If the study includes multiple phases, the team will indicate in which phase they will participate on the DART Protocol Review Form.

OnCore:

Pick the appropriate Phase from the drop-down list. Typical options include IB/II or I-II.

DART Protocol Review Form:

If the study includes multiple phases, indicate which phase(s) Yale will be participating in.

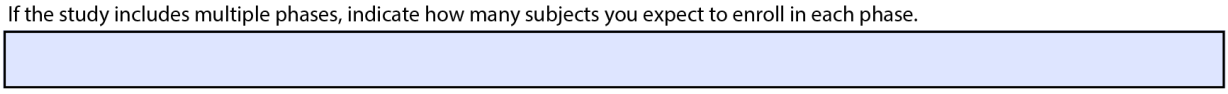
Accrual Target

The accrual target for each phase will be noted in OnCore and within the DART Protocol Review Form for multi-phase studies that include dose escalation and dose expansion. The RC

[Research Center] Total Accrual Goal (Lower) will be used to note the Dose Escalation accrual target. After dose escalation is complete, the RC Total Accrual Goal (Lower) may be changed for accrual monitoring purposes by the study team. If the dose escalation and dose expansion target enrollment changes during the conduct of the study, the study team will update the targets in OnCore following IRB of record approval (if required). The dose escalation and dose expansion accrual targets will be noted in the DART Protocol Review Form.

OnCore:

DART Protocol Review Form:

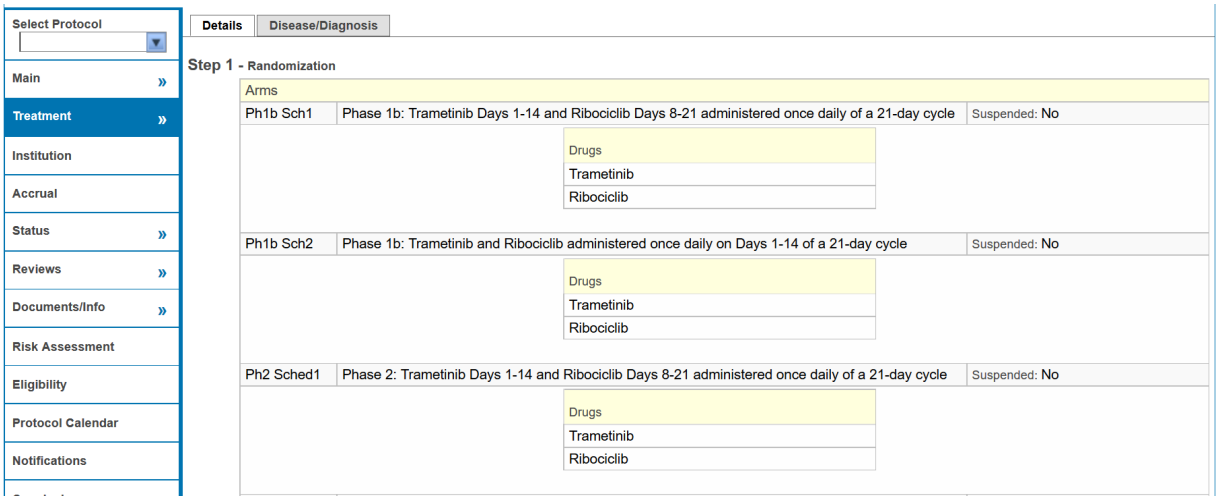


Suspending Arms/ Phases in OnCore

The Phases are noted in the Details Section of the Treatment tab in OnCore. The study team will ensure all relevant phases are noted at the time of OnCore Calendar Review before the study initially opens to accrual and when revisions are made due to an amendment.

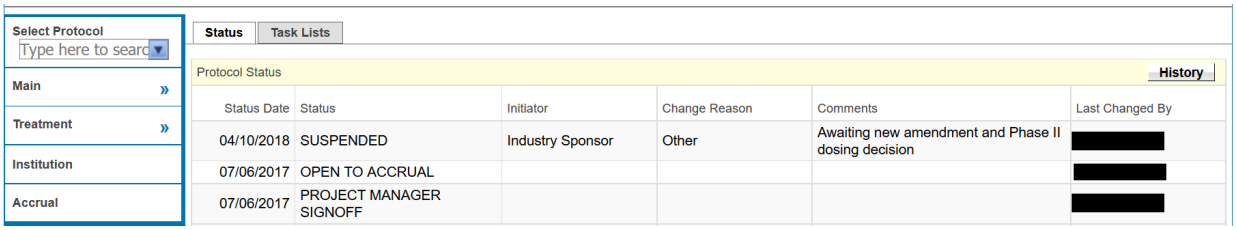
Individual phases and arms will be suspended by the study team in the Details Section of the Treatment tab rather than at the Study Status level during dose escalation as enrollment is temporarily held by the sponsor. To avoid non-compliance, it is recommended that consent document(s) and study conduct document(s) that relate to suspended portion(s) of the study be temporarily removed from the Attachments Section of the Documents/ Info tab in OnCore. The phase/ arm suspension will be lifted when the sponsor allows enrollment to resume and the study team will update OnCore accordingly.

When a phase permanently closes to further accrual, i.e., the dose escalation period ends, the dose escalation phase(s) will be suspended in the Details Section of the Treatment tab. Consent document(s) and study conduct document(s) that relate to the permanently closed portion(s) of the study should be removed from the Attachments Section of the Documents/ Info tab in OnCore.



Study-wide Suspensions in OnCore

If at any time, enrollment to all enrolling parts of a study are suspended for any reason, the Status Section of the Status tab in OnCore will be updated to reflect a status of suspended for the study overall. Comments may be added to provide a rationale for the suspension.



Accrual Monitoring by Protocol Review Committee

The Protocol Review Committee (PRC) will consider accrual rates during dose escalation compared to dose expansion. It is expected that accrual will progress more slowly during dose escalation. For these considerations to be made by the PRC, the study team must adhere to the requirements listed above. The PRC will apply the *Accrual Monitoring Policy* to all open to accrual, non-rare, interventional cancer and cancer-related studies.