



Protocol Selection: A Multidisciplinary Team Approach

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Purpose

The purpose of the Protocol Selection Committee (PSC) is to conduct an online meeting to review cooperative group trials and assess feasibility for our consortium's participation.

The PSC includes:

- treating investigators
- referring investigators
- research nurse coordinators
- clinical research associates
- financial and regulatory staff
- administration

Investigators are disease specific champions as well as sub-investigators and are:

- medical and hematologic oncologists
- surgical oncologists
- radiation oncologists
- radiologists
- pathologists

This multidisciplinary approach results in real-time assessment of protocol requirements, patient population, and any barriers to study conduct or patient recruitment.

Selected Trials

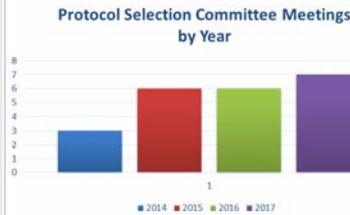
Trials are brought to PSC for review via:

- research base activation announcements
- Cancer Trials Support Unit broadcasts
- by request

Prior to the meeting: study documents and materials are reviewed, the protocol selection checklist is created, and investigators are sent a survey for early feedback.

By the Numbers

Figure 1



Since its inception in October 2014, the PSC has conducted 24 meetings (Figure 1) and has reviewed 159 trials (Figure 2). On average 30 consortium staff participate in each call and an average of 20 investigators respond to the monthly online survey. This number is variable based on which disease indications are represented by trials at a specific meeting.

Figure 2

All Trials Reviewed 2014-Present



PSC results for reviewed protocols are as follows:

- approved
- declined
- tabled

All approved trials are prioritized for placement in IRB queue and assigned an estimated number of annual expected enrollments within our consortium. The PSC also allows each of the sites within the consortium to opt out of consortium approved trials as appropriate.

Tracked results from PSC meetings also include:

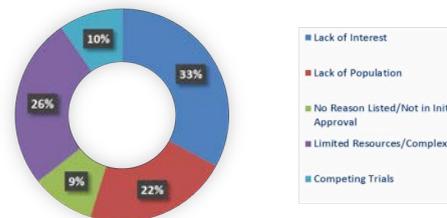
- ✓ protocol number and title,
- ✓ IRB of record,
- ✓ notes taken for each individual study,
- ✓ trial champion (if assigned),
- ✓ any credentialing/training/regulatory requirements.
- ✓ Reasons why studies are declined (Figure 3).

Clear, Concise Data

A single study may be reviewed by PSC multiple times. Tabled studies are sent to the appropriate disease champions following the meeting to discuss and provide feedback. As necessary, tabled studies are brought back to the PSC for a more in-depth review so a final decision can be made. Studies that had previously been declined may be re-reviewed should an investigator express interest or a future amendment improve feasibility or expand population. Results of these multidisciplinary meetings are clear, concise, and communicated via email to all consortium staff at the conclusion of the meeting.

Figure 3

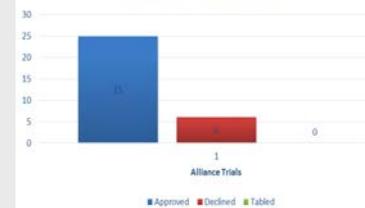
Reasons for Declined Trials



Added Benefits

An additional benefit of the PSC has been increased physician investigator and staff engagement. The system for tracking results of the meeting has in turn lead to investigators being held accountable for enrolling to studies that they championed during the PSC. Across the consortium the use of the PSC has led to investigators and staff spending little or no time on low priority or declined trials. Time is instead spent on those approved trials that will be open to accrual. The Protocol Selection Committee has enabled our large consortium to collectively review and select trials in an efficient and effective manner.

Alliance Trial Outcomes



Contact Us

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