

SWOG
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Policy Memorandum No. 33

Subject: Institutional Performance Review

Departments Affected: All

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INSTITUTIONAL PERFORMANCE REVIEW

The quality of clinical trials depend on the timely submission of data which accurately reflect the participant's care and status, and are free of queries. The Statistics and Data Management Center (SDMC) monitors the submission of data (including forms, vital status updates, source documents and specimens) by each institution and their responsiveness to queries. Performance metrics and reports of missing data, participants overdue for follow-up and unresolved queries are provided monthly to each Principal Investigator (PI) who is responsible for their institution and their associated components and affiliates. An institution's registration privileges may be suspended when performance is delinquent for three consecutive months in any one or more performance categories.

There are five performance categories, and their specifications are:

Initial Forms Set (IFS): The Initial Forms Set is protocol specific and typically consists of some or all of the following: on-study form, baseline disease assessment form, specimens needed for eligibility, stratification or treatment assignment or future endpoint determination, operative and pathology reports, radiology reports and other study-specific forms, reports or uploads. A registration is delinquent if any item within the IFS has not been submitted and it is more than 30 days overdue. A site's performance is inadequate if greater than 10% of registrations within the past 13 months have one or more item unsubmitted, or if IFS submission for ANY registration more than 13 months ago has one or more item unsubmitted.

Vital Status Update: A participant's status is delinquent if the date of the expected update to a participant's last contact is more than 60 days overdue. Included in this measure are participants requiring follow-up who are still known to be alive, whether they are on or off treatment. A site's performance is inadequate if greater than 15% of their participants are delinquent for this measure.

Post-baseline Forms Submission: Post-baseline forms including Treatment, Adverse Event, Disease Assessment and Follow-Up Tumor Assessment Forms, Quality of Life questionnaires, or other protocol-specified forms or documents as outlined in the data Submission section of the protocol are included in this measure. Vital Status forms are NOT included in this measure. A form is delinquent if it is missing and more than 60 days overdue. A site's performance is inadequate if greater than 5% of the required materials expected in the last 13 months are overdue. Any form more than 13 months overdue is also included in this measure.

Responsiveness to Queries: Queries posted by the SDMC, biorepository, Quality Assurance staff or other non-"Site from System" queries are included in this measure. Sites are expected to respond to queries within 15 days; any query that is unresolved and is more than 30 days overdue is delinquent. A site is non-compliant if > 5% of the queries posted in the last 13 months are delinquent or any query > 13 months ago is still open.

Specimen Submission: This measure includes SWOG-tracked baseline specimens not needed for eligibility, stratification or future endpoint determination, and SWOG-tracked post-baseline specimens. A specimen is delinquent if the expectation has not been resolved and it is more than 30 days overdue. A site's performance is inadequate if greater than 10% of specimen expectations posted within the past 13 months are delinquent or if any specimen expectations posted more than 13 months ago have not been resolved.

A letter of warning will be sent to the site PI after two consecutive months of delinquent performance in one or more performance categories. If performance is still inadequate at the third month, and there is no evidence of improvement, a letter of suspension of registration privileges will follow. If the information in the overdue categories is based on a small denominator or under other extenuating circumstances, the Group Chair, Executive Officer for Quality and Group Statistician may choose to waive the suspension. When a suspension letter is sent, the institution is given until the following month's report before the suspension is activated, to provide the site adequate time to complete registrations for eligible participants who are currently engaged in the pre-registration eligibility process. If the IPR statistics are found to be within compliance on the following month's report, the site's registration privileges will not be suspended. To lift a suspension, an institution must have all performance categories within acceptable limits, regardless of which category caused the suspension.

Other performance tools:

Site Score: The Site Score is a weighted measure of the current IPR metrics and is a tool for leadership at the sites and SWOG leadership to evaluate a site's overall performance compared to other sites' performance. Scores will be categorized as either Excellent, Very Good, Good, Adequate, or Poor. The Site Score will be provided to sites quarterly. No direct action is taken based on the Site Score alone.

Site Report Card: The Site Report Card is another summary of a site's activity. In addition to the IPR metrics and Site Score, other indicators of a site's activity and performance will be provided including timeliness of Serious Adverse Event (SAE) reporting, rates of participant ineligibility, and investigator and site staff engagement.