MEMBER INSTITUTION
Institutional Performance Monitoring Program

Policy Number: MI-004
Revised Date: 10/21/2024

CHILDREN'S ONCOLOGY GROUP

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Introduction

The Children's Oncology Group (COG) Institutional Performance Monitoring Program is established by the COG Constitution & Bylaws. The purpose of this Program is to institute a performance data monitoring mechanism that reviews COG member institutions for adherence to performance standards set forth by COG.

Policy Statement

It is the policy of COG that all COG member institutions are expected to comply with performance requirements established in the Institutional Performance Monitoring Program.

Purpose

The purpose of this policy is to document the expected standards for Main Member and Affiliate Member institution performance and the consequences for failing to meet the established standards.

Scope

This policy applies to all COG Main Member and Affiliate Member institutions' performance monitoring

Institutional Performance Monitoring Committee

The Institutional Performance Monitoring Committee (IPMC) is a COG administrative committee that is responsible for monitoring and reporting on COG member institutions' performance data. For more information about the committee, refer to the Institutional Performance Monitoring Committee Charter.

Monitoring Cycles

IPMC reviews COG member institution's performance data once a year, though they can convene to review specific circumstances that may arise at any time.

For example, IPMC can be called upon throughout the year to review sites referred to them by COG Quality Assurance (QA) & Audit or the Statistics & Data Center (SDC). If the investigation yields potential Executive Committee action, IPMC will present at the next Executive Committee meeting.

Performance Data

IPMC and the IPMC Chair use various reports/information to monitor an institution's performance including but not limited to:

- APEC14B1 enrollments for North American institutions and new patient registrations for Non-North American institutions*
- therapeutic and non-therapeutic trial enrollment data*
- data currency information *
- radiation therapy data submission and protocol compliance information*
- diagnostic imaging data submissions*
- biopathology specimen submissions*
- audit information*
- studies approved by the Institutional Review Board (IRB)*
- audit outcome reports
- other information provided by QA & Regulatory Affairs and SDC

*Information included in the annual Institutional Report Cards (IRC).

Annual Institutional Report Cards

SDC posts institutional performance summaries at annual intervals to the COG Member Website. These summaries are documented on an IRC and include the current year assessments based on the yearly composites provided for the past three years as well as a three-year rolling average where appropriate.

Performance Data Review Process

IPMC reviews the IRC for member institutions that are not in compliance with the performance monitoring requirements. For audit compliance, IPMC initially uses the IRC, then, in collaboration with COG QA & Audit, considers the timing of the institution's last routine audit, or its membership date for provisional audits, when making the final determination if the standards are being met. IPMC may contact member institutions to provide the opportunity to discuss site specific issues that may help explain compliance issues. In addition, sites currently on probation or suspension may be contacted to discuss their progress.

IPMC meets before and at the time of the Spring Group Meeting to discuss the information and develop recommendations to present to the Executive Committee. IPMC also meets at the time of the Fall Group Meeting to evaluate ongoing issues and will present to the Executive Committee at the Fall Group Meeting as needed. Committee recommendations are presented to the Executive Committee for discussion and to decide on the action to be taken. IPMC then notifies the sites of the Executive Committee's decisions which may result in a warning, probation, suspension, site termination, or a return to active status. See Deviation Notification to PIs/LIs.

Note: In the course of investigating performance requirements, if the IPMC is made aware of any institutional membership violations (e.g. personal and service requirements), the IPMC will refer the site to the Membership Committee for further action.

Performance Monitoring Requirements

COG member institutions are expected to meet the following minimum standards in order to remain in good standing. The Data Currency and IROC submission requirements apply equally to both Main Member and Affiliate Member institutions unless otherwise identified. See Alternative Requirements.

- Data Currency – a score of ≥ 90% (case report forms based)
- Imaging and Radiation Oncology Core (IROC) Rhode Island Submissions
    - Radiation Therapy Data Submissions – a score of ≥ 90%.
    - Radiation Therapy Protocol Therapy Compliance – a score of ≥ 90% (sites are only considered out of compliance if the low score is due to more than one non-compliant case).
    - Diagnostic Imaging Submissions – a score of ≥ 90%.
- New Patient Registrations/Enrollments –
    - North American Institutions – Main Member institutions must enroll a minimum of 12 and Affiliate Member institutions a minimum of 6 new patients each year on APEC14B1 based on a three-year rolling average.
    - Non-North American Institutions – Main Member institutions must register a minimum of 12 and Affiliate Member institutions a minimum of 6 new patients each year based on a three-year rolling average.
- Cases Available for QA Audit (refer also to Quality Assurance Audit Program)
    - For Established Main Member Institutions – a minimum of 10 therapeutic cases to be audited for the three-year audit cycle.
    - For Established Affiliate Member Institution – a minimum of 5 therapeutic cases to be audited for the three-year audit cycle.

- For Provisional Main Member Institutions – at least 5 therapeutic cases enrolled within 18 months of membership.

Note: Other performance monitoring criteria may be added or modified as determined by the Executive Committee at the recommendation of IPMC and SDC.

Consequences for Failure to Meet Performance Monitoring Requirements

Consequences for failure to meet performance requirements apply equally to both Main Member and Affiliate Member institutions unless otherwise noted.

- Failing Data Currency or IROC Rhode Island Radiation Therapy or Diagnostic Imaging Data Submissions – If an institution fails to meet the (forms-based) data currency or IROC Rhode Island data submission requirement (see Performance Monitoring Requirements), IPMC may make recommendations to suspend the institution until its delinquent data is received. Institutions with persistent or recurrent delinquent data deficiencies may be placed on probation with corrective actions/improvements required to remove the probation. This information will be communicated to the institution's Principal Investigator/Lead Investigator (PI/LI) in a formal notification (see Deviation Notification Letters to PI/LI). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see Notes below).

- Failing IROC Rhode Island Protocol Compliance–The consequences for failing to meet the RT protocol compliance performance requirement (see Performance Monitoring Requirements) is pre-review of radiation therapy treatment plans by IROC-Rhode Island for the next 5 patients or until radiation therapy compliance is 90% or greater (evaluated annually). If an institution fails to demonstrate timely improvement in RT Protocol Compliance, the institution may be placed on probation. This information will be communicated to the institution's PI/LI in a formal notification (see Deviation Notification Letters to PI/LI). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see Notes below).

- Failing New Patient Registrations/Enrollments– If an institution fails to meet the new patient enrollment (see Performance Monitoring Requirements), the institution will be placed on probation with corrective actions/improvements required to remove the probation. This information will be communicated to the institution's PI/LI in a formal notification (see Deviation Letters Notification to PI/LI). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see Notes below).

- Failing QA Audit Case Requirement – if an institution fails to meet the required number of patient cases for a QA audit (see Performance Monitoring Requirements).
  - Established Member Institutions – The institution is referred to the IPMC Chair for consideration of probation or termination for cause. The IPMC Chair will determine if a full committee review is needed and then if the findings should be submitted to the Executive Committee for consideration.
  - Provisional Main Member Institutions – The institution is referred to the IPMC Chair for consideration of continued provisional status or termination for cause. The IPMC

Chair will determine if a full committee review is needed and then if the findings should be submitted to the Executive Committee for consideration.

An institution that does not successfully meet the conditions of probation will be notified of impending termination. Refer to Member Institution Status Change Guidelines & Process for information about probation, suspension, and termination. Refer also to Transition of Research Subjects for Terminated Member Institutions.

Note: For member institution status changes and the impact on Main Member/Affiliate Member relationships, refer to the COG Constitution & Bylaws and Member Institution Status Change Guidelines & Process.

Deviation Notifications to PIs/LIs

When an institution deviates from the standards of performance requirements, the IPMC Chair, after consultation with the Executive Committee, prepares a formal notification to the institution's PI/LI. This notification includes the:

- deviation(s)
- institution's status change, if applicable
- expected corrective actions/improvements needed

Alternative Requirements

COG research activity needs to take place at COG rostered institutions. COG holds rostered institutions to Performance Monitoring Requirements. There may be instances where requirements for all sites, or a subset of unique sites, may require a modification to the requirements.

- The Executive Committee may temporarily modify the Cases Available for QA Audit performance monitoring requirements due to unique circumstances (e.g. closure of a high accruing trial[s]). Sites will be notified of the change in requirements and the information will be posted to the COG Member Website. During this time, the temporary audit case number requirements approved by the motion will take precedent over the requirements noted above in Cases Available for QA Audit.

- The Executive Committee, upon recommendation by the IPMC, may grant exceptions to the New Patient Registrations/ Enrollments and/or Cases Available for QA Audit requirements to a specific site/subset or sites on a case-by-case basis. In rare instances, the Membership Committee may also make an exception recommendation based on institution membership criteria.
    - The site(s) must provide a unique or critical service for COG, serve a unique patient population, or for any other reason as agreed upon by COG Leadership and the Executive Committee.
    - Exceptions will be noted in the Executive Committee minutes, and will specify if the exception is to registration, therapeutic enrollment, or both requirements.

    - These will be communicated to the site(s) by the IPMC Chair on the memo for such notifications and COG Membership will retain this correspondence with the member institution record. It will be noted in the site's record that there is a performance requirement exception. IPMC will also notify COG QA & Audit.
    - Exceptions will be reviewed annually at the Executive Committee meeting at the Spring Group Meeting, and COG reserves the right to end the exception should any of the conditions under which it was granted change. If an exception is lifted, the timeframe for when the site(s) will need to adhere to standard requirements will also be decided.

- All COG member institutions that have therapeutic enrollments attributed to them are required to be audited by the COG QA & Audit Program per Clinical Trails Monitoring Branch (CTMB) guidelines.

- Sites are required to adhere to all other membership requirements, such as active Federalwide Assurance (FWA) and CTEP ID, personnel and service requirements, responsible investigators, etc. as outlined in the COG Constitution & Bylaws and Types of Individual Membership & Application Processes.

Notes:
- Exceptions cannot be granted to any site that has not yet undergone a provisional audit.
- A member institution that the Executive Committee has approved for termination cannot site this exception process as a means to appeal the termination as the Executive Committee would have already ruled out granting an exception prior to termination.

Other Related P&P

- COG Constitution & Bylaws
- CS-006 (Institutional Performance Committee Charter)
- MI-005 (Member Institution Status Change Guidelines & Process)
- QA-001 (Quality Assurance Audit Program)
- MI-008 (Transition of Research Subjects for Terminated Member Institutions)
- MI-002 (Conduct of Clinical Research for Member Institutions)
- OM-002 (Radiation Oncology Participation Requirements)
- MI-012 (Affiliate Member Institution Guidelines)
- IM-001 (Types of Individual Membership & Application Processes)

Who Should Be Knowledgeable About This Policy

Those who are responsible for following the guidelines/performing the procedures that implement this policy (including all COG members, and applicable operations/administrative personnel involved in the Scope of this policy), those who have the oversight and/or supervisory responsibility for these guidelines/procedures, and those who have the responsibility to authorize this policy and its related guidelines/procedures should be knowledgeable about this policy.

SOP Maintenance Responsibility

- SOP Owner – COG Membership Department
- SOP Contact – Manager, COG Membership Department

SOP Authorization

Approval Indicator: Approved by the Executive Committee on 10/21/2024

Version/Revision History

Per *COG Policy & Procedure (P&P) Documentation*, reassessment of this policy will occur at least once every 36 months; interim revisions will be incorporated as needed. The table below documents the version/revision history for this policy. A cumulative history for this document is maintained for ten years.

Approval Date	Version	Version/Revision Summary
05/2002	V1.0	Initial documentation/publication.
06/2008 & 04/2010	V2.0	Reassessment and revisions.
01/08/13	V3.0	Reassessment and republication. Program information from Admin. Section 5.1.
04/12/13	V3.1	Note added to Consequences section.
09/19/14	V4.0	Reassessment and republication.
03/11/16	V5.0	Reassessment and republication.
03/31/17	V5.1	Update to IROC Rhode Island information.
12/14/23	V6.0	Reassessment and revisions. Added requirements for Affiliate Member institutions, updated performance data information, added *Performance Data Review Process,* and added Lead Investigators throughout.
10/21/24	V7.0	Reassessment and revisions. Updated to address instances when site requirements may require modification. Additionally clarified the performance data review process.