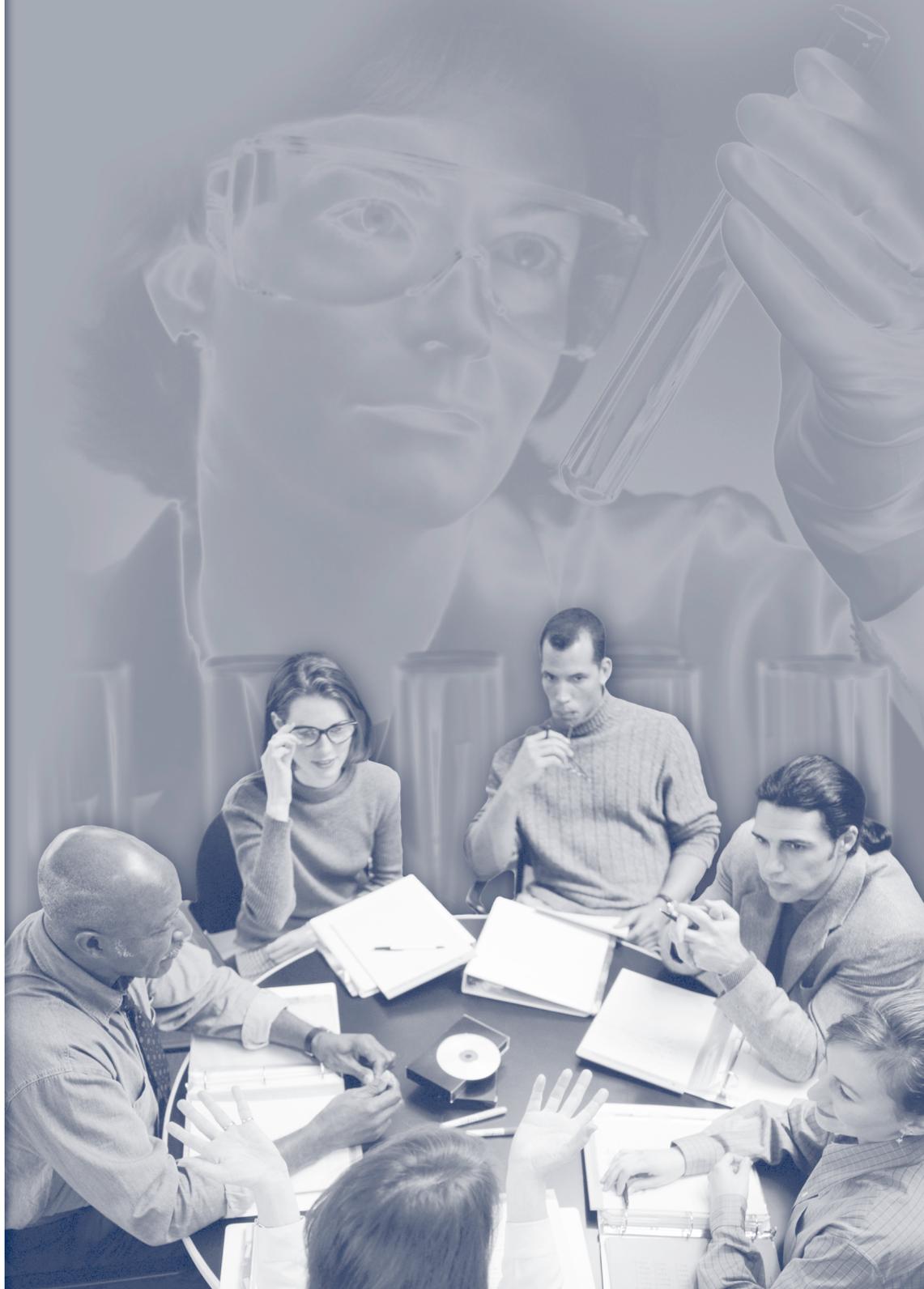




Progress Review Group Primer



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Overview

Our nation faces a formidable challenge—to control and eliminate disease. Ongoing research efforts have laid the groundwork to address this challenge. However, with the fast-paced flow of innovative thinking and research discoveries, a need has arisen to chart the course and develop plans to hasten progress. Progress Review Groups (PRGs) represent one mechanism to assess the state of the science for a particular disease or group of related diseases, identify research gaps and resource needs, and generate recommendations for future research that could guide the field over the next 5 to 10 years. The PRG process entails a comprehensive, collaborative, and integrated approach with three phases: (1) developing recommendations with input from clinical, research, and advocacy communities; (2) planning for and implementing strategies to achieve scientific advances based on PRG recommendations; and (3) reporting on progress made in addressing PRG recommendations. Thus, the PRG process can continually evaluate progress by tracking current and future research trends and can provide a framework for a national effort to control and eliminate disease.

PRG Charge Example

- Identify and prioritize scientific research opportunities and needs to advance medical progress against the disease focus and describe the scientific resources required to address these opportunities and needs
- Compare and contrast these priorities with the sponsoring agency's research portfolio
- Prepare a written report that provides recommendations for addressing opportunities and meeting needs
- Discuss a plan of action with the sponsoring agency leaders to ensure that the priority areas are addressed

This primer is designed to provide both an overview of the PRG process and guidelines for planning and conducting the process. Information included in this primer is based in large part on the 11 PRGs sponsored by the National Cancer Institute (NCI) and implemented by the NCI's Office of Science Planning and Assessment. The NCI PRG website (<http://prg.cancer.gov/>) contains copies of all the reports that have been developed through the PRG process. In combination with this primer, the website can be used as a resource for organizing a PRG.

As a funding agency undertakes this challenge, consideration must be given to the significant investment in tools and resources that are needed to successfully manage the PRG process, including electronic resources and staffing. After careful consideration, if the funding agency decides that the PRG process is the best means to move research forward, the sponsoring agency's staff may establish a charge for the PRG (see example) that emphasizes the importance of identifying scientific opportunities, needs, and resources.

Summary of the Process – Three Phases



The PRG process involves individuals both within and outside the sponsoring agency and is conducted in a sequence of three phases: *Recommendation*, *Implementation*, and *Reporting* (**Figure 1**). Additional details about each phase can be found in the corresponding sections of this primer.

- The *Recommendation Phase* takes approximately 9 to 12 months to complete. The goal of this phase is to prepare a PRG Report that provides an overview of the state of the science, outlines top research priorities and resources needed to address a given disease, and serves as a benchmark from which progress can be assessed. This report is prepared by the PRG, a panel of 20 to 30 prominent members of the scientific, medical, and advocacy communities. An important element of this phase is the Roundtable meeting, a forum in which the PRG receives additional information from a larger group of 80 to 100 renowned leaders from the scientific and advocacy communities.



- The *Implementation Phase* takes approximately 9 months to accomplish. The end product of this phase is an Implementation Strategy that delineates approaches, applications, and resources that will be used to successfully address the PRG recommendations. A working group internal to the sponsoring agency is responsible for developing this plan. Upon approval by the sponsoring agency’s leaders, the plan is implemented, promoted, and monitored over subsequent years.
- The *Reporting Phase* is initiated 3 to 5 years after the publication of the Implementation Strategy. It includes an assessment of progress made in addressing the PRG recommendations and results in the development of a Progress Report by the sponsoring agency that summarizes progress and evolving needs.



Figure 1. The PRG Process

PHASE I

The Recommendation Phase

The purpose of the Recommendation Phase is to identify top research priorities and resources needed to advance the field. The tasks for this phase, the participants' responsibilities, and the projected timeline are depicted in **Table 1**. This process involves bringing together prominent members of the scientific, medical, and advocacy communities who evaluate the state of the science, discuss the impediments to progress against the disease, and identify the research and resources needed to drive the field forward. The primary product of this phase is a PRG Report.

Table 1. Recommendation Phase Tasks, Participants' Responsibilities, and Timeline

<i>Task</i>	<i>Sponsoring Agency Staff</i>	<i>PRG Leadership Team</i>	<i>PRG Members</i>	<i>PRG Roundtable Participants</i>	<i>Approximate Duration</i>
Appoint PRG Leadership Team	✓				< 1 month
Hold Leadership meeting	✓	✓			1/2 day
Recruit PRG members and prepare for Planning meeting	✓	✓			2 to 3 months
Hold PRG Planning meeting	✓	✓	✓		1 to 2 days
Prepare for Roundtable meeting	✓	✓	✓	✓	2 to 3 months
Hold Roundtable meeting	✓	✓	✓	✓	2 to 3 days
Prepare PRG Report	✓	✓	✓	*	3 months
Present PRG Report to sponsoring agency leaders and release report	✓	✓			2-hour meeting/ call

* Some Roundtable participants may contribute to writing portions of the main report if their expertise is necessary or they co-chaired a Breakout Group.

PRG Leadership Team Appointed



The sponsoring agency appoints a Leadership Team composed of an internal agency staff member to serve as Executive Director and two Co-Chairs from the extramural scientific/medical community. The selection of the Leadership Team is critical to the success of the PRG, so each member of the Leadership Team should be a recognized leader in the targeted disease(s) or field and have complementary areas of expertise, e.g., basic scientist, clinician, or consumer advocate. The Leadership Team members should be able to cover a broad spectrum of scientific issues and also have the vision and foresight to develop recommendations that are innovative, promising, and attainable. The Leadership Team members must be able to work effectively as a team; have excellent communication, management, and facilitation skills; and be willing and able to make the significant commitment of time and effort required.

An appropriate high-ranking official within the sponsoring agency invites the nominees to serve as PRG Co-Chairs and Executive Director, clearly outlining the roles and responsibilities associated with the appointment. A written invitation letter and information packet follow this oral invitation.

Hold Leadership Meeting

The Leadership meeting is the first gathering of the two PRG Co-Chairs, the Executive Director, and the sponsoring agency leaders. An important task of this meeting is scheduling the Phase I activities, including conference calls and PRG Planning and Roundtable meetings.

During the Leadership meeting, prominent members of the scientific, medical, and advocacy communities are nominated and tentatively selected, based on their expertise with the targeted disease(s) or field. Consideration is given to adequate disciplinary, institutional, and private sector representation, as well as geographic, gender, and ethnic distribution. A prioritized list of potential PRG members is compiled, and 20 to 30 individuals on this list are typically selected.

Recruit PRG Members and Prepare for Planning Meeting

PRG Member Characteristics

- Expert scientific knowledge (both junior and senior level)
- Representation from scientific, medical, advocacy, and private sector communities
- Adequate disciplinary and institutional representation
- Adequate geographic, gender, and ethnic distribution
- Team players
- Commitment and time to attend three meetings and contribute to preparing the PRG Report

During this 2- to 3-month interval, two important activities take place: (1) recruiting PRG members and (2) preparing for the Planning meeting.

Recruit PRG Members: PRG members are recruited based on nominations made at the Leadership meeting. The PRG Leadership Team, with assistance from sponsoring agency staff, contacts nominees and explains the PRG purpose, process, tasks, and time commitment. A written invitation letter and information packet follow this oral invitation. A PRG website and participant database may be useful tools during member recruitment.

Prepare for the Planning Meeting: While recruiting PRG members, the Leadership Team and the sponsoring agency staff prepare for the Planning meeting. Tasks include: (1) assessing the current research, needs, and gaps and (2) addressing Planning meeting logistics.

Current Research, Needs, and Gaps Analyses. An assessment of current research, needs, and gaps can provide a baseline to frame the Planning and Roundtable meeting discussions. The sponsoring agency can use various methods to accomplish this, including: (1) funding analyses, (2) research portfolio analyses, (3) literature reviews or background papers, and (4) concept mapping.

- A *funding analysis* is a summary of the sponsoring agency's financial investment relevant to the targeted topic. This can be in the form of summary charts showing trends over time, breakdowns by scientific areas, etc. This analysis may be augmented by information from other agencies.
- A *research portfolio analysis* is a compilation of the current research activity funded by the sponsoring agency. It should include ongoing agency-sponsored research in all areas including basic, clinical, and population-based research. These can be in the form of lists of all research projects, clinical trials, and other activities. If the number of ongoing activities is large, it may be useful to sort the activities into categories. For example, the NCI-sponsored portfolio is classified into seven major types of research: (1) biology; (2) etiology; (3) prevention; (4) early detection, diagnosis, and prognosis; (5) treatment; (6) cancer control, survivorship, and outcomes; and (7) scientific model systems.



- *Literature reviews or background papers* summarize the current state of the science, based on peer-reviewed and other relevant scientific publications, emphasizing the nature, key issues, and underlying correlates of the disease field.
- *Concept mapping* is a structured process that enables groups to view relationships among issues, priorities, and subtopics that are considered important. Concept mapping is a multistep process through which a large set of concepts is grouped into a smaller number of clusters. Initially, experts are asked to respond to a specific statement, such as, “Complete the following sentence: Specific actions that should be taken to eliminate this disease are ____.” A long list of responses is culled down to eliminate redundancy (e.g., 500 responses can be culled to 100). Experts are then asked to group similar statements. By statistically analyzing these results, a short list of clusters of related topics are identified (e.g., 100 responses may be grouped into 10 clusters). These clusters can then be used to define Breakout session topics and/or serve as a basis for Roundtable discussions.

Planning Meeting Logistics. Logistics for the Planning meeting are often developed during weekly teleconferences. Specific tasks for the PRG Leadership Team and sponsoring agency staff are outlined in **Table 2**.

Table 2. Planning Meeting Preparations

Participant	Roles/Responsibilities
PRG Leadership Team	Review prior Planning and Roundtable meeting agendas
	Prepare Planning meeting agenda (Figure 2)
	Propose approaches to encourage Planning meeting discussions
	Prepare options for organization of the PRG Report
	Create presentation summarizing current state of the field
Sponsoring Agency Staff	Collaborate with Leadership Team
	Provide guidance to Leadership Team
	Update website, if available
	Prepare current research, needs, and gaps analysis reports
	Track PRG member recruitment
	Provide logistical support
	Send invitation letters, logistics, and other pertinent information to PRG members

Hold PRG Planning Meeting

The PRG Planning meeting is the first meeting of the sponsoring agency and PRG members (see **Figure 2** for sample agenda). Details on the purpose and content of this meeting are provided below. The primary goal is to cooperatively design the Roundtable meeting, which will include 80-100 experts. During the Planning meeting, the PRG develops methods for identifying recommendations and achieving consensus. Usually, both Breakout and consensus sessions are built into a Roundtable meeting. Specific roles and responsibilities are provided in **Table 3**.

During the Planning meeting, PRG members develop Breakout session topics for the approximately 100 attendees at the Roundtable meeting (Figure 2). Breakout session topics should be designed in a manner that will lead to the development of a limited number (typically three) of high-quality recommendations that address the PRG charge (see sample charge on page 2). PRG members should also agree on a strategy for developing a final consensus list of approximately 10 overall recommendations.

PRG Planning Meeting Agenda		
Day 1		
5:30 p.m.	Dinner	
6:45 p.m.	Welcome/Introductions	PRG Co-Chair
7:00 p.m.	Sponsoring Agency's Commitment & Role in Eliminating the Target Disease	Sponsoring Agency Director
	Charge to the PRG: The Role of the PRG	PRG Executive Director
	Current Context	PRG Leadership Team
	- What We Know—State of the Science	
	- Summary of Current Research, Needs, & Gaps Analyses Documents	
8:20 p.m.	Preparation for the Next Day	PRG Co-Chair
8:30 p.m.	Adjourn	
Day 2		
7:00 a.m.	Breakfast	
8:00 a.m.	Review & Discussion of Current Research Needs & Gaps Analyses Documents	PRG Leadership Team
9:00 a.m.	Determine Roundtable Breakouts	PRG
10:30 a.m.	Break	
11:00 a.m.	Identify Breakout Co-Chairs	PRG
12:45 p.m.	Lunch	
2:00 p.m.	Select Breakout Participants	Small Groups
3:15 p.m.	Draft Breakout Agenda	Breakout Co-Chairs/Small Groups
3:45 p.m.	Draft Overall Roundtable Agenda	PRG Co-Chair
4:00 p.m.	Review of Action Items/Closing Comments	PRG Leadership Team
4:15 p.m.	Adjourn	

Figure 2. Sample Planning Meeting Agenda

Table 3. Planning Meeting Roles/Responsibilities

Participant	Roles/Responsibilities
PRG Leadership Team	Present current state of the field
	Facilitate the meeting
PRG Members	Design Roundtable meeting <ul style="list-style-type: none"> - Identify Breakout topics - Nominate Roundtable participants - Identify 2 to 3 Breakout Co-Chairs (at least 1 PRG and 1 non-PRG member) for each Breakout - Draft Roundtable meeting and Breakout agendas
	Draft PRG Report's organization/outline
	Agree upon strategy for reaching consensus and identifying and prioritizing key recommendations
Sponsoring Agency Staff	Provide insight on overall PRG process
	Offer guidance and direction for specific components
	Coordinate meeting and logistics

The PRG is usually given latitude in the design of Breakouts. The sponsoring agency staff provides the PRG with general guidance, such as time limits and examples of Breakout topics used by other PRGs. Breakouts can focus on specific scientific areas (e.g., biology and treatment) or disease topics (e.g., childhood forms of the disease and special issues of the elderly) and may be further subdivided for more in-depth discussions.

Roundtable participants are nominated based on their expertise in the context of the identified Breakouts. The criteria used to select Roundtable participants are similar to those used for PRG members (see page 6). A comprehensive and diverse composition for this group ensures that all research areas, initiatives, and issues will be considered. A prioritized list of potential Roundtable participants is compiled. Eighty to 100 individuals should be selected and assigned to the specific Roundtable Breakouts. Two to three Co-Chairs, including at least one PRG member and one Roundtable participant, are identified to lead each Breakout. The Roundtable meeting and Breakout agendas are drafted, and the organization of the PRG Report is established.

Prepare for Roundtable Meeting

Roundtable Preparation Tips

- Prepare advocates and science writers for their Roundtable meeting roles
- Provide Breakout Co-Chairs and science writers with sample reports, templates for preparing Breakout Reports, and templates for slides to present Breakout recommendations
- Ask Breakout Co-Chairs to draft background information/current state of knowledge in their Breakout topics before the Roundtable meeting

This part of the Recommendation Phase is typically marked by periods of intensive work as the PRG Leadership Team, PRG members, and sponsoring agency staff prepare for the Roundtable meeting. Specific tasks to be accomplished include finalizing the agenda(s) and report formats, inviting Roundtable participants, confirming non-PRG Breakout Co-Chairs, preparing science writers and advocates, and addressing meeting logistics (e.g., hotel, travel, and reimbursement). The roles and responsibilities for this stage are summarized in **Table 4**.

Hold Roundtable Meeting

Roundtable Meeting Goals

- Discuss current knowledge and identify gaps
- Develop recommendations to fill gaps
- Consolidate overlapping recommendations identified by Breakouts
- Build consensus around the recommendations
- Identify approximately 10 consensus recommendations to focus on in the main report
- Draft Breakout Reports
- Outline main PRG Report

The Roundtable meeting provides a forum to discuss the current state of knowledge, identify gaps in efforts, and develop and prioritize scientific recommendations that will advance the field (see sample Agenda, **Figure 3**). The roles and responsibilities for this meeting are summarized in **Table 5**.

The Roundtable meeting may include opening and closing plenary sessions for all participants before and after the Breakouts. In the opening session, participants can be oriented to the meeting process and informed about the current state of scientific knowledge concerning the disease focus so that they enter the Breakouts equally and fully informed.

During the Breakout sessions, participants engage in detailed discussions of their Breakout topics and identify a set number (usually three) of Breakout recommendations. Breakout participants should identify new or existing resources for implementing each recommendation, as well as barriers. Their recommendations can be informed by analyses of the sponsoring agency's current research, needs, and gaps reports (see pages 6 and 7 for possible types of analyses). Upon completion of Breakout group deliberations, the Breakout Co-Chairs and science writers prepare presentations for the plenary session and draft

Table 4. Roundtable Meeting Preparations

Participant	Roles/Responsibilities
PRG Leadership Team	Assist PRG members and Breakout Co-Chairs in inviting Breakout participants
	Finalize Roundtable meeting agenda (Figure 3)
	Prepare presentation(s) on current state of the field and current research, gaps, and needs analyses
PRG Breakout Co-Chairs	Contact and confirm non-PRG Roundtable participants, including non-PRG Co-Chairs
	Finalize Breakout agendas and distribute to Breakout participants
	Prepare draft background/current state-of-knowledge section of the Breakout Reports
Roundtable Scientists	Review meeting support information (e.g., travel information; current research, needs, and gaps reports; and background information prepared by Co-Chairs)
Roundtable Advocates	Review meeting support information (e.g., travel information; current research, needs, and gaps reports; and background information prepared by Co-Chairs)
	Contact Breakout Co-Chairs with questions
	Attend pre-Roundtable teleconference and orientation, if offered
Sponsoring Agency Staff	Work with Leadership Team, Breakout Co-Chairs, Roundtable participants, and lead science writers to complete all pre-meeting tasks
	Coordinate and facilitate teleconferences and other planning activities, (e.g., advocate and Leadership Team teleconferences)
	Send official correspondence and other meeting support information, (e.g., travel information; current research, needs, and gaps reports; and background information prepared by Co-Chairs)
	Secure 10 to 18 science writers (at least 1 science writer is assigned to each Breakout), including 1-2 lead writers
	Hold teleconference with science writers to discuss process and expected product(s)
	Check for potential conflicts of interest among participants who will be making recommendations
Science Writers	Participate in pre-Roundtable science writer teleconference
	Review relevant background literature, previous PRG reports, and templates and software to be used at the meeting

PRG Roundtable Meeting Agenda

Day 1

3:00 p.m.	Pre-Meeting Planning Sessions (Concurrent) - Leadership Pre-Meeting - Advocates Meeting - Science Writers Meeting	
4:00 p.m.	Pre-Meeting Breakout Co-Chair Session	PRG Leadership Team
5:00 p.m.	Dinner	
6:30 p.m.	Welcome/Introductions/Charge to the PRG & Roundtable Participants Sponsoring Agency's Commitment & Role in Eliminating the Target Disease Current Context - What We Know-State of the Science - Summary of Current Research, Needs, & Gaps Analyses Documents	PRG Co-Chair Sponsoring Agency Director PRG Leadership Team
8:20 p.m.	Preparation for the Next Day	PRG Co-Chair
8:30 p.m.	Adjourn	

Day 2

7:00 a.m.	Breakfast	
8:00 a.m.	Plenary - Overview of Breakouts	PRG Co-Chair
8:15 a.m.	Concurrent Science-Centric Breakouts - Prevention - Etiology - Biology - Detection, Diagnosis, & Prognosis - Clinical Studies - Communication & Outcomes	
11:45 a.m.	Lunch	
1:00 p.m.	Plenary Session: Science-Centric Breakout Presentations (15 min. each)	Breakout Co-Chairs
2:30 p.m.	Break	
3:00 p.m.	Concurrent Cross-Cutting Breakouts - Training & Education - New Targets for Development & Therapy - Optimizing Existing Care - Partnership Platforms - Scientific Models	
6:00 p.m.	Adjourn for Dinner	
7:30 p.m.	Note: Co-Chairs & science writers meet after dinner to draft Breakout Reports	

Day 3

7:00 a.m.	Breakfast	
8:00 a.m.	Plenary Session: Cross-Cutting Breakout Presentations (15 min. each)	Breakout Co-Chairs
9:15 a.m.	Prioritize Recommendations	All Participants
10:00 a.m.	Break	
10:15 a.m.	Prioritization Discussions Continue	All Participants
12:15 p.m.	Next Steps & Closing	PRG Co-Chair
12:30 p.m.	Roundtable Adjourns	
12:30 p.m.	Lunch for PRG Members, Breakout Co-Chairs, Science Writers, & Support Staff	
1:30 p.m.	Breakout Co-Chairs and PRG Writing Session	Breakout Co-Chairs & PRG
4:00 p.m.	Draft Breakout Reports Submitted	

Figure 3. Sample Roundtable Meeting Agenda

Table 5. Roundtable Meeting Roles/Responsibilities

Participant	Roles/Responsibilities
PRG Leadership Team	Facilitate Roundtable meeting discussions
	Provide an overview and orientation for all meeting participants
	Provide oversight and guidance for Breakouts
	Lead development and prioritization of key recommendations and resources
	Build consensus around priority recommendations and resources
	Outline main PRG Report
PRG Breakout Co-Chairs	Facilitate Breakout sessions
	Provide input regarding key scientific questions
	Achieve consensus on Breakout recommendations and resources
	Draft Breakout Reports
	Present Breakout group's recommendations to all Roundtable participants
Roundtable Advocates	Offer consumer, patient, advocacy, and family member perspectives
	Identify key questions and barriers
Roundtable Scientists	Offer current state of scientific knowledge and identify gaps
	Identify key scientific questions and barriers for potential recommendations
	Suggest resources for implementing each recommendation
Science Writers	Record discussions and decisions
	Assist Breakout Co-Chairs in preparing draft Breakout Reports and presentations
Sponsoring Agency Staff	Provide oversight and logistic support for Roundtable meeting
	Provide oversight for development of Breakout Reports
	Obtain signed conflict of interest forms from all participants who do not work for the sponsoring agency

Breakout Reports with a background/current state-of-knowledge section (prepared by the Co-Chairs in advance of the meeting) and the group's recommendations, resources, and barriers.

Each Breakout group presents its recommendations to all Roundtable participants. Using a strategy agreed upon during the Planning meeting, the Roundtable participants can then prioritize the Breakout recommendations and select the final list of approximately 10 recommendations to highlight in the PRG Report.

Roundtable Meeting Tips

Breakouts

- Ask Co-Chairs to prepare background summary for Breakout Report prior to meeting. Solicit input from Breakout participants on the background and summary that was prepared by the Breakout Co-Chairs
- Encourage participants to limit the number of recommendations per Breakout to no more than three
- Construct clear and specific recommendations
- To assist in reaching consensus, use a projection system to display recommendations to the entire room

Coordination among Breakouts

- Have PRG Leadership Team and sponsoring agency leadership visit all Breakout sessions, providing facilitation as needed
- Prior to the start of Breakout sessions, hold a dedicated session for advocates to provide additional guidance and support

Roundtable Consensus Recommendations

- Hold a closing consensus session for all attendees to discuss priority recommendations. Complete presentation templates that outline similar summary information for each Breakout
- Focus on specific, clear recommendations rather than numerous overlapping, vague recommendations
- Limit the number of PRG priority recommendations to approximately 10

Reports

- Collect all draft Breakout reports for incorporation into the final PRG Report before PRG members depart
- Draft an outline for the main PRG Report

Signatures

- Collect signatures from PRG members for use on concurrence page in final PRG Report (this can also be done during the Planning Meeting)
- Collect signed Conflict of Interest forms after opening session and ensure that all forms are complete and any potential conflicts are addressed early in the meeting

Prepare PRG Report

The PRG Report provides an overview of the state of the science; outlines top research priorities, resources, and barriers for a given disease or group of diseases; and serves as a benchmark for future assessments of progress. The report reflects the opinions of approximately 100 individuals who have a vested interest in the nation's future research on the targeted disease. A key element of this report is the list of consensus recommendations that will help advance future research. Examples of PRG Report tables of contents are shown in **Figure 4**. In addition, reports from NCI-sponsored PRGs are posted on the Web (<http://prg.cancer.gov/>).

The PRG Leadership Team, with the support of the lead science writers and sponsoring agency staff, is responsible for the overall

development and content of the report. With support from science writers and sponsoring agency staff, Breakout Co-Chairs are responsible for reviewing and coordinating comments from their group members and preparing their Breakout Reports. Each PRG member is given an opportunity to review, comment on, and approve the PRG Report. Finally, concurrence of all PRG members with the content of the PRG Report can be shown by including their signatures in the report.

Present Key Findings to Agency Leaders and Release Report

The PRG Leadership Team may summarize the findings and priority recommendations of the report and present them to the sponsoring agency's Director and senior leadership for suggestions and acceptance. Upon acceptance, the PRG Report is published in electronic and print format and widely disseminated. Posting the electronic version on the website immediately upon approval facilitates public access until the print version is available.

Sample 1 Table of Contents		Sample 2 Table of Contents	
From the PRG	i	From the PRG	i
Executive Summary	ii	Introduction	4
Section I: Scientific Focus Areas	3	Scope of the Problem	5
Biology	5	PRG Charge	5
Etiology	6	State of the Science	5
Prevention	8	Opportunities for Scientific Advancements	7
Early Detection and Diagnosis	8	Challenges to Be Addressed	8
Treatment and Prognosis	9	Ten PRG Consensus Recommendations	8
Control, Survivorship, and Outcomes	9	Discovery	9
Section II: Overarching and Resource Issues	10	Translational Research	9
Environment and Lifestyle	10	Treatment	10
Partnership Platforms	11	Control	10
Behavioral and Health Services Research	12	Infrastructure	11
Scientific Models	13	Conclusion	11
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Other Priorities Identified by the PRG Roundtable	A	Appendix 2: About the Sponsoring Agency's PRG	1-1
About the PRG Process	A	Appendix 3: PRG Member Roster	2-1
PRG Member Roster	A	Appendix 4: Roundtable Participant Roster	3-1
Roundtable Participant Roster	A		4-1

Figure 4. Sample Tables of Contents for PRG Reports*

*Sample NCI PRG Reports can be found at: <http://prg.cancer.gov>.

PHASE II

The Implementation Phase

The purpose of the Implementation Phase is to develop strategies that the sponsoring agency will use to address the recommendations outlined in the PRG Report. This process is used to identify potential gaps and serves as a platform for developing an Implementation Strategy that outlines how the sponsoring agency can address the PRG recommendations. During this phase, a Response meeting provides a forum for the sponsoring agency and the PRG members to discuss approaches proposed for the Implementation Strategy. The tasks for this phase, the participants' responsibilities, and the projected timeline are given in **Table 6**.

Table 6. Implementation Phase Tasks, Participants' Responsibilities, and Timeline

<i>Task</i>	<i>Sponsoring Agency Staff</i>	<i>Working Group</i>	<i>PRG Members</i>	<i>Sponsoring Agency Director</i>	<i>Approximate Duration</i>
Establish internal Working Group	✓				< 1 month
Map agency's initiatives and projects to PRG recommendations	✓	✓			2 to 3 months
Prepare proposal for addressing PRG recommendations	✓	✓			4 to 6 months
Hold Pre-Response meeting	✓	✓		✓	1/2 day
Hold Response meeting	✓	✓	✓	✓	1/2 day
Prepare and promote Implementation Strategy	✓	✓	✓	✓	3 to 4 months
Identify measures of progress	✓	✓			2 to 3 months

Establish Internal Working Group

A group of approximately 7 to 10 disease-specific experts from within the sponsoring agency is established to develop an Implementation Strategy. Members of this Working Group should be able to address the scientific issues within the PRG Report and be familiar with the agency's research portfolio. Working Group members should represent multiple scientific divisions and departments within the

agency, work well on a team, and have the time to perform tasks associated with the Implementation Phase. In addition, it is helpful for the Executive Director of the PRG and/or other agency staff that served on the PRG to join the Working Group. This phase requires periods of concentrated effort.

Map Agency's Initiatives and Projects to PRG Recommendations

The Working Group begins the Implementation Phase by reviewing the PRG Report and mapping the agency's existing initiatives, activities, resources, and funded projects to the PRG recommendations. The end product is a Mapping Document listing sponsoring agency initiatives and projects addressing the PRG recommendations. A Mapping Document can be prepared in outline form with major headings for each PRG recommendation and subheadings for current and planned research activities. It is used to identify both strengths and gaps in the agency's activities and can serve as the baseline for reporting progress in Phase III.

Mapping Document

Information that can be provided for every PRG recommendation includes:

→ Directly Relevant Initiatives

- *List of Requests for Applications (RFAs) and Program Announcements (PAs) that address recommendation*
- *Number of projects funded, both total and disease specific, for each listed RFA/PA*
- *Titles of funded disease-specific projects*

→ Potentially Relevant Initiatives

- *List of relevant RFAs/PAs*
- *Number of projects funded*
- *Titles of funded disease-specific projects*

→ Planned Initiatives

- *Summary description of initiatives in sponsoring agency's current plan and budget proposal that could address the PRG recommendation*

→ Relevant Resources

- *List of sponsoring agency-supported resources, e.g., tissue banks and gene databases*

→ Other Relevant Projects

- *Titles of projects supported by the sponsoring agency that were not solicited through an RFA/PA listed in other sections of the mapping document, e.g., investigator-initiated projects*



Prepare Proposal for Implementing PRG Recommendations

Upon review of the Mapping Document, the Working Group develops a Proposed Strategies to Address Gaps and Needs document. Like the Mapping Document, this proposal is divided into sections that align with each PRG recommendation. It can contain additional details on each recommendation, current agency activities, and proposed strategies. The proposed strategies are designed to fill gaps and needs that are not being addressed by current agency-supported activities and initiatives. These strategies should help expedite progress in each of the areas identified by the PRG.



Proposed Strategies to Address Gaps and Needs Document

Information that can be provided for every PRG recommendation includes:

- *Research Issues/Rationale – Excerpts from the PRG Report that support the recommendation*
- *Current Activity Analysis – Summation of lists included in the Mapping Document*
- *Recommended Position – A brief summation of the Working Group's strategies for future investments*
- *Suggested Strategies*
 - *In Process/Planned – A list and brief description of activities that are/may be supported by the sponsoring agency. This includes both ongoing and new initiatives proposed in the agency's most recent budget*
 - *Newly Proposed – A list and brief description of activities that are not yet included in any current or proposed budgets*

Pre-Response Meeting

The purpose of the Pre-Response meeting is for the Working Group to discuss the proposed strategies with the sponsoring agency's Director. During the Pre-Response meeting, the Director advises the Working Group on a preferred strategic approach, commenting on which proposed strategies can be publicly presented. The Working Group then revises the proposal to reflect the Director's guidance and prepares for the Response meeting.

Response Meeting

To prepare for the Response meeting, PRG members are sent the Mapping Document and a truncated form of the Proposed Strategies to Address Gaps and Needs document (see previous sections for descriptions of these documents) containing only the research issues/rationale and current activity analysis subsections.



During the Response meeting, the sponsoring agency leaders, the Working Group, and the PRG review the agency’s current activities and proposed strategies for implementing the PRG recommendations. The strategies that were agreed on by the sponsoring agency during the Pre-Response meeting can be presented to the PRG by a Working Group member. In addition, PRG members may suggest additional strategies during the meeting. The entire group then discusses the most important strategies for implementing the PRG recommendations and comes to a consensus on key implementation strategies. The roles and responsibilities for the meeting are summarized in **Table 7**.

Table 7. Response Meeting Roles/Responsibilities

Participant	Roles/Responsibilities
Sponsoring Agency Leaders, Staff, and Working Group	For each recommendation, identify current sponsoring agency activities and gaps
	Present proposed strategies to address PRG recommendations
	Assess additional strategies presented by the PRG
	Discuss and select key strategies
PRG Members	Review current sponsoring agency activities and gaps
	As needed, identify additional strategies for addressing PRG recommendations
	Assess strategies proposed by Working Group

Prepare and Promote Implementation Strategy

The Working Group uses the list of proposed approaches presented during the Response meeting and incorporates modifications based on discussions with the PRG as the basis for building the Implementation Strategy. For each approach, the Working Group determines cost, feasibility, available infrastructure, potential impact, and opportunities for partnerships within and outside the agency. To identify which approaches should be incorporated into the Implementation Strategy,

Criteria Used for Prioritizing Strategies

The Implementation Strategy document highlights existing and proposed strategies that the sponsoring agency will support. Factors that can be considered when prioritizing strategies include:

- Does the strategy address the highest priority needs and gaps identified by the PRG?
- Does the strategy build on existing initiatives and leverage existing mechanisms?
- Is the strategy feasible to execute, e.g., based on cost, availability of staff to coordinate, and availability of expertise?
- Does the strategy have the potential to result in a significant return on investment?
- Is the strategy adequately developed?
- Is the strategy new and not overlapping with other initiatives both within and outside the sponsoring agency?



criteria (such as those listed previously) can be established to compare approaches. As illustrated in **Table 8**, a categorization scheme may then be set up for organizing approaches and activities in the Implementation Strategy.

The Working Group drafts a comprehensive Implementation Strategy detailing agency strategies to hasten progress against the disease(s). The draft plan is usually presented to the sponsoring agency’s Director and other high-ranking officials to determine which strategies will be implemented. The report is revised as needed and prepared for publication and dissemination. The Implementation Strategy may be available in electronic and print forms. Examples of Implementation Strategy documents, in the form of NCI Strategic Plans, can be found on the Web (<http://prg.cancer.gov/>).

Table 8. Potential Implementation Strategy Scheme

Activity/Strategy	Description
Ongoing Activities	Initiatives currently supported by the agency
New Activities	Initiatives the agency has started within the past year
Immediate Strategies	Initiatives the agency has started to implement
Short-Term Strategies	Initiatives that the agency is currently developing as a first step toward implementation (Actual implementation may depend upon availability of funds and a final determination that the strategy is feasible and scientifically sound)
Mid-Term Strategies	Initiatives that the agency will further develop over the next several months
Long-Term Strategies	Important strategies that the agency will not be able to implement in the near future

Identify Measures of Progress

The final task for the Working Group is to identify qualitative/quantitative measures to monitor progress on PRG recommendations and activities outlined in the Implementation Strategy. These measures should include both short- and long-term milestones. If appropriate, monitoring systems may be established that could include progress reports or meetings.

In addition, the sponsoring agency may establish a system to track and quantify research activities and accomplishments. For example, a database may be used to link individual projects to the PRG recommendations that they address. Publications, patents, and research findings that result from agency-supported projects may also be tracked in a database.

PHASE III

The Reporting Phase

The purpose of the Reporting Phase, which take place 3 to 5 years after the Implementation Phase, is to assess progress since the PRG Report was published. This process involves review and analysis by the sponsoring agency staff and the Working Group of initiatives and projects that supported research on the targeted disease. The results of this assessment are incorporated into a progress report. The tasks for this phase, the participants' responsibilities, and the projected timeline are depicted in **Table 9**.

Table 9. Reporting Phase Tasks, Participants' Responsibilities, and Timeline

Task	Sponsoring Agency Staff	Working Group	PRG Members	Approximate Duration
Reconvene Working Group	✓			1 month
Collect and analyze data	✓	✓		3 to 10 months*
Prepare Progress Report	✓	✓		2 to 4 months*
Discuss progress with sponsoring agency leaders and advisors	✓	✓		1 to 2 months
Reconvene PRG and hold a PRG meeting (optional)	✓	✓	✓	1 to 2 months*
Refine Implementation Strategy	✓	✓	✓	1 to 2 months

*Overlapping activities

Reconvene Working Group

Three to 4 years after the publication of the Implementation Strategy, the Reporting Phase is initiated by reconvening the Working Group. The agency may augment the initial Working Group members with additional members who bring scientific expertise in areas that have been very active in recent years. For example, during the Implementation Phase, one member of the Working Group may represent basic biology. However, if biology has been a very active research area, it may be necessary to add additional members with this expertise to the Working Group.

Collect and Analyze Data



Collecting and analyzing data are the steps that require the majority of time in the Reporting Phase. However, while these require the most time, they do not have to be completed before beginning to write the report. In general, measures of progress can be categorized into four groups: standard metrics used to assess research progress, number of projects responsive to PRG recommendations, initiatives implemented as a result of the Implementation Strategy, and research accomplishments.

- Standard metrics include measures that are commonly viewed by the scientific community as markers of progress. These can include trends in numbers of publications and patents, and clinical trials, funding, and disease statistics. Data can be analyzed over time and presented by year from a few years preceding the PRG Report to the present.
- The sponsoring agency's responsiveness to PRG recommendations can be gauged, in part, by the number of projects addressing each recommendation. During the Implementation Phase, ongoing projects were mapped to each PRG recommendation to establish baseline support and identify gaps. Projects supported since the publication of the PRG Report can be mapped to each recommendation and the number of these projects can be compared to baseline data.
- The Implementation Strategy outlined ongoing, new, and proposed initiatives that could address PRG recommendations. Details on the status of these and other relevant initiatives and resulting research projects and findings can be assessed.
- Since research accomplishments can be quite extensive, it could be difficult to develop a comprehensive list of accomplishments covering research results for a specific disease. However, examples can be collected that cite particularly exciting, novel, or emerging areas of investigation. These examples can be used to illustrate progress and complement the statistics reported for the previous three measures of progress.

Prepare Progress Report

The sponsoring agency staff collaborate with the Working Group to prepare a Progress Report. The goals of the report are to provide a synopsis of progress over the previous 3 to 5 years and to report on agency actions in response to PRG recommendations and the Implementation Strategy. Since the Progress Report, in part, provides a forum for accountability and communication, both positive and negative trends should be included. (See **Figure 5** for a sample Table of Contents. Completed NCI progress reports can be found at: <http://prg.cancer.gov>.)

Discuss Progress with Sponsoring Agency Leaders and Advisors

The Progress Report can be used as a basis for experts to discuss progress made by the sponsoring agency. These experts can be from within the agency or they can be a group of external advisors, e.g., a reconstituted PRG (see below). Based on the advice of experts, the sponsoring agency may make course corrections, as needed.

Reconvene PRG and Hold a PRG Meeting (optional)

A 20- to 30-member PRG can be reconstituted for the purpose of reviewing the Progress Report, discussing progress with sponsoring agency staff, and recommending adjustments to current and future implementation strategies. As with the original PRG, members represent the scientific, medical, and advocacy communities, as well as the private sector. Consideration is given to adequate disciplinary, institutional, geographic, gender, and ethnic representation. If available, members of the original Leadership Team can be invited to coordinate the reconstituted PRG. The reconstituted PRG may contain a combination of individuals from the original panel and new members.

A PRG meeting can be held to provide an opportunity for the sponsoring agency to discuss progress with experts in the field. Based upon the Progress Report, the PRG can discuss (1) measures of progress, (2) how well the agency has addressed recommendations developed in Phase I by following through on the Implementation Strategy developed in Phase II, and (3) continuing and new gaps in the research portfolio. The PRG may suggest revising, or retiring, recommendations and strategies that were instituted through Phases I and II or developing new ones.

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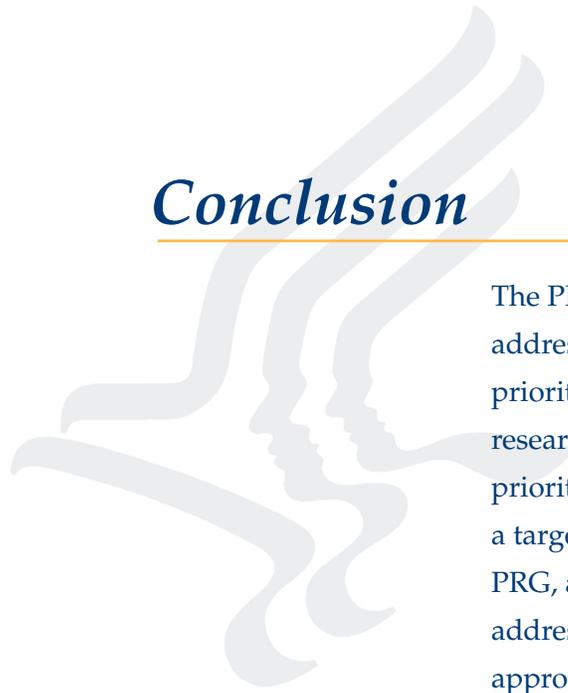
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Figure 5. Sample Progress Report Table of Contents

Refine Implementation Strategy

Based upon the Progress Report, the sponsoring agency may revise the Implementation Strategy. The format of this update will depend upon the issues related to the disease and the extent of change since the PRG was first convened and the Implementation Strategy was developed.

This final step addresses the overall goal of the PRG process: To provide a vehicle through which an agency can chart a course to hasten research progress. This course may be different from the one established 3 to 4 years earlier; however, this flexibility provides a means to adapt to changing and emerging needs.



Conclusion

The PRG process can help agencies sustain high-quality science, address emergent needs, and make appropriate course corrections for prioritizing research investments. A PRG can assist in shaping research directions by providing an agency with guidance on research priorities, gaps, and resources that are needed to advance research on a targeted disease or field. Based upon the guidance provided by a PRG, a sponsoring agency can develop an Implementation Strategy to address these priorities. Through continued communication and appropriate course corrections, the agency can respond and adjust its plan to address the fast-paced flow of new and emerging research needs.

