



Portfolio Strategy & Management Board

Terms of reference

1. Aim of the Portfolio Strategy & Management Board

The Portfolio Strategy & Management Board (PSMB) is the CEPI Management decision-making body with accountability for identification, selection, management and evaluation of CEPI's Research & Development and Manufacturing (R&D&M) portfolio, which comprises vaccine candidate, platform technology, manufacturing and enabling sciences investments.

The remit and operating practices of the PSMB are outlined in these terms of reference. In outbreak situations requiring rapid decision-making under conditions of high uncertainty, a focused “outbreak response PSMB” may be established. Specific adaptations to PSMB terms of reference that apply for “outbreak response PSMB” are provided in Appendix I.

2. Relation of the PSMB within CEPI's governance structure

The PSMB is CEPI Management's principal decision-making authority relating to the R&D&M investment portfolio. The PSMB is accountable to the CEPI Leadership Team and operates as the Leadership Team's delegated authority for R&D&M portfolio decision-making. Decision-making follows delegation of authority and ultimately the PSMB is advisory to the CEO's decision authority. The PSMB provides overall oversight of portfolio progress and serves to: guide portfolio strategy; endorse new investments; provide resolution of significant project issues escalated by the Vaccines Research & Development & Manufacturing Committee (VRDMC); and approve recommendations for project progression provided by the VRDMC at Stage Gate Reviews. The PSMB receives scientific and technical input and advice from the VRDMC, and from CEPI's Scientific Advisory Committee as required. A summary of the relationship of the PSMB in CEPI's governance structure is provided in Figure I.

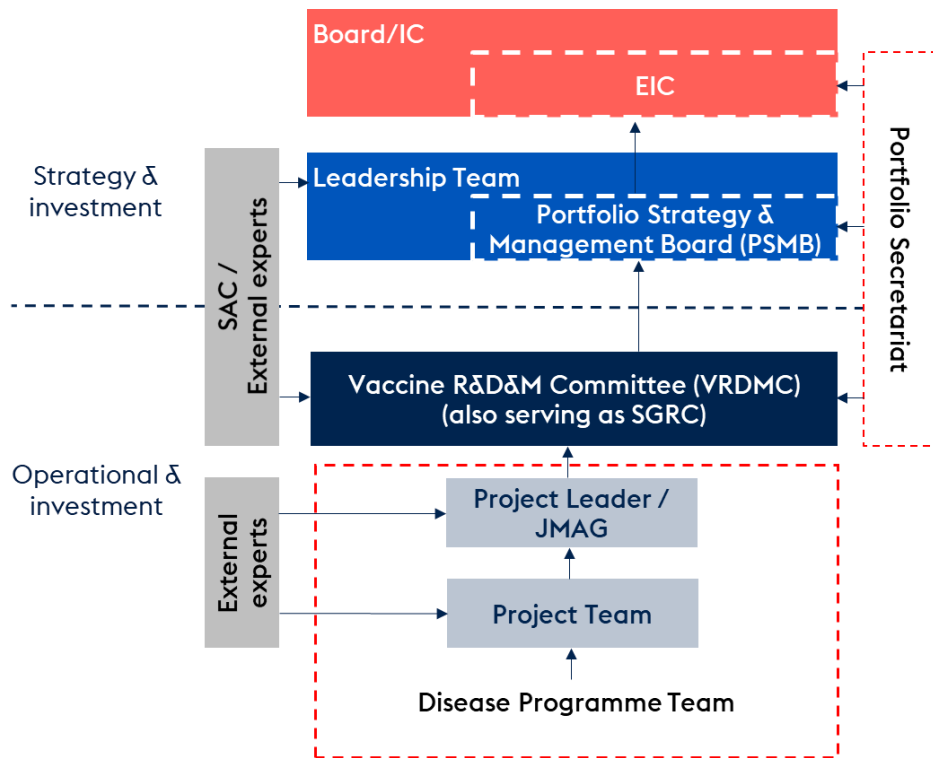


FIGURE I: Summary of the relationship of the PSMB in CEPI's governance structure

3. Objectives of the PSMB

The principal objectives of the PSMB are:

1. Define and oversee the R&D and manufacturing portfolio and investment strategies needed to achieve CEPI's overarching strategic objectives and targets.
2. Define the target vaccine candidate, platform technology, manufacturing and enabling sciences portfolio composition, diversity, investment allocation and risk.
3. Drive portfolio and project decision-making to achieve the target portfolio, and deliver on strategic targets:
 - i. Opportunity identification - **define** strategic priorities for the portfolio and per investment area and **approve** scope and launch of calls for proposals
 - ii. Opportunity prioritisation and selection – **approve** investment in new projects / new partnerships
 - iii. Portfolio execution and monitoring – **approve** change requests of strategic/portfolio importance; resolution of strategic issues
 - iv. Portfolio review and evaluation – **approve** Stage Gate Review decisions, **approve** project terminations
4. Surface and address cross-portfolio challenges, interdependencies and decisions.
5. Oversee progress of the portfolio of vaccine candidate, platform technology, manufacturing and enabling sciences projects.

The activities and deliverables of the PSMB include (but are not limited to):

- Development of portfolio and investment strategies for R&D and manufacturing investment areas (pathogens, technology platforms, modalities etc.).
- Definition of target vaccine candidate, platform technology, manufacturing and enabling sciences portfolio composition, diversity, investment allocation and risk.
- Decisions on project prioritisation and selection (and investment and resource allocation if necessary).
- Decisions on project termination.
- Endorsement of recommendations for investment priorities for disease and other investment areas. Monitoring of overall project progress and resolution of escalated project issues.
- Approval of project change requests that meet the delegation of authority for PSMB
- Approval of recommendations for project progression (Stage Gate Reviews).

An overview of CEPI's R&D&M portfolio management cycle, and the accountabilities of PSMB within each phase is provided in Appendix 2 Level I Portfolio Management Process Flows.

4. Membership of the PSMB

The PSMB is comprised of the CEPI CEO, Deputy CEO, Executive Directors or Directors of relevant CEPI departments, external technical experts and a Portfolio Secretariat.

Additional external experts may attend PSMB meetings to provide topic or project specific input as required.

Members

Core members (attend all meetings and consulted on all decisions):

- Strategic Advisor to the CEO (Chair), Luc Debruyne
- Executive Director R&D (vice-Chair), Melanie Saville
- CEO, Richard Hatchett
- Deputy CEO, Frederik Kristensen
- Executive Director Manufacturing, Anand Ekambaram
- Executive Director Preparedness and Response, Nicole Lurie
- Director Finance & Operations, Mads Høgholen
- Director Access and Private Partnerships, Emma Wheatley
- Director Strategy & Portfolio, Stephen Mayhew
- External technical expert (R&D) & Vice-Chair CEPI SAC, Laura Palomares
- External technical expert (manufacturing) & Vice-Chair CEPI SAC, Mike King
- External technical expert (clinical trials/epidemiology), Shabir Madhi
- External technical expert (vaccine development/clinical/regulatory) & member of CEPI SAC, Peter Dull

Extended members:

- Director Governance, Risk and Compliance
- Director of Programmes and Technology
- Head of Technology Office
- Chief of Staff
- Portfolio Secretariat (consisting of representatives from Portfolio Management, R&D, Finance, GRC and APP)
- Pathogen area leads / Disease Programme Leads
- R&D Leadership Team (RDLT) members

Roles and responsibilities

Chair / vice-Chair:

- Oversees agendas to ensure strategic focus and has final say over agenda and time allocated for each topic.
- Provides input and perspectives into progress with CEPI 2022 priorities.
- Ensures appropriate information flows with the LT and other CEPI Committees
- Responsible for conducting the meeting and for fostering a culture of inclusivity, transparency and accountability.
- Responsible for steering discussions and ensuring relevant perspectives and all core members input are contributed.
- Accountable for ensuring decisions are taken and arising actions are captured.
- If there is no consensus, the Chair decides and has ultimate decision-making accountability for each topic.
- Provides decision recommendation to the CEO / EIC.

Portfolio Secretariat:

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- Manage, administer and provide high quality support to the PSMB including making practical arrangements for the meetings, maintaining a forward plan of agenda items and liaising with the Chair to prepare agendas, and preparing, checking and issuing accurate minutes.
- Advise and support the Chair as appropriate to ensure they are sufficiently supported in carrying out their functions and meeting their objectives, including; preparing briefings and arranging briefing meetings.
- Ensure high quality information is issued to the PSMB by supporting the preparation of presentations, progress reports and other materials as needed.
- Ensure that all documentation (pre-read, presentation materials, minutes etc) is stored appropriately and that systems are in place for logging and tracking decisions.
- Ensure that actions from meetings are followed up by designated staff to ensure that issues raised are appropriately tracked; take ownership and management of any governance issues; take follow up or remedial actions if required.
- Support and maintain a culture of continuous improvement and operational excellence, ensuring that all governance processes are robust and fit for purpose and conducting annual effectiveness survey.
- Develop and maintain excellent relationships with internal and external stakeholders on governance issues to improve information exchange and understanding of the roles of CEPI internal governance bodies.

Core Member:

- Attends all meetings (i.e., cannot delegate participation unless in exceptional circumstances).
- Accountable for topics and projects delegated to self or department.
- Actively contributes to discussions to shape decisions and consulted on all decisions.
- Accountable for actions delegated to self or department.

Extended Member:

- Attends meetings on an agenda-driven basis to provide topic or project specific input and periodic disease specific reviews.
- Actively contributes topic or project specific expertise / insight as required on relevant topics.
- Accountable for actions delegated to self.

Invited Presenter:

- Presents structured summary of topic or project and highlights areas that require decisions and input from the PSMB.
- Responsible for communicating / incorporating feedback into future topic or project plans.
- Accountable for actions delegated to self or Project Team.

PSMB members may be appointed to act as “PSMB Sponsors” of specific topics and/or projects, with accountability for overall leadership of topics and/or projects in

alignment with PSMB expectations. Sponsors will work directly with department and/or team members to set and deliver topic and/or project objectives; and will represent the topic and/or project during PSMB meetings.

5. PSMB operating practices

PSMB decisions will be driven on consensus. If consensus cannot be reached, decision will be by the PSMB Chair.

The PSMB will meet on a monthly basis either face to face or by video conference. Meeting logistics and calendar invitations will be managed by the Portfolio Secretariat. Ad hoc meetings may be called on time-sensitive decisions with request made to the PSMB Chair. In exceptional cases, items requiring time-sensitive decision may be sought by e-mail. E-mail decisions will be officially reported in the minutes of the next scheduled meeting.

The PSMB must have a quorum (attendance for the PSMB to session) of at least two thirds of PSMB core members, including the Chair and at least one additional external core member.

PSMB meeting agendas will follow a standard format and include i) opening remarks ii) a routine portfolio overview; iii) arising project specific topics requiring PSMB attention; and iv) project or topic and disease deep-dives.

A calendar of agenda topics will be developed on a rolling six-month basis based on portfolio and project milestones, and strategic / business cycle requirements (e.g., new calls for proposals). Meeting agendas will be developed by the Portfolio Secretariat with input from PSMB members and approved by the Chair.

Standard monthly portfolio and project reports will be prepared by the Portfolio Secretariat and shared with PSMB members before each meeting as part of the meeting pre-reading materials. Presentation materials will be prepared by the topic lead and reviewed with the Portfolio Secretariat prior to inclusion in the meeting pre-reading materials. Agenda topics will be clearly marked as for information / discussion / decision, along with any specific requests of PSMB. Pre-reading materials will be issued to all PSMB members by the Portfolio Secretariat in advance of the meeting (targeted at least two working days beforehand).

PSMB meeting minutes and actions will be prepared by the Portfolio Secretariat, reviewed and approved by the Chair and issued to PSMB members.

For recording purpose, the Portfolio Secretariat should be copied on all communication related to the PSMB.

Appendices:

1. Specific adaptations to PSMB terms of reference for “outbreak response PSMB”
2. Level I Portfolio Management Process Flows

Appendix I: Specific adaptations to PSMB terms of reference for “outbreak response PSMB”

An outbreak situation requires adaptation of portfolio decision-making:

- Need for faster decision-making
- Need for greater flexibility in decision-making processes
- Need for more frequent review
- Need to more closely monitor external developments (epidemiology, non-CEPI funded vaccine efforts, political and economic impact)
- Limited data availability and, potentially, reliability
- Greater public attention and, potentially, public / investor scrutiny

Specific adaptations to PSMB terms of reference that apply to “outbreak response PSMB” are described below.

Relation of the “outbreak response PSMB” within CEPI's governance structure

An “outbreak response PSMB” is the CEPI secretariat’s decision-making authority relating to a portfolio of R&D investments specifically intended to address a given outbreak. The “outbreak response PSMB” is a delegated authority of CEPI’s full PSMB with accountability for “outbreak portfolio” decision-making. An “outbreak response PSMB” will interact closely with the CEPI Leadership Team, the R&D Leadership Team and any outbreak-specific Incident Management Team (IMT – if established beyond the Preparedness and Response Department). A summary of the relationship of an “outbreak response PSMB” in CEPI’s outbreak governance structure is provided in Figure AI.

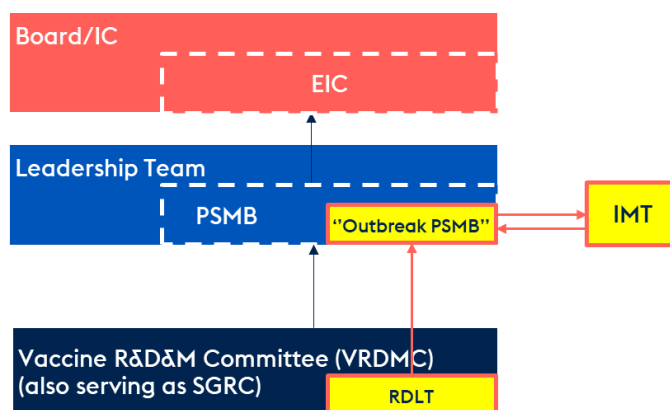


FIGURE AI: Summary of the relationship of an “outbreak response PSMB” in CEPI’s outbreak governance structure.

Membership of the “outbreak response PSMB”

The “outbreak response PSMB” is comprised of core PSMB members, key additional R&D Leadership Team (RDLT) members (as nominated), CEPI’s Chief of Staff and IMT lead. The “outbreak response PSMB” is chaired by the PSMB Chair, or a separate Chair may be nominated by the CEO.

“Outbreak response PSMB” operating practices

The “outbreak response PSMB” will meet on a weekly basis either face to face or by video conference.

The “outbreak response PSMB” must have a quorum of at least two thirds of PSMB core members and include either the Chair or vice-Chair to session.

Decision-making relating to an “outbreak portfolio” will follow CEPI’s established portfolio decision principles and framework for i) opportunity identification, ii) opportunity prioritisation and selection, iii) portfolio execution and monitoring and iv) portfolio review and evaluation, adapted as required to enable rapid response and account for gaps in information.

Portfolio and project decisions will follow CEPI’s established decision criteria, which may be tailored for specific “outbreak portfolio” objectives (e.g. scalability, speed, access).

More flexible go / no decision points may be introduced to enable rapid on / off-ramping based upon corresponding technical and portfolio Stage Gate criteria that will be developed to meet “outbreak portfolio” objectives.

Weekly outbreak portfolio and project reports will be prepared by the Portfolio Secretariat (in conjunction with Project Teams) and shared with “outbreak PSMB” members before each meeting as part of the meeting pre-reading materials.

The implications of an “outbreak portfolio” on CEPI’s core portfolio projects and activities will be routinely monitored, and any interdependencies will be managed on a case-by-case basis by CEPI’s full PSMB.

Appendix 2: Level I Portfolio Management Decision Flows

CEPI's R&D&M portfolio management operating model comprises a defined portfolio cycle (figure A2-1) for all vaccine candidate, platform, manufacturing & enabling sciences investments. Portfolio management is a cross-functional activity concerned with identification, selection, management and evaluation of CEPI's R&D&M portfolio in line with strategic objectives and capacity to deliver, with the goal of optimising return on investment. Level I portfolio management decision flows are described in figures A2-2, A2-3, A2-4 and A2-5.

In scope:

- Vaccine candidate investments
- Platform technology investments
- Manufacturing investments
- Enabling sciences investments (assays & standards, epidemiology, diagnostics, clinical research)

Not in scope:

- Business / administrative investments and non-portfolio public partnership investments

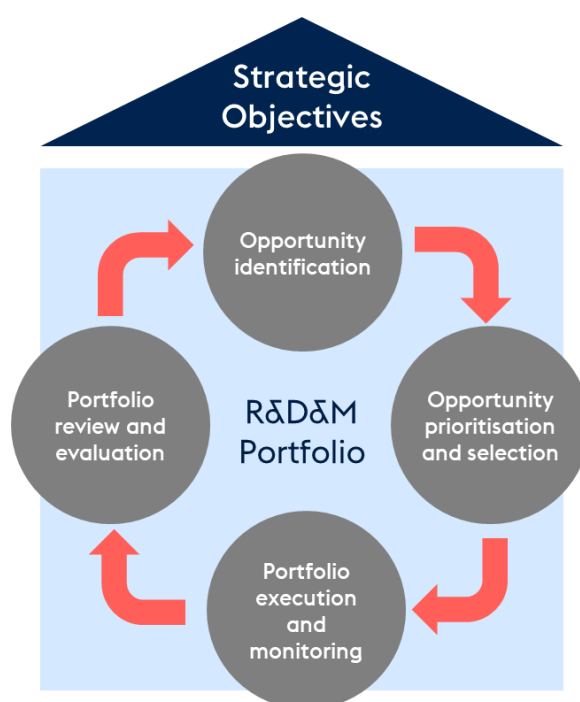


FIGURE A2-1. CEPI's R&D&M portfolio management cycle

L1 Portfolio Decision Processes | Opportunity Identification¹⁾

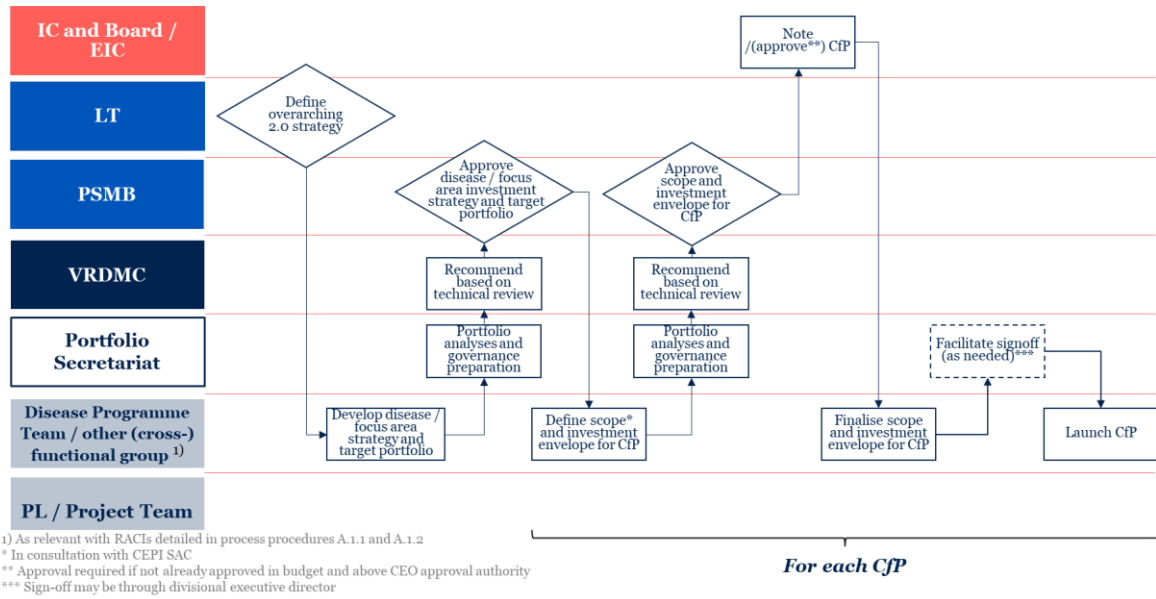


FIGURE A2-2. LI Portfolio Decision Processes: Opportunity Identification

L1 Portfolio Decision Processes | Opportunity prioritisation and selection¹⁾

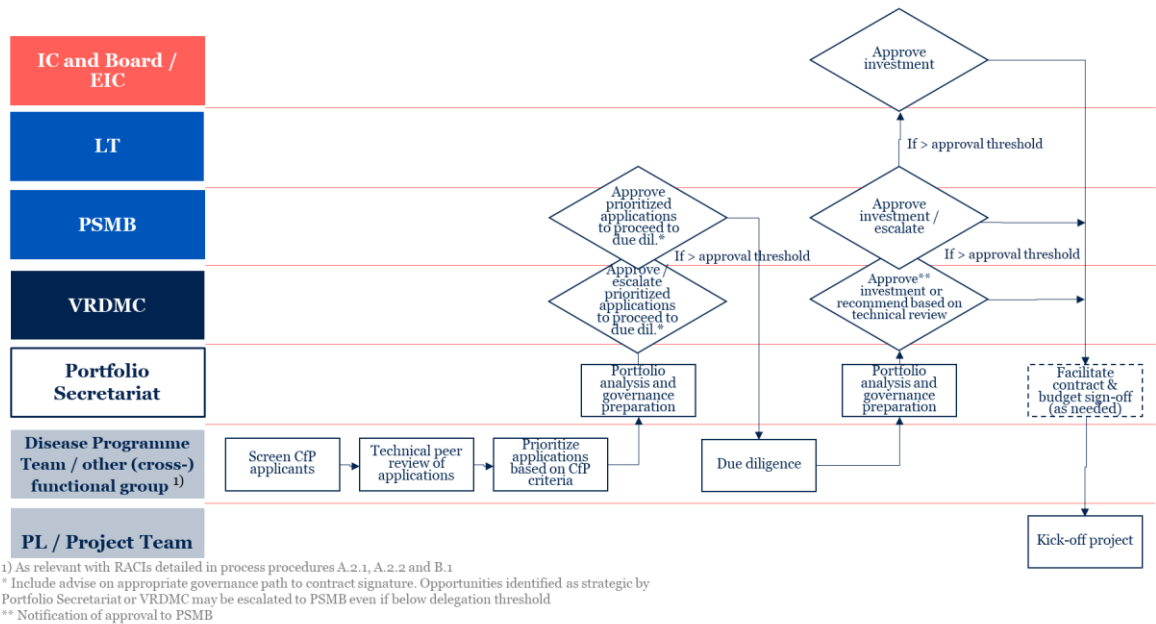


FIGURE A2-3. LI Portfolio Decision Processes: Opportunity prioritisation and selection

L1 Portfolio Decision Processes | Portfolio execution and monitoring¹⁾

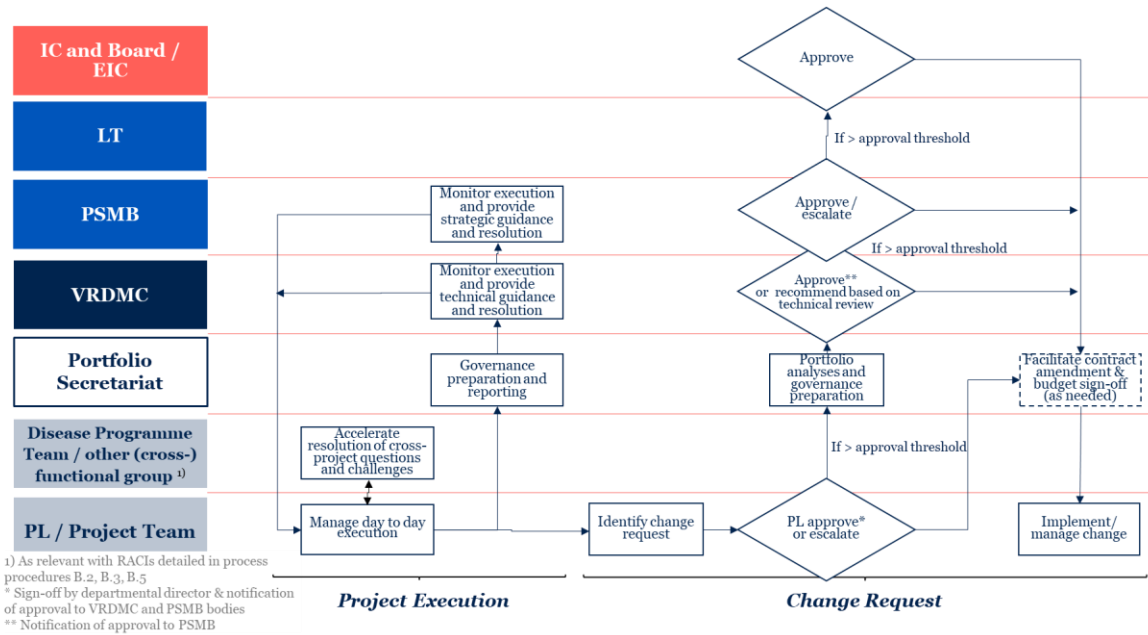


FIGURE A2-4. LI Portfolio Decision Processes: Portfolio execution and monitoring

L1 Portfolio Decision Processes | Stage Gate and Portfolio Reviews¹⁾

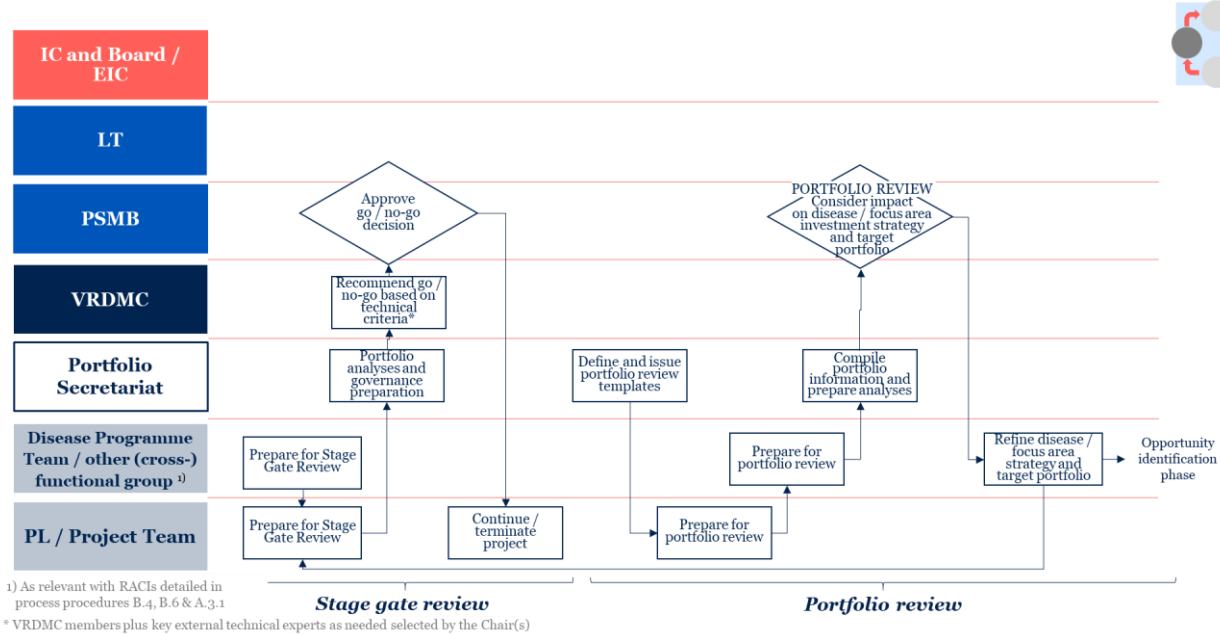


FIGURE A2-5. LI Portfolio Decision Processes: Stage Gate and Portfolio Reviews