

Kidney Health Initiative Governance Task Force Recommendations

EXECUTIVE SUMMARY

BACKGROUND

The mission of the Governance Task Force was to make recommendations on Kidney Health Initiative's (KHI) governance and oversight structure. These recommendations were approved by the KHI Board of Directors (BOD) on July 20, 2022.

These recommendations addressed a need to:

- Determine a decision-making framework that: defines KHI's strategic priorities, approves projects aligned to strategic priorities, and approves the composition of the BOD membership.
- Develop strategies for membership engagement into KHI priorities and activities.
- Decide charge and governance of advisory groups to guide decision-making.

SUMMARY OF RECOMMENDATIONS

1. Update KHI's Governance Structure
2. Establish the Charge and Governance of Standing Committees
3. Establish a Framework for Strategic Priorities
4. Establish a Framework for Approving Activities and Projects

TASK FORCE RECOMMENDATIONS TO KHI BOD

1. Update KHI's Governance Structure

- a. Revise the BOD structure as four standing committees.
 - i. Strategy Committee
 - ii. Biologics Committee (includes xenotransplantation; cellular, tissue, and gene therapies; and vaccines)
 - iii. Devices Committee (includes devices, diagnostics, and digital health)
 - iv. Drugs Committee
- b. Increase BOD engagement of KHI members through the standing committees.
 - i. KHI member organizations are represented through interactions with the Biologics, Devices, and/or Drugs Committees.
 - ii. These committees identify challenges and opportunities facing the member and broader kidney community in developing treatment options for people with kidney diseases.

- iii. These committees translate findings into KHI activities, e.g., projects and forums, as recommendations to the Strategy Committee.
- c. Update the responsibility for the Chair of the KHI BOD to include service as Chair of the Strategy Committee.
- d. Update the KHI BOD Chair nomination and selection criteria.

2. Establish Charge and Governance of Standing Committees

- a. Create a Strategy Committee that acts on behalf of the entire KHI BOD to approve priorities recommended by the Biologics, Devices, and Drugs Committees as aligned to KHI's mission, values, and availability of resources.
- b. Establish Strategy Committee functions and responsibilities.
 - i. Prioritizing and approving proposals for projects and activities based on alignment to KHI priorities, deliverables, and resource availability.
 - ii. Approving major revisions to project scope and budget.
 - iii. Approving final project deliverables.
 - iv. Establishing and closing out ad hoc committees and task forces.
 - v. Approving KHI membership applications.
 - vi. Approving changes to member categories and annual membership fee structure.
 - vii. Approving chairs and themes for the Annual Stakeholder Meeting.
 - viii. Developing and approving three-year objectives.
 - ix. Refining and approving annual goals and key performance indicators.
 - x. Conducting routine review of three-year objectives and annual goals, adapting as needed.
 - xi. Updating ASN Council on KHI strategy and accomplishments.
- c. Establish composition of the Strategy Committee. This committee consists of up-to nine individuals, not including non-voting ex-officio members.
 - i. Chair
 - ii. Ex-Officio (Nonvoting)
 - FDA Liaison
 - ASN Council Liaison
 - Chair, KHI Patient and Family Partnership Council
 - ASN Executive Vice President
 - ASN Vice President of Research, Discovery, and Innovation
 - iii. In Attendance
 - Chairs of Biologics, Devices, and Drugs Committees
 - Patient advocate interested in kidney diseases and related conditions
 - Representative from large-sized private sector company that encompasses the breadth of FDA's mission
 - Representative from small to mid-sized private sector company that encompasses the breadth of FDA's mission

- Health professional with expertise in kidney diseases
 - At-large member
- d. Elevate the Biologics, Devices, and Drugs subgroups to committees responsible for oversight of activities and projects approved by the Strategy Committee. The committees also recommend to the Strategy Committee strategic priorities that represent their communities.
- e. Establish functions and responsibilities for the Biologics, Devices, and Drugs Committees.
- i. Engaging the KHI member and broader community.
 - ii. Soliciting, developing, reviewing, and endorsing concepts for projects and activities based on criteria related to pre-competitive and patient-focused regulatory science and innovation.
 - iii. Approving activity and project work plans, and rosters of working groups.
 - iv. Approving minor project revisions in scope and budget.
 - v. Recommending ad hoc committees and task forces.
 - vi. Recruiting, reviewing, and recommending prospective KHI members.
 - vii. Developing topical themes for the KHI Annual Stakeholder Meeting.
 - viii. Defining strategic opportunities with input from KHI members, BOD, FDA, ASN as relevant to KHI's three-year objectives and annual goals.
 - ix. Drafting annual goals and selecting key performance indicators that track progress.
 - x. Communicating annual strategic goals to the KHI membership.
- f. Establish composition for the Biologics, Devices, and Drugs Committees. These committees will consist of individuals who are experts in their field with diverse representation from areas such as government, industry, academia, and the patient advocacy community.
- i. Chair of either Biologics, Devices, or Drugs Committee, as represented in Strategy Committee
 - ii. Ex-Officio (Nonvoting)
 - Government representatives serving as Federal liaisons
 - ASN staff liaison
 - iii. In Attendance
 - Patient advocates interested in kidney diseases and related conditions
 - Representatives from commercial interests that encompass the breadth of FDA's mission
 - Health professionals with expertise in kidney diseases

3. Establish Framework for Defining KHI Strategic Priorities

- a. Implement a framework for the BOD to engage members, FDA, ASN leadership, and other BOD members on the strategic direction of KHI.
 - i. Identify strategic issues through the Biologics, Devices, and Drugs Committees.
 - ii. Prioritize and approve through the Strategy Committee.
- b. Establish long-term objectives every three years that frame annual strategic goals. The Strategy Committee monitors progress and updates as needed.

Framework for establishing three-year objectives

Engage the Community	Shape the Strategy	Finalize the Strategy	Manage Performance
<ul style="list-style-type: none"> • Define opportunities with input from KHI members, BOD, FDA, ASN • Assess strategic issues 	<ul style="list-style-type: none"> • Review mission and vision • Draft three-year objectives 	<ul style="list-style-type: none"> • Finalize objectives • Submit to ASN Council for discussion 	<ul style="list-style-type: none"> • Communicate strategic objectives to the KHI membership • Review annually
Biologics, Devices, Drugs Committees	Strategy Committee	Strategy Committee, ASN Council	All Committees, KHI staff

- c. Develop short-term annual goals that focus KHI activities and projects, and where possible, implementation.

Framework for developing annual goals

Engage the Community	Shape the Strategy	Finalize the Strategy	Manage Performance
<ul style="list-style-type: none"> • Define opportunities with input from KHI members, BOD, FDA, ASN • Assess strategic issues 	<ul style="list-style-type: none"> • Review mission, vision, long-term objectives • Draft annual goals • Select indicators to track progress 	<ul style="list-style-type: none"> • Refine annual goals and indicators • Align with resources • Approve annual goals and indicators 	<ul style="list-style-type: none"> • Communicate strategic goals to KHI membership • Adapt quarterly • Update annually
Biologics, Devices, Drugs Committees	Biologics, Devices, Drugs Committees	Strategy Committee	All Committees, KHI staff

4. Establish Framework for Approving KHI’s Activities and Projects

- a. Implement a process for the Biologics, Devices, and Drugs Committees to identify activities that address unmet needs of their respective community and if a project is warranted, refine into a deliverable-based project.

The committees will:

- i. Solicit, develop, review, and endorse proposals for projects and activities.
 - ii. Present proposals to the Strategy Committee for majority-level endorsement.
- b. Implement a process for the Strategy Committee to prioritize and approve proposals on a regular basis as aligned to KHI’s mission, values, and resource-availability, on behalf of the KHI BOD.
- c. Establish a framework for approval of projects and activities (summarized below).

Review Criteria for KHI Projects and Activities	Biologics, Devices, Drugs committee Approves	Strategy Committee Approves
Addresses a broad regulatory science gap	√	
Advances innovative product candidates (drugs, devices, biologics) for people with kidney diseases	√	
Leverages a pre-competitive platform across organizations to create a shared solution	√	
Incorporates patient engagement and patient insights to complete the deliverable	√	
Aligns with KHI’s annual priorities		√
Focuses on a deliverable that can be produced with quality under existing staffing/financial resources		√
Commitment of KHI resources to activities or project		√