Call for Integrated Data Access Governance Council Member Nominations

The IDERHA Consortium is seeking nominations for leaders from across the health care ecosystem to establish an advisory council tasked with supporting the development of consensus driven policy recommendations. The aim is to accelerate the access and use of health data to inform patient care and improve outcomes. IDERHA is committed to transparent engagement with the broader community, with this public call for nominations as part of that commitment.

IDERHA (Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance) is one of the first European public-private partnerships (PPP) within the Innovative Health Initiative (IHI). The partnership between the EU and Europe’s life science industries was launched in April 2023 and focuses on advances in the digitization of health data, research methods, and health care innovations.

We are seeking nominations for members of the Integrated Data Access Governance Council (IDAGC), which is being established to advise IDERHA work package 6 (WP6). WP6 is a key component of the project and is focused on creating multi-stakeholder alignment to build recommendations that accelerate policy development. The aim is to enable the use of heterogeneous health data for product research and development, and to inform regulatory and HTA decision-making.

We will accept self-nominations or nominations for other individuals. For nominations submitted by someone other than the nominee, IDERHA may share the information with the nominated individual and contact the nominee to collect additional information.

To submit a nomination, you must complete the [online form](#) by 5:00 p.m. CET on Monday, October 2, 2023.

What is the Integrated Data Access Governance Council?

The IDERHA WP6 approach aims to create multi-stakeholder alignment to address critical policies gaps to advance the broader acceptance and use of high-quality and reliable heterogeneous health data research. The Integrated Data Access Governance Council (IDAGC) is being established to guide and advise the WP6 and Task leaders on developing policy recommendations for:

- Ethical and legal governance of heterogeneous health data access and data sharing to enable multi-stakeholder research, and
- Criteria for the evaluation of research derived from heterogeneous health data for regulatory, Health Technology Assessment (HTA) and payor for decision-making associated with medicines and medical devices.

The IDAGC is intended to include individuals able to provide important insights and perspectives to guide the WP6 team’s work to ensure that the policy recommendations are balanced and address potential barriers for policy acceptance and adoption.
Establishing the IDAGC

The IDAGC will include approximately 12 senior leaders and experts who represent the perspectives of different key stakeholder groups (e.g., Health Authorities, HTA organizations, patients, health systems, professionals, academia, and industry). This public call is for individuals who are not with the IDERHA Consortium partners. The membership will include individuals from organizations within the IDERHA consortium, as well as individual experts drawn from outside the consortium. The IDAGC is co-chaired by the Danish Medicines Agency (DKMA) and European Cancer Patient Coalition (ECPC).

IDAGC members will be volunteers who contribute their time and expertise to advance the work of the IDERHA public-private partnership. Members will not be compensated for their time but will be reimbursed for IDAGC-related travel costs.

Open Call for Members

The goal of the public call for nominations is to expand the IDAGC membership with additional perspectives and expertise. We are seeking to select up to 7 members who are not currently part of the IDERHA Consortium partnership. Nominees will be selected, based on their ability to:

- represent the perspectives/interests of their specific stakeholder views
- provide individual expertise (e.g., technical, policy, business)
- contribute to a balanced and diversity of the Council membership

The call for nominations will be open until October 2, 2023. The selection process will be overseen by the current IDAGC members and the IDERHA leadership. All nominees will be contacted by the end of October.

Stakeholder Representation Sought

This call will be for nominations specifically for individuals with expertise and experience to represent the following stakeholder groups:

- Health system/provider organization: This includes healthcare organizations (e.g., physician practices, hospitals, skilled nursing facilities) that provide health care services to patients and may be jointly managed (foundation models are considered a form of joint management)
- EU health authority
- National/regional health authority
- Notified body(ies)
- Health technology assessment
- Healthcare IT/Big data authority

Areas of Individual Expertise/Experience Sought

As well as representing their stakeholder communities, the nominated individuals should have well established experience and expertise in fields relevant to the program. Some areas of interest include, but are not limited to the following:

- Legal: data privacy, intellectual property
- Research: analytical methods, planning/conducting clinical studies,
- Real-world evidence study design, execution, review and oversight
- Patient/consumer engagement and concrete measures for patient/consumer participation
- Public-private partnerships engagement and governance
- Regulatory decision-making
- Health technology assessments review and decision-making
- Hospital and health care administration
- Data management, compliance, ELSI, management of large databases
Balanced and Diverse Membership
The selection process will consider the overall composition of the IDAGC and how to make it representative of the broader European community. Potential factors may include, but are not limited to:
- Geographic and national diversity in line with the European community
- Diversity in age, sex/gender
- Varying perspectives on innovative data, research and product regulation and access

Membership Commitment Expectations
The IDAGC will meet quarterly throughout the 5-year duration of the project. Ideally, there will be two in-person meetings and two virtual meetings per year. We anticipate the in-person meetings will require approximately 10-15 hours (i.e., pre-meeting preparation, travel and meeting time). The virtual meetings will require approximately 5-6 hours (i.e., pre-meeting preparation and meeting time).

IDAGC members may be called upon to provide input on WP6 activities outside the regular meeting cycle or convene ad hoc meetings as needed based on the project. The WP6 Leadership commits to limiting these requests. During the first year after the IDAGC is convened, we anticipate these requests will be more frequent as the work is getting established.

Please note that IDAGC members will be volunteers who contribute their time and expertise to advance the work of the IDERHA public-private partnership. Members will be reimbursed for IDAGC-related travel costs but not be compensated for their time.

IDERHA Governance
The members of the IDAGC, must conform to the broader IDERHA governance and policies for project management, communications, interactions with other IDERHA Work Packages and external engagement. The members of IDAGC will be asked to sign an IDAGC charter intended to establish a governance and operating structure for the IDGAC members. The WP6 Leadership will manage the day-to-day activities of the project and will coordinate the IDAGC meetings and communications.