Thank you for your participation!

TABLE OF CONTENTS

Preamble .................................................................................................................................................. 1
Purpose of the IDAGC .................................................................................................................................. 2
Role and Responsibilities ................................................................................................................................. 2
Membership .................................................................................................................................................. 3
Council Modus Operandi ................................................................................................................................. 4
About this charter ......................................................................................................................................... 5
ANNEX 1: Confidentiality .............................................................................................................................. 7
ANNEX 2: Publication and authorship ............................................................................................................. 8
ANNEX 3: Remuneration ............................................................................................................................... 8

PREAMBLE
Integration of Heterogenous Data and Evidence towards Regulatory & HTA Acceptance (IDERHA) is a consortium of 32 public and private partner organizations that was established in April 2023 through funding by the Innovative Health Initiative (IHI). The IDERHA consortium is working to address critical technical and policy obstacles inhibiting appropriate digital healthcare data access to support innovation and research. To meet this goal, the IDERHA activities are focused on creating a pan-European data space that will seamlessly integrate diverse data at scale and finding solutions to address the policy challenges hindering the adoption of these new approaches.
Work Package 6 (WP6) is a key component of the IDERHA mission and is tasked to build consensus recommendations to inform policies for the use of integrated health research in regulatory and HTA decision-making.

The Integrated Data Access Governance Council (IDAGC) is being established to provide leadership and oversight of the IDERHA WP6. This document defines the respective role, responsibilities and authority of the Integrated Data Access Governance Council (IDAGC) for the IDERHA Work Package 6 (WP6) tasks and deliverables.

This charter is intended to establish a governance and operating structure for the IDAGC membership and the WP6 Task Leaders. Modifications can be made to this charter as needed with the consensus of the IDAGC membership and WP6 leadership.

PURPOSE OF THE IDAGC

WP6 is tasked with developing recommendations to accelerate policy development to meet the current and future advances in the digitalisation of health and research data. The consensus policy recommendations are for:

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

To ensure that the eventual policy recommendations will have the support of the broader health care ecosystem, it is essential to obtain ongoing multi-stakeholder input. The IDAGC is designed to provide stakeholder input and leadership to the WP6 Task Leaders. The Council’s oversight is critical for both the WP6 project activities but also the long-term applicability and acceptance of the policy recommendations for future legal, regulatory, and HTA requirements and institutional barriers for the use of heterogeneous health data.

ROLE AND RESPONSIBILITIES

WP6 Tasks, and the IDAGC, must conform to the broader IDERHA governance and policies for project management, communications, interactions with other IDERHA Work Packages and external engagement. IDERHA is led by the Fraunhofer Institute for Translation Medicine and Pharmacology ITMP as Coordinator and Johnson & Johnson Medical GmbH, part of Johnson & Johnson MedTech, as Project Leader to form the Management Board. The consortium activities are overseen by a Steering Committee and program support is provided by a Program Management Office (see Fig 1). DEFACTUM is a member of the IDERHA consortium and responsible for the reimbursement of certain travel-related costs to the IDAGC (see Annex 3).

IDAGC is tasked to provide guidance to WP6 Task leaders on the direction of the activities, the quality and timeliness of the WP6 milestones and deliverables.
Role
The IDGAC’s role is broadly defined to:

- Ensure that the policy recommendations are developed based on both the council’s collective expertise and the input received, including those from WP6 task deliverables, the Patient Advisory Board (WP7) and other important sources such as expert advice and research literature.

- Engage with diverse stakeholders and their perspectives to provide meaningful guidance to shape consensus for the best possible policy recommendations that can serve the interests of patients and health care systems.

Additional, when appropriate to their positions, IDAGC members may be called to participate in external public activities (e.g., meetings, conferences) commenting on IDERHA’s work and the need to accelerate the development of regulatory and HTA policy approaches for the evaluation and acceptance of heterogeneous health data research for decision-making.

IDAGC members shall ensure that the terms and conditions of confidentiality as set forth in Annex 1 of this charter shall at all times be complied with. For any breach of confidentiality, each IDAGC member acknowledges that damages alone might not be an adequate remedy for the breach.

Members of the IDAGC are free to publicly support the eventual policy recommendations produced by the project. However, IDAGC members will not be asked by IDERHA or WP6 to actively advocate for specific policies or programs.

Responsibilities
The WP6 activities are organized to:

1) Identify policy gaps and best practices for high-quality heterogeneous health data research.
2) Build multi-stakeholder consensus policy recommendations through multi-stakeholder workshops and meetings.
3) Stay up to date with the latest research and analysis to ensure the policy recommendations are evidence-based, relevant, effective, and aligned with the developments of EHDS and AI acts.
4) Transparently and iteratively publicly share and solicit input on policy recommendations.

The IDERHA project description tasks the IDAGC with:

- Setting multi-stakeholder engagement and convening priorities
- Having an overview over the other IDERHA Work Packages (see Fig 1)
- Overseeing the quality and timeliness of the Work Package 6 deliverables (see Figs 2 & 3)
- Establishing reasonable processes to meet transparency commitments.

MEMBERSHIP
The IDAGC is intended to be a small and multi-stakeholder council with representatives from key groups engaged in the health care system. As dictated by the project description, the IDAGC will be co-chaired by a representative from a regulatory authority (the Danish Medicines Agency) and a
representative from a patient organization. The IDAGC will include approximately 12 to 15 experts and advisors who would be able to represent the perspectives of the different stakeholder groups. IDAGC members will be chosen based on their experience, expertise and ability to represent the perspectives of key stakeholder groups (e.g., Health Authorities such as HTA bodies and Regulatory Authorities, Notified bodies, patient organizations, health institutions, Health Care Professionals, academia, patients and industry).

As part of the WP6 transparency and engagement commitments, the IDAGC will include Consortium and non-consortium members. The inclusion of non-IDERHA members will enable the group to engage different interests and provide fresh insights on the work.

*Delegates*

Members may designate an official delegate to participate in a meeting if they are not available. A delegate should meet the same criteria as the IDAGC member that they are representing. Also, at the very least a member should provide sufficient notice re. their absence at a meeting and reason or explanation to WP6 Task Leaders. Confidentiality requirements should always remain protected. However, the expectation is that members will attend the meetings in person at least 3 of the 4 quarterly meetings per year. IDAGC members must provide their delegates with the necessary information and resources, including this charter, in order to carry out their roles and responsibilities effectively.

*Service Terms*

Members are appointed for the duration of the project. If they decide to withdraw, they will be replaced by a member with similar expertise.

**COUNCIL MODUS OPERANDI**

To ensure effective oversight and coordination of the project, the IDAGC has the following operational approach.

*Standing Meetings*

The IDAGC will establish a regular meeting schedule to meet quarterly throughout the duration of the project. These meetings will provide an opportunity for the council to review the progress of WP6, re-prioritize if applicable and to ensure execution in a timely and efficient manner. Ideally, there will be two in-person quarterly meetings and two virtual meetings. The IDAGC may be convened for ad hoc meetings as needed based on the project needs. Whenever possible, the in-person meetings will be aligned with the IDERHA meetings. The council recognizes the importance of transparency and of effective communication and collaboration across different work packages. The IDAGC will use the quarterly meetings as an opportunity to exchange updates and information with other work packages, and to identify areas where further collaboration may be needed.

*Off-Cycle IDAGC Input*

IDAGC members may be called upon to provide input on WP6 activities and materials outside the regular meeting cycle. The WP6 task leaders commit to limiting these requests. During the first 12-24 months of the work, we anticipate these requests will be more frequent as the work is getting established.
Internal WP6 Communications
The WP6 task leaders commit to working with the IDAGC to ensure that internal communication frequency and content is appropriate to maintain an effective project through transparent cooperation among as well as the timely generation and collection of project information.

IDAGC Decision-Making
In cases where a formal decision is needed by the IDAGC, a simple majority is sufficient for a quorum. Formal decisions shall be made in writing (e-mail is sufficient). Members will be notified in writing prior to the meeting when a decision will be needed. If they or their delegate are unable to participate personally, they will be allowed to provide their decision to the WP6 leadership in writing.

ABOUT THIS CHARter
This charter, version..., was authored by
  • [to be finalized]
The charter with its annexes (Annex 1 Confidentiality; Annex 2, Publication and Authorship; Annex 3, Remuneration) was approved by the IDAGC Council on (date....)

Chairperson signature / date
Chairperson signature / date

Signing page both members and delegates
**Figure 1: IDERHA Governance**

**Figure 2: Work Package 6 Tasks Organization**

**Figure 3: Grant Commitments for Work Package 6 Deliverables**

**Task 6.2.** Analysis of policies affecting access to real-world data sources to enable high-quality multi-stakeholder research.
- Gap Analysis for public comment (1st draft) – Due Nov 2023
- Final report released – Due Nov 2024

**Task 6.3.** Establish multi-stakeholder consensus policy recommendations for data sharing, access and use governance policies.
- Policy Recommendations for public comment (1st draft) – Due Dec 2024
- Policy Recommendations for public comment (2nd draft) – Due Mar 2026
- Policy Recommendations for public comment Final – Due Apr 2027

**Task 6.4.** Advance the acceptance of heterogeneous health data research in regulatory and HTA decision-making.
- Report on Global Best Practices Analysis – Due Mar 2024
- Regulatory Recommendations draft for public comment (1st Draft) – Due Mar 2026
- Final Recommendations – Due Mar 2027
Non-disclosure agreement

Purpose

The IDAGC member undertakes to hold in strict confidence any information, in particular without limitation scientific, technical or commercial information relating to the business, products or research of the IDERHA Consortium and consortium partners, which becomes known to IDAGC member during the course of this collaboration, together with any information regarding the IDERHA Action and all results of the cooperation with the Consortium, to use such information and results only for the purposes of this Council, and not to disclose such information or results to any third party without a prior written consent of the Consortium or applicable consortium partner owning the results.

The foregoing restrictions on use and disclosure will not apply to any of such information which: at the time of receipt by IDAGC member is available to the public; or becomes public knowledge other than by an act or omission on the part of IDAGC member; or which IDAGC member can prove was known to IDAGC member before the date of its disclosure; or is legally acquired by IDAGC member from a third party not bound to Consortium or any of its Beneficiaries by any express or implied obligation of secrecy, or IDAGC member can prove was developed independently by him/her without reference to or use of the information.

Furthermore, the IDAGC member may disclose such information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that IDAGC member shall give reasonable advance notice to the Consortium or relevant Consortium partner and on request, shall cooperate with the Consortium or relevant Consortium partner to seek a protective order or other appropriate remedy. The IDAGC member will use his/her reasonable efforts to secure confidential treatment of any such information that will be disclosed.

Information shall not be deemed to be or have become public knowledge merely because any part of such Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.

IDAGC member agrees to duly preserve all information and documentation provided to IDAGC member and to ensure that no third parties gain access thereto. Any documentation provided must be returned to the Consortium or relevant Consortium partner at Consortium’s or relevant Consortium partner’s request at any time, and shall be returned to the Consortium or relevant Consortium partner.
ANNEX 2: PUBLICATION AND AUTHORSHIP

The relevant aspects of the work in IDAGC will be made public under careful consideration of the above described in Annex 1. The IDERHA WP6 lead-partners will be responsible for drafting the reports and scientific papers, which will be made available for comments from IDAGC before submission. All authors should have made a clear contribution to the published article. We adhere to the authorship criteria that have been developed by The International Committee of Medical Journal Editors (ICMJE). The members of IDAGC will be acknowledged in relevant reports and scientific publications. For the avoidance of doubt, for all publications involving any authorship of IDERHA WP6 lead-partners or any other partners of the IDERHA Consortium Agreement, the process for reviewing and approving these publications shall comply with Article 6.6.2 of the IDERHA Consortium Agreement.

ANNEX 3: REMUNERATION

The parties agree that the IDAGC members shall not be compensated for the performance of the Services as a member of the council.

Meeting related travel costs: IDAGC members from organizations within the IDERHA Consortium will use their organizations’ IHI funding to cover reasonable travel related costs for meetings organized by the WP6 team (no more than 2 per year).

For IDAGC members (or selected member delegates) whose organizations are not members of the IDERHA Consortium, they are eligible for reimbursement of reasonable travel related costs in compliance with the applicable laws, regulations and codices, offer to pay for reasonable travel expenses and hospitality, work related meals and transportation. The IDAGC member shall be responsible for all other taxes payable on account of payments made hereunder. IDAGC members agree that the Consortium (by stating IDAGC member’s private information) may store, process and publish any payments made by the Consortium, if such disclosure is required by statutory or internal regulation or any binding Code of Conduct.

VERSION HISTORY

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