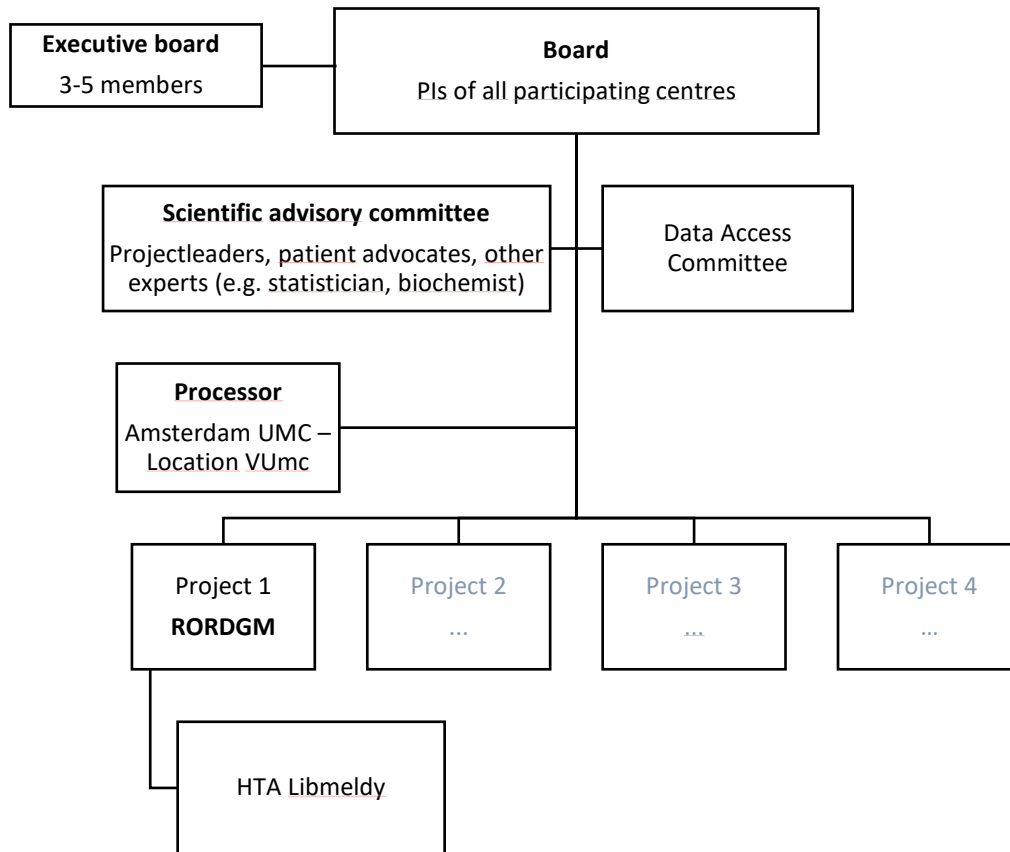


# The MLD initiative

## Governance Model

Version	2.0
Status	Approved
Date of Approval	11-4-2022
Revision date	11-4-2022



## Activities and responsibilities

### **Board**

- Board members are ‘Controllers’ of the data
- Future direction and development of MLDi
- Makes decisions about projects, acquisitions etc
- Assess data requests and advises & decides on the use of data
- Responsible for the formation of the SAB (board members cannot take place in scientific advisory committee)

### **Executive board**

- Rotating delegation of the board
- Allowed to make easy and simple daily decisions itself
- Responsible for recruiting new projects and new partners

### **Scientific advisory committee**

- Advise board on scientific and clinical matters
- Represent stakeholders’ interests

### **Data Access Committee**

- Ad hoc formation with (a representation of) the Board and one or more members of the Scientific Advisory Committee
- To prevent the DAC from becoming an unworkably large group, it may happen that a delegation of the Board will be presented. The remaining Board members have the ability to reject or adopt the advice of the DAC before their data are released.
- Assess data requests and give advice on the use of data by approving or rejecting the request

#### **Coordinator**

- Amsterdam UMC is 'Controller' and 'Processor'
- Center that initiated and funded the building of the registry
- Implements the registry and manages the infrastructure

#### **Projects**

- The MLD initiative includes different projects
- Every project has a project group and a project leader
- Projects can be started and can also be ended
- **Project 1 – Regulatory project orphan drugs: RORDGM**
  - Temporary project group until 2023. Creates strategy to make the registry suitable for regulatory and HTA purposes. Special focus on post-marketing evaluation of new (expensive) treatments
  - **Subproject: HTA Libmeldy**
    - Collaboration with EMA + Beneluxa and Ireland

Please note: the official legal and regulatory responsibilities of the Processor and the Controllers of the MLD initiative are regulated in the Regulatory Document.