



Technical Assistance Facility (TAF) for Industrial Modernisation and Investment

Creating an open science governance model to facilitate a participant centric ecosystem platform

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DISCLAIMER

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Executive Summary

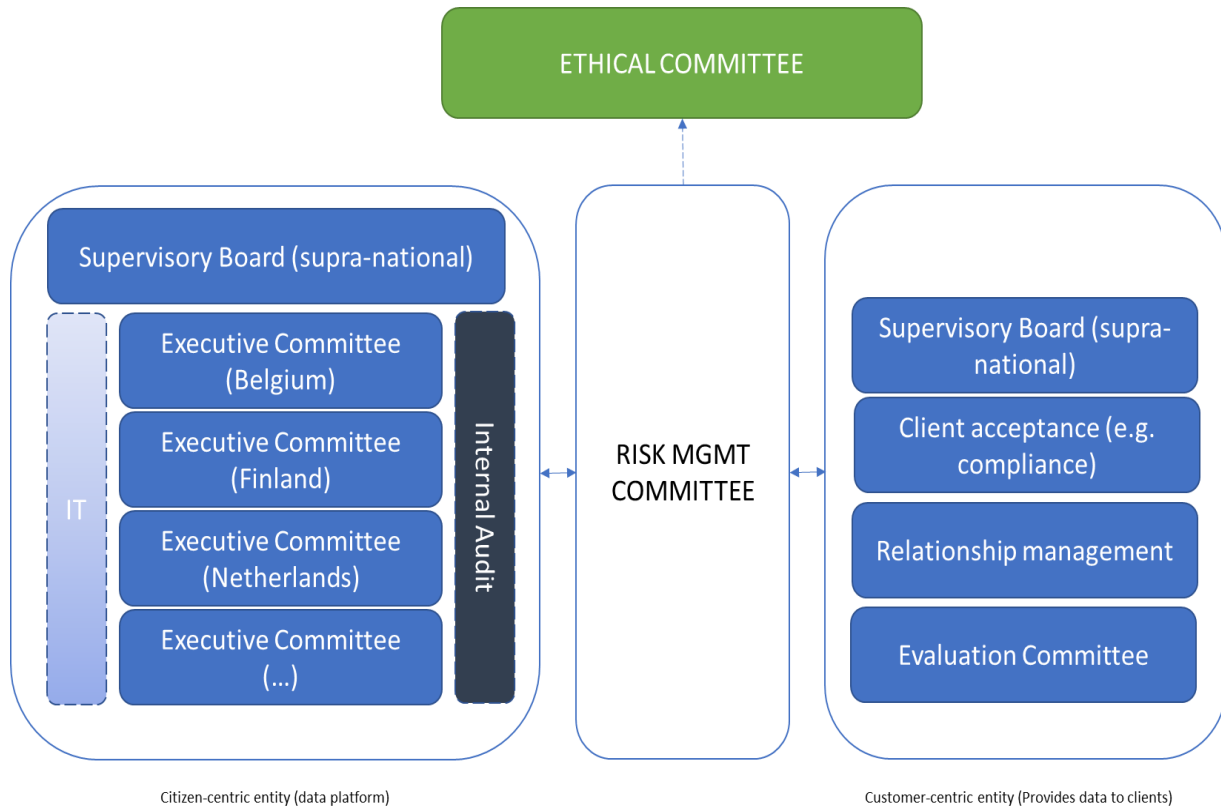
The primary objective of PDP is to promote the use of a citizen-centric data management in the fields of preventive health. With this set-up, data providers (i.e. citizens) will keep an ongoing control on their data and may decide at any point in time to review their consent to data access. To ensure the future platform meets this societal objective, we propose a general framework with two different designs. The merits of the proposed framework is to distinguish the citizen aspiration from the commercial aspects of data, thereby ensuring the societal aspirations are immune to any profit-oriented concerns.

The Set-Up of an Ethical Committee is here to create trust within the data providers community. From our perspective, trust is created by: (i) setting up and promoting a set of Values & Beliefs that could be appealing to a wide audience, (ii) communicating on the stated objectives of data usage, hereby providing the data providers with an understanding and expectation as to how data will be used and (iii) setting up standards regarding usage within the data users community.

Separating the Ethical aspects from strategy and execution also helps to safeguard the reputation and trust of the citizen in case new development emerge / the platform needs to change.

Across the organization, citizen involvement is encouraged although we believe citizen role should purely be consultative and not decisive. This is to ensure that the organization moves onward with the project.

Compartment 1: Citizen/Participant/Patient Centric Silo



With the first governance structure, we propose PDP to adopt a dual structure whereby the Citizen-centric entity and the Customer centric entity are separately managed and operationally independent from each another. Both entities form together the “Eco-System”.

The Citizen centric entity’s primary responsibility is to collect, aggregate and protect data shared by the citizen. It also plays a central role in the way the citizen consents his/her data to be made available to corporate.

The Customer centric entity is responsible to give access to (meta)data to interested corporates. On the one hand, it ensures the data are accessed by counterparties complying with the Values & Beliefs promoted by the Eco-System while ensuring the whole Eco-System is self-funded.

The advantage of this structure is that it creates silos whereby the citizen data is unaffected by the Customer centric entity. Under this structure, the Ethical Committee plays a central role by laying the grounds for the operations of both structures, yet not influencing them on a day-to-day basis.

Ethical Committee

The Ethical Committee is formed by a panel of independent experts providing founding values and beliefs that will shape the operations of the Eco-System in general.

Yet, we believe the Ethical Committee's role is bound to evolve as the platform matures. Its role will be essential as the Eco-System is developing - the decisions taken regarding the Values & Beliefs, the Ethical Charter (see below) will form the cornerstone of the development of the Eco-System. Then as the platform matures and the respective executive bodies will gain experience, its main activity is expected to shift to a validation role (see below).

Members

The Ethical Committee is the cornerstone for this project and should be made of independent experts who have a long-lasting experience / excellent credentials in relevant fields such as data management, health data, etc. Ideally members should come from different horizons (e.g. academics, scientific, research, civic platforms, other open sourced data, philosophers etc.).

One could imagine members to have a mandate of 4 à 5 years. Selection and appointment of new members of the Ethical Committee should be official with a (qualified) majority. Citizen could provide a view on whether a candidate is suited for the role. Yet, we would refrain from providing the decision to the citizens on the selection / appointment of Ethical Committee's members to ensure a smooth operation of the Eco-System. At this stage, we believe the key criteria for the selection / appointment of new members pertain to the diversity of experience / role / nationality / gender in the Ethical Committee. Of course, other constraints could be added if required.

Role & responsibilities

At the onset of the Eco-System, the Ethical Committee has to create **trust** among the citizens.

Trust can be created by setting up an **inclusive** platform where the point of views of different stakeholders¹ are taken into account whilst working on the values and beliefs. Based on their views and perspectives, the Ethical Committee will propose a set of founding values that will characterize the Eco-System. These could also be communicated to the citizen through online channels.

At this stage, we do not believe it will serve the platform to give citizen a decisive voice / choice in the values set forth. By doing this, on the one hand the concept of the Eco-System can move forward with its design and operations whilst ensuring already some visibility on the citizen side (i.e. data providers). Also, the diversity among the members of the Ethical Committee should warrant wide adherence and trust within the community of citizen.

. Values & Beliefs should be clear, easily understood by everyone and transparent. It should be made clear that, at least on an annual basis, the activities of the both entities are assessed by the Ethical Committee based on these principles. Values & Beliefs should also be flexible and could change upon occurrence of major issues (to be defined) or due to societal / technological changes for instance. It is advised that these changes are discussed openly with the citizen and / or different stakeholders

Furthermore, besides the Values & Beliefs, we propose the Ethical Committee to publish an **Ethical Charter** where the Eco-System will set rules for the health data provision to innovative / R&D companies. This would create a set of clear expectations for the citizen so that he/she knows who and for which purposes the data is being used. For instance, the Ethical Charter could ban the utilization of public health data for companies not meeting the criteria set by the Charter.

The difference between the Values & Beliefs and the Ethical Charter resides in the fact that the Ethical Charter will:

¹ Stakeholders at this stage would naturally include citizen but also IT specialist, health data record managers or the innovation industry.

- Be directed exclusively to data users community.
- Be accessible on an ongoing basis to the data provider community (i.e. citizen)
- Articulate in details the Values & Beliefs for the specific purposes of the Customer centric entity (more concrete)
- Be used by the Customer Centric entity when accepting a new client or assessing the use of the data by the client (for instance, the client should accept and sign the Ethical Charter)

Finally, the Eco-System should be made available in all transparency, the remuneration mechanism of the platform and of its staff so to ensure there is no conflict of interest and that all possible conflicts that could be raised by the public are tackled upfront.

Ethical Committee will have only three counterparts: the Supervisory Board of the Citizen-centric platform, the Supervisory Board of the Customer platform and the Risk Management Committee.

Citizen involvement and interactions with the Ethical Board

Apart from a consultative role as detailed during the definition phase of the Values & Beliefs, further interactions with the citizen could be promoted by:

- Encouraging feedbacks and surveys from citizen on their satisfaction towards the use of data or the adequacy of Values and Beliefs with current societal principles.
- Being accessible - i.e. allowing citizen to 'drop' certain ideas / thoughts or issues regarding the platform. In line with government platforms², one could imagine that the citizen initiatives are grouped together and submitted to other citizen vote. If an initiative has collected a certain number of votes, the members of the Ethical Committee will have to debate the idea seriously
- Contacting directly members of the Eco-System directly
- Watching in live streaming the meeting of the Ethical Committee or of the Supervisory Committee
- Providing training materials on data management principles, raising awareness among citizen on the importance of their personal data. This possibly could emulate also similar initiatives as PDP in other fields.
- A rotating civil panel could be established composed of a representative group of society. Different parameters could be applied: age, gender, social class, education, profession. A rotation system (every year/two year) based on a lottery out of a pool of interested citizens can be implemented. The panel could advise the Ethical Committee on specific topics/decisions. The specific topics/decisions could be covered within the bylaws of the platform.

Citizen centric platforms

Supervisory Board

The Supervisory Board of the citizen centric platform will articulate the Values & Beliefs laid out by the Ethical Committee into strategic decisions. The Supervisory Board shall be held responsible for providing the different national executive committees with the direction, the infrastructure and general guidelines to fulfil the national executive committee's 'custodian' obligation toward the EU citizen.

² For instance in the UK or Finland, citizen actions can be submitted to the domestic parliament. Provided the actions reached a minimum number of signatures, the parliament has the obligation to debate on the citizen launched initiative and eventually take action.

<https://www.coe.int/en/web/bioethics/-/finland-citizen-s-initiative-to-the-parliament-2012->

Members

The members of the Supervisory Committee should regroup different competences and have the required qualifications / experience to run an international organization. The Supervisory Board members should be goal-oriented³ and have experience in strategy, (health) data management, data record management, law and / or IT mainly. Other experience might of course be necessary.

To ensure the Supervisory Board decisions are accepted by the domestic executive committees, a permanent representative of the latter should also be present in the supervisory board meeting. Risk Management Committee members shall not be seating in the Supervisory Board so to ensure full independence.

Whilst we will remain muted on the number of members the Ethical Committee should include, we believe a maximum of 10 persons (incl. chairperson) should be present within the Supervisory Board. Having max. 10 persons should help the Eco-System to define clearly the responsibility of each of its members, hereby creating ownership and responsibility within the Supervisory Board.

The Supervisory Board would report at least on an annual basis to the citizens and to the Ethical Committee on the different actions taken to protect the data whilst following up on action list reported by internal audit / Risk Management Committee. Furthermore, as mentioned above, interactions with the citizens could be warranted through live streaming of board meeting and by direct contact of their members.

Roles and responsibilities

The Supervisory Board will have as a duty to:

- Define the best ways to collect data (e.g. providing guidelines as to data formatting, data quality, data subset, questionnaire / surveys format and frequency)
- Provide guidelines to the domestic executive committees as to their respective communication to the citizen (in terms of reporting, contact etc.)
- Promote communication and collaboration between the domestic platforms, ensuring successful initiatives taken at a domestic level are implemented in the different countries
- Assist and train the domestic platforms in their respective daily care of the citizen issues and concerns.
- Mitigate the risks identified by the Risk Management Committee
- Establish a strategy to expand the data collection from the citizen whilst ensuring the IT infrastructure in place is robust and aligned with the strategy pursued
- Follow up on the internal audit findings and recommendations either on a macro-level or at the domestic level (if required)
- Control the communication to the citizens - especially for the reporting, ensuring the information provided is accurate, clear and transparent. This shall be done by co-signing the reporting together with the appropriate domestic executives.
- Provide the citizens with a clear, frequent and widely understandable information campaign rolled out via different media channels at appropriate points in time. It is extremely important that the citizens are aware of the activities undertaken by the platform and that ideas from the public can be submitted easily (cfr. Infra).

The Supervisory Board has direct report from the IT infrastructure and internal audit.

They could also decide to take over the responsibility of the domestic executive in case it consistently deviates from the guidelines provided or that a serious breach in data security / trust has been proved. In such instance, the Supervisory Board would take over for a limited period of time the executive role before handing it over either to another local domestic executive or to a dedicated person.

³ The Citizen centric platform's goal is oriented towards citizen's consent and security of the data and is not profit-oriented.

IT Infrastructure

The responsible for the IT Infrastructure should be held accountable for:

- Sharing the information he/she decides to share (incl. consent management) Maintaining the information up-to-date and the accessibility thereof on an ongoing basis
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- Providing a safe harbour, insulated from data breaches and hackers
- Informing the citizen on where the data is stored at all time
- Providing IT-support to all questions the citizen might ask whilst sharing the information
- Supporting Internal Audit and Risk Management by either providing tailor-made solution to mitigate flaws in internal processes or providing reporting to Risk Management Committee
- Providing IT support to domestic executive committee (if required)
- Monitoring access from the Client centric entity on the data

IT would have a separated budget allowing the deployment of IT infrastructure that meets the objectives stated by the Supervisory Board. Depending on the set-up elected by national executives, they might support local IT executives by deploying targeted solutions fitting specific domestic needs.

IT Infrastructure should be reporting on a frequent basis to the Supervisory Board on a number of KPIs (e.g. total volume of data, number and location of data servers, number of new data hosted, data quality controls, data inconsistencies, etc.). The reporting should be made available to the Risk Committee.

IT is headed by a person who is directly liable to the Supervisory Board.

Internal Audit

Internal Audit's role is essentially to ensure the operations are carried on in line with the guidelines and procedures established either at the supervisory board level or at the business unit level. They should be consulted when new procedures are being drafted by the business units so to ensure consistency with the Ethical Committee's Values & Beliefs and Ethical Charter and across the different geographies.

As inherent part of the daily processes, they report directly to the Supervisory Board. The Supervisory Board, together with the Internal Audit responsible, drafts and validates on an annual basis, an internal audit plan - identifying what part of the Eco-System will be subject to an internal audit process. Furthermore, the head of Internal audit is responsible for reporting on the progress of Internal Audit, on the proposed recommendations and on following-up on the implementation of the recommendations with the respective business units.

Internal Audit releases to the citizen on an annual basis - together with the Risk Management Committee - a report highlighting the actions and key findings raised and discussed internally. Furthermore, Internal Audit's activity plan may take into account citizen proposals submitted on the platform (see above).

Ethical Committee may request on an ad-hoc basis insight on specific internal audit activities.

Internal Audit should not be replicated at the different domestic level, it shall remained remoted from domestic influence and be impartial in its way to deal with procedures flaws.

Internal Audit keeps a record of all procedures in place together with an overview of all recommendation being processed. It works closely with IT infrastructure to ensure the implementation of automated solutions, hence reducing human interventions and therefore the risks of errors / inconsistencies.

Executive Domestic Committee

Executive Committees make up the link between the strategic decisions made by the Supervisory Board and the citizen. They articulate the strategy in visible actions. The Executive Committee should actively promote, at the domestic level, the utilisation of the platform and communicate on the merits of it vs. competitors, alternatives.

Executive Committee should take stock of the salient concerns expressed by the citizen and take appropriate actions if required. This could be by asking IT Infrastructure to deploy specific functionalities to meet citizen concerns.

Eventually, Domestic Executive Committees may independently decide to adopt a structure allowing them to better meet national concerns - for instance by having a local IT infrastructure or designing specific procedures. If this is the case, the local experts should always work in tandem with the supra-national experts so to ensure there are no solutions that are devised that could only be working in one jurisdiction. Executive Committees are responsible for:

- Executing the strategy of the Supervisory Board at their domestic level
- Engaging with the public
- Reporting on a regular basis on the data usage of the citizen
- Allaying concerns, in a transparent manner, on IT infrastructure
- Working on recommendation of the Internal Audit and work in full transparency with the Risk Management Committee and Supervisory Board
- Collaborating with other national executive members on data collection and promotion of solutions increasing data security and quality
- Recommending to the Supervisory Board new areas of development in terms of data collection or treatment
- Eventually assisting Supervisory Board whenever one of the Domestic Executive Committee members is not deemed fit for the position anymore, eventually by taking over his/her role either permanently or ad interim

The Executive Members are held liable to the Supervisory Body and have to share all information deemed required with the Internal Audit Team or the Risk Management Committee. Yet, Executive Members have to a large extent the freedom to organize themselves (i.e. they can also edit / release their own procedure) as long as they meet the ambitions of the platform and that their operations are aligned to risk management and internal audit.

Risk Management Committee

Risk Management Committee is the only body within the Eco-System that works with both entities of the Eco-System. All members of the Risk Management Committee shall be impartial, that means in this instance, they shall be barred from taking on roles in either platforms so to avoid (future) conflicts of interest.

Risk Management Committee identifies the different risks that the Eco-System in general can be exposed to. Risks includes, a.o., reputation risk, IT risk, risks related to utilization of data, platform funding risk, ethical risks, etc.

These risks are identified together with the Ethical Committee and the respective Supervisory Board. Yet the ultimate body responsible for putting the risks on the radar is the Risk Management Committee. The Committee will then monitor the different risks on an ongoing basis and has the right to direct individual business units to take on specific actions to mitigate the risks where it is needed. It reports directly to Supervisory Boards and Ethical Committee on its actions. IT infrastructure or any individual business units should be made responsible for providing Risk Management Committee with automated reporting it feels are requested for its duties. Please note that the should not be a risk burden on all business units operations.

The risk management committee needs to operate independently and objectively in order to fulfil its duty properly. This means that no board members of others boards can participate in the board of the risk committee, separation is key. In order to create a smooth working environment between the different oversight boards but still maintain the autonomous character of the risk management committee, it is appropriate to provide the risk committee with the status reports of the evaluation committee (and if necessary additional guidance next to the reports).

Members

Members of the Risk Committee should also be used working in an international environment and have proven track record in risk management function. As risk management tends to be a relative abstract concept in multiple industries, we would recommend appointing persons having actually working in either banking or insurance industries where risks requirement tend to be high.

The members of the Risk Committee should all have different experience as to risk management - risk from counterparty, operational risk, data management risk, IT risk, etc.

Client centric entity

This entity is entrusted with the responsibility to cater the data to the clients. They have only a reading right on the health data but cannot change or amend the data provided by the citizen. Access rights are monitored by the IT Infrastructure. Data provided to the data user community are pseudonymized / anonymized beforehand by the IT Infrastructure team.

Access is activated only upon request from the Relationship Manager by the IT Infrastructure team. The access request needs to be signed by the Client Acceptance Team and a member of the Executive Board of the Client centric entity. Access might be granted for a defined period of time. The request forms are sent by the Client Acceptance Team to the IT Infrastructure Team.

The Client Centric Entity is a commercial vehicle, i.e. it generates the revenues that will fund the citizen centric platform and the IT enhancement made to the Eco-System. Remuneration mechanisms for members of the supervisory / executive board could be linked to the actual use of data instead of the sales of a given volume of data. This would align the objectives of the commercially-oriented platform to the citizen-centred platform.

This entity is headed by a Supervisory or Executive Team that is rather corporate-minded with experts in marketing, sales, finance being on its board. The objectives of the entity is to turn lead into repeated sales, yet the Ethical Committee could step in in order to curb what could be deemed an aggressive or unethical handling of the data.

Risk Management would oversee the operations of the Client Centric Entity from a risk perspective and report eventual flaws directly to the Ethical Committee and Executive Board of the Client centric entity. Whilst the role of the Ethical Committee is to remain as far as possible immune to the daily operations, it might have a constraining role in editing new rules / guidelines that limit the commercial aspirations of the Client Centric Entity.

Client Acceptance Team

The Client Acceptance Team's (CAT) role mainly encompasses compliance checks with the stated values and beliefs and ethical charter edited by the Ethical Committee. The team is responsible for ensuring the client lives up or at least complies with the values promoted by the Eco-System. This can be achieved partially by signing a the Charter (see above).

To this end, the CAT maintains a client record where all past operations are recorded together with the conclusion of the assessment committee and an updated view on the client organization.

Client Acceptance Team is a gatekeeper for the client. Only clients who are approved by the Client Acceptance Team could request access to data base. This is the reason why the request form sent to the IT infrastructure needs to be signed by the Client Acceptance Team.

Their role is to improve the internal knowledge of the client's operation and how the data are bound to be used by the client. Prospective clients could receive forms to be completed whereby they are requested to detail their operations, the objective of the research and a description of the way the personal health data will be used together with a stated ambition for the research.

The CAT would then compare these forms with the Values and Beliefs and Ethical Code and validate whether a client is deemed fit with the societal objective of the platform.

Furthermore, CAT would have to maintain an appropriate set of record (e.g. contact person, researchers and head of research for the different projects, etc.)

On a yearly basis, a reporting file will be prepared by the Client Acceptance Team and reviewed by the Evaluation Committee. This reporting will then be made available for approval to the Ethical Committee (and therefore also Civil Panel).

Relationship Manager

The Relationship Manager team fulfils the commercial role within the organisation. His/her remuneration should depend to some extent to the quality of the research performed instead of the volume of data shared with the client. Through this mechanism it is believed the incentive will be on the quality of the client rather on the volume, thereby also enhancing the level of trust from the citizen.

The Relationship Manager is in charge of a client portfolio and acquire new client. He/she needs to articulate request set forth by a client and pro-actively communicate with both Client Acceptance Team and the Evaluation Committee. The Relationship Manager is directly held responsible toward the Supervisory / Executive Committee of the Client centric entity.

On top of his/her commercial objectives, the Relationship Manager is the sole contact person between the Eco-System and the Client. He / She will ensure all the information requested by the CAT or the Evaluation Committee is accurate and delivered timely. This sole contact person principle should guarantee independence and impartiality towards clients from the organisation in general.

Evaluation Committee

The Evaluation Committee conducts 'post-mortem' analysis whereby the outcome of a research conducted with private information posted by citizen is compared to the initial objectives.

The Committee should carry on these analysis to first ensure the data have been used for their stated purpose and second to perform a posteriori check on the reliability of the client. The data could then be used to rank / prioritize / favour client for their next request, depending on their perceived quality.

The Assessment Committee is made of scientific and at least one member of the Risk Committee and of the Supervisory Board of the Client Centric Entity. The presence of Risk Management in the Evaluation Committee will guarantee that any unidentified risks / undesired behaviours are correctly and timely captured and met by new measures if required.

Apart from the scientific outcome, other criteria such as reports on the access of the data could also be checked in this committee.

The committee fills in a report that is directed to

- The Executive Board of the Client Centric Entity. Based on this report, the different person (executive members, relationship manager) could potentially have a bonus
- The Ethical Committee so to cross check the adequacy of the Values & Beliefs and Ethical Charter of the Eco-System
- The Supervisory Board of the Citizen-Centric Platform. This report could be served to communicate on the real impact the citizen has on research, thereby improving transparency and trust in the platform.

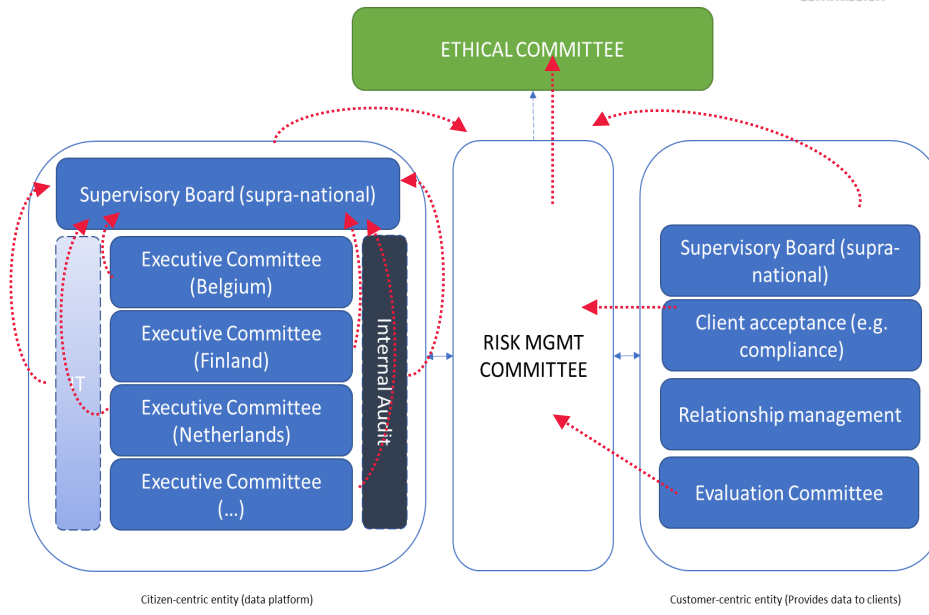
Incident reporting

The set up of incident reporting should be handled with care and done in different steps.

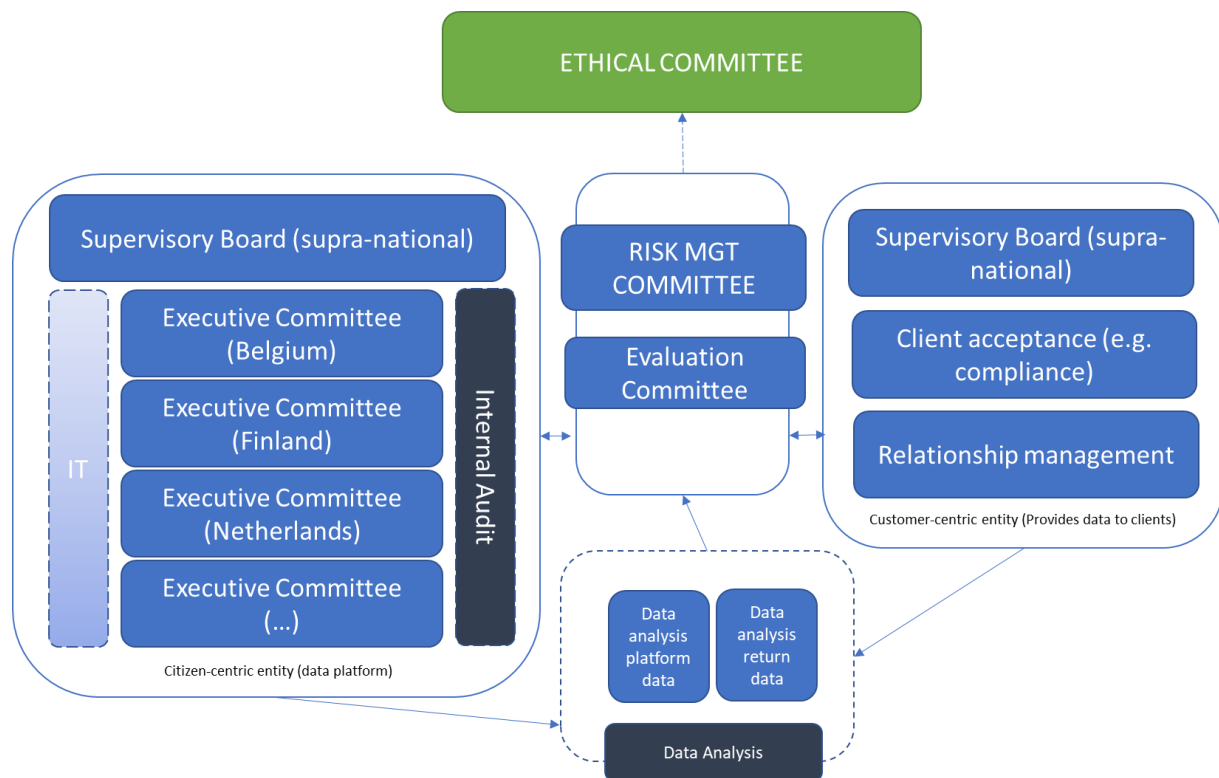
1. Defining a major incident:
The first important step in incident reporting is defining the assumptions that make up a list of major incident. This can be defined by the supervisory boards and / or internal audit.
2. Steps to be taken when a major incident occurs:
It is very important that when there is a major incident, the supervisory board tackles this issue with care and tries to protect the data at all cause.
3. Report the issue
Information regarding the issue should be transferred towards the Risk Management Committee and the Ethical Committee. The issue is assessed from a Risk and Ethical point of view. Solutions and recommendations to the current platform/data management should be addressed and implemented.
4. After a period of time, the new implemented recommendations and adjustments should be evaluated and modified if necessary.

Reporting lines overview

After discussing all the separate bodies, boards and responsibilities, an overview of the reporting lines can be found in the overview below. It can be concluded that the most important reporting lines are the supervisory boards who report to the risk management committee and the risk management committee that reports its findings towards the ethical committee.



Alternative Governance Model



An alternative structure would be to keep the initial dual structure and responsibilities but transfer the evaluation committee to an **overarching function** and create a **separate body that performs data analysis on both source data and results**.

Evaluation Committee

The **evaluation committee** then exists out of two teams: (i) a team that focusses on the Citizen-centric entity and (ii) another teams that focuses on the customer centric entity.

The two teams report then towards an overall evaluation committee.

The committee fills in a report that is directed to

- The Executive Board of the Client Centric Entity. Based on this report, the different person (executive members, relationship manager) could potentially have a bonus
- The Ethical Committee so to cross check the adequacy of the Values & Beliefs and Ethical Charter of the Eco-System
- The Supervisory Board of the Citizen-Centric Platform. This report could be served to communicate on the real impact the citizen has on research, thereby improving transparency and trust in the platform.

Data Analysis

A separate body focussed on **Data Analysis** exists in order to have a overall and complete view on the data uploaded in the data platform and the data returned from clinical/commercial studies.

This body fills in recurring reports that are directed to:

- The Evaluation committee
- The Executive Board of the Client Centric Entity. **Based on this report, additional data could be requested to be added to the platform based on the recommendations proposed by the data analysis team.**
- The Supervisory Board of the Citizen-Centric Platform. This report could be served to communicate on the real impact the citizen has on research, thereby improving transparency and trust in the platform. **The outcome could reveal any additional need of data useful for trials/studies.**

Reporting lines overview

After discussing all the separate bodies, boards and responsibilities, an overview of the reporting lines can be found in the overview below. It can be concluded that the most important reporting lines are the supervisory boards who report to the risk management committee together with the Evaluation committee and the risk management committee and evaluation committee that reports its findings towards the ethical committee.

