



Health by Advanced Therapies

D 1.2
Draft of Governance (structure and processes) of the
candidate LSRI RESTORE
Public

Delivery date: 01/04/2019

Lead Beneficiary: Charité (Partner 1)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 820292.

www.restore-horizon.eu

Table of contents

1. Deliverable's description	3
2. Management structure and procedures for the running CSA	3
3. Management structure and procedures the LSRI RESTORE	5

1. Deliverable's description

The objective of this deliverable is to prepare a draft of the governance (structure and processes) of the candidate LSRI RESTORE. Included is the governance of the CSA as it currently is and our summarised concept for the LSRI RESTORE, which will be expanded in more depth once we have determined in which legal form a large-scale research initiative is possible.

2. Management structure and procedures for the running CSA

The **Project Coordinator** is Hans-Dieter Volk, Charité (partner 1), who is well experienced in coordinating regional (e.g. Berlin-Brandenburg Center for Regenerative Therapies), national (e.g. multi-centre consortium projects of different German funding organisations), and international (e.g. EC-funded RIA-projects, such as PACE) joint projects. The **Administrative Manager** is Gabriella Dessolet (partner 8). If required, they will interact on a daily base.

The **Executive Project Management Team (EPMT)** will be formed by the Project Coordinator and one representative (who can be replaced by a nominated deputy) of each of the 10 partners. The role of the EPMT will be to advise and support to the Project Coordinator in governing the CSAs of the project in order to optimally prepare the large-scale research initiative RESTORE. The EPMT will serve as the main forum for strategic review, problem solving and decision-making, enabling efficient discussion and exchange on any issues that arise. It will also be responsible for approval of suggestions made for amendments to the Consortium Agreement. It is expected that this structure will allow decisions to be made rapidly and flexibly to drive forward successful tasks, while redirecting and refocusing resources from areas (working groups) that are less productive. The EPMT will approve decisions with at least 3/5 majority. In the case of a tied vote the Project Coordinator will hold the casting vote. The EPMT will meet (face-to-face or by webinar/tele conference) monthly to accurately define the evolution of the consortium towards the defined objectives and will have continuous contact by e-mail or by telephone, in order to achieve the different CSA objectives.

The formation and work of the working groups on the various subtasks of the WPs represents a central element of the preparatory phase of the large-scale research initiative RESTORE. Through the working groups, the entire RESTORE community, which currently consists of >300 supporters (signed LOS) and also includes most partners of the currently funded horizon 2020 Advanced Therapy projects, will be actively involved in the preparation of the large-scale research initiative RESTORE.

Work Package Leaders: Beside their role in the EPMT, the WP leaders will be responsible for:

- Planning, managing and coordinating the Work Package activities, in particular of the working group activities
- Overseeing the information flow between the working groups within the WP and the work packages in general
- Ensuring that deliverables are achieved on time
- Updating their work package information on the website
- Proposing plans for future sustainable activities
- Disseminating and communicating project output and results to local stakeholders (patients, scientific and public societies).

Because of the complexity of the WPs, we decided to have WP leader teams for various WPs.

The management structure is illustrated in Fig. 1.

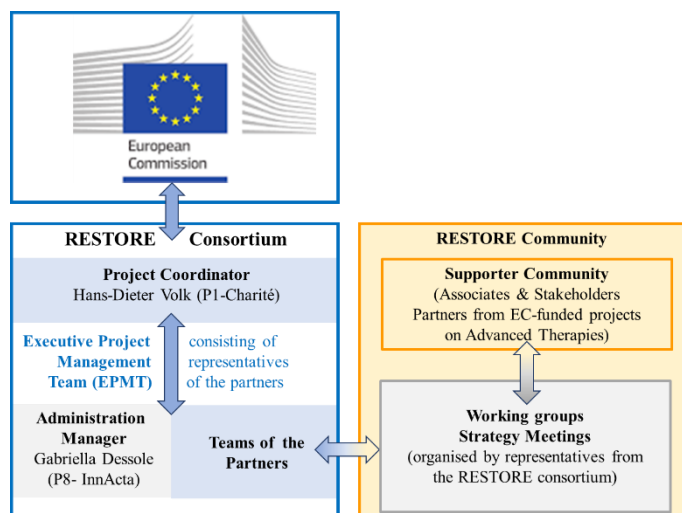


Figure 1
Organisational structure of the preparatory action for large-scale research initiative RESTORE

Because of the specific nature of the preparatory phase (CSA, 12-month running time, involvement of a broad RESTORE community) **External Boards** are not required for this stage of RESTORE.

Decision-making structure and progress monitoring

- At the WP level: the CSAs of each WP and the respective working groups will be monitored by the WP Leader(s) and this information will be summarized and reported to the EPMT every two months. The report shall include 1) Summary of activity since last report, 2) Progress towards Projects Milestones and Deliverables, 3) Risk areas with any decisions required from the EPMT, and 4) New developments.
- At the Coordinator level: the Project Coordinator will have regular contact with and pay regular visits to the RESTORE partners. The Project Coordinator will regularly consult, either electronically or via telecommunication, all members of the EPMT to identify urgent issues that may require rapid and appropriate actions. When important issues arise, which require focused management as well as the collection and sharing of relevant information in order to make a decision, the EPMT will meet F2F or by electronic media to discuss these topics. Problems should be resolved in a reasonable time by partners without affecting the progress of the project.
- At the overall project level: the Project Coordinator and the EPMT will monitor the progress of each objective. All participants in the project will meet regularly (usually every two months) using electronic media to report work progress. It is expected that the F2F and webinar meetings will be attended not only by the Principal Investigator in charge of the project, but also by the scientists directly working on the project and its respective working groups.

Communication with the European Commission

The Project Coordinator will manage the contacts between the consortium and the Commission. Progress reports will be submitted to the EC as stated in the Grant Agreement. The report must circulate among the Consortium members in due time before the deadline. To facilitate contacts and communication between the Consortium and the responsible EC officers, the Project Coordinator will keep the latter informed about scheduled meetings of the consortium and ensure timely distribution of the progress reports and other relevant information.

3. Management structure and procedures the LSRI RESTORE

The current draft for the proposed governance of the large-scale-research-initiative RESTORE cannot be fully finalised. The future of RESTORE is currently unclear due to the cancellation of the FET flagship programme. In the case of funding, the pillars of proposed governance would be as detailed below.

Based on our own networking experiences and after consulting running FET-flagships, we can take advantages from their experiences as well and adapt our governance draft accordingly.

The governance frame we would propose for the LSRI, which will be further streamlined and consolidated as the future of RESTORE becomes clearer, is as follows:

Main objectives of the governance are excellently summarised by the Quantum FET-flagship team:

- to facilitate and support management & steering,
- to ensure coordination & networking
- to organize communication & outreach

Main Core structures should be:

- board of funders (EC, MS/AC)
- Strategy Board (<30, ca.50% from industry, at least 2 from the IMI programme Advanced Therapies)
- Science Board (project leaders from the FET-flagship RESTORE supported projects and of other EU-funded or nationally funded consortia on Advanced Therapies)

Key Performance Indicators: Similar as proposed for the recently launched Quantum FET-Flagship, we recommend monitoring the RESTORE Flagship progress by regular evaluation of a set of key performance indicators to facilitate decision-making processes and optimal allocation of resources. Examples for those might be:

- Number of early and late clinical trials on new Advanced Therapies
- Number of academic hubs approved/certified for translational research on Advanced Therapies
- Number of technologies developed within the FET-flagship that will be applied in European and non-European countries for research and clinical routine
- Number of Advanced Therapy products that got marketing authorization and became accessible to patients
- Number of filed and granted patents (IP portfolio generation)
- Commercial success rate with ATMP/bio-MD (increased revenues)
- Number of patients treated with and cured by Advanced Therapy products
- Number of scientists and physicians who moved into the research field of ATMP/bio-MD
- Level of mobilization of additional public and preferentially private money invested in Europe into this field

Rules for Intellectual Properties should be defined from the beginning based on rules in horizon2020 consortium agreements. Models applied by consortia in North America (e.g. Palmer ICI and CCRM) should be taken into consideration.

Education & Training: plays a central role for the sustained success of the mission-driven approach and concepts will be prepared during preparatory phase – first draft:

- To ensure high-level quality of application of Advanced Therapies in clinical trials and routine
 - Training as certified "ATMP physician" - optional or obligatory must be discussed
- To attract the best junior clinical and basic scientists for the field of Advanced Therapies
 - implementation of a postgraduate and a training program
 - Kick-off grants for innovative, high-risk research of junior scientists
- To increase the awareness and educate in the medical community
 - Videos, further education courses for physicians and nurses
- To increase awareness and scientific literacy in the public community
 - information events patients, TV/YouTube science channels, training courses for patient advocates,

Approach to engage with relevant initiatives in the MS and AC, industry and interdisciplinary research communities

- European level: Interlinking with IMI programme Advanced Therapies
- National level: Member states will be encouraged to devise and implement regional and national support mechanisms for Advanced Therapies under the umbrella of RESTORE as early as possible, preferably before 2021
- Regional level: Implementation of academic translational hubs (see above); approaching regional research clusters
- International level: Primary focus is the support of RIAs in Europe with high impact on European society and economy, but the community is positioned globally and collaboration according to the horizon2020 rules should be promoted with some restrictions for the industry (clear benefit for Europe has to be figured out) –
- Non-profit patient organisation level: strong connection to patient advocates – meetings, position paper
- Industry: preparing rules for partnerships, co-developments, academic translational hubs for de-risking strategies
- Academic researchers in the social sciences: RESTORE will engage in addition to life science researchers also excellent researchers in the fields of health policy, economics, sociology, and ethics to reflect the full spectrum of the research society affected by a game changer of the health care system.