

WG5. Management, data handling and ethics

D5.1: Report on the activity and management co-ordination and progress monitoring plan.

1. Introduction

COST Action CA21151 HAPLO-IPS was organised around seven Working Groups (WG) addressing different scientific, regulatory, management, training and clinical aspects of the Action. Effective coordination between the different Working Groups and monitoring of the implementation of the Action were required to ensure that activities were conducted in accordance with the objectives defined in the Memorandum of Understanding (MoU).

This deliverable defines how the activities will be co-ordinated and managed and how progress against the Memorandum of Understanding (MoU) will be monitored.

2. Management structure of HAPLO-IPS. Roles and responsibilities

The management structure of HAPLO-IPS included:

- **Management Committee (MC)**

The Action is governed by the Management Committee (MC), it approves the work plan and budget, decides on the use of the networking instruments and monitors implementation of the MoU. MC constituted the formal decision-making body of the Action, in accordance with the COST management framework. Its role included overall governance and oversight of the Action, review of progress, discussion of implementation issues, approval of relevant activities and provision of strategic guidance.

- **Chair and Vice-Chair**

The Chair, Vice-Chair facilitated communication and implementation of the Action and supported coordination between the different actors involved.

- **WG Leaders and Co-leaders**

The WG constituted the main implementation level of the Action. WG Leaders and Co-leaders coordinated activities within their respective Working Groups and communicated progress, issues and plans to the Action leadership.

The seven Working Groups are:

- **WG1:** Sample selection
- **WG2:** hiPSC production
- **WG3:** Quality control, Biobanking and Registration of cell lines
- **WG4:** Safety and Regulation

- **WG5:** Management, Data Handling and Ethics
- **WG6:** Training and Dissemination
- **WG7:** Clinical Application

- **Project coordinator**
Provides support to the Action Chair coordinating the overall implementation of the Action, facilitating communication between the different Working Groups and supporting the follow-up of activities and objectives.

- **Grant Awarding Coordinators**
Coordinate and oversees the organisation and implementation of the Action's grant-awarding activities.

- **Scientific Communication Coordinator**
Coordinates the communication and dissemination of the Action's scientific activities and results.

- **Young researchers Group Leader and Co-leader**
Support the involvement of young researchers in the Action and facilitates their participation in relevant activities and coordination processes.

- **Grant Holder Manager**
Provides administrative and financial support to the MC.

- **Core Group**
Supports the Action leadership in the coordination, implementation and follow-up of the Action's activities and facilitates communication between the different management and Working Group structures.
The Core Group is composed by the Action Chair, Vice-Chair, WG Leaders and Co-leaders, YR Group leader and Co-leader, project coordinator, Science Communication coordinator, Grant Awarding coordinators and Grant Holder Manager.

3. Activity coordination

During the initial meetings of the COST Action 21151 HAPLO-iPS Core Group, consensus was reached that co-ordination of activities and management, and monitoring of progress, will be achieved through regular CG, MC and WG meetings with associated reports. CG and MC meetings are planned roughly bi-annually and WG meetings will be held in conjunction with the MC meetings and separately as needs arise. Management Committee and CG meetings provided a framework for discussing the implementation of the Action and addressing issues requiring coordination or decisions.

WG leaders and co-leaders will be in regular contact with the HAPLO-iPS leadership. Activity coordination was therefore carried out through the interaction between WG, their leaders and the Action management structure. This communication supported the coordination of activities, the identification of issues affecting implementation and the follow-up of activities across the Action.

An important element in co-ordination of activities will be the development and implementation of the website (<https://haplo-ips.eu/>), which is placed under WG6 (Training and dissemination). In addition, WG leaders will employ regular communication with WG members by email and dedicated internal and cross-WG interactions related to deliverables. Where practical, physical meetings and interactions will be aligned with conferences and workshops set up by other community players, such as the International iPS Cell Banking Initiative (ISCBI), the Global Alliance for iPSC Therapies (GAiT), the International Society for Stem Cell Research (ISSCR) and national stem cell societies.

Another important element in the coordination of activities will be utilization of Short Term Scientific Missions that promote knowledge and technology transfer, and of Training Schools that integrate knowledge aims among WGs.

4. Progress monitoring

Progress will also be monitored through activity reports and archival of documents related to specific deliverables on the HAPLO-iPS website.

We will keep track of progress using a monitoring table that lists each deliverable and milestone, who is responsible, the due date, status, and any supporting documents. At each MC meeting, we will review the deliverables, milestones, and risks, then include everything in regular reports to COST. Progress will also be evidenced by the Action's outputs, by the numbers of Short-Term Scientific Missions, Training Schools and participants, by ICT conference grants and virtual networking tools, as well as by young researcher participation.

WG Leaders followed the implementation of activities within their respective WGs and communicated progress, issues and plans to the Action leadership. The combination of Working Group-level and Action-level monitoring provides a framework for following the overall implementation of the Action.

Risks, such as delayed deliverables, low participation in meetings or instruments, and data protection and other ethics concerns will be identified and monitored by the CG. Mitigation measures include early scheduling of meetings and calls, the use of virtual and hybrid participation, and early consultation on data handling and ethics through WG5.

WG5 will develop and propose ethical core documents required for cord blood donation and banking. These will include informed consent and information sheet templates covering issues related to donors, parents/guardians and re-consent. Compliance with national and EU frameworks will be co-ordinated with the regulatory roadmap developed under WG4.

4.1 Progress reporting and follow-up

Progress monitoring was supported by evidence including:

- Management Committee minutes
- Working Group minutes

- Core Group and coordination records
- Working Group presentations
- Progress Reports
- Deliverables and milestones
- Training and networking activities
- Dissemination activities
- Website and repository information
- Participation and membership information

The Second Progress Report constitutes formal evidence of the structure and progress of the Action during its first 24 months.

5. Cross-WG coordination

The implementation of the Action involved links between the objectives and activities of different Working Groups.

The main dependencies included:

WG1 - WG2

Sample selection provided the basis for hiPSC production.

WG2 - WG3- WG4

hiPSC production was linked to quality control, characterisation and biobanking activities.

WG2- WG3 - WG4

Quality and characterisation activities were linked to safety and regulatory considerations.

WG3 - WG4 - WG7

Quality, characterisation, safety and regulatory aspects were relevant to the progression towards clinical application.

WG5 - all WGs

Management, data handling and ethics were cross-cutting aspects relevant to the activities of the Working Groups.

WG6 - all WGs

Training and dissemination activities were linked to the outputs and activities of the different Working Groups.

Cross-WG issues and dependencies could be addressed through communication between WG Leaders and Action leadership, coordination meetings, Management Committee meetings and follow-up of agreed action points.

The purpose of this coordination is to ensure that relevant dependencies are communicated and considered during implementation.

6. Conclusion

D5.1 documents the framework used by HAPLO-iPS for the four main aspects identified in its scope:

1. **Action management**, including the management structure and distribution of responsibilities
2. **Activity coordination**, including coordination between Working Groups and the Action leadership
3. **Progress monitoring**, including the follow-up of objectives, activities, milestones and deliverables
4. **Cross-WG coordination**, including the identification and follow-up of dependencies between Working Groups.

The framework combines the governance role of the Management Committee, the operational coordination provided by the Action leadership and the implementation activities of the seven Working Groups.