MELCAYA

NOVEL HEALTH CARE STRATEGIES FOR MELANOMA IN CHILDREN, ADOLESCENETS AND YOUNG ADULTS

Grant Agreement: 101096667

D10.1 Project management plan

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Executive Summary

This document serves as a guideline for the monitoring, control and execution of the different administrative and financial aspects of the project to ensure that the action described in the Grant Agreement is properly implemented according to European Commission rules and practices. In the first part of the document, the management structure of the project is explained, including the different governing structures (such as the General Assembly or the Steering Committee) and the roles and responsibilities of the partner institutions involved in them. The work plan for the project is also detailed, including a list of work package broken down in their composing tasks, the effort in persons month, the assigned responsible institution and due delivery date. Gantt and PERT charts are also included to make it easier to understand the distribution and relationships between the different tasks to be performed. The different project deliverables and milestones are also listed including the responsible institution, due date and means of verification. Finally, the different types of reporting to be performed during the project are presented, both internally and towards the European Commission.

Contents

Figures

Tables

Acronyms & Abbreviations

Term	Description
EU	European Union
EC	European Commission
PO	Project Officer
GA	Grant Agreement
CA	Consortium Agreement
IP	Intellectual Property
WP	Work Package
D	Deliverable
M	Month
CAYA	Children, Adolescent and Young Adults
AI/XAI	Artificial Intelligence/Explainable Artificial Intelligence
PERT	Program Evaluation and Review Technique
L/GCMN	Large/Giant Congenital Melanocytic Nevus
DNA/cfDNA	DeoxyriboNucleic Acid/circulating free DeoxyriboNucleic Acid
H	Human
POPD	Processing of Personal Data
PN	Proliferative Nodules
DMP	Data Management Plan
eCRF	Electronic Case Report Form
KOL	Key Opinion Leaders

1 Introduction

The overall goal of this project management plan is to serve as a guide to monitor the successful implementation of the different research activities proposed in the MELCAYA project within the agreed time and cost. This is particularly important due to the complexity of the current project, which has a total of 21 participating partners (18 beneficiaries and 3 affiliated entities) and a total of 66 deliverables. This document establishes the framework for the project coordination so that every member of the consortium is able to conduct their contractual project activities in the most effective way possible.

2 Project consortium

MELCAYA consortium is composed of 25 partners from 10 different countries and incorporates key stakeholders in the whole value chain, including 12 hospitals, 3 research centers, 2 small and medium-sized enterprises (SMEs), 1 technological center, 2 patient organizations, 3 policy makers and 1 ethical expert. In table 1, a detailed list of the participating institutions is provided:

Table 1 Participant institutions in MELCAYA consortium

Legal name	Short name	Role
Fundació Clínic per a la Recerca Biomèdica	FCRB	Coordinator
Hospital Clínic de Barcelona	HCB	Affiliated entity
Eberhard Karls Universität Tübingen	UT	Beneficiary
Université d'Aix-Marseille	AMU	Beneficiary
Università degli Studi Firenze	UNIFI	Beneficiary
Università degli Studi di Perugia	UNIPG	Beneficiary
Deutsche Krebsforschungszentrum	DKFZ	Beneficiary
Prinses Máxima Centrum voor Kinderoncologie	PMC	Beneficiary
Region Stockholm	RS	Beneficiary
Fondazione IRCCS Istituto Nazionale dei Tumori	INT	Beneficiary
Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie-Panstwowy Instytut Badawczy	NIO-PIB	Beneficiary
Leibniz-Institut für Umweltmedizinische Forschung GmbH	IUF	Beneficiary
Technion – Israel Institute of Technology	TECH	Beneficiary
Athena Tech SL	AT	Beneficiary

SYNYO GmbH	SYNYO	Beneficiary
Università Cattolica del Sacro Cuore	UCSC	Beneficiary
Fondazione Policlinico Universitario Agostino Gemelli IRCCS	FPG	Beneficiary
Institut Català d'Oncologia	ICO	Beneficiary
Fundació Institut d'Investigació Biomèdica de Bellvitge	IDIBELL	Affiliated entity
Agenzia Nazionale per i Servizi Sanitari Regionali	AGENAS	Beneficiary
Asociatia Melanom Romania	AMER	Beneficiary
Institut Curie	ICP	Associated partner
Gdański Uniwersytet Medyczny	MUG	Associated partner
Charité – Universitätsmedizin Berlin	CH	Associated partner
Nevus Netwerk Nederland	NNN	Associated partner

3 Management structure

3.1 Overview of management structure

The project organizational structure and governing bodies are represented in the diagram below. The rules for composition, organisation and decision making of the project's governing bodies are part of the Consortium and Grant Agreements (CA and GA).

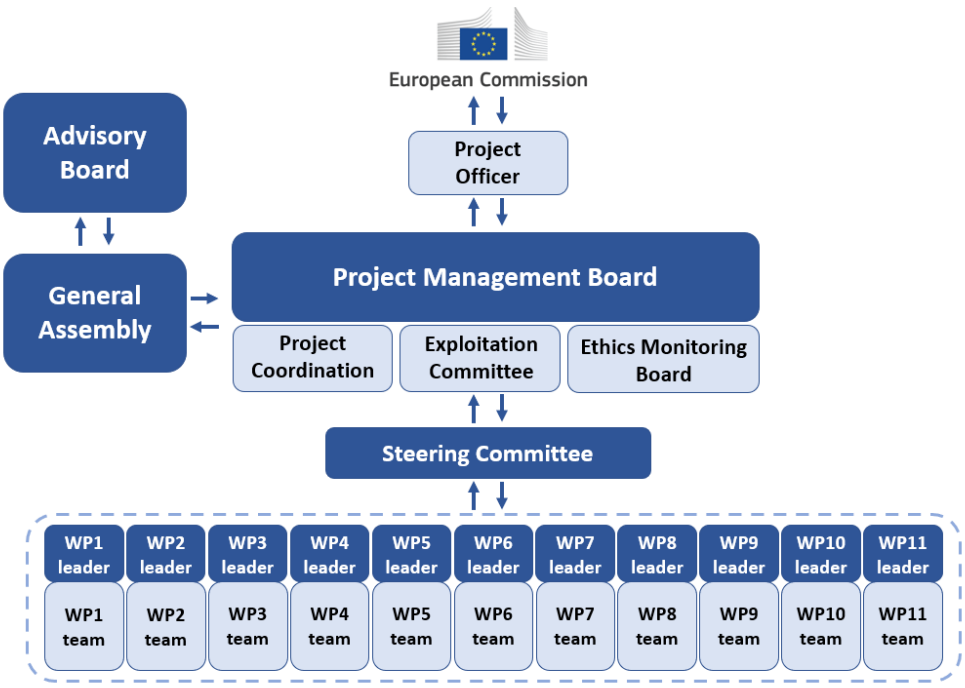

Figure 1 Project management structure

3.2 Roles and responsibilities

European Commission Project Officer

The main role of the project officer is to act as a representative of the European Commission (EC) in the evaluation, monitoring, negotiation and financial evaluation of the project. The PO interacts with the consortium through the Project Coordination team and participates in activities such as the kick-off meeting, the periodic review meetings and the final project meeting.

Table 2 Project officer details

Name	Institution
Laura García Ibañez	European Commission

Project Management Board

This governance structure is in charge of the efficient management and coordination of the MELCAYA consortium and acts as the contact point for the partners for all scientific, financial and administrative issues. It is composed by three bodies:

Project Coordination

This governing body is composed by the project coordinator and a project manager (see table 3). The main responsibilities of the project coordination team are the following:

- Monitor that the action is implemented properly according to EC rules and practices.
- Act as an intermediary for all communications between the beneficiaries and the EC and keep them informed about any changes in the project finances, legal issues (such as contract amendments), etc.
- Prepare, request and review documents or information required by the EC (deliverables, periodic reports, etc.), verify their completeness and correctness and submit them to the EC.
- Ensure that all payments are made to the beneficiaries without unjustified delay.

Table 3 Project coordination team members

Role	Name	Institution
Project coordinator	Susana Puig	FCRB/HCB
Project manager	Adrián López	FCRB

Exploitation Committee

This committee will address the development of an exploitation plan for the new technology generated throughout the MELCAYA project and find the most suitable route to the market. It will be composed by scientific representatives from the institutions involved in the technological developments (DKFZ, AT, TECH) as well as the communication/dissemination manager of MELCAYA (SYNYO) and a tech transfer specialist from the coordinating institution (FCRB). The main responsibilities of this committee include:

- Identification of commercial and knowledge exploitable results (technological offerings, intellectual property, added-value services, etc.).
- Perform an intellectual property (IP) analysis and define intellectual property registration (IPR) strategy taking into account the already existing background on IP (defined in the CA).
- Analyze possible regulatory pathways and create a market access plan (business plan) for commercially exploitable results.
- Analysis of the financial sustainability of the market strategy, including market potential, finding additional funding opportunities, investments, etc.

Table 4 Exploitation committee members

Name	Institution
Adrián López	FCRB
Susana Puig	FCRB/HCB
Teresa Lloret	FCRB/HCB
Romana Hessler	SYNYO
Joan Ficapal	AT
Gidi Shani	TECH
Tabea Bucher	DKFZ

Ethics Monitoring Board

The main objective of this board is to provide ongoing support to the MELCAYA consortium on all ethical and legal issues that may surface. The board consists of a centralized service that provides the essential advice, support and supervision regarding ethical issues that may be encountered within the project as it progresses. The team is composed of the following members:

Table 5 Ethical monitoring board members

Name	Institution
Dario Sacchini	UCSC
Pietro Refolo	UCSC
Costanza Raimondi	UCSC

The general responsibilities of the EMB include:

- Ensure that for all tasks carried out by participating partners, adequate ethical procedures as described in the MELCAYA Consortium and Grant Agreement will be applied.
- Ensure that for all tasks carried out by participating partners, adequate compliance with legislations and ethical guidelines are applied.
- Check that all participating partners are on a common ground regarding ethical issues.
- Oversee the work throughout the entire course of the project to help the Consortium move forward and address possible issues that might arise (i.e., assuring a state of compliance with ethical standards within the relevant research fields).
- Validate reports and statements regarding the ethical adequacy of the planned research.

Advisory Board

This group of renowned international experts from the industry and academy will support the consortium whenever critical decisions need to be made. These people have already previous general knowledge of the works and the resources developed by the consortium groups (as they have previously collaborated with consortium members) and provide relevant advice on their scientific areas of expertise (see table 5).

Table 6 Advisory board members

Name	Institution	Expertise
Veronique Bataille	Kings College London	Genetic epidemiology of melanoma
Juan Naya	ISDIN	Photoprotector products for melanoma prevention
Miguel Reyes Múgica	Children's Hospital of Pittsburgh	Biology of congenital nevi and neurocutaneous melanocytosis
Veronica Kinsler	Great Ormond St Hospital for Children	Children's moles, all types of nevi, birthmarks, problems of pigmentation, rare skin diseases

General Assembly

The General Assembly is the ultimate responsible for the strategic planning and decision-making in the consortium. It is composed of one representative from each consortium partner and chaired by the project coordinator. It is important to highlight that members can appoint a substitute or proxy to attend and vote at any meeting on their behalf. This governing body shall be free to act on its own initiative to formulate proposal and take decisions. The decisions to be taken by this body are the following:

- Content, finances and intellectual property rights: this includes changes in the GA (description of the action, budget, etc.) or CA (background, list of third parties, etc.).
- Evolution of the consortium: entry, withdrawal or termination of a participant institution in the consortium, proposals for a change in the coordination, suspension or termination of the project, etc.

The procedures regarding decision-making and conflict-resolution processes for the General Assembly have been defined in detail in the CA.

Table 7 General assembly members

Name	Institution
Susana Puig	FCRB/HCB
Ines Brecht	UT
Heather Etchevers	AMU
Daniela Massi	UNIFI
Mario Mandala	UNIPG
Titus Brinker	DKFZ
Karijn Suijkerbuijk	PMC
Hildur Helgadottir	RS
Andrea Ferrari	INT
Anna Szumera-Cieckiewicz	NIO-PIB
Tamara Schikowski	IUF
Gidi Shani	TECH
Joan Ficapal	AT
Romana Hessler	SYNYO

Dario Sacchini	UCSC
Josep Maria Borras	ICO
Marco Marchetti	AGENAS
Violeta Astratinei	AMER
Adrián López	FCRB

Steering Committee

This governing body is responsible for the supervision of the proper execution of the project, the implementation of the decisions of the General Assembly and the proposal of any changes in the project or consortium plan. It is composed by the project coordinator and parties appointed by the General Assembly. The main tasks of the Steering Committee include:

- Prepare meetings, propose decisions and prepare the agenda of the General Assembly.
- Monitor the proper execution and implementation of the decisions of the General Assembly and the overall project.
- Collect information at least every 6 months on the scientific progress of the project, evaluate the information and propose modifications to the consortium plan if needed to the General Assembly.
- Support the project coordinator in preparing meetings with the EC and prepare related data and deliverables.
- Prepare the content and timing of press releases and joint publications by the consortium or proposed by the EC.
- Advise the General Assembly on ways to rearrange tasks and budgets.

Table 8 Steering committee members

Name	Institution
Susana Puig	FCRB/HCB
Ines Brecht	UT
Heather Etchevers	AMU
Daniela Massi	UNIFI
Mario Mandala	UNIPG
Titus Brinker	DKFZ

Gidi Shani	TECH
Laura Sampietro	HCB
Romana Hessler	SYNYO
Violeta Astratinei	AMER
Adrián López	FCRB

Work package leaders

The leaders of each WP will be responsible for the detailed implementation of the WP and tasks, as well as the preparation of the corresponding deliverables and milestones. Their main responsibilities are the following:

- Preparation and execution of the tasks in their WP according to the work plan (see section 4), including coordination of the task leaders.
- Collaborate with other WP leaders and deliver results that are needed as input for other tasks or WP on time.
- Report on a regular basis about the work progress to the Steering Committee and General Assembly and inform them as soon as possible about any deviation encountered that may impact the overall work plan.

Table 9 List of WP leaders

WP	Name	Institution
1	Ines Brecht	UT
2	Heather Etchevers	AMU
3	Daniela Massi	UNIFI
4	Mario Mandala	UNIPG
5	Titus Brinker	DKFZ
6	Susana Puig	FCRB/HCB
7	Laura Sampietro	HCB
8	Romana Hessler	SYNYO
9	Violeta Astratinei	AMER
10	Adrián López	FCRB

4 Work plan

The goal of MELCAYA project is to better understand the mechanisms of melanoma development and progression in childhood, adolescence and young adults (CAYA) to allow for better prevention, diagnosis and prognosis strategies. To achieve this, the consortium will implement a work plan consisting of 10 complementary WP and subsequent tasks during a four-year period (48 months) that will be detailed in the following sections:

4.1 Work package list

The different WP of the project, including the starting/end month and leading institution, are shown in table 10:

Table 10 List of WP

WP number	WP name	WP leader	Start month	End month
1	Identification of risk factors, exposomics and genetic susceptibility of melanoma in CAYA	UT	1	48
2	Understanding triggers and transitions from normal melanocytes to nevus to melanoma	AMU	1	48
3	Pathology and molecular pathology for subtypes classification	UNIFI	1	48
4	Retrospective analysis of the activity and efficacy of anti PD-1 antibodies in CAYA melanoma	UNIPG	1	48
5	Image analysis and machine learning for early diagnosis and risk prediction	DKFZ	1	46
6	Use of minimally- and non-invasive technologies for early detection of metastasis and prognosis	FCRB	1	40
7	Health care system strategies implementation to inform policy and ethical dimension	HCB	1	44
8	Communication, dissemination, exploitation and networking	SYNYO	1	48
9	Research engagement, patient education and advocacy	AMER	1	48
10	Project management	FCRB	1	48

4.2 Interaction between work packages

A deep analysis of registries and databases will be performed in WP1 to 4, as well as the creation of standardized protocols for data integration and processing for risk detection and early diagnosis of melanoma in CAYA. The results of these analysis will be used to identify patients to involve in the retrospective clinical studies included in these WP. In parallel, a molecular characterization of intermediate tumors (WP2), the creation of a model to understand their progression (WP3) and establishing of diagnostic criteria (WP4) will be carried out. The knowledge obtained from the 4 retrospective clinical studies will be exploited through the creation of a pan-European platform (WP3) that will integrate and harmonize European knowledge about melanoma in CAYA.

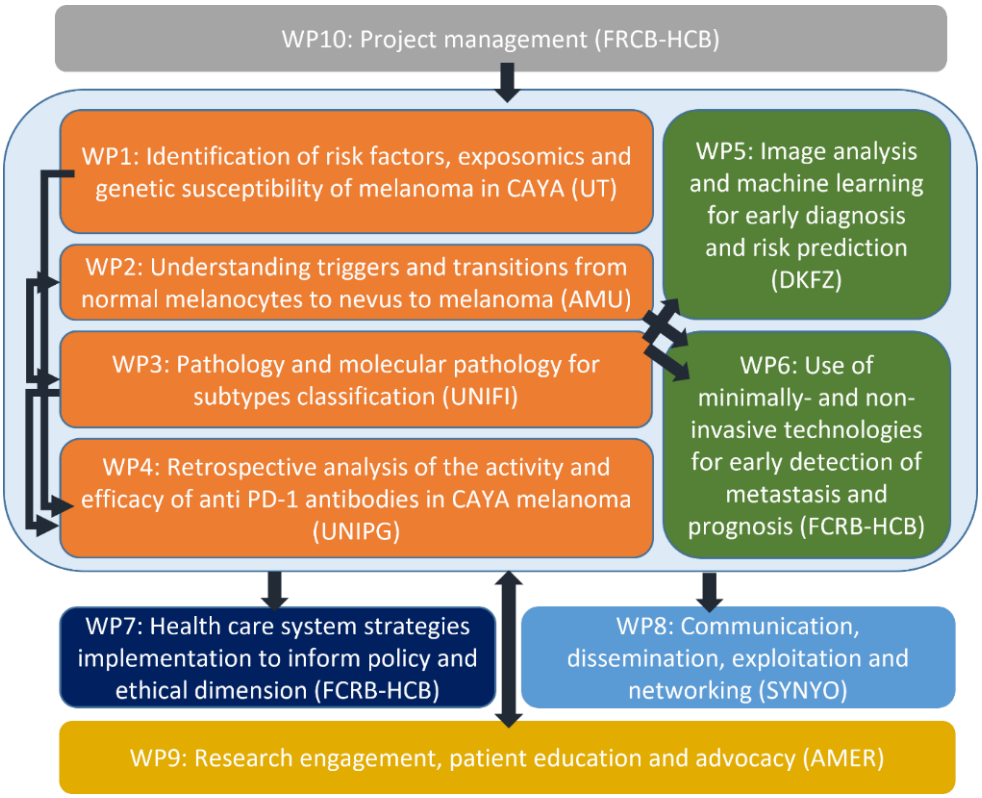

Figure 2 PERT chart showing the relationship between WP

This data will also be used for the validation of AI-based tools for early diagnosis in WP5, as well as early detection and prognosis of metastatic patients in WP6. All the knowledge obtained in previous work packages will be integrated in WP7 to create effective recommendations in terms of health policy strategies for the prevention of melanoma in CAYA, which are currently non-existent. In parallel, dissemination, communication and exploitation activities will be carried out in the framework of WP8 to ensure impact maximization. Melanoma patient associations will work in WP9 to ensure that patient involvement is maintained throughout the project at all times. Finally, WP10 will be devoted to the implementation of project management strategies to ensure the implementation of the different

project tasks within the agreed time and cost. A visual representation of the relationships between the tasks is shown by means of a PERT chart in figure 2.

4.3 Task breakdown

The breakdown of each WP into tasks (including the starting/end month and leading institution) is shown in table 11:

Table 11 WP breakdown into tasks

Task number	Task name	Task leader	Start month	End month
WP1 - Identification of risk factors, exposomics and genetic susceptibility of melanoma in CAYA				
1.1	Harmonizing of data from the available registries in CAYA and L/GCMN	INT	5	30
1.2	Exposome data analyses in melanoma in CAYA and L/GCMN	IUF	6	30
1.3	Molecular germline genetics analyses in CAYA with melanoma or L/GCMN	UT	7	48
WP2 - Understanding triggers and transitions from normal melanocytes to nevus to melanoma				
2.1	Screening and collection of biological resources	AMU	1	36
2.2	Genomic characterization of cell-free DNA and affected patient tissues	FCRB/HCB	1	24
2.3	Bulk somatic methylomics for precursor lesions	AMU	12	24
2.4	Assessing alternatives for determining copy number variations	UT	12	30
2.5	High-resolution identification of cell populations in whole tissues through spatial transcriptomics and single-cell multi-omics	AMU	6	36
2.6	Single-cell multi-omics analyses of cultured CAYA melanoma progenitors in vitro	AMU	6	42
2.7	Bioinformatics analyses and public-facing results dissemination	AMU	9	48
2.8	Wider integration across work packages	AMU	24	48
2.9	Repository archiving	AMU	36	48
WP3 - Pathology and molecular pathology for subtypes classification				
3.1	Standardization and tissue quality control	UNIFI	1	18

3.2	Histopathology and computational pathology	UNIFI	4	36
3.3	Comprehensive somatic, transcriptional and DNA methylation landscape and data integration	UNIFI	13	48
3.4	Pan-European digital second opinion platform	FPG	22	48
WP4 - Retrospective analysis of the activity and efficacy of anti PD-1 antibodies in CAYA melanoma				
4.1	Activity and efficacy of anti PD-1 antibodies in CAYA with early and advanced melanomas: a multicenter transnational European retrospective analysis	UNIPG	1	18
4.2	Acute and long-term toxicity of anti PD-1 antibodies in CAYA with early and advanced melanomas: a multicenter transnational European retrospective analysis	UNIPG	4	24
4.3	Fertility of CAYA with early and advanced melanomas treated with anti PD-1 therapy: a multicenter transnational European retrospective analysis	UNIPG	13	48
4.4	Incidence of second cancers in CAYA with early and advanced melanomas treated with anti PD-1 therapy	UNIPG	22	48
WP5 - Image analysis and machine learning for early diagnosis and risk prediction				
5.1	Data acquisition and pre-processing	DKFZ	1	12
5.2	Generation of classifiers	DKFZ	10	22
5.3	Implementation of XAI	DKFZ	20	30
5.4	Evaluation of results in conjunction with dermatologists and pathologists	DKFZ	30	46
WP6 - Use of minimally- and non-invasive technologies for early detection of metastasis and prognosis				
6.1	Develop a disruptive algorithm for precision medicine in melanoma for children	AT	6	40
6.2	Breath analyser device	TECH	1	12
6.3	Disposable sensing patch	TECH	1	12
6.4	Clinical pilot study to test volatilomics in melanoma and L/GCMN	FCRB	13	36
WP7 - Health care system strategies implementation to inform policy and ethical dimension				
7.1	Analysing current health system policies/health care strategies on rare cancer	ICO	1	18

7.2	Guidance for assessing innovative health technologies for secondary prevention and diagnosis of melanoma in CAYA	AGENAS	1	30
7.3	Ethical, legal and social implications	UCSC	1	26
7.4	The melanoma patient journey mapping / design thinking workshop	AMER	1	24
7.5	Design of CAYA melanoma health care system strategies to inform policy and implementation in EU-27	FCRB/HCB	1	44
WP8 - Communication, dissemination, exploitation and networking				
8.1	Dissemination and communication plan	SYNYO	1	6
8.2	Developing an exploitation plan for the validated minimally and non-invasive technologies	SYNYO	24	36
8.3	Establishing an online and media presence	SYNYO	1	48
8.4	Public outreach and joint activities with other EU funded initiatives and networks	SYNYO	1	48
WP9 - Research engagement, patient education and advocacy				
9.1	Ensure consistent patient involvement throughout the project	AMER	1	48
9.2	Regular touchpoints between consortium partners and the European Melanoma Community	AMER	1	48
9.3	Understanding the barriers to early diagnosis, screening and treatment in order to set better healthcare strategies for CAYA	AMER	1	48
WP10 – Project management				
10.1	Project management and coordination	FCRB	1	48
10.2	Monitoring project activities and reporting	FCRB	1	48
10.3	Gender monitoring, quality assurance and risk management	FCRB	1	48
10.4	Data management	FCRB	1	48
10.5	Ethics management	UCSC	1	48

4.4 Staff effort per WP

The effort in persons month to be devoted to each WP of the project by the beneficiaries (and their affiliated entities) is summarized in table 12:

Table 12 Participant effort per work package

Institution	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10
FCRB	9.00	9.00	9.00	5.00	9.00	60.00	-	4.00	1.00	43.00
HCB	6.00	6.00	6.00	8.00	-	6.00	20.00	-	-	4.00
UT	34.00	8.00	6.00	3.00	2.00	-	2.00	1.00	1.00	1.00
AMU	2.00	55.00	-	-	-	-	1.00	2.50	1.00	1.50
UNIFI	-	-	52.00	-	6.00	-	1.00	2.00	1.00	1.00
UNIPG	14.00	-	14.00	62.00	-	-	2.00	3.00	2.00	1.00
DKFZ	-	-	-	-	46.00	-	1.00	3.00	1.00	1.00
PMC	12.00	-	-	10.00	-	-	-	1.00	-	1.00
RS	17.00	-	-	10.00	-	-	-	1.00	-	1.00
INT	13.00	3.00	11.00	14.00	-	-	1.00	1.00	-	1.00
NIO-PIB	-	-	24.00	20.00	-	-	-	1.00	-	1.00
IUF	22.00	-	-	-	-	-	-	1.00	-	1.00
TECH	-	-	-	-	-	48.00	1.00	2.00	1.00	1.00
AT	-	-	-	-	-	42.00	1.00	3.00	1.00	1.00
SYNYO	-	-	-	-	-	-	-	20.00	1.00	1.00
UCSC	-	-	-	-	-	-	8.00	3.00	-	11.00
FPG	-	-	12.00	-	-	-	-	2.00	1.00	1.00
ICO	-	-	-	-	-	-	8.00	1.00	-	1.00
IDIBELL	-	-	-	-	-	-	-	-	-	1.00
AGENAS	-	-	-	-	-	-	10.00	2.00	-	1.00
AMER	1.00	-	-	-	-	-	5.00	2.00	7.00	1.00
ICP	0.17	0.17	0.17	0.17	-	-	-	0.17	0.17	0.17
MUG	0.17	0.17	0.17	0.17	-	-	-	0.17	0.17	0.17
CH	0.33	0.33	0.33	0.33	-	-	-	0.33	0.33	0.33
NNN	-	0.40	-	-	-	0.40	0.40	0.40	0.40	0.40

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10
Total	130.67	82.07	134.67	132.67	63.00	156.40	61.40	56.57	19.07	77.57

4.5 Gantt chart

The distribution of the different tasks and work packages throughout the timeline of the project is summarized in the Gantt chart shown in figure 3 (resolution adapts automatically when zooming in/out).

5 Deliverables

The list of deliverables that have to be prepared for each of the WP of the project, including the delivery month and the leading beneficiary, is summarized in table 13:

Table 13 List of project deliverables

Deliverable number	Deliverable name	Leader	Due month
WP1 - Identification of risk factors, exposomics and genetic susceptibility of melanoma in CAYA			
1.1	Risk factors and exposome for melanomas in CAYA	INT	24
1.2	Genetic dataset on germline analyses and phenotypes of CAYA patients with melanoma and L/GCMN	UT	30
1.3	List of identified candidate variants/genes contributing to melanoma risk	UT	36
1.4	Genetic score that includes variants in high-risk, moderate-risk genes and PRS	UT	42
1.5	ExpoMel initiation package	UT	11
1.6	ExpoMel midterm recruitment	UT	23
1.7	ExpoMel report on the status of posting the results in a repository	UT	36
WP2 - Understanding triggers and transitions from normal melanocytes to nevus to melanoma			
2.1	Partner registration status	AMU	12
2.2	Report on molecular data collection of L/GCMN	AMU	28
2.3	cfDNA protocol for CAYA and L/GCMN monitoring	FCRB	12
2.4	Midterm report on quality control	AMU	27

2.5	Tertiary web portal live for single-cell data	AMU	48
2.6	NevustoMel initiation package	FCRB	11
2.7	NevustoMel midterm recruitment report	FCRB	24
2.8	NevustoMel report on the status of posting results in a repository	FCRB	40
WP3 - Pathology and molecular pathology for subtypes classification			
3.1	Standardized protocols for tumor tissue processing	UNIFI	18
3.2	Standardized protocols and procedures for melanoma sub-classification	UNIFI	36
3.3	Integrated analysis of somatic, transcriptomic and methylation profiles	UNIFI	48
3.4	IT infrastructure creation to connect existing national/institutional digital pathology platforms	FPG	48
3.5	Mol-Mel initiation package	UNIFI	11
3.6	Mol-Mel midterm recruitment report	UNIFI	24
3.7	Mol-Mel report on the status of posting results in a repository	UNIFI	36
WP4 - Retrospective analysis of the activity and efficacy of anti PD-1 antibodies in CAYA melanoma			
4.1	Generation of data collection and management system and sites activation	UNIPG	10
4.2	Immuno-Ped initiation package	UNIPG	9
4.3	Immuno-Ped midterm recruitment report	UNIPG	24
4.4	Immuno-Ped report on the status of posting results in a repository	UNIPG	46
4.5	Immuno-Ped II initiation package	UNIPG	16
4.6	Immuno-Ped II midterm recruitment report	UNIPG	36
4.7	Immuno-Ped II report on the status of posting results in a repository	UNIPG	46
WP5 - Image analysis and machine learning for early diagnosis and risk prediction			
5.1	Dermatoscopic melanoma/nevus classifier: conventional and spitzoid melanomas	DKFZ	24
5.2	Histological melanoma/nevus classifier: conventional and spitzoid melanomas	DKFZ	36

5.3	Skin age classifier and evaluation	DKFZ	46
5.4	AI-Mel initiation package	DKFZ	11
5.5	AI-Mel midterm recruitment report	DKFZ	24
5.6	AI-Mel report on the status of posting results in a repository	DKFZ	46
WP6 - Use of minimally- and non-invasive technologies for early detection of metastasis and prognosis			
6.1	Algorithm for precision medicine in melanoma for CAYA patients	AT	36
6.2	Breath analyser for CAYA patients	TECH	12
6.3	Disposable sensing patch for CAYA patients	TECH	12
6.4	Precis-Mel initiation package	FCRB	11
6.5	Precis-Mel midterm recruitment report	FCRB	24
6.6	Precis-Mel report on the status of posting results in a repository	FCRB	40
WP7 - Health care system strategies implementation to inform policy and ethical dimension			
7.1	Framework for assessing innovative health technologies	AGENAS	44
7.2	Set of health care system strategies	HCB	30
WP8 - Communication, dissemination, exploitation and networking			
8.1	Dissemination and communication plan 1	SYNYO	6
8.2	Dissemination and communication plan 2	SYNYO	24
8.3	Dissemination and communication plan 3	SYNYO	48
8.4	Exploitation strategy	SYNYO	36
8.5	Online and media presence 1	SYNYO	12
8.6	Online and media presence 2	SYNYO	48
8.7	Engagement summary report	SYNYO	48
8.8	Project website	SYNYO	3
8.9	Common work plan for scientific collaboration under the ‘Understanding’ cluster	FCRB	3
8.10	Common video and/or common cluster brochure	FCRB	12
WP9 - Research engagement, patient education and advocacy			
9.1	Patient engagement plan	AMER	3

9.2	Impact assessment of patient engagement	AMER	48
9.3	Report on the methodology for ethnographic citizen to understand barriers in CAYA patients	AMER	48
9.4	Citizen engagement summary report	FCRB	48
9.5	Addressing inequalities recommendations	FCRB	48
WP10 – Project management			
10.1	Project management plan	FCRB	3
10.2	Quality assurance and risk management plan	FCRB	6
10.3	Data management plan 1	FCRB	6
10.4	Data management plan 2	FCRB	24
10.5	Data management plan 3	FCRB	36
10.6	Plan for ethic-legal monitoring and ethical submissions 1	UCSC	3
10.7	Plan for ethic-legal monitoring and ethical submissions 2	UCSC	12
10.8	Conclusions of common annual meeting on the 'Understanding' cluster 1	FCRB	12
10.9	Conclusions of common annual meeting on the 'Understanding' cluster 2	FCRB	24
10.10	Conclusions of common annual meeting on the 'Understanding' cluster 3	FCRB	36
10.11	Conclusions of common annual meeting on the 'Understanding' cluster 4	FCRB	48
10.12	Policy brief formulating recommendations based on the research and innovation strand of the 'Understanding' annual cluster meeting 1	FCRB	12
10.13	Policy brief formulating recommendations based on the research and innovation strand of the 'Understanding' annual cluster meeting 2	FCRB	24
10.14	Policy brief formulating recommendations based on the research and innovation strand of the 'Understanding' annual cluster meeting 3	FCRB	36
10.15	Policy brief formulating recommendations based on the research and innovation strand of the 'Understanding' annual cluster meeting 4	FCRB	12

Ethics			
11.1	H-Requirement No.2	FCRB	3
11.2	POPD-Requirement No.3	FCRB	1
11.3	AI-Requirement No.4	FCRB	3

6 Milestones

The progress of the project will be monitored according to a series of milestones that are detailed in table 14, including the responsible institution, the due month and the means of verification.

Table 14 List of project milestones

Milestone number	Milestone name	Leader	Due month	Means of verification
WP1 - Identification of risk factors, exposomics and genetic susceptibility of melanoma in CAYA				
1	Study protocol, study centers and data sets identified	UT	9	Preparation of the study protocol
2	Development of harmonized exposure models for risk assessment	INT	24	Submission of D1.1 to the EC
3	Collection of blood from 100 indexed patients	UT	36	Submission of D1.7 to the EC
4	Integration of exposome and germline genetics for determining final risk	UT	42	Submission of D1.4 to the EC
WP2 - Understanding triggers and transitions from normal melanocytes to nevus to melanoma				
5	Sequencing of DNAs from selected L/GCMN, PN an CAYA melanomas	FCRB	40	Submission of D2.8 to the EC
6	Report on molecular data collection of L/GCMN	AMU	48	Preparation of a report on the bioinformatic analyses
WP3 - Pathology and molecular pathology for subtypes classification				
7	Standardized protocols of tissue processing and structured synoptic templates for melanoma pathology	UNIFI	36	Submission of D3.1 and D3.2 to the EC
8	Tumoral protein expression atlas, tumoral cells and immune-contexture automated analysis	UNIFI	48	Submission of D3.3 and D3.4 to the EC

9	Tumoral mutational analyses, transcriptomic and methylation arrays, profiling and correlation with demographics, clinical data and morpho-phenotypic features	UNIFI	48	Submission of D3.3 to the EC
10	Digital pan-European second opinion platform	FPG	48	Submission of D3.4 to the EC
WP4 - Retrospective analysis of the activity and efficacy of anti PD-1 antibodies in CAYA melanoma				
11	Protocol approval by the Ethical Committee	UNIPG	9	Submission of D4.2 to the EC
12	Generation of a central system of data collection, management and eCRF with sites activation completed	UNIPG	16	Submission of D4.2 and D4.5 to the EC
13	Inclusion of 50 % data about activity and drug-related acute and chronic toxicity on the eCRF	UNIPG	36	Submission of D4.3 and D4.6 to the EC
14	Inclusion of full data about fertility and second cancers on eCRF	UNIPG	44	Submission of D4.7 to the EC
26	Completion of statistical analysis	UNIPG	46	Submission of D4.5 to the EC
WP5 - Image analysis and machine learning for early diagnosis and risk prediction				
15	Complete data acquisition for initial classifier training	DKFZ	10	Preparation of a technical report
16	Generation of classifiers	DKFZ	24	Uploading of the codes to GitHub
17	Evaluation of the potential usefulness of the classifiers	DKFZ	36	Publication of the results in a scientific journal
WP6 - Use of minimally- and non-invasive technologies for early detection of metastasis and prognosis				
18	Technological validation of AI tools	AT	36	Final code ready
19	Volatilomics-based devices ready for validation in the clinical setting	TECH	12	Prototype ready
20	Volatilomics-based devices validated in the clinical setting	TECH	40	Submission of D6.6 to the EC
WP7 - Health care system strategies implementation to inform policy and ethical dimension				

21	Review and questionnaire/survey on the current EU rare cancer policies	ICO	18	Questionnaire ready and answered by at least 2 KOL from 5 EU countries
22	Results from KOL interview on current state-of-the art assessment of rare diseases and its implementation in EU	HCB	24	Interviews to 5 health technology assessment scientists ready
23	Results from virtual focus groups on ethical, legal and social implications to consider when designing policies to prevent and diagnose melanoma in CAYA	UCSC	30	Virtual focus groups performed
WP9 - Research engagement, patient education and advocacy				
24	Interactions between consortium partners and the European melanoma community	AMER	3	8 documented interactions
25	Establishment of the methodology for ethnographic citizen science to understand the barriers in CAYA patients	AMER	48	Submission of D9.3 to the EC

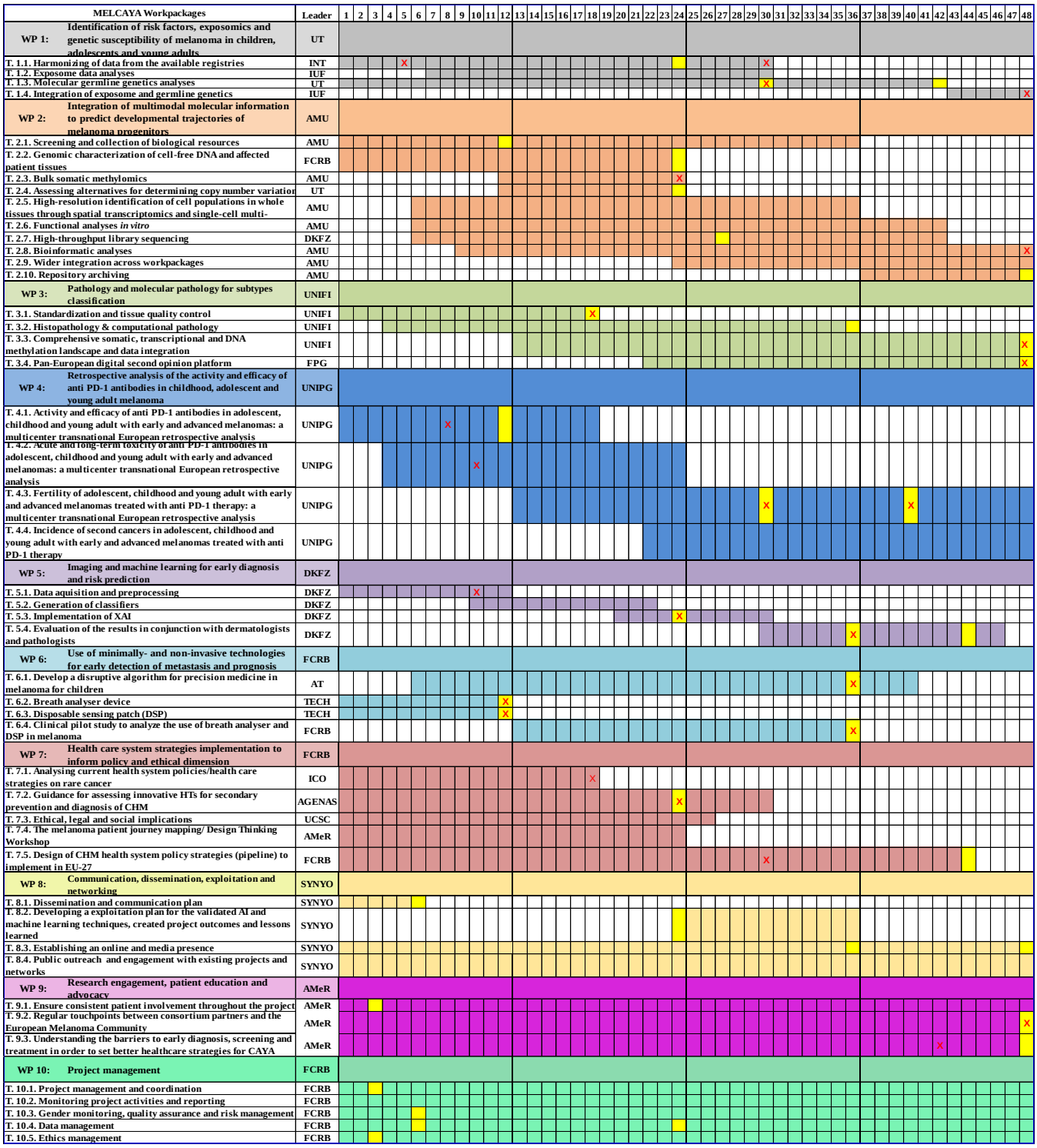

Figure 3 Gantt chart including WP and tasks

7 Reporting

Throughout the project, different types of reporting will be carried out by the consortium to inform about the financial and technical progress and compare it to the initial plan set out in the GA:

7.1 Internal reporting

This type of reporting is implemented for efficient project management purposes and it will require WP leaders to inform the Project Coordination team about technical progress in each of the tasks, incurred costs, use of resources and dissemination activities following the EC guidelines. These reports will be shared with all the consortium and discussed with the Steering Committee to evaluate achievements, make adjustments in the work plan (if significant deviations are detected) and facilitate risk management. The details of internal reporting procedures for MELCAYA will be given in D10.2.

7.2 Continuous reporting to the EC

This type of reporting involves the submission of the project deliverables and reporting on milestones achievement to the EC through the Project Coordination team. The details of deliverable review and quality control for MELCAYA will be given in D10.2.

7.3 Periodic reporting to the EC

These reports are aimed at informing the EC about how the project is progressing in terms of scientific work, financial and resource management. They are used to demonstrate that the Consortium is fulfilling its duty as set out in the GA and is eligible for EC payment. Reports have to be submitted at 3 timepoints (M18, M36 and M48) and must include a technical part detailing the work carried out by the participants during the reporting period and a financial part that includes an individual financial statement and an explanation on the use of resources. The financial statement has to declare all eligible costs for each budget category, even if the costs exceed the amount indicated in the estimated budget. For the final report (M48), a certificate on the financial statements has to be issued by an independent auditor for those partners that requested a total contribution equal or higher than 430.000 €

8 Conclusions

Throughout this document, the main elements related to the project management of MELCAYA have been reviewed. In the first part of the document, the management structure of the project, the different governing bodies and their roles and responsibilities were explained. Then, the different WP that compose the project were detailed, including a work breakdown structure in the different tasks, an explanation on the interrelations between the different WP, as well as a Gantt chart summarizing the schedule and responsible partner per task. The effort per work package, related deliverables and milestones were also detailed, including due delivery date, responsible institution and means of verification. Finally, the reporting to be performed during the project was also detailed, including the internal monitoring and the continuous and periodic reporting to the EC.