MELCAYA

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

Grant Agreement: 101096667

D10.2 Quality assurance and risk management plan

Funded by the European Union

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

Document Information

Deliverable number:	D10.2
Deliverable title:	Quality assurance and risk management plan
Deliverable version:	v1.0
Work Package number:	WP10
Work Package title:	Project management
Due Date of delivery:	31.05.2023
Actual date of delivery:	31.05.2023
Dissemination level:	Public (PU)
Type:	R - Document, Report
Author(s):	Adrián López (FCRB)
Contributor(s):	-
Reviewer(s):	Dario Sacchini (UCSC) Pietro Refolo (UCSC) Costanza Raimondi (UCSC) Gidi Shani (TECH) Romana Hessler (SYNYO)
Project name:	Novel health care strategies for melanoma in children, adolescents and young adults
Project Acronym:	MELCAYA
Project starting date:	01.12.2022
Project duration:	48 months
Rights:	MELCAYA consortium

Document history

Version	Date	Beneficiary	Description
0.1	11.05.2023	FCRB	First draft version
0.2	12.05.2023	UCSC	Revised draft
0.3	16.05.2023	TECH	Revised draft
0.4	17.05.2023	SYNYO	Revised draft
1.0	29.05.2023	FCRB	Final draft

Executive Summary

This document defines the guidelines and general working procedures to ensure that the work performed during the project is delivered on time, within budget and meet the high-quality standards of the European Commission (set out in the definitions and regulations of the Grant and Consortium Agreements). In the first part of this document, the procedures to organize the internal communication of MELCAYA are detailed, including e-mails, teleconferences and explanation of the rules concerning meetings of the governing bodies such as the General Assembly or the Steering Committee. A detailed description of the reviewing process to ensure the quality of the deliverables and project reports (both internal and to the European Commission) is also presented, assigning clear deadlines and responsible persons. Documentation management procedures are also explained, including a description of the shared workspace created for document storage, the templates for the official project documents and the versioning conventions to keep track of reviewed documents. Finally, the risk management strategy is presented, including a list of critical risks and the contingency measures to be taken.

Contents

Figures

Tables

Acronyms & Abbreviations

Term	Description
EC	European Commission
WP	Work Package
WPL	Work Package Leader
PC	Project Coordination
GA	Grant Agreement
CA	Consortium Agreement
IP	Intellectual Property
IFS	Individual Financial Statement
CAYA	Children, Adolescents and Young Adults
DNA	DeoxyriboNucleic Acid
RNA	RiboNucleic Acid
CRF	Case Report Form
GCP	Good Clinical Practice
CRO	Clinical Research Organization
KOL	Key Opinion Leaders

1 Introduction

The goal of this document is to serve as a guide for all consortium partners to understand the procedures to review project outcomes such as deliverables and periodic reports, so that they meet the high-quality standards expected from this project, both in terms of the work performed and produced documentation. In a complex project such as MELCAYA, which has a total of 21 participating partners (18 beneficiaries and 3 affiliated entities) and a total of 66 deliverables, this is a particularly critical point. The document also establishes a framework for the project coordination team to effectively carry out all management activities and monitor current and future risks, and for the partners to maintain a high-quality output level and engage in an effective collaboration scheme. Generating project outcomes of inferior quality can affect the overall sustainability of the project and have cascading effects that disrupts the progress of the project and prevents the consortium from achieving its contractual obligations.

2 Internal communication

For the overall success of the project, it is key that the communication between participant institutions remains open and transparent, so that everyone is kept up-to-date on work progress, next steps, outcomes of meetings and task allocation. The following tools will be used to implement the most effective internal communication to achieve the project goals:

2.1 Shared workspace (*Microsoft OneDrive*)

In order to provide a common workspace to serve as a repository for all documents, project information (deliverables, reports, protocols, etc.) and allow for co-operative work, a web-based, easy-to-use and safe space in *Microsoft OneDrive* has been created and shared with all partners. This folder is administered and maintained by MELCAYA's coordinating institution, Fundación Clínic per a la Recerca Biomèdica (FCRB). The repository has a folder structure that provides well-arranged access to all documents (see figure 1).

2.2 Contact list

A centralized contact list with all consortium members has also been created by FCRB and made available in the shared workspace to facilitate collaboration among MELCAYA partners. This list includes the name and email of the person and type of communication they wish to be contacted for (scientific, financial/administrative or both). Each participating institution is responsible for communicating to FCRB any changes in the contact details as well as the inclusion/removal of team members in order to keep the list up-to-date.

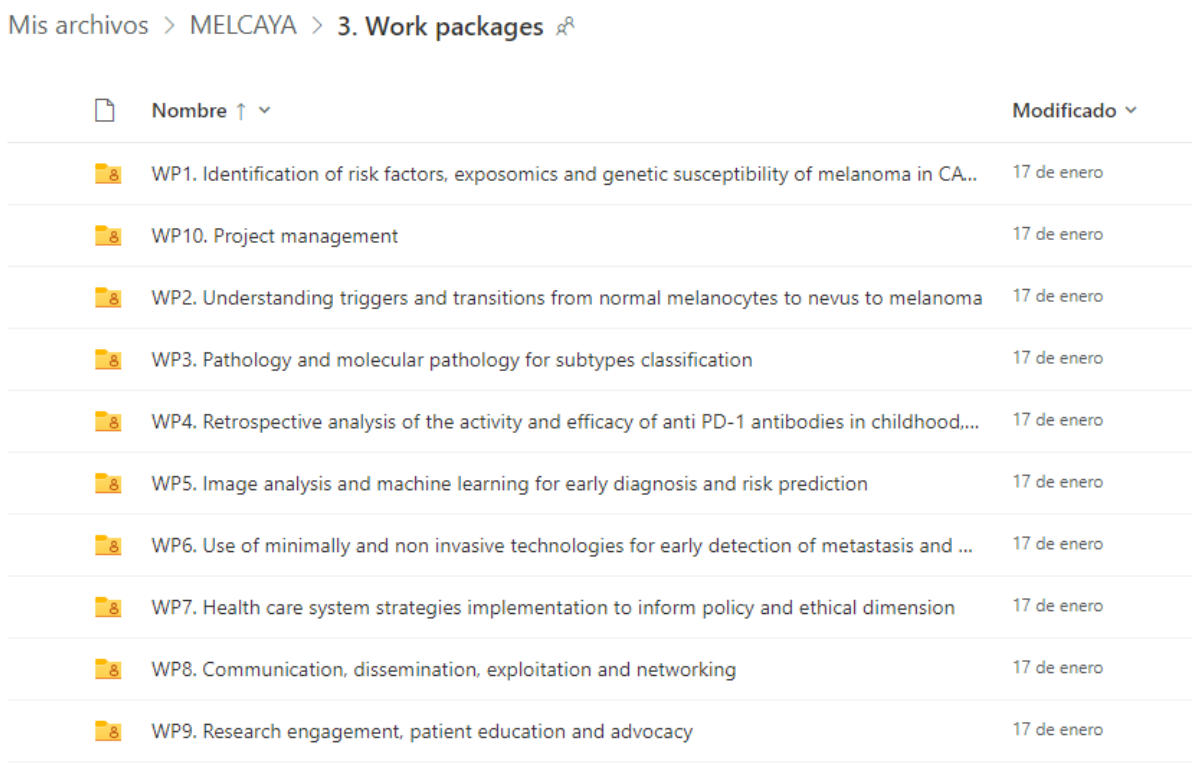

Figure 1 Screenshot of shared workspace for MELCAYA

2.3 E-mail

Email is expected to be the primary form of communication for MELCAYA project. In order to help to quickly recognize project-related communications among the high number of mails that the people involved in the project is likely receiving every day, the following subject fields should be used:

- *[MELCAYA] – Topic* for a general communication. For example *[MELCAYA] – General Assembly Meeting*
- *[MELCAYA] – WPx: Topic* for a WP-level communication. For example: *[MELCAYA] - WP5: Clinical study.* For particular project items the following naming conventions will be used: *WPx_Tx.x* (for tasks), *WPx_Dx.x* (for deliverables), *WPx_Mx.x* (for milestones).

It is required that the project coordination team (Susana Puig and Adrián López) is included in copy in all the most important project communications.

2.4 Teleconferencing/virtual meetings

This type of communication will be routinely used complimentarily to mail communications to discuss all sorts of scientific or financial/administrative issues related to the project. The preferred platform to organize the online conferences will be *Microsoft Teams*, although other platforms such as *Zoom* and

Google Meet will also be considered depending on the preferences of the organizing institution. The main meetings to be organized will be detailed in the following subsection.

2.5 Meetings of consortium bodies

For an effective management of the consortium and monitoring of work progress, the Project Coordination team (PC) will be in charge of organizing periodic meetings of the main project governing bodies (for definitions, see D10.1 Project management plan):

Table 1 Meetings of general assembly and steering committee

Governing body	Timing	Modality
General Assembly	Once a year	Hybrid (in person with the possibility to attend virtually)
Steering Committee	Every 6 months*	Virtual

** Extraordinary meetings can be organized at any time upon request of the Steering Committee or 1/3 of the Members of the General Assembly.*

To ensure an adequate meeting organization, a notice will be sent by mail to each of the members of the consortium bodies as soon as possible and no later than the minimum number of days stipulated in the Consortium Agreement (CA, see table 2). The PC will try to make their best effort to combine General Assembly meetings with other events such as conferences to save costs and optimize the travelling within the consortium. Decision-making and conflict resolution procedures, such as voting rules and quorum or veto rights are defined in detail in the CA. Every member of the governing bodies should be presented or represented at any meeting. If attendance is not possible, they are responsible for appointing a substitute or proxy to represent them and vote in the meeting.

To optimize meeting organization and ensure an efficient use of time, the PC will prepare and circulate in advance a clear and well-structured agenda with the points of discussion to allow for preparation. Modifications or addition of agenda items are also allowed (all time limits are shown in table 2). Any agenda item requiring a decision by the members of the consortium body must be identified as such. The PC will also be in charge of chairing the meeting, preparing the minutes and distributing them among participants in the project consortium and within the time limits set out in table 2. The minutes shall be considered accepted within 15 calendar days from receipt if no member has sent an objection by written notice to the PC. Every decision taken during the meeting will only be considered as binding after acceptance of the minutes. If all participants agree before the meeting, recordings will be made and uploaded along with meeting minutes to the shared workspace for consultation.

Table 2 Notice periods for General Assembly and Steering Committee meetings

	General Assembly	Steering Committee
Notice of a meeting	45 calendar days* (before the meeting)	14 calendar days* (before the meeting)
Sending the agenda	21 calendar days* (before the meeting)	7 calendar days (before the meeting)
Adding agenda items	14 calendar days* (before the meeting)	2 calendar days* (before the meeting)
Sending the minutes	10 calendar days (after the meeting)	10 calendar days (after the meeting)
Accepting the minutes	15 calendar days (after receiving the minutes)	15 calendar days (after receiving the minutes)

In the case of **extraordinary meetings, the number of calendar days is reduced to 15 (General Assembly) and 7 (Steering Committee) for the notice period, 10 calendar days for sending the agenda (General Assembly) and 7 calendar days for adding agenda items (General Assembly).*

Other meetings that will be required for adequate project monitoring are the following:

Table 3 Meetings of other governing bodies

Governing body	Timing	Modality
Work Packages	Monthly*	Virtual
Project Coordination	Twice a month*	In person
Ethics Monitoring Board	Monthly*	In person
Exploitation Committee	Once a year (years 1 and 2)* Twice a year (years 3 and 4)*	Virtual

***Additional **extraordinary meetings** can be organized at any time upon request of a member of the consortium body with due observation to the notice periods.*

In all these cases, the notice period for the meeting and sending the agenda should not be later than 14 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting. The addition or modification of agenda items should be done no later than 7 calendar days preceding the meeting. The preparation of the minutes of the sessions is recommended as a good practice but will not be compulsory.

3 External communication, dissemination and exploitation

The details regarding the procedures to ensure the quality of the outputs from the communication and dissemination activities such as scientific publications, conferences, press-releases, etc. will be detailed in D8.1 Dissemination and communication plan (and subsequent updates D8.2 and D8.3). Intellectual property (IP) will also be an intrinsic element of the project, with some deliverables having the potential for commercial exploitation and further development (particularly for WP5 and WP6). All the details related to the definition of pre-existing know-how, establishment and protection of IP and ensuring confidentiality of shared information can be found in the CA.

4 Review process for deliverables

All the deliverables prepared by the MELCAYA consortium (see list in D10.1 Project management plan) must undergo a process of internal review before submission to the European Commission (EC). Each deliverable has been assigned a lead partner in charge of creating it in both the Grant Agreement (GA) and D10.1 Project management plan. This lead will be referred to from now on as the editor. The process of review for the deliverable will be the following:

1. The PC sends a reminder to the editor to start preparing the deliverable and informs about document review deadlines.
2. The editor creates the document draft.
3. Editor sends the draft to all work package (WP) members for internal review.
4. Editor adjusts the deliverable according to the comments received from WP members and sends back the draft. Steps 2 and 3 may be repeated if necessary.
5. WPL checks if corrections have been applied and approves the document to the editor and PC by e-mail.
6. The editor sends the final draft to all consortium partners to receive external feedback. If no comments are received within the deadline, it is considered that the document is approved (silent approval).
7. If comments are received, the editor makes changes in the document and sends them back to the consortium. Steps 6 ad 7 may be repeated if necessary.
8. The editor sends the final draft to the PC team to run the final formal check (format, structure, labelling, etc.) and get the final approval (to be sent by e-mail).
9. PC uploads the deliverable to the Participant Portal of the EC.

The goal of the review process is to identify weaknesses in the document and improve it as much as possible to meet the quality standards of the EC and avoid the publication of unwarranted conclusions. The role of the reviewers should be not only to screen the document so it meets the minimum acceptance criteria, but also to make recommendations about changes to improve the overall document. This includes, for instance, suggestions regarding a better organization, more effective use of tables and figures, additional conclusions, advise on scientific or technical validity of the findings, etc. Additional aspects could include an adequate review of relevant literature, adequate description of data sources, proper interpretation of empirical data or statistical results, clear exposition, etc. To ensure the successful implementation of the review process, certain deadlines have been set and summarized in table 4:

Table 4 Deliverable review process with associated deadlines

Task	Responsible	Deadline
Send reminder to the editor to start preparing the deliverable	PC	60 calendar days before due date
Send draft for internal WP review	Editor	20 calendar days before due date
Send comments and changes to the editor	WP members	14 calendar days before due date
Send back final draft version to WP members	Editor	11 calendar days before due date
Final draft approval by WPL	WPL	10 calendar days before due date
Send final draft to all consortium partners	Editor	10 calendar days before due date
Send comments and changes to the editor	Consortium members	6 calendar days before due date
Send corrected version to consortium partners	Editor	3 calendar days before due date
Send final deliverable version to PC	Editor	2 calendar days before due date
Run formal check and send final acceptance	PC	1 calendar day before due date
Deliverable submission	PC	Submission date

All documentation exchanges should be carried out by e-mail. The deliverable will be created using a *Microsoft Word* document template (more details in section 6.2). The review process has to be performed using the revision mode with "*Record Changes*" switched on. Reviewers should carefully follow naming conventions (explained in section 6.3) for adequate version keeping in MELCAYA's shared workspace. Always include the PC in copy when sharing e-mails as they will double-check version names.

5 Review process for reports

5.1 EC periodic reports

As explained in D10.1 Project management plan, the EC will monitor the progress of MELCAYA not only through a continuous monitoring of project deliverables and the milestones achieved, but also trough the evaluation of periodic reports presented in table 5 (the deadline for the presentation of the reports is 60 calendar days after the end of each reporting period).

Table 5 MELCAYA reporting periods and associated deadlines

Report	Period	Deadline
Interim report 1	M1 (01/12/2021) to M18 (31/05/2024)	30th July 2024
Interim report 2	M19 (01/06/2024) to M36 (30/11/2025)	29th January 2026
Final report	M37 (01/12/2025) to M48 (30/06/2026)	20th January 2027

These reports present evidence to the EC that the project is progressing according to the plan set out in the GA and that the consortium is fulfilling its duty and is eligible for payment. It must include explanations for any deviations (budget and content) with respect to the GA. The reports will consist of two parts:

1. **Technical report:** it includes a publishable summary of the project and explanations of the work carried out by the beneficiaries during the reporting period, including the progress made on tasks, deliverables and attained milestones. Any deviations with respect to the plan set out in the GA must be explained. A list of dissemination and communication activities and generated intellectual property must also be included, as well as an explanation on the issues related to the action implementation and the economic and societal impact. Each WPL will be responsible to compile all the technical information for their WP using the EC template. The project coordinator will consolidate the received information, run a formal check and send back the

report to the consortium for corrections if needed. The final approved version will be uploaded to the EC Participant Portal by the PC.

2. **Financial report:** it includes the individual financial statement (IFS) detailing eligible costs for each budget category (even if they exceed the amounts indicated in the estimated budget) and an explanation on the use of resources. For the final report, a certificate on the financial statements has to be issued by an independent auditor for those beneficiaries that claimed an EU contribution higher or equal than 430.000 €. Each institution will be responsible for submitting the IFS to the PC team using the EC templates. The PC may request partners to correct any error or clarify discrepancies with the budget that could be due to accounting errors. In case of major inconsistencies between the activities carried out and the achievements in the technical report, the PC will discuss the issue with the partner and, if necessary, bring it to the attention of the General Assembly.

In order to ensure a successful preparation of the reports for the EC, the deadlines shown in table 6 have been set:

Table 6 EC periodic reports review process and associated deadlines

Process	Responsible	Deadline
Send notice of EC reporting and templates	PC	60 calendar days before due date
Send contributions to technical report	WPL	30 calendar days before due date
Send financial report	Beneficiaries/affiliated entities	30 calendar days before due date
Feedback on technical and financial reports	PC	14 calendar days before due date
Send final contribution to technical report	WPL	7 calendar days before due date
Send revised financial reports	Beneficiaries/affiliated entities	7 calendar days before due date
Report submission	PC	Submission date

5.2 Internal reports

As commented in D10.1 Project management plan, internal reports are envisioned as an internal management tool to monitor and maintain control over the project, allowing to detect deviations early and take corrective measures as soon as possible. They also serve the purpose of helping in the

preparation of the EC periodic reports by allowing to evaluate the progress towards the aims and obligations of the period. As a result, these reports will be prepared at every mid-point between the reporting periods. The templates used will be similar to those used for the EC. The general information that must be included is:

- A description of the work progress towards the completion of tasks, deliverables and milestones.
- A list of the communication and dissemination activities carried out (including publications, conferences, press releases, etc.).
- An estimation of the budget and time consumed following EC guidelines.

The internal review will be managed in a similar way to the EC reports: it will be coordinated by the PC team and each beneficiary will be responsible to send all the technical/scientific information about the tasks performed in each WP along with the budget and effort used to date. If required, the PC will ask for corrections. The deadlines for the review process of the internal reports are shown in table 7.

Table 7 Internal reports review process and associated deadlines

Process	Responsible	Deadline
Send notice of internal reporting along with templates	PC	45 calendar days before due date
Send contributions to technical report	Beneficiaries/affiliated entities	7 calendar days before due date
Send financial report	Beneficiaries/affiliated entities	7 calendar days before due date
Feedback on technical and financial reports	PC	3 calendar days before due date
Send explanations/revised reports	Beneficiaries/affiliated entities	Submission date

After completion, the report will be circulated within the consortium and presented in the Steering Committee meeting, in which each WPL will present their activities to ensure cohesion between the different WP. It will also allow to decide whether there is need to take corrective actions and if necessary, changes will be proposed to the General Assembly in terms of budget or description of the action.

Table 8 Estimated calendar for internal reports and Steering Committee meetings

Process	Estimated date	Comments
Internal report 1	M6	Deadline 31/05/2023

Steering Committee meeting 1	M7	Meeting during 06/2023
Internal report 2	M12	Deadline 30/11/2023
Steering Committee meeting 2	M14	Meeting during 01/2024 (coincident with General Assembly)
Internal report 3	M18	It will be replaced by the EC periodic report 1
Steering Committee meeting 3	M19	Meeting during 06/2024
Internal report 4	M24	Deadline 31/11/2023
Steering Committee meeting 4	M26	Meeting during 01/2025 (coincident with General Assembly)
Internal report 5	M30	Deadline 31/05/2024
Steering Committee meeting 5	M31	Meeting during 06/2025
Internal report 6	M36	It will be replaced by the EC periodic report 2
Steering Committee meeting 6	M38	Meeting during 01/2026 (coincident with General Assembly)
Internal report 7	M42	Deadline 31/05/2026
Steering Committee meeting 7	M43	Meeting during 06/2026
Internal report 8	M48	It will be replaced by EC final report
Steering Committee meeting	M48	Final meeting during 11/2026

6 Documentation management

During the course of the MELCAYA project, many documents will be produced, being of vital importance to implement document management processes to allow users to locate and identify relevant files and ensure version control.

6.1 Storage

As previously commented in section 2.1, the PC will be in charge of creating a shared workspace in *Microsoft OneDrive* to store all the project documentation and allow for collaborative work. The general structure of the folder will be as follows:

0. **General documentation:** it will include subfolders for consortium contracts (GA and CA), amendments, templates, project identity (logos, flyers, images, etc.) and other documentation (to be defined).
1. **Consortium meetings:** it will include subfolders for kick-off, General Assembly and Steering Committee meetings. For each meeting, different information will be stored such as photos and videos, presentations, minutes, etc.
2. **Work packages:** it will include subfolders for each work package (WP1, WP2, WP3, etc.) in which all the scientific/technical documentation, internal meetings, etc. will be stored.
3. **Deliverables:** it will include subfolders for the four different years of the project. In each of them, folders with all the different versions of the deliverables will be stored (following the conventions presented in section 6.4).
4. **Reporting:** it will include two subfolders, one for internal and other for EC periodic reporting. Within them, two other subfolders will be created, one for technical reports and the other for the financial information.

6.2 Templates

The PC will provide the consortium with templates elaborated by SYNYO that incorporate the project identity (such as MELCAYA logo, funding statement, etc.) as well as a standard format for styles, page layout and content structure. Some of the templates that have been made available are:

- Template for presentations (*Microsoft Power Point*)
- Templates for deliverables (*Microsoft Word*)
- Template for clinical study protocols (*Microsoft Word*)
- Template for meeting minutes (*Microsoft Word*)
- Templates for internal reporting (*Microsoft Word/Excel*)

The PC will be in charge of supervising that every partner uses them and that they are kept up-to-date. The templates can be found in the shared workspace in *0. General documentation → Templates.* Some examples of templates can be found in Annex I of this deliverable.

6.3 Versioning

Keeping track of the different document revisions is a critical point when performing a review process between different partners. The main documents that are going to undergo revisions in this project are going to be the following:

Deliverables

The file name should follow this structure: project acronym (*MELCAYA*), document identifier (*D*) with deliverable number as reflected in the GA (*x.y*), deliverable title, revision number (*z*) and acronym of the partner performing the review. The following convention is used for the different stages in document preparation:

- Draft: *MELCAYA_Dx.y_Deliverable Title_**v1**.z_Partner acronym*
- First final version (after approval and verification process): *MELCAYA_Dx.y_Deliverable Title_**v1**.z_Partner acronym*
- Second final version (corrections after EC submission): *MELCAYA_Dx.y_Deliverable Title_**v2**.z_Partner acronym*

For example: ***MELCAYA_D10.1_Project management plan_v1.0_FCRB***

Clinical study protocols

The file name should include the following fields: project acronym (*MELCAYA*), document identifier (*CSP*) with study number as reflected in the GA (*x*), clinical study title, revision number (*y*) and acronym of the partner performing the review. The following convention is used for the different stages in document preparation:

- Draft: *MELCAYA_CSPx_Clinical study title_**v0**.y_Partner acronym*
- First final version (after approval and verification process): *MELCAYA_CSPx_Clinical study title_**v1**.y_Partner acronym*

For example: ***MELCAYA_CSP1_ExpoMel_v0.1_FCRB***

7 Risk management

The creation of a risk management strategy is required for such a complex project in order to minimize the impact of any negative deviation from the work plan set out in the GA. The general process involves identifying the most critical risks, the proposal of risk-mitigation measures (contingency plans) and the continuous update and follow-up of these measures. A list of major risks has been created during the grant preparation stage (and revisited during the kick-off meeting) along with the preliminary contingency measures to avoid or at least mitigate situations that could hamper the successful completion of the project (see table 9).

This list needs to be maintained and updated throughout the project with new risks identified within the different WP by their respective leaders or in the general project by the PC team. This risk register

will be reviewed by the Steering Committee at each board meeting (see table 8) and all the newly identified risks will be adequately evaluated using standard methods such as the likelihood/severity matrix to assess the potential impact and if the creation of a contingency plan would be needed. If changes in the GA are envisioned in any of the contingency measures for the newly identified risks, a proposal for amendment may be presented to the General Assembly for approval.

Table 9 List of critical risk and respective mitigation plan

Risk number	Description of risk	WP	Proposed mitigation measures
1	Low number of cases collected due to the rarity of melanomas in CAYA *Likelihood: low* *Severity: low*	WP1 WP3	WP1: identification of large registries in Europe and big hospital-based databases with associated biobank collections. WP3: include atypical melanocytic proliferations and extend the collection of cases to other hospital centers
2	Insufficient quality of the extracted RNA due to the old age of the cases retrospectively collected *Likelihood: medium* *Severity: high*	WP3	Exclude molecular studies using RNA and keep the rest of the molecular studies
3	Insufficient amount of DNA due to the small size of the lesion *Likelihood: low* *Severity: low*	WP3	Change the molecular study protocol in certain cases
4	Low number of patients who had received systemic therapy due to the rarity of melanomas in CAYA *Likelihood: medium* *Severity: low*	WP4	A clinical European database will be generated by using electronic CFRs, containing information from patients enrolled outside clinical trials. Furthermore, data related to medical issues will be recorded in conformity with privacy and data protection regulations and handled according to the current GCP rules
5	Confidentiality and data protection *Likelihood: low* *Severity: high*	WP4	A certified CRO will be in charge of creating and maintaining the study database, also providing technical support throughout the study and

			long-term data storage. Patient data generated by this study will be maintained in confidence and protected through pseudoanonymization and key-code creation (managed by the study investigators) in accordance with regulatory requirements
6	Low availability of biological samples/poor sample quality *Likelihood: low* *Severity: medium*	WP4	The clinical centers will ensure the availability of the necessary samples through its available biobank and prospective collection of samples. Quality will be ensured by the coordinating center and research collaborators through the use of shared protocols for sample procurement, processing and analysis
7	Too few slides/too heterogenous data to train the classifiers properly *Likelihood: low* *Severity: high*	WP5	Many clinics will contribute to data collection. Open-source data will also be available
8	Classifiers do not perform well *Likelihood: low* *Severity: high*	WP5 WP6	Adaptation of previously successfully trained prototypes for melanoma/nevus classification and a basic age classifier can be fine-tuned for the classification of young patients
9	Low participation of KOL in surveys and Delphi *Likelihood: low* *Severity: medium*	WP7	The partners directly involved in this WP are very well connected with EU KOL in the area of rare cancers, health technology assessment and ethics. They will be very active communicating the project from its start to colleagues aiming to raise interest and willingness to participate across the KOL

8 Conclusions

Throughout this document, the general procedures to maintain a high-quality standard in terms of project outcomes has been presented. In the first part of the document, the internal communication strategies to achieve an effective collaboration and fulfil the project goals have been described, with a particular emphasis on the description of project governing bodies meetings. A detailed description of the review procedures of project outcomes such as deliverables and periodic reports (both internal and to the EC) has also been presented, including a calendar with associated deadlines and responsible persons. Documentation management procedures have also been described, including the shared project workspace for storage and collaborative work, the document templates (for deliverables, presentations, etc.) and versioning conventions. Finally, the risk management strategy for MELCAYA including a list of critical risks and associated contingency plans has been detailed.

