



# MELCAYA

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

Grant Agreement: 101096667

## D9.1 Patient engagement plan



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<b>Author(s):</b>	Violeta Astratinei (AMER) Gilliosa Spurrier (AMER)
<b>Contributor(s):</b>	-
<b>Reviewer(s):</b>	Dario Sacchini (UCSC) Pietro Refolo (UCSC) Costanza Raimondi (UCSC) Adrián López (FCRB) Heather Etchevers (AMU)
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1.0	27.02.2023	FCRB	Final version

## Executive Summary

This Patient Engagement Plan (PEP) describes the principles and activities for patient engagement to ensure effective research partnerships throughout the MELCAYA project. The PEP uses methodology developed by the Melanoma Patient Network Europe as a starting point for further development. It is also intended as a guidance document for use by consortium partners beyond the MELCAYA project. The patient engagement plan will be reviewed annually and updated if necessary.

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## Acronyms & Abbreviations

Term	Description
AI	Artificial Intelligence
CAYA	Children, Adolescent and Young Adults
CAYA-MIG	CAYA-Melanoma Interest Group
CCI- Europe	Cancer Childhood International-Europe
DT4PCR	Design Thinking for Patients in Cancer Research
D	Deliverable
MPNE	Melanoma Patient Network Europe
M	Month
PE	Patient Engagement
PEP	Patient Engagement Plan
POs	Patient Organisations
RCE	Rare Cancer Europe
SIOPE	European Society for Paediatric Oncology
T	Task
WP	Work Package

# 1 Introduction

## 1.1 Objectives and context of the patient engagement plan

The purpose of this Patient Engagement Plan (PEP) is to establish and foster an effective research partnership between the MELCAYA consortium and the European melanoma patient community. Its ambition is not only to ensure the consistent integration of patient input into the project but to further develop methodologies in this area to benefit the entire melanoma research community. It thereby builds on established relationships between researchers, melanoma patients and patient advocates.

Concrete PEP objectives in MELCAYA are:

- To ensure consistent and appropriate involvement of patients throughout the project.
- To facilitate regular interaction between the European melanoma patient community and consortium partners.
- To educate and build capacity (methods and tools) within the European melanoma patient community to ensure impact beyond the end of the project.
- To develop and build capacity on patient engagement methodology in the melanoma research community.
- To advocate for appropriate healthcare strategies for CAYA with melanoma.
- To contribute to the outreach and overall impact of the project.

This PEP corresponds to D9.1 of WP9, Research engagement, patient education and advocacy.

## 1.2 MELCAYA tasks and deliverables with foreseen patient engagement

In addition to open interactions and exchange based on interests and opportunities, the following tasks and deliverables have pre-planned patient engagement activities:

**Table 1** D9.1 Output for other tasks and deliverables

Deliverable/Task	Due Date (Lead)	Output from D9.1
D7.1 Framework for assessing innovative HTs: secondary prevention and diagnosis of CHM and how to transfer/adopt results in EU health systems under HTA new Regulation	M24 (FCRB)	Plan the design thinking workshop on melanoma patient journey mapping, results to be incorporated in D7.1

Deliverable/Task	Due Date (Lead)	Output from D9.1
T7.1 Analysing current health system policies/health care strategies on rare cancer	M1-M18 (ICO)	Plan documented interactions with European POs, including their perspective and experience in identifying national stakeholders and data collection (overlap task 9.2)
D7.2 Set of Health care system strategies: secondary prevention and early diagnosis of childhood melanoma	M44 (AGENAS)	Input on overall deliverable D7.2 and guidance for assessing innovative health technologies
T7.2 Guidance for assessing innovative Health Technologies for secondary prevention and diagnosis of CHM	M1-M30 (AGENAS)	Revise guidance for assessing innovative health technologies within D7.1
T7.3 Ethical, legal and social implications (ELSI)	M1-M26 (UCSC)	On partner request-participation of patient advocate experts in the Ethical Committee; revise ELSI within D7.1
T7.4 The melanoma patient journey mapping	M1-M24 (AMER)	Plan Design Thinking workshop with European patients and patient advocates
T7.5 Design of CHM health care system strategies (pipeline) to inform policy and implementation in EU-27	M1-M44 (FCRB, HCB)	Online participation in EU Forums of stakeholders and 2 round tables (year 1, 2), review and consensus on the set of health strategies, participation in the 1-day meeting to agree on the final set of healthcare strategies
D8.1/T8.1 Dissemination & communication plan	M6, M24, M48 (SYNYO)	Contribution to and review of the Dissemination & Communication Plan/alignment of activities
D8.3 Online and media presence	M12, M48 (SYNYO)	Activities to be aligned with SYNYO (M6), communication and dissemination activities will address the special needs of the CAYA melanoma community
D8.4/T8.4 Engagement report/public outreach and joint activities	M1-M48 (SYNYO)	Reach out organisations and facilitate connections with consortium partners (e.g., Naevus Global, CCI Europe, RCE)
T9.1 Ensure consistent patient involvement throughout the project	M1-M48 (AMER)	Plan two workshops on effective research involvement; seek opportunities to involve all partners

Deliverable/Task	Due Date (Lead)	Output from D9.1
D9.2 Impact assessment of patient engagement (PE)	M48 (AMER)	Plan of partner reports with predetermined format, retrospective evaluation, workshops on effective research partnership (T9.1) and documentation of regular interactions (T9.2) to feed the impact assessment of PE in MELCAYA
T9.2 Regular touchpoints between consortium partners and the European Melanoma Community	M1-M48 (AMER)	Plan 8 regular meetings/touchpoints between POs and consortium partners plus their documentation and partner reports (twice per year)
D9.3/T9.3 Report on the methodology for ethnographic citizen science to understand barriers to healthcare for CAYA melanoma patients/ethnographic research	M48 (AMER)	Plan subcontracting, ethnographic research and report writing

## 2 Patient engagement in cancer research

### 2.1 Background

Patient engagement (PE) in research, in general, fulfils two main objectives:

1. To increase the impact and relevance of research projects.
2. To ensure transparency and accountability towards those for whose benefit the project is primarily conducted and society at large.

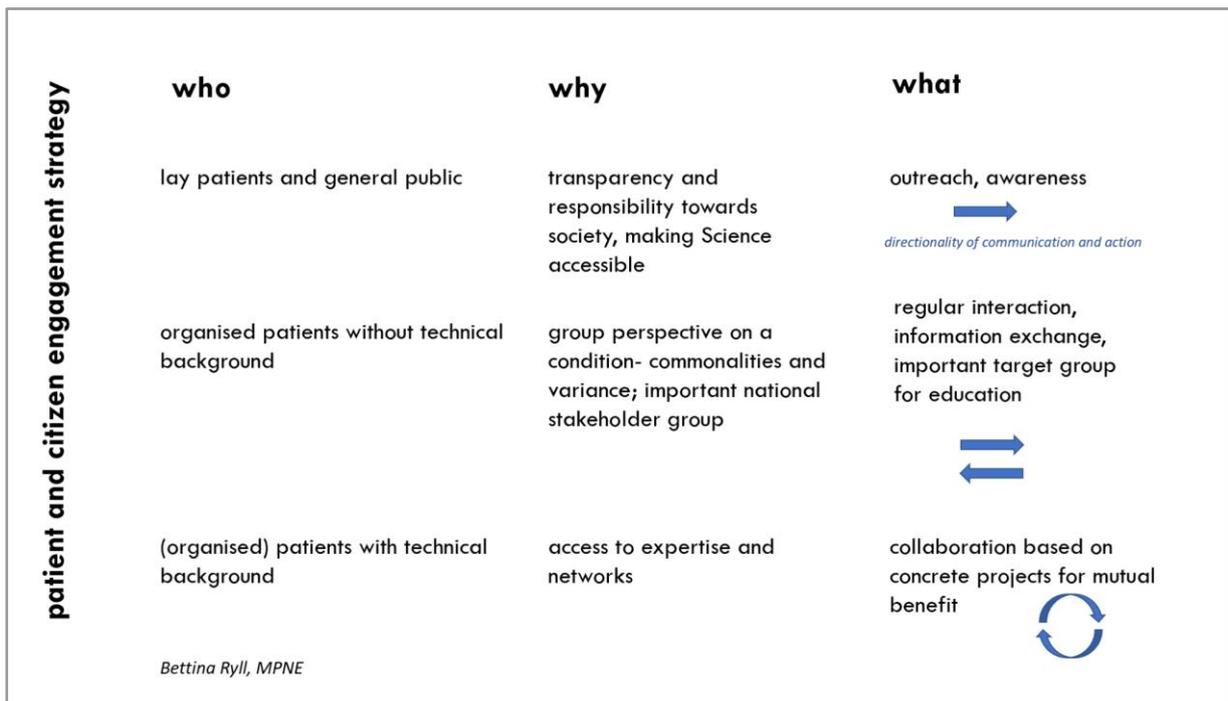
AMER is a national melanoma patient organisation that has been active since 2014 [3], and is affiliated with MPNE, the Melanoma Patient Network Europe [4]. Consequently, AMER benefits from MPNE experience in advocacy, education and research involvement strategies, including the most recent concepts, tools and methodology in the area of Patient Engagement in cancer research. As such, the MELCAYA Patient Engagement Plan builds on the experience of the Melanoma Patient Network in patient engagement developed in prior European projects funded under the Horizon 2020 program UMCURE (grant agreement no 667787), Share4Rare (grant agreement 780262), iToBoS (grant agreement 965221) and current patient engagement methodology under development by MPNE in collaboration with the Ministry of Education and Research Germany (BMBF), Bordeaux's Integrated Cancer Research Site (BRIO-SIRIC France) and Nollvision-Vinnova Sweden, notably in the area of Design Thinking. Design Thinking, a human-centered approach to innovation and an iterative process born in

the entrepreneurial field [5] is used in PE of MELCAYA to facilitate partnerships, understand their complexity and identify solutions to improve CAYA melanoma care.

## 2.2 Patient engagement principles

### Stratification of patient involvement activities

Patient communities are heterogeneous and fulfil different functions (Figure 1). Patient engagement strategies should therefore be stratified to target different subgroups and address these different aspects.



**Figure 1** Stratification model of patient involvement

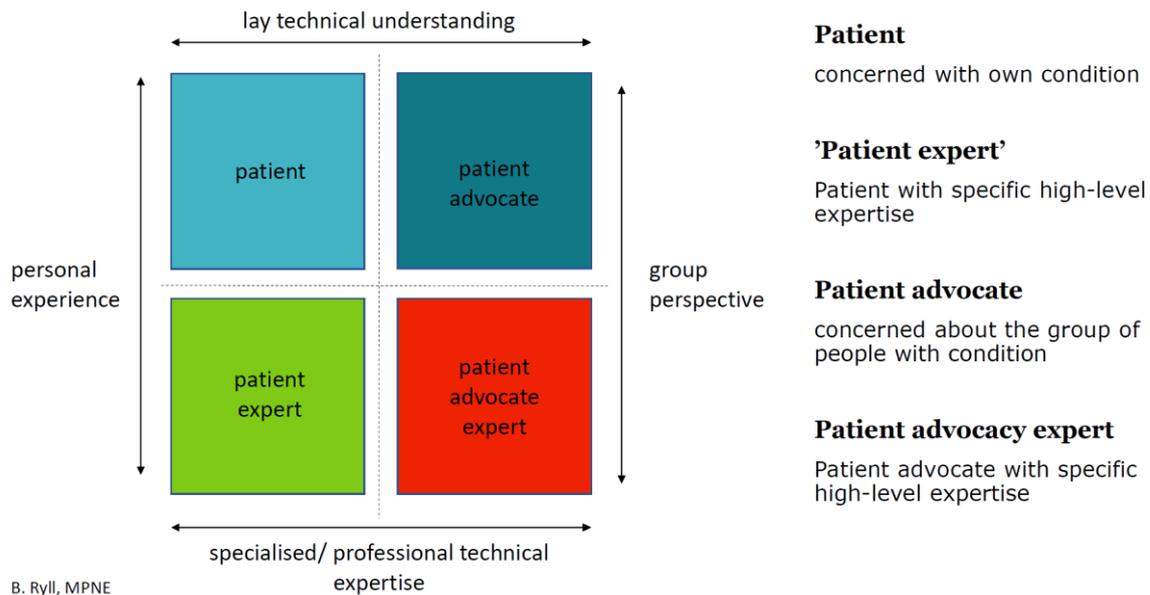
We currently stratify into:

- Lay patients and the general public for outreach and awareness (covered in the WP8, communication and dissemination).
- National and local patient groups affected by or with potential influence on the outcome of the project but who do not seek deeper engagement with the project (T8.4, facilitation within T9.2).
- Involvement in the project on the technical level and concrete tasks (WP9, WP7, WP8, WP10).

### Identifying appropriate research partners

Early identification of the right person to match project activities is essential for patient engagement success (Figure 2).

## Patients, patient advocates and levels of expertise

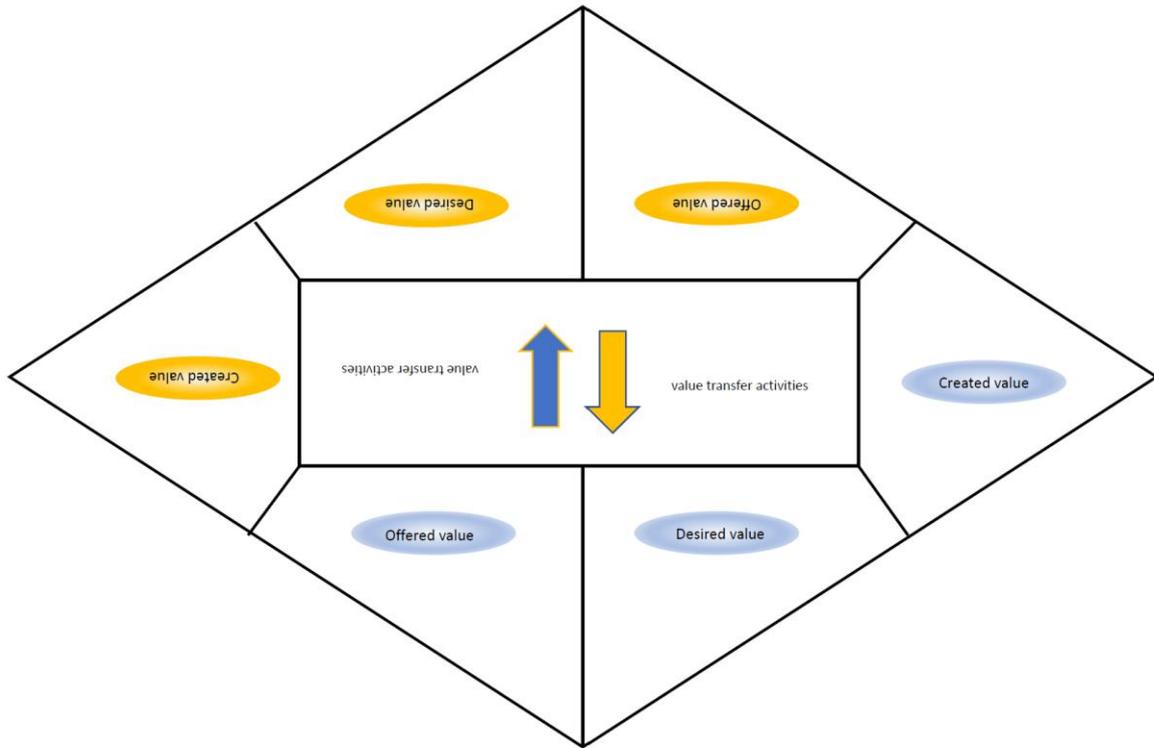


**Figure 2** Patients, patients advocates and levels of expertise

Patients and their families can help a research project in sharing their personal experiences with the disease and its care, while a patient expert can also assist with technical topics such as clinical trial design or biobanks. In contrast, the community perspective can be fulfilled by patient advocates: people with personal experience who are concerned about a group with a particular condition. Patient advocate experts will bring both the community and specific technical expertise, and are more likely to access large networks as well as negotiate interfaces with other experts.

### Mutually beneficial relationships

Mutually beneficial relationships generally drive any tentative involvement in research projects of melanoma patient community [6]. Relationships between patient organisations (POs) and consortium members are thereby to be mutually beneficial, with all parties involved contributing as well as benefiting from the interaction. MPNE developed and tested in 2022 [7] a version of the Partnership Canvas, created by the business developer Bart Doorneveert [8-9]. The Advocacy Partnership Canvas: Design Thinking for Patients in Cancer Research-DT4PCR was developed in collaboration with BMBF Germany, SIRIC-BRIO France and Nollvision Sweden (Figure 3). The new tool will be used in the Patient Engagement activities of MELCAYA to clarify expectations for both sides, arrive at mutually beneficial agreements and create new value.



Advocacy Partnership Canvas  
CCBYSA DT4PCR developed by MPNE in collaboration with BMBF, SIRIC-BRIO and Nollvision

**Figure 3** Design Thinking for Patients in Cancer Research-DT4PCR

The role of AMER as a project partner, will be to facilitate, support and help organise the interaction between the consortium and the wider melanoma community in collaboration with Melanoma Patient Network Europe, and other European and national POs. In this role, AMER will benefit from the support of MPNE and the proposed CAYA Melanoma Interest Group.

It is important to note that consortium partners will be strongly encouraged to initiate their patient engagement activities with umbrella organisations or local patient communities, ideally in the national language, to increase the project's reach and impact.

The process of patient engagement throughout the project will be monitored, evaluated and documented by AMER as part of the WP9, and its results shared in D9.2 Impact assessment of patient engagement.

### 3 Patient engagement in detail

#### 3.1 Overview of patient involvement activities

Please see table 2 for a comprehensive overview of all MELCAYA patient engagement activities:

MELCAYA Patient Involvement Plan 1.0 (2023)									
Work Packages/Tasks	year 1	year 2	year 3	year 4	Activity/ Outcomes	Associated Deliverables	Task Duration	Lead Responsible	Participants
<b>Patient engagement in research, education and capacity building - AMeR as coordinator</b>									
WP9.1. Ensuring consistent patient involvement throughout the project	x	x	x	x	elaborate the Patient Engagement Plan, revise and document in progress every year	D9.1-M3	M3-M48	AMeR	AMeR
WP9.1. Ensuring consistent patient involvement throughout the project	x	x	x	x	2 workshops on effective research partnerships expectations/outcomes (M6, M4)	D9.2- M48	M1-M6; M42-M48	AMeR	All
WP9.2. Regular touchpoints between consortium partners and the European Melanoma Community	x	x	x	x	regular touchpoints between POs and consortium partners - inviting partners to share results and participate in patient education- 2 documented interactions per year, around M5, M11, M17, M22, M23, M34, M41, M48	D9.2- M48	M1-M48	AMeR	All
WP9.3 Report on the methodology for ethnographic citizen science to understand barriers to healthcare for CAYA melanoma patients	x	x	x	x	subcontracting year 1: elaborate and run ethnographic research within melanoma community (years 2, 3); report the ethnographic methodology and results (M48)	D9.3- M48	M1-M48	AMeR	AMeR
Establishing a CAYA Melanoma CAYA- Melanoma Interest Group	x	x	x	x	providing monitoring and input within the regular touch points (T9.2)	D9.1-M3	M1-M8	AMeR	AMeR
Impact Assessment of Patient Engagement (PE)	document PE	document PE	document PE	x	partners reports in predetermined format M5, M17, M29 and M44; documentation of 8 regular meetings and retrospective reflections, and two research workshops on effective partnership (Task 9.1 and Task 9.2. Learnings to be included in the Impact Assessment (D9.3)	D9.2-M48	M1-M48	AMeR	AMeR
<b>Opportunities for education and interaction in other WPs</b>									
WP1. Identification of risk factors, exposures and genetic susceptibility of melanoma in children.	x	x	x	x	updates on environmental and genetic risk factors (WP9.2 schedule)	NA	M1-M48	UT	All
WP2. Understanding triggers and transitions from normal melanocytes to nevus to melanoma.	x	x	x	x	updates on the progress in understanding melanogenesis and molecular mechanism that cause melanoma (WP9.2 schedule)	NA	M1-M48	AMU	All
WP3. Histological, computational and molecular pathology for improved diagnosis	x	x	x	x	I2I workshop (M8) and regular updates: challenges in CAYA melanoma diagnosis, standardization and harmonization and setting a second opinion platform (WP9.2 schedule)	NA	M1-M48	UNIFI	All
WP4. Retrospective analysis of the activity and efficacy of anti PD-1 antibodies in childhood, adolescent and young adult melanoma	x	x	x	x	I2I or online input on clinical trials developed by partners (WP9.2 schedule)	NA	M1-M48	UNIQ	All
WP6. Artificial intelligence-based imaging tools for early diagnosis and risk prediction	x	x	x	x	updates on new AI digital tools for risk prediction and early diagnosis of melanoma in CAYA (WP9.2 schedule)	NA	M1-M48	DKFZ	All
WP9. Use of minimally- and non-invasive technologies for early detection of metastasis and prognosis	x	x	x	x	updates on minimally- and non-invasive technologies through skin and breath to detect metastasis and prognosis in melanoma patients (WP9.2 schedule)	NA	M1-M48	FCRB/HCB	All
<b>Patient Advocacy: AMeR as participant in WP7 and WP10</b>									
WP7.1 Analyzing current health system policies/health care strategies on rare cancer	x	x			2 interactions with European POs, to include their perspective and experience in the identification of national stakeholders and data collection (M5, M17 or online when necessary)	D7.1- M24	M1-M18	ICO	FCRBIAMeR
WP7.2 Guidance for assessing innovative Health Technologies for secondary prevention and diagnosis of CHM	x	x	x		On partner request input on the guidance for assessing innovative health technologies	D7.1- M24	M1-M30	Agemas	FCRBIAMeR
WP7.3 Ethical, legal and social implication (ELSI)	x	x	x		On partner request- participation of patient advocate experts in the Ethical Committee; revise ELSI within D7.1 in M24	D7.1-M24	M1-M26	UCSC	AMeR/AMeR
WP7.4The melanoma patient journey mapping	x	x		x	1 Design Thinking Workshop with European patients and patients advocates- Patient Journey (M23-24)	D7.2- M44	M1-M24	AMeR	AMeR/FCRB/HCB/ Agemas/COUCSC/ AMeR
WP7.5 Design of CHM health care system strategies (pipeline) to inform policy and implementation in EU-27	x	x	x	x	Participation in the EU Forums of stakeholders and 2 round tables (year 1, 3); participation to the 1 day meeting to agree on the final set of healthcare strategies acc. schedule of partner, review and consensus on the set of health strategies (M44)	D7.2- M44	M1-M44	FCRB/HCB	Agemas/COUCSC/ AMeR
WP10.4 Data management	x	x	x	x	Input in data management plan and patient privacy (personal data), with focus on images and genetic data collection (M6, M24, M36)	D10.4- M6, M24,M36	M1-M48	FCRB	All
WP10.5 Ethics management	x				Input on the Plan for ethical and legal monitoring (M3, M12)	D10.5- M3, M12	M1-M48	UCSC	All
<b>General public, lay patient communities and networking- AMeR as participant in WP8</b>									
WP8.1 Dissemination and communication plan	x	x	x	x	contribution and revision of the Dissemination & Communication Plan in M6, 24, M48	D8.1- M6, M24, M48	M1-M6	Synyo	All
WP8.3 Establishing an online and media presence	x	x	x	x	communication and dissemination activities addressing the special needs of the CAYA melanoma community acc with Synyo Plan	D8.3- M12, M48	M1-M48	Synyo	All
WP8.4 Public outreach and joint activities with other EU funded initiatives and networks	x	x	x	x	synergies with other patient organisation projects - participation in the online meetings organised by Synyo, joint publications and communications at related events	D8.4- M48	M1-M48	Synyo	All
Outreach and engage	x	x	x	x	Facilitate connections with Naevus Global, SIOPE, Rare Cancer Europe (year 1, update each year with new opportunities)	D8.4- M48	M1-M48	Synyo	All

Figure 4 Patient Engagement Plan in overview [10]

Patient engagement in MELCAYA will be facilitated and supported by WP9 Research engagement, education and advocacy. WP9 includes two virtual or face-to-face workshops on effective research partnerships, one at the start and one towards the end of the project (T9.1), a series of eight meetings (two per year) for education and capacity building to ensure impact beyond the end of the project (T9.2) and the ethnographic research within the European patient community (T9.3, see Figure 3). Overall WP9 ensures that the project’s results align with the expectations of the melanoma patient community.

Patient perspective will also be included in WP7, T7.1, T7.2, T7.3, T7.5 and particularly T7.4. Design Thinking Workshop on Patient Journey in healthcare (M23), in WP8, T8.1, T8.3, and T8.4 dissemination, communication activities and networking and WP10 for the review of the plans for Data management (D10.3, M6, M24, M36) and Ethical and legal monitoring (D10.4, M3, M12). The plan of patient participation is detailed in section 3.10.

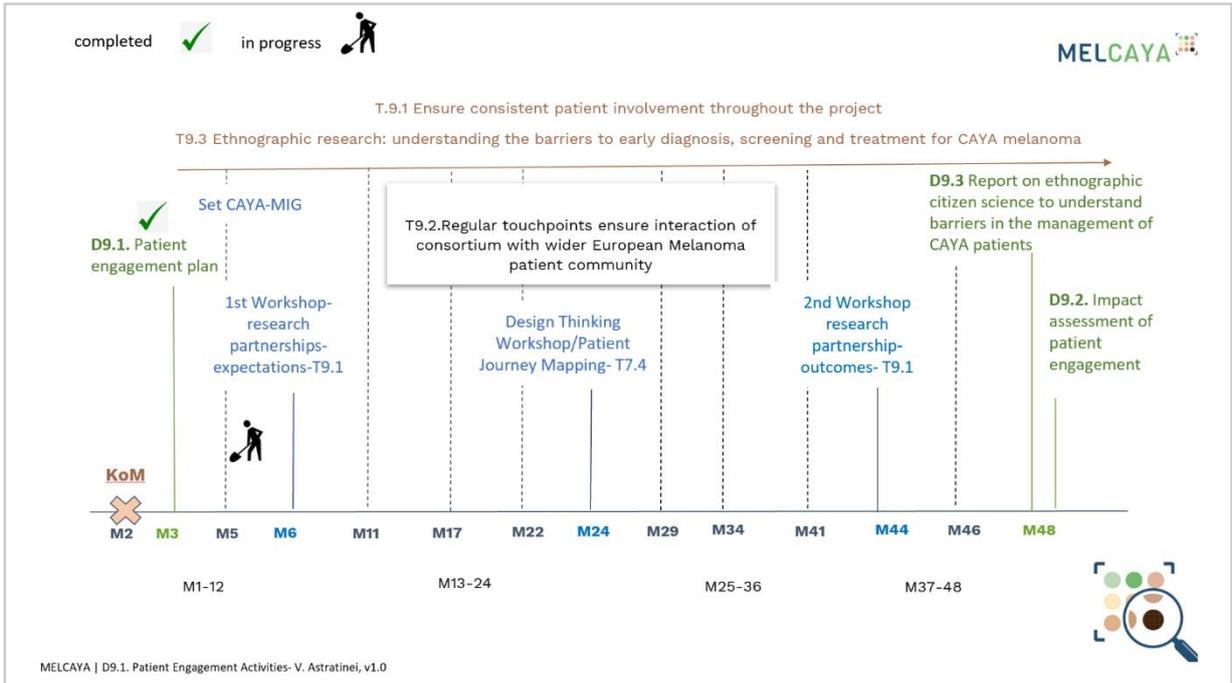


Figure 5 Timeline of the main engagement activities

### 3.2 Regular touchpoints between consortium and melanoma community

- **Delivery:** M5, M11, M17, M22, M29, M34, M41, and M46
- **Lead:** AMER; **partners:** FCRB, UT, AMU, UNIFI, UNIPG, DFKZ, TECH, AT, SYNIO, FPG
- **Related tasks and deliverables:** T9.2, D9.2

The purpose of regular interactions (T9.2) between consortium partners and patients/patient advocates is to build capacity and education within the melanoma community regarding CAYA with melanoma and promote mutual learning. At the same time, each meeting will be documented and analysed retrospectively, and lessons learned will be included in D9.2. Impact assessment of patient engagement.

AMER plans eight online or face-to-face interactions, twice a year (Figure 2, dashed lines) as part of Task 9.2. The meetings are expected to take place in M5, M11, M17, M22, M29, M34, M41, and M46 and run within the main MPNE conference and national patient meetings whenever possible.

Researchers from FCRB, UT, AMU, UNIFI, UNIPG, DFKZ, TECH, AT, SYNIO and FPG with dedicated PMs to patient engagement (WP9) will be invited to participate in the patient national and European meetings and workshops to exchange ideas, share results and ask for input or test the tools developed in MELCAYA.

Opportunities for education and engagement include face-to-face presentations or short online communications concerning risk factors and genetic susceptibility (WP1), melanoma genesis and molecular mechanism that predispose to or cause melanoma (WP2), patients' perspectives on standardisation and harmonisation of diagnostics and the second opinion platform (WP3), input on retrospective and prospective clinical trials (WP4), presentation and discussions on early detection, AI and non-invasive diagnostic tools (WP5 and WP6).

Additionally, all MELCAYA project partners will be encouraged to reach out to their respective local and regional melanoma patient or rare cancers communities to ensure the inclusion of local patient groups and maximum project outreach.

### 3.3 Workshops at MPNE2023 conference

- **Delivery:** M5
- **Lead:** AMER; **partners:** UNIFI, FCRB
- **Related tasks and deliverables:** T9.2, D9.2

A MELCAYA focused workshop is scheduled for 28th April, during the MPNE conference in Brussels, 28-30th April 2023. A possible participation of AMU to the Science Workshop, with a topic on malignant transformation is foreseen on Saturday 29th April. These 2 face-to-face workshops are the first of a series of eight periodic touchpoints between the MELCAYA consortium and the melanoma community (T9.2). It aims to introduce MELCAYA to the European melanoma community, discuss challenges of melanoma diagnosis in CAYA, and provide input over the second opinion platform, topics presented by UNIFI (WP3). Partners from FCRB will introduce the strategy and implementation plan for the health technologies developed in MELCAYA (WP7).

### 3.4 Establish the CAYA Melanoma Interest Group

- **Delivery:** M5
- **Lead:** AMER; **collaborators:** MPNE and Naevus Global
- **Related tasks and deliverables:** T9.1, T9.2, D9.2

In collaboration with MPNE and Naevus Global, AMER will establish a CAYA Melanoma Interest Group to connect network members with a particular interest in melanoma that affects CAYA and consolidate a knowledgeable community. Other potential members are CCI Europe (Cancer Childhood International-Europe), SIOPE (European Society for Pediatric Oncology) and Rare Cancer Europe (RCE). The CAYA-MIG will be established at the main meeting of MPNE taking advantage of the presence of European melanoma and other cancer patient advocates, held in Brussels, on 28-30th 2023 (M5).

CAYA-MIG members will then be involved in developing educational and design thinking workshops (WP7, WP9), ethnographic research (WP9) and communication and networking activities (WP8).

### 3.5 Workshop on effective research partnerships expectations

- **Delivery:** M6
- **Lead:** AMER; **partners:** all
- **Related tasks and deliverables:** T9.1, D9.2

As part of T9.1, AMER will organise two Design Thinking Workshops to support effective partnerships and leverage the potential of patient communities to contribute to and learn about different work packages. The first workshop will likely run online in M6 and focus on the expectations of the whole consortium regarding the partnership, in particular, with patient organisations. The Design Thinking Tool is adapted after the Partnership Canvas, created by business developer Bart Doornerweert [7-8] and previously tested within MPNE with different stakeholders [6]. The idea behind this tool is that by applying design thinking, ineffective discussions can be turned into structured exchanges and generate value for each partner (see also section 2.2).

### 3.6 Workshop on effective research partnerships outcomes

- **Delivery:** M44
- **Lead:** AMER; **partners:** all
- **Related Tasks/Deliverables:** T9.1, D9.2

The 2nd Workshop on effective research partnership is scheduled in the last six months of the project (M44) and focuses on the outcomes of the partnership. The lessons learned derived from both workshops (M6 and M44) will be incorporated in D9.2 Impact assessment of patient engagement in research.

### 3.7 Subcontracting and ethnographic research work

- **Ongoing:** years 1- 3
- **Lead:** AMER; **partner:** research agency
- **Related tasks and deliverables:** T9.3, D9.3

Subcontracting the research agency to support AMER on ethnographic research is foreseen at the end of year 1. The observation and interviews are planned in years 2 and 3 around the European and

national melanoma patient conferences, usually annually, between March and June in different European locations. Online work will complement the on-site work whenever possible.

### 3.8 Ethnographic research within the European melanoma community

- **Delivery:** M48
- **Lead:** AMER; **partners:** all
- **Related tasks and deliverables:** T9.3, D9.3

The ethnographic research planned for MELCAYA aims to understand the barriers to early diagnosis, screening and treatment to set better healthcare strategies for CAYA Melanoma Patients and to provide European melanoma patient advocates with a methodology to accurately observe and document the concerns and needs of their group. Year 4 is dedicated to writing and reporting on ethnographic methodology and results interpretation within D9.3 (M48).

### 3.9 Impact assessment of patient engagement

- **Delivery:** M48
- **Lead:** AMER; **partners:** all
- **Related tasks and deliverables:** T9.1, T9.2, D9.2

Patient engagement will be documented and evaluated for impact. Based on prior observations on the limited tools and methods to evaluate impact of PE in research [1-2] and the experience of patient organisations, the approach in MELCAYA is to focus on the complexity and context of partnerships, rather than performing a quantitative evaluation.

By documenting interactions (T9.1), partner reports and retrospective reflections, and two workshops on effective research partnership, AMER aims to gather data about:

- Project at baseline (M1-M6), original plans, assumptions and expectations.
- What input was received from Patient Organizations, Patients and Patients Advocates.
- What changes occurred during the project as a result of interaction: the newly created value.
- What outcomes were observed and how these relate to the initial assumptions (M42-M48).

Partner reports and retrospective reflections: AMER will write a protocol to collect in a predetermined format, the needs, views on patient engagement, and activities of consortium at M5, M17, M29 and M44, which coincides with the regular interactions prespecified in T9.2. Examples of questions: *What*

*did you plan? How did it go? What have you learned?* SAMOLO exercises (Same, More Of, Less Of) will be run online for the retrospective analysis [11].

Documented experiences during touchpoint interactions (T9.2), partner reports and learnings from the two research workshops on effective partnerships (T9.1) will be included in the Impact Assessment final report D9.2 (M48).

### 3.10 Patient advocacy perspective in melanoma healthcare strategies and data management

- **Delivery:** various per task and deliverable within WP7 and WP10
- **Lead:** FCRB; **partners:** FCRB, UCSC, HCB, AGENAS, ICO, AMER (WP7), all (WP10)
- **Related tasks and deliverables:** T7.1, T7.2, T7.3, T7.4, T7.5, D7.1, D7.2, D10.4, D10.5

WP7 Healthcare system strategies implementation to inform policy and ethical dimension includes specific engagement of POs with national healthcare agencies, as a particular group of stakeholders with high influence on healthcare policies. As such, PE in WP7 is crucial, and even more than other activities, dependent on partners views on the need of patient engagement, thus we foresee it as a continuous negotiation and development process.

AMER plans to contribute to developing the assessment framework and the designing of healthcare strategies to inform policy and implementation (WP7). Within T7.1 we intend to include patient advocates perspectives and experience in identifying national stakeholders and data collection (M5, M17 or when necessary). Participation of patient advocate experts in the Ethical Panel of Experts can be organised within the prespecified regular touchpoints (T9.2) or according with the partners' schedule (T7.2, T7.3). The Ethical, legal and social implications (ELSI) framework (T7.3) can include POs input preferably during elaboration (M1-M26) and taking advantage of the regular interactions with POs prespecified in T9.2. Final ELSI revision is scheduled within D7.1.

Within T7.4 a design thinking workshop to map the pathway of melanoma CAYA in the healthcare systems is scheduled in the project's second year (M23) with the participation of FCRB, HCB, AGENAS, ICO and UCSC (see also 3.11).

For T7.5 participation in EU Forums of stakeholders and 2 round tables (years 1, 2), participation in the 1-day meeting to agree on the final set of healthcare strategies and final revision of D7.2 in M44 are envisaged, mostly according to the schedule of partners (M1-M44).

Regarding WP10, the specific interest of patients concerns image and genetic data privacy, collection and sharing. Input in Data Management Plan (M6, M24, and M36) and Ethical and Legal Monitoring (M3, M12) is foreseen.

Patient involvement in WP7, WP8 and WP10 will be adjusted yearly based on interactions with partners and new opportunities.

### 3.11 Workshop on patient journey mapping

- **Delivery:** M23
- **Lead:** AMER; **partners:** FCRB, HCB, AGENAS, ICO and UCSC
- **Related tasks and deliverables:** T7.4, D7.2

The workshop will be conducted in Year 2 at the MPNE main conference (M23) with a pan-European Melanoma patient audience, including paediatric melanoma advocates and colleagues from Naevus Global and CCI Europe. The objectives of this design thinking workshop are to map the melanoma patient journey for CAYA with melanoma, to identify pain points, particular gaps and challenges in the CAYA melanoma care pathway to inform implementation strategy, and to ensure that implementation strategies are patient-focused. Particular policy interest will be placed on the inter-dependencies of diagnostics and diagnostic workup.

### 3.12 General public, lay patient communities, and networking

- **Delivery:** M6, M26, M48
- **Partners:** all
- **Related tasks and deliverables:** T8.1, D8.1, T8.3, D8.3, T8.4, D8.4 (WP8)

AMER will align with the activities that will be specified in the D8.1 (M6). AMER will revise and contribute to the Dissemination and Communication Plan (M6, M24, M48). Within the overall communication strategy of the project described in WP8, patient advocates, patients, and their families are a distinct stakeholder group. Publications and the customised information produced by WP8 will be translated and adapted and shared with the European Melanoma patient community via the usual distribution channels (online patient forums, social media and websites). Communication, dissemination, exploitation and networking focus on communication and dissemination activities addressing the special needs of the CAYA melanoma community. AMER will identify synergies with other projects, participate in the online meetings organised by SYNNO, and jointly create publications according to the communication and dissemination plan.

### 3.13 Outreach and engagement of other organisations

- **Delivery:** M6
- **Lead:** AMER; **lead WP8:** SYNYO
- **Related Tasks/Deliverable:** T8.1, D8.4

During first six months AMER will reinforce the connections with Naevus Global (associated partner to MELCAYA) and CCI Europe to include their experience and views in the project and facilitate their interactions with interested partners (e.g., AMU, UT, UNIFI, UNIPG, DFKZ). Consortium partners will be encouraged to develop further their specific activities with Naevus Global and CCI Europe. Via MPNE, AMER also proposes interactions with Rare Cancer Europe [12], to identify synergies with other initiatives. Opportunities will be considered on a continuous basis.

### 3.14 Next revision

The patient engagement plan will be reviewed annually (February, each year) and updated if necessary to incorporate new developments and opportunities.

## 4 Conclusions

This document describes the Patient Engagement Plan (PEP) and its objectives. The patient engagement approach and methodology are introduced. The plan includes eight regular touchpoints between the consortium and melanoma patient community, first MELCAYA sessions at the MPNE2023 conference, the start of the CAYA-Melanoma Interest Group, two Workshops on Effective Research Partnerships, the workshop on Patients' Journey and the preparation of ethnographic and impact assessment work. The advocacy perspective in developing melanoma healthcare strategies, and communication and networking are included in the regular schedule of WP9 or adapted to partners plan (WP7, WP8, WP10). The patient engagement plan will be reviewed annually and updated if necessary to incorporate new developments.

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