MELODIC

Mental Health Support for Young Adults with Cancer

Project Number: 101101253

WP2: Needs assessment

Deliverable 2.1: Data Management Plan

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Executive Summary

In the first phase of the MELODIC project, the mental health needs of young adults with a lived cancer experience and their family members are explored by using a qualitative research approach through conducting interviews. In addition, health care professionals working with people with lived experience of cancer will be interviewed to explore their perceptions on mental health needs of these young adults. In the same period, a survey study will be conducted to identify the educational needs of healthcare professionals working in cancer units and/or mental health services. As both studies are conducted in six European countries data safety and management are important. To ensure compliance with all relevant privacy and data safety regulations, we have developed this data management plan, which has been approved by the medical ethical research committee of Erasmus University Medical Center Rotterdam, the Netherlands.

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1. MELODIC project

This project entitled 'Mental health support for young adults with cancer' (MELODIC) aims to promote mental health and wellbeing of young adults (YA) with lived experience of cancer and their family/caregivers by improving screening, early detection and efficient and person-centered management of mental health needs during the first year post-cancer diagnosis.

Specifically, MELODIC will:

1) examine mental health needs of YAs with lived experience of cancer and their family members /caregivers,
2) examine the training needs of Health Care Professionals (HCPs) and develop and implement an online training programme for them,
3) implement an intervention which includes physical activity in natural surroundings (green/blue space), with information support for YAs with lived experience of cancer and their family members/caregivers, and
4) develop guidance and practical recommendations for HCPs on how to provide support for YA adults and their family/caregivers with mental health needs.

These objectives will be realized through in-depth information gathered via interviews (YAs with a lived cancer experience, their family/caregivers, and HCPs), and surveys (HCPs). An intervention inspired by social prescribing is developed and tested to support YAs and their families to maintain and improve their mental health and wellbeing. As part of the overall project, in WP3, training for health care professionals, will be developed and implemented. In WP4 the natural spaces intervention will be implemented and evaluated. In WP 5 overall project evaluation is conducted.

2. Data safety and management

In the MELODIC project, ethical issues are considered from the beginning of the project as an essential part of the whole project. Ethics in the project are two-dimensional: Data ethics and person ethics. Data ethics concern the collection, processing, storage, and security of data. Personal ethics concern consent, confidentiality, and privacy.

Data will be collected in a way that ensures fairness, transparency and accountability of the data processing, data quality and confidentiality. Participants (YAs with lived experience of cancer, family members, carers, health care professionals) will be involved in the delivery of this project. Personal data will be collected, analyzed, stored and shared in full compliance with European and national legislation, conventions, declarations and manuals relevant to the country where data collection takes place. Data collection will be based on the informed consent of the informants.

The **data collected** will only be used for the purposes of the current project. No data will be collected that is not strictly necessary to complete the current study. All partners will be asked to nominate a Data Protection contact person who will be responsible for overseeing all personal data processes at that research site.

Data processing and storage: The data will first be collected, then analysed and converted into a usable form as required. Finally, all non-personal data will be freely available as an open anonymized resource for further research. During data processing, where any personal information or data is involved, the data will be anonymized and access to the data will be restricted only to those involved in the MELODIC project. No information linking the participant as an individual physical entity to the data held about them will be removed. In addition, the project leaders in each participating country will ensure that all materials and data collected are securely stored during and after the project.

Data storage and security: Non-anonymized data will be stored (locked) separately from other datasets, will be password protected and stored locally by the partners on their servers. After data processing, partners will be required to comply with EU and national data protection legislation and best practices. Project participants will be required to comply with the EU General Data Protection Regulation (GDPR) and the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data on the free movement of such data. Hard copies of consent forms, information sheets, and data collected will be stored by project responsible persons on the premises of the local organization in a secure (locked) environment (safe, locked filing cabinet or cupboard).

Details of local arrangements for data collection, storage, protection, retention and destruction will be provided by each partner in the application for ethical approval to the local ethics committee and will be collected by the local project manager.

Confidentiality and privacy: When applying for ethical approval, partners must provide detailed information on how the privacy and confidentiality of participants' data will be ensured. Before consent is obtained from participants and before the research begins, project staff must inform participants of the purposes for which the personal data they provide will be used, any potential risks related to the confidentiality or anonymity of the personal data, and which individuals and organizations will have access to the personal data, and under what circumstances such access will be granted.

All data will be managed in line with the **FAIR principles** (**Findable, Accessible, Interoperable, Reusable**). Adherence to FAIR principles is ensured as follows:

Findability: A description of the research data (metadata schedule) will be made available after termination of the project.

Accessibility: After completion of the project, the research data will be anonymized and made accessible for verification and re-use, whenever possible. All individuals providing data to the project will be asked to give informed consent for sharing data after completion of the project, as a separate item on the informed consent form. Based on the EU's General Data Protection Regulation (GDPR), data can be shared only after careful assessment if the aims of the individual or organization whose is requesting the data comply participants' consent as provided and under the condition that the data will be adequately and securely stored and handled.

Interoperability: To ensure reproducibility of research outputs, we will where possible use existing validated questionnaires, semi-structured interview guide and broadly used software for data analysis.

Reusability: The metadata schedule, such as study protocol and codebook, will give a clear description of the data and the database itself will be clear and consistent, complying with e.g. Erasmus MC data management guidelines. Usage rights and obligations will be elaborated in the project's Data Management Plan. Data storage and curation: all project data are stored in a safe and secure data management software package (Castor) at Erasmus MC, during and after the project. The project consortium will establish a committee of consortium members that will be responsible for curating and sharing the data after completion of the project.

3. Data Safety and Management in WP2

For all sub-studies conducted during the MELODIC project, we will adhere to the data protection and management guidelines described in Chapter 2.

A Data Management Plan (DMP) (Annex 1) and a Data Transfer Agreement (DTA) (Annex 2) have been developed for the survey of healthcare professionals and the interview study of young people with lived experience of cancer, their family/carers and healthcare professionals. Both documents comply with EU regulations and have been approved by all partners.

3.1 Data Management Plan

Research data management is the process of organizing, documentation, storage, archiving and sharing of digital and analogue data. Data management applies to the entire life cycle of research data, i.e. discovery and initiation, planning, collection, processing and analysis, documentation and archiving, and publication and dissemination. The WP2 team developed the Data Management Plan for WP2 according to the Erasmus MC template (Annex 1). This template has been validated and accepted by European funders such as EU Horizon.

After the first draft, the DMP is discussed with all partners during a partner meeting and all partners were able to give their feedback and comments via the shared document via Teams. After overall agreement, the final version is submitted to the Ethical Research Committee of the Erasmus MC, as part of the ethical approval of MELODIC II, the interview study. The Ethical Research Committee approved the DMP (Annex 1).

3.2 Data Transfer Agreement

As the interview study, MELODIC II, will be conducted in the six participating centres, these data (transcripts of the interviews) will have to be sent to the leading centre, Erasmus MC. These data will be anonymized and sent to the Erasmus MC in a secure way and in accordance with the applicable data protection law. The legal representative of the Erasmus MC has drafted a Data Transfer Agreement (Annex 2). This DTA has been discussed with all participating centres and all partners have agreed to this version. The DTA will be signed after local ethical approval in the participating centres. We expect this to be completed within the next two months.

As in the survey study, MELODIC I, data from an online questionnaire will be centrally collected by Erasmus MC, no transfer of data will take place.

4. Data on training of Health Care professionals (WP3)

The objectives of WP3 are to create a training programme for HCPs working in cancer unit and/or mental health/psychosocial services, implement the training and evaluate the impact and feasibility of the training and to create a guide for health professionals on continuing education on mental health of people affected by cancer.

The data is collected on the training participants, including their names and email addresses and responses on before and after the training to evaluate a) the impact of the training and b) feasibility of the training. The evaluation is conducted by using pre-post survey design.

4.1 Data on training participants

Data is collected to identify the participants and to provide them the certificate of attendance. For attendance certificate, the participants need to be identified (name, email address, organization) and information gathered on completion of the training. The participant's data is collected on a) recruitment of participants and b) the online learning platform (only participant names, and completion of learning units). The information obtained is deleted in the end of the project. Participant name, contact information and organization collected during recruitment is managed by local coordinators in secure data platform. The local organization is responsible on data storage in a locked filing cabinet or cupboard (EU General Data Protection Regulation (GDPR).

4.2. Surveys

In the impact evaluation survey, background information and data are collected from the participants, informed consent is obtained from the respondents. The data is collected by survey created on Turku UAS Wepropol eSurvey software and the obtained information will be stored by project responsible persons on the Turku UAS premises in a locked filing cabinet or cupboard (EU General Data Protection Regulation (GDPR). Data is not transferred across borders among the partners. Data on pre-post survey (as in GAP) on self-assessed readiness and skills on mental health of people affected by cancer, post: self-assessed readiness and skills on mental health of people affected by cancer. On post survey a question on intention to change practice is added.

Data Feedback and feasibility includes general feedback of the programme and usability of the attaining implemented.

For the impact evaluation personal information is collected including name and email address. The survey is sent to participants and contact information is ID coded to identify the respondent in pre and post survey phase. The original data will be managed and handled by a statistician and research group members of Turku UAS, other research group members will only have access on anonymized analysis results.

5. Data on Intervention Study (WP4)

Research plan including the study protocol and data management plan for the intervention study will be created according to the project plan. UoG Galway will lead the process with UNIWA as co-lead. Final decision on instruments to be used on impact evaluation is made according to results from WP2. Ethical approval process is conducted to ensure the research ethics of the study. YCE will participate on protocol development to ensure that target groups experiences and perspectives are well recognized.

Intervention will be conducted in six countries. Participants are recruited via university hospitals participating the project consortium. Equality, diversity and inclusion will be considered in recruitment. In screening and recruitment, the project will use the assistance of specialist cancer nurses, experts on assessing patients' level of distress. Screening is targeted on defined group with purposeful sampling.

Intervention implementation includes the collecting measurement data prior (baseline), at the end of the intervention and after the intervention. The duration of the intervention is 9 months (recruitment and pre-measurement, intervention implementation, post measurement). Evaluation of the intervention will be conducted with the young adults, their carers and health and social care professionals. This evaluation will focus on the physical and mental health impacts of the intervention, such as whether there was reduced anxiety or an increase in physical or mental health, as well as the feasibility of the intervention. The instruments to be used will be informed by the results of WP2 and are likely to include surveys and/or interviews, which will be subject to the same data safety and management framework and approach as applied to WP2.

Data Management Plan

For human-related research (mensgebonden onderzoek)

Please read the manual for guidance and examples!

#0 General Information

0.1	Version of DMP	1
0.2	Name of person writing this DMP	S. Morsink MD
0.3	ORCID iD of person writing this DMP	0009-0005-4903-1793
0.4	Function of person writing this DMP	Psychiatrist, PhD student
0.5	Role in project of person writing this DMP	Coordinating investigator
0.6	Data management support staff consulted?	☐ Yes: ☒ No
	If Yes: Describe the support team, name, email address and date of conversation	
0.7	Name of Principal Investigator	WH Oldenmenger
0.8	ORCID iD of Principal Investigator	0000-0001-6855-6505
0.9	Function of Principal Investigator	Wetenschappelijk medewerker
0.10	Department of Principal Investigator	Medical Oncology
0.11	Date of authorisation by Principal Investigator	1/23/2025

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#1 Project Details

This section covers the general information about the project. You can copy this information from the grant application or other existing information about the project (e.g. from PaNaMa).

1.1	Full project title	'Identifying mental health needs of young adults with cancer, their family members and health care providers'
1.2	Acronym	MELODIC I and II
1.3	Funder	☒ Funder: HaDEA Grant #: 101161023 ☐ None
1.4	PaNaMa project ID	13238 and 13239
1.5	(Planned) data collection start date	1/27/2025
1.6	(Planned) data collection end date	10/31/2025
1.7	Project type(s)	☒ Prospective ☐ Retrospective ☐ Observational, invasive ☒ Observational, non-invasive ☐ Interventional ☐ Study on Medical Aid ☐ Drug Research ☐ Other:
1.8	Research objectives	- to gain insight into the mental health needs of young adults with cancer, their family members and health care professionals from six European countries: Estonia, Finland, Greece, Ireland, Netherlands, and Portugal. - to identify educational needs of HCP related to mental health screening, detection and support of YA with cancer

#2 Agreements and Intellectual Property

This section covers the involved parties and the agreements that were made with these parties, and intellectual property.

2.1 Multicenter study

☒ Yes
☐ No

2.2 Involvement of external parties and their roles. Please describe below.

Organization/Department	*Location* *(European Union (EU) otherwise describe)*	*Function* *(e.g. sponsor, initiating center, participating center, data processor, data owner/recipient (if re-used data),…)*	*Data transfer*	*Agreement Type*
	☒ EU	*Participating Center*	☒	*Consortium agreement*
	☒ EU	*Participating Center*	☒	*Consortium agreement*
	☒ EU	*Participating Center*	☒	*Consortium agreement*
	☒ EU	*Participating Center*	☒	*Consortium agreement*
	☒ EU	*Participating Center*	☒	*Consortium agreement*

2.3 The contracts/agreements in place have been checked by the appropriate support offices (PCP, TTO, JZ and/or PKO).

☒ Yes
☐ No

2.4 Describe how ownership and intellectual property rights are managed.

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#3 Ethical and Legal Considerations

This section addresses ethics review and requires you to confirm your awareness of and compliancy with the applicable laws and regulations.

3.1	What is the population of your research?	☒ Patients ☒ Healthy Volunteers ☒ Adults ☐ Minors ☐ Mentally incompetent adults ☒ Other: Patients with cancer, family members and health care professionals (HCP)
3.2	Is this study subject to the Wbo or WMO?	☒ non-WMO ☐ WMO → 3.4 ☐ Wbo → 3.4
3.3	Did you receive a non-WMO-declaration?	☐ Yes ☒ Not yet: submitted
3.4	Was this proposal approved by a MREC/METC, the CCMO, the RIVM/CvB or non-WMO review committee?	☐ approved Reference #: ☒ Not yet: submitted
3.5	What is the legal basis of your research?	☒ written Informed Consent (IC) ☐ verbal Informed Consent ☐ not applicable (anonymous data)* ☐ deferred Informed Consent ☐ Exception Informed Consent * ☐ Other*
	*If *:* Explain why this project involves the collection, processing or analysing of personal data without informed consent. Describe whether the PKO template is used and whether it was discussed with PKO. → 3.9	
3.6	Describe the recruitment and informed consent procedure or the location where the procedure is explained in detail.	a. Survey HCP, recruitment via professional societies and social media. Informed consent online before start survey b. Interviews patients, family members and HCP. (see non-WMO protocol) - As a first step in approaching eligible participants, clinicians will be informed about the study. Information about the aim, data collection, outcome measures and the way of including participants will be presented. For each partner, the optimal procedure for patient recruitment will be established. - When it is not possible to approach possible participants via HCPs, national/ local patient

		societies or trusts will be approached to ask for interesting young adults with cancer. Potential participants, that is the young adults with cancer, will then receive information concerning the study's purpose, their role and the informed consent procedure. Furthermore, identification of the family member will be performed, by asking the young adult to identify their chosen person. This information will be provided verbally and, after the conversation, also in writing in the form of an information letter and informed consent form. When a young adult gives permission to share contact details with the researcher, the researcher will contact them by telephone within 7 days to answer their questions and to ask consent to participation. If the young adult is willing to participate, an appointment for the interview will be made. A letter of consent must be signed by the participant before the interview takes place. If the family member is present when the information is provided, the information about the interview will be provided. The family member will be requested to give contact information, if it diverges from the young adult's contact information.
3.7	Does this informed consent form provide consent for the data to be reused for future research?	☐ Yes, via a mandatory condition ☒ Maybe, via an optional condition ☐ No → 3.9
3.8	By whom may data be reused according to the subject information sheet and/or informed consent form?	☒ Own research group (internally) ☐ Other research institutes ☐ Commercial parties
3.9	The following GDPR/AVG participant rights apply to scientific research: • Right to be informed • Right of access to copy of data and processing information • Right to object • Right to erasure Describe what happens when participants make use of their GDPR/AVG rights and what procedures are put in place to ensure an appropriate response to their request.	Participants are informed about the processing of their data and their rights through the subject information sheet. When a participant refuses to participate, their data will not be collected. When a participant withdraws consent, the data collected up to the moment of withdrawal will be used (according to GDPR/AVG Article 89(1)), but no further data will be collected.
3.10	☒ I confirm that in case of a data breach we follow the Erasmus MC rules for security incidents: *: inform the Privacy Contact Person; determine together if there is a data breach involving personal information; inform the department head or supervisor; and make an internal report.* ☐ We have an additional/other process for security incidents in place. Describe the process:	

3.11 The following laws and regulations apply to this project:

Personal data		🇬🇧 General Data Protection Regulation (GDPR)
	☒	🇳🇱 Algemene Verordening Gegevensbescherming (AVG)
Patient care data	☒	🇬🇧 Medical Treatment Contracts Act 🇳🇱 Wet op de Geneeskundige Behandelingsovereenkomst (WGBO)
WMO	☐	🇬🇧 Medical Research Involving Human Subjects Act 🇳🇱 Wet Medisch-Wetenschappelijk Onderzoek met mensen (WMO)
	☐	🇬🇧 Guideline Quality Assurance of Research Involving Human Subjects 🇳🇱 Richtlijn Kwaliteitsborging Mensgebonden Onderzoek
Wbo	☐	🇬🇧 Population Screening Act 🇳🇱 Wet op het Bevolkingsonderzoek (Wbo)
Non-WMO	☒	🇬🇧 Code of Conduct for Health Research 🇳🇱 Gedragscode Gezondheidsonderzoek
Human embryos	☐	🇬🇧 Embryo Act 🇳🇱 Embryowet
All	☒	🇬🇧 Erasmus MC Research Code 🇳🇱 Erasmus MC Research Code
	☒	🇬🇧 Netherlands Code of Conduct for Research Integrity 🇳🇱 Nederlandse Gedragscode Wetenschappelijke Integriteit
	☒	**I confirm** that I am aware of and compliant with the laws and regulations as indicated above, and any relevant supplementary laws and/or regulations, e.g., for research involving medicinal products, medical devices and/or in vitro diagnostics.

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#4 Data description

This section covers the description of the data that will be collected, used or generated during this project.

4.1	Which type(s) of data will be collected, (re)used and/or generated during this project?	☒ Quantitative data (e.g., databases, spreadsheets) ☒ Qualitative data (e.g., images, audio, video, text) ☐ Other:
4.2	Next to data, will you have other research outputs? Please describe.	☐ digital (e.g., software, workflows, protocols, models, etc.): ☐ physical (e.g., new materials, antibodies, reagents, samples, etc.):
4.3	Will data be *re-used*?	☒ No existing data will be re-used → 4.4. ☐ Yes:
	If yes, please indicate the source(s).	☐ From treating physician/medical specialist/ Electronic Healthcare Records (EPD) ☐ From previous studies (e.g. EudraCT, EU clinical trial number, PaNaMa ID): ☐ From a public repository Identifier (i.e. DOI): ☐ From publications Identifier (i.e. DOI): ☐ Other, please indicate:
4.3.1	Describe which (kind of) data will be re-used.	
4.3.2	Will new consent be obtained for the re-use of this data?	☐ Yes ☐ No:
	If not, please describe if how and by whom permission was granted to reuse the data and describe the terms of use (if applicable).	
4.4	Will new data be generated?	☐ No new data will be generated → 4.5 ☒ Yes
4.4.1	Please describe which (kind of) data will be collected or generated and from which source(s).	We will collect new data on A. Survey – educational needs of HCPs B. Interviews – qualitative data psychosocial needs

4.5	Will you (re)use or generate biological materials (e.g. blood, tissues)?	☐ Yes ☒ No → 4.6
4.5.1	Is standardization of the pre-analytical phase part of your research plan?	☐ Yes ☐ No
4.5.2	Is sample data included to cover the pre-analytical aspects where a risk might be expected in your research?	☐ Yes ☐ No
4.6	Will machine learning be part of your project?	☐ Yes ☒ No → 4.7
4.6.1	Describe the hardware specifications and configurations necessary for replication (e.g. graphic card, hardware settings, …). Alternatively, describe the location (e.g. local SOP) where these specifications can be found.	
4.7	Describe how existing and/or new data will be collected, (re)used or generated for this project, including for each data source: the origin, the sample size, the data collection tool or method and the file format (if applicable).	A. Survey among HCP. We will use Castor to send surveys to HCP including educational needs and some additional sociodemographic questions. We intend to get 200 responses from six European countries. We will make SPSS-exports for the data capture tool for analysis in SPSS and for long-term durability we will also export the data to csv-format. B. We will collect data on psychosocial needs from 30 young adults with cancer, 30 family members and 30 HCPs using semi-structured interviews that will be recorded using local data recording instruments.
4.8	Describe how all the different kind of data described above will be processed, combined and/or (re)used, including the tools and file formats that will be used.	A. We will combine and process the aforementioned data in SPSS using SPSS syntaxes (.sps). B. Interviews will be transcribed in txt-format and will be analysed using NVivo software and stored in REFI-QDA-format.
4.9	Describe by whom and where the data will be analysed?	☐ Within the data collecting site only ☒ Within the research group/consortium ☐ At the sponsor ☒ Within the EU ☐ Outside the EU

4.10	If data is transferred from/to the Erasmus MC, please describe the transfer process.	A. Castor will be used as electronic data capture tool, where each participating centre only has access to their own data and the initiating centre has access to all data. B. Summary of interviews and local analysis will be transferred from participating center to Erasmus MC for purpose of the analysis of this study via an encrypted link (SURFfilesender).
4.11	Describe how the data quality control will be ensured.	A. We will use Castor which is a certified data capture tool that includes skips, validation checks and an audit trail. XXX (e.g., reviewer, data manager, quality manager, data monitor) will perform source data verification on the entered data. We will check the dataset for completeness, correctness, duplicates, uniformity and consistency using XXX (please specify: e.g., a statistical package). If as result of the dataset checking the data need to be cleaned, we will apply corrections to the data in XXX (please specify where corrections would be applied, e.g., HiX or Castor) in a traceable way. Raw data will be locked when all data validation checks are completed to avoid (accidental) modifications of the raw data." "Raw data will be stored as a read-only source data file. Subsequent analyses will be performed with a copy of the source dataset. B. Summary of each interview will be translated into English and shared via an encrypted link with Erasmus MC as analysing center.

4.12	Which non-sensitive type of information will be collected from study participants?	☐ Name ☐ Address ☒ Date of Birth or Age ☒ Gender ☐ Telephone Number of Email address ☐ BSN (social insurance number) ☐ Insurance information ☐ Non-medical images ☐ tracking information ☐ access and identification information ☐ Criminal Records ☐ None of the above
	Please describe per chosen data why it is necessary for your research question to collect this data.	Age in years and gender are required to describe the study population.
4.13	Which sensitive type of information will be collected from study participants?	☒ Medical Records ☐ Biometric Records ☐ Ethnical Background ☐ Genetic Information (e.g. DNA profiles) ☐ Sex Life ☐ Political conceptions ☐ Religion ☐ membership of unions ☐ none of the above
	Please describe per chosen sensitive data why this data is collected.	Type of cancer of year of diagnosis are required to describe the study population
4.14	Who will have access to the data?	Local researchers only for their own participants and Erasmus MC as analysing center will have access to all participants.
4.15	What type of linkage is available between data and individual subjects?	☐ Direct connection (data marked with e.g., initials, date of birth, timestamps of hospital admission) ☒ Pseudonymised connection (data marked with code, e.g., 001-2022, 002-2022). Key table is available. ☐ No connection, data are anonymized (I.e. data can neither directly nor indirectly be linked to the subject) →4.16
4.15.1	*In case of pseudonymised/anonymized*, please describe when, how, by whom and which data will be pseudonymised and/or anonymised during the project.	A. Survey is complete anonymized as the researchers have no idea who will complete the survey B. The research data will be pseudonymised by the local research coordinator as soon as the first record of the participant is created in the

		research database. The data that is entered in the database does not contain any directly identifying data. This way, the identity of the subject is only to be re-identified by using the pseudonymisation key. This key is stored separately from the data and is managed by the local research coordinator. After the project is completed, only the local research coordinator will have access to the pseudonymisation key file.
4.15.2	*In case of pseudonymised data,* who will have access to the key table?	Only the local research coordinator.
4.15.3	*In case of pseudonymised data*, where will the key table be stored?	On the server of the local institution, separate from the interview data
4.16	Which other steps will be taken to safeguard the privacy and confidentiality of the participants and to ensure compliance with (institutional) legislation and regulation on personal data?	Our project is registered in PaNaMa and the tasks for filling in the required information for the GDPR processing registry have been completed. Participants will be asked to provide informed consent. We will be using Castor to collect only these data variables that are necessary to answer our research question and not directly identifying personal data. As for the data values, we will limit the use of free text fields and use pre-defined answer options in order to limit unnecessary levels of detail. Date variables that are only needed to perform calculations within Castor will not be exported, in order to limit potentially identifiable data in the output files. Email addresses will only be accessible to authorised users and will not be exported. The Castor study is only accessible using 2 factor authentication. The data in the Castor study that was collected by the Erasmus MC is only accessible by members of our research team; other sites (except the initiating centre in this multicentre study) do not have access to our data. The personal data (e.g., pseudonymisation key file) and the research data will be stored separately, with additional access restrictions on the personal data storage location. In order to access the data, 2 factor authentication is required. For data transfer (interview summaries) with SURFfilesender, we will use encryption. We will destroy personal data when no longer needed.

4.17	Are facilities required for data collection and/or generation already present?	☒ Yes ☐ No:
	If No: Describe what needs to be arranged.	

#5 Data storage and backup

This section covers the data storage and backup during the project.

5.1	Give an estimation of the total amount of digital data that will be stored during this project.	☒ 0-10 GB ☐ 10-1000 GB ☐ 1-100 TB ☐ >100 TB
5.2	Which storage location(s) will be used?	☐ Research storage & compute services ☒ Digital Research Environment (DRE) ☐ Isilon file services ☒ SharePoint ☐ V-drive ☐ Central Cold Storage via Central Biobank ☐ Other:
5.3	Describe the exact location of the project files (e.g. DRE name or \\storage.erasmusmc.nl\MyDocs\Research Project X).	SharePoint: https://erasmusmc.sharepoint.com/:f:/r/sites/int_MELODIC/Gedeelde%20documenten/General/Dataverzameling%20MELODIC%20II?csf=1&web=1&e=cNu6cK
5.4	Who is the manager of the data?	Sid Morsink
5.5	Describe how access control of the storage location(s) is managed.	Share Point files are encrypted. Access has to be approved by the coordinating or principal investigator
5.6	Describe the backup protocol (e.g., frequency, automatically or manually).	The standard backup procedure of the storage location is applicable which means that backups occur at least on a daily basis.
5.7	Describe how you manage your files (i.e. version control, file naming conventions, folder structure, etc)	Separate folder structure for MELODIC I and II separating audio/castor data/analysis/drafts and final versions of reports. File naming will contain version number, date and description of the content.
5.8	What is your (primary) datamanagement software? (e.g. CASTOR)	Castor

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#6 FAIR data (Findable, Accessible, Interoperable, Re-usable)

This section covers the aspects of FAIR data of your project. Applying the FAIR principles will improve the output of your project.

6.1 Findable

6.1.1	Describe why the findability of this data is important or explain why not.	Data will be transferred from other European centres in this multicentre study.
6.1.2	Will the (meta)data (partly) be made available for reuse?	☐ Yes ☒ No
	If No: Explain why not:	Specific data for the objective of this study
6.1.3	When will (meta)data be made available for re-use?	☐ (Underlying) data will be made available alongside with the publication. ☒ (Underlying) data will be made available after termination of the project ☐ (Underlying) data will be made available after termination of the project (embargo period):
6.1.4	Will a data repository be used for long term archiving and sharing of (meta)data? *If yes,* which one(s)?	☐ Yes: ☒ No
6.1.5	Will an online catalogue or web portal be used to register the dataset? *If yes,* which one(s)?	☐ Yes: ☒ No
6.1.6	Will a metadata schema be used to describe information about this project in the data repository? *If yes,* which one(s)?	☐ Yes: Choose an item. ☒ No
6.1.7	Will a persistent identifier be assigned to the (meta)data in the online data repository to ensure persistent linking to the (meta)data? *If yes,* which one(s)?	☐ Yes: Choose an item. ☒ No

6.2 Accessible

By choosing a certified public repository or catalogue for your (meta)data you probably comply to this principle (Refer to questions 6.1.4 and 6.1.5).

6.3 Interoperable

6.3.1	Will a terminology standard or standardised form be used to standardise the data?	☒ Yes: ☐ No:
	Describe which terminology and/or form standard(s) will be used or explain why not.	We will be using an interview guide to capture data on psychosocial needs in a standardised manner
6.3.2	Describe how the data-level documentation will be described.	We will be using Castor to capture the data, and we will export the metadata both in csv (human readable) and XML (machine readable) file formats. We will use a metadata schema that is common in our field of research to describe the dataset documentation: interviews with patients, family members and HCPs.
6.3.3	Describe how the project-level documentation will be described.	We will document all our decisions regarding data processing and cleaning in comments in our SPSS-syntaxes.

6.4 Re-Usable

6.4.1 Which data and other end products from this project will be made available for future research?

- ☒ Study protocol
- ☐ Documentation
- ☐ Data management plan
- ☐ Data validation plan
- ☐ Data analysis plan
- ☐ Raw data
- ☐ Processed data
- ☐ Final data
- ☐ Metadata
- ☐ Synthetic data
- ☐ Test data
- ☒ Codebook
- ☐ Version control repository
- ☐ Scripts to process data
- ☐ Scripts to analyse data
- ☐ Scripts to generate tables and figures in the publication
- ☐ Lab journals
- ☐ Biological material
- ☐ Audio-visual material
- ☐ ReadMe file with an overview of files and file content and use
- ☐ Other:

6.4.2 Are there additional changes required before the dataset can be shared (e.g., aggregation, filtering)?

☒ Yes:
☐ No

	If Yes: Describe which changes will be made to the dataset before it will be shared.	Check for aspects such as privacy, public security and ethical limitations.
6.4.3	Which data access strategy will be used?	☐ Open access ☐ Access for registered users ☒ Restricted access (on approval) → 6.4.5
6.4.4	Which license will be attached to the data?	
6.4.5	What are the reasons to restrict the access to the data (fully and/or partly restricted)?	Privacy Related: Data consists personal information which needs additional safeguarding to adhere to GDPR.
6.4.6	Are there any special conditions for sharing and reusing the data included in the terms of use?	☒ Yes: ☐ No
	If Yes: Describe the special conditions.	The PI will verify the authenticity of the requesting researcher and will check whether their intentions are in line with the informed consent and whether the intended methodology is suitable and will approve the request before providing access to the data.
6.4.7	Describe the process of how others can request access to the data and how the data will be made available to them.	
6.4.8	When sharing, what type of linkage is available between data and individual subjects?	☐ Direct connection (data marked with e.g. initials, date of birth) ☐ Pseudonymised connection (data marked with code, e.g. 001-2022, 002-2022) ☒ No connection, data are anonymized (I.e. data can neither directly nor indirectly be linked to the subject)
6.4.9	Does this project involve the use or generation of specific software that is required in order to access and interpret the data?	☐ Yes: ☒ No
	If Yes: Describe how this software can be found and used.	

#7 Data archiving

This section covers the data archiving after the project. Please note that archiving is for compliancy and verification purposes but also enables sharing of the data for reuse.

7.1	Describe which criteria will be used to determine which data will be archived.	If the research data has great value, is unique, difficult or expensive to (re)produce or should be preserved for the long term due to obligations, the data will be archived. Data that can easily be reproduced (e.g., processed versions of data) will be destroyed, because this would cost too much archiving capacity and costs. Data or metadata with no use at all in the future will be destroyed (e.g., contact details). At least all raw and final data, used scripts and original paper documents with wet signatures will be archived.
7.2	Are there changes required to make the data and/or documentation readable and usable in the long term (e.g., conversion to preferred file formats)?	☒ Yes: ☐ No
	If Yes: Describe which changes will be made.	For the interoperability and reusability of the data, we will convert the used file formats to preferred file formats that are compatible with generally used software packages. Documentation files that were originally created in Word, will be saved as PDF files.
7.3	For which duration will the data be archived?	☐ At least 30 years (ATMPs) ☐ At least 25 years (medicinal products) ☐ At least 15 years (WMO) ☒ At least 10 years (non-WMO, non-implantable medical device) ☐ Other:
7.4	Where will the data be archived after the project?	☒ Research storage & compute services ☐ Isilon archive services ☐ Paper document storage via OASIS ☐ Central Cold Storage via Central Biobank ☐ Other:
7.5	Who will have access to the archived data (to allow re-use) and ensure long-term preservation?	The Dutch research team will have access to the archive.
7.6	Who will have access to the archived key table?	The local research team in the six EU countries

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7.7	Describe how access control of the archive will be managed.	The Dutch research team will have access to the archive. The PI is responsible for the access control of the archive and will handover this responsibility upon termination of employment.

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#8 Costs

This section requires you to estimate the costs during and after the project. Think about the resources (for example time and financial) dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable).

8.1	Give an estimation of the costs (€) for making data or other research outputs FAIR (e.g. direct and indirect costs related to storage, archiving, repositories, licences, re-use, security, etc.)? Describe how the costs will be covered.	n/a, as we can store the data at our department
8.2	Will you have dedicated resources (FTE) responsible for data management? *If yes*, please describe how these costs will be covered.	☐ Yes: ☒ No

The End

AGREEMENT ON THE SHARING OF PSEUDONYMIZED PERSONAL Data (for academic research)

This agreement (hereinafter referred to as "Agreement") is made and entered by and between:

Erasmus University Medical Center Rotterdam, an institution organized in accordance with public law of the Netherlands (article 1.13,2 WHW), with principal place of business at Dr. Molewaterplein 40, 3015 GD Rotterdam, The Netherlands, acting exclusively for and on behalf of its Department Medical Oncology, legally represented by the undersigned, hereinafter referred to as "**Recipient**"

and

TURUN AMMATTIKORKEAKOULU OY (TURKU UAS), having its principal office at JOUKAHAISENKATU 3A, TURKU 20520, legally represented by the undersigned, hereinafter referred to as "**Provider 1**";

ESCOLA SUPERIOR DE ENFERMAGEM DE LISBOA (ESEL), having its principal office at AVENIDA PROF EGAS MONIZ, LISBOA 1600-190, Portugal, legally represented by the undersigned, hereinafter referred to as "**Provider 2**";

PANEPISTIMIO DYTIKIS ATTIKIS (UNIWA), having its principal office , PETROU RALLI KAI THIVON, AIGALEO 12244, Greece, legally represented by the undersigned, hereinafter referred to as "**Provider 3**";

SIHTASUTUS TARTU ULIKOOLI KLIINIKUM (TUH), having its principal office at ,PUUSEPA 1A, TARTU 50406, Estonia, legally represented by the undersigned, hereinafter referred to as "**Provider 4**";

UNIVERSITY OF GALWAY (NUI GALWAY),having its principal office at UNIVERSITY ROAD, GALWAY H91 TK33, Ireland, legally represented by the undersigned, hereinafter referred to as "**Provider 5**".

Providers 1 through 5 are hereinafter collectively referred to as "**Provider**".
Provider and Recipient hereinafter jointly referred to as "**Parties**" and individually as "**Party**;"

WHEREAS

a) Parties have entered into a consortium agreement for the project called Melodic, Mental health support for young adults with cancer, effective as of 1st September 2024 (hereinafter referred to as the "**Consortium Agreement**").
b) Provider has obtained and / or generated Data as further defined below;
c) Recipient has requested Provider to provide Recipient with the Data for use by Recipient for the purpose of the project for which the Parties have entered into the Consortium Agreement (hereinafter referred to as the "**Project**");
d) Provider is willing, subject to the terms and conditions of this Agreement, to provide the Data to Recipient.

I Definitions

1. **Agreement**: this agreement, including all annexes attached to it.

2. **Annex**: an annex to this Agreement.

3. **Applicable Data Protection Law***:* the GDPR (General Data Protection Regulation) and any additional locally applicable data protection legislation.

4. **Confidential Information**: All information in whatever form or mode of communication, which is disclosed by Provider to Recipient in connection with this Agreement during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Provider.

5. **Data**: the personal data being transferred under this Agreement is the Data that is further specified in Annex I to this Agreement, provided without directly identifying personal information. The Data constitutes Pseudonymized personal health data under the GDPR.

6. **Effective Date**: 01 March 2025.

7. **GDPR**: the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal Data and on the free movement of such Data (General Data Protection Regulation).

8. **Pseudonymized**: means that the Data is processed in such a manner that the Data can no longer be attributed to a specific natural person without the use of additional information (e.g. a code), provided that such information is kept separately and is subject to technical and organizational measures to ensure that the Data are not attributed to an identified or identifiable natural person.

9. **Subject(s)**: shall mean the patient or other person from whom the Data was obtained.

II. Terms and Conditions of this Agreement:

1. The Data and any other information provided is made available for use in the Project and no ownership rights in the Data and any other information shall be obtained by Recipient under this Agreement.

2.
   a) Data shall be provided by Provider in a sufficiently secure manner and Parties shall handle all Data in accordance with the Applicable Data Protection Law and shall keep such Data confidential without any of the exclusions contained in Article 11 below.
   b) With respect to the Data, Parties shall be considered to be joint Data controllers under the Applicable Data Protection Law for the processing of the Data for the Project.
   c) Recipient shall implement appropriate technical and organizational measures to meet the requirements for Data controllers of the Applicable Data Protection Law.
   d) If Recipient becomes aware of a personal Data breach concerning the Data, Recipient shall promptly notify the relevant Provider. In such a case those Parties will fully cooperate with each other to remedy the personal Data breach, fulfill the statutory notification obligations timely and cure any damages. The term 'personal Data breach' refers to articles 33 and 34 of GDPR.
   e) In the event that Subject withdraws his/her permission for the use thereof, Provider shall supply Recipient with sufficient information and Recipient shall immediately cease all use of the relevant Data and shall delete all copies of the relevant Data. Upon request from Provider, Recipient shall confirm in writing the complete deletion of such Data.

   The Parties' contact details for inquiries regarding handling and protection of Data are as follows:

For Recipient, to:	For Provider 1, to:

Name: H. Kart	*Name:*
Address: Dr. Molewaterplein 40, 3015 GD Rotterdam, The Netherlands	*Address:*
Tel: +31 6 296 592 28	*Tel: +*
E-mail: privacy.daniel@erasmusmc.nl	*E-mail:*

For Provider 2, to:	For Provider 3, to:
Name:	*Name:*
Address:	*Address:*
Tel: +	*Tel: +*
E-mail:	*E-mail:*

For Provider 4, to:	For Provider 5, to:
Name:	*Name:*
Address:	*Address:*
Tel: +	*Tel: +*
E-mail:	*E-mail:*

3. Recipient shall not carry out any procedures with the Data - such as linking, comparison, or processing - with which the identity of the Subject could be derived. The Recipient agrees that the Data:
   a) is to be used only for the academic purposes as described in the Project; and
   b) will not be used for other - including commercial - purposes.

   Furthermore, in carrying out the Project, Recipient shall not allow third parties to access or otherwise process the Data without prior written approval of Provider. However, as an exception to the foregoing, such prior approval shall not be required for service providers in the context of the standard business operations of Recipient, such as parties who supply ICT infrastructure maintenance. Recipient will safeguard that any Data processors who have access to the Data are instructed by a binding agreement to process the personal Data in accordance with the requirements stated in the GDPR.

4. Recipient shall keep Provider informed of the results arising from the Project conform the plans as agreed upon in the Consortium Agreement.

5. Ownership and use of Results (as defined in the Consortium Agreement) through the use of the Data shall be determined in accordance with the provisions as agreed upon in the Consortium Agreement. Inventions will follow inventorship.

7. The Data will be provided to Recipient at no cost.

8. Data will be provided to the Recipient by Provider's Scientist in a sufficiently secure manner and in a format to be agreed upon between Recipient and Provider.

9. Provider warrants that:
   a) it has verified that there is an appropriate legal ground for the provision of the Data to Recipient in accordance with the GDPR (such as Article 6 and/or 5.1 sub b GDPR); and
   b) there is a valid exception to the prohibition for processing personal health Data (Article 9 GDPR); and
   c) it shall be provided under approval from the relevant ethics committee to the extent required.

   Apart from this, it is expressly understood that Provider does not make any warranties regarding the Data and specifically does not warrant or guarantee that the Data will be accurate, be merchantable or useful for any particular purpose. Provider cannot and shall not be held liable for any claims or damages by Recipient or any third party, in connection with or as a result of the use of Data by Recipient. Unless and to the extent caused by Provider's gross negligence

or willful misconduct, Recipient undertakes to hold harmless Provider at all times against all of such damages or claims.

10. Recipient agrees in its use of the Data to comply with all applicable international and national laws, statutes, regulations and guidelines.

11. Recipient shall treat all Confidential Information related to this Agreement in accordance with the provisions as agreed upon in article 10 of the Consortium Agreement.

12. If a Party (or Parties) wish to disseminate the Results of the use of the Data under this Agreement, they shall do so in accordance with the provisions as agreed upon in article 8.4 of the Consortium Agreement.

13. This Agreement will become effective on the Effective Date and will terminate the same date as the Consortium Agreement is expired or terminated. Any clauses which will be expected or are intended by their nature to survive the termination or the expiration of this Agreement, shall survive the termination or the expiration of this Agreement.

    Upon expiration or termination of this Agreement, the right to use the Data and Confidential Information will automatically end. After expiration or termination of this Agreement, Recipient will delete or return all Data received from Provider. Upon request for deletion of the Data from Provider, Recipient shall confirm in writing the complete deletion of such Data and Confidential Information.

14. This Agreement will be exclusively construed, governed, interpreted and enforced according to the provisions as agreed upon in articles 11.7 and 11.8 of the Consortium Agreement.

15. This Agreement will be binding upon and inure to the benefit of the respective successors and assignees of the Parties hereto. However, Recipient may not assign this Agreement in whole or in part without the prior written consent of the Provider.

16. This Agreement may only be altered or amended by an instrument in writing signed by all of the Parties.

17. If any portion of this Agreement is in violation of any applicable regulation, or is unenforceable or void for any reason whatsoever, such portion will be inoperative and the remainder of this Agreement will be binding upon the Parties.

18. Both Parties acknowledge that the signatories to this Agreement are authorized representatives of each of the Parties and legally authorized to sign this Agreement.

19. If the lawful performance of any part of this Agreement by a Party is rendered impossible by or as a result of any cause beyond such Party's reasonable control, such Party will not be considered in breach hereof as a result of failing so to perform.

IN WITNESS WHEREOF, the Parties have executed this Agreement, in duplicate originals or as a signed PDF, as of the Effective Date.

For the **Recipient**

By: _____
Name: :_____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Recipient's scientist

For **Provider 1**,

By: _____
Name: _____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Provider 1's scientist

For **Provider 2**

By: _____
Name: :_____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Provider 3's scientist

For **Provider 3**,

By: _____
Name: _____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Provider 4's scientist

For **Provider 4**

By: _____
Name: :_____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Provider 4's scientist

For **Provider 5**,

By: _____
Name: _____
Title: :_____
Date: _____

READ AND ACKNOWLEDGED:

_____
Provider 5's scientist

ANNEX I

Description of the Data, methods of transfer and storage, allowed processors

Data Subjects The personal Data transferred concern the following categories of Data Subjects:	Transcripts of interviews including basic characteristics of the participants.
Purpose of the transfer(s) The transfer is made for the following purpose:	Thematical analysis of the interviews by the receiving center.
Categories of Data The personal Data transferred concern the following categories (types) of Data:	Basic characteristics (age, gender, level of education, profession etc.) NB: All health information qualifies as sensitive Data as meant in the field below
Sensitive Data (if appropriate) e.g.: •racial or ethnic origin, •political opinions, •religious or philosophical beliefs, •trade union membership, •genetic Data, biometric Data, •health Data, •sex life and sexual orientation	Health information concerning diagnosis and treatment
Method of transfer e.g.: Soft- or hardware encrypted USB drive, Database entry such as in Castor, etc.	Protected data transfer via SURFcontext or by uploading in protected sharepoint.
Method of Data storage and security measures (e.g. method of encoding)	Encrypted storage in digital sharepoint of the receiving center, accordign the EU privacy regulations (GDPR). Participants will be assigned a code, which is not traceable to the person. The key file and data file will be stored separately from each other in the providing center.
Authorized processors, if applicable, as indicated in clause 3 of the Agreement	Principal and coordinating investigators of the receiving center

Erasmus MC
University Medical Center Rotterdam

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MELODIC
MENTAL HEALTH SUPPORT FOR YOUNG ADULTS WITH CANCER

Agenda

Meeting	Melodic WP2 meeting
Date	06 and 07 February 2025
Time	09:00 hrs (CET)
Location	Erasmus MC Rochussenstaat, Rotterdam, the Netherlands
	Brug. s'Jacobplein 51, 3015 CA Rotterdam (see attached)
Contact if needed:	Wendy Oldenmenger +31 6 510 72 608

Agenda

Thursday 06 February

09:00 – 09:30	Walk-in Room GK-012	
09:30 – 10:30	Welcome Opening and introductions	Project lead & Rotterdam delegation
10:30 – 11:45	MELODIC project – general Project organisation Public Relation & Communication guidelines	Melodic Coordination WP5
11:45 – 12:15	Two day program	Rotterdam delegation
12:15 – 12:45	*Lunch* *Room GK-022*	
12:45 – 13:45	*Guided Art tour in the Erasmus MC*	
14:00 – 14:15	WP2 Planning, milestones and timelines Room SP-3417	Wendy Oldenmenger
14:15 – 14:45	Current situation MELODICI and MELODICII	Sid Morsink
14:45 – 15:45	Lecture Qualitative research	Leonieke Kranenburg
15:45 – 16:00	Feedback	
19:00	*Dinner, ntb*	

Agenda

Friday 07 February

09:00 – 09:15	Opening second day Room GK-023	Wendy Oldenmenger
09:15 – 10:45	Feedback Pilot Interviews All participant conduct at least 1 pilot interview before the meeting. They give a presentation of max 10 minutes of their experiences. Afterwards discussion	
09:15 – 09:45	*Rotterdam, the Netherlands*	*Sid Morsink*
09:45 – 10:15	*Galway, Ireland*	*Martin Power*
10:15 – 10:45	*Lisboa, Portugal*	*Joaquim Oliveira-Lopes*
10:45 – 11:00	*Coffee break*	
11:00 – 11:30	*Turku, Finland*	*Mari Lahti*
11:30 – 12:00	*Greece*	*(Evanthia Sakellari)*
12:00 – 12:30	*Tartu, Estonia*	*Siret Kivistik*
12:30 – 13:30	*Lunch*	
13:30 – 14:30	Discussion experiences and how to go further	Wendy Oldenmenger and Leonieke Kranenburg
14:30 – 15:00	Summary of the meeting and farewell	Melodic Coordination