



MELCAYA

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

Grant Agreement: 101096667

D4.2 Immuno-Ped 1 initiation package



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the European Union**

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Document Information

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Contributor(s):	-
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Project Acronym:	MELCAYA
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Rights:	MELCAYA consortium

Document history

Version	Date	Beneficiary	Description
0.1	24.02.2023	UNIPG	First draft version
0.2	05.04.2023	UNIPG	Revised draft
0.3	27.06.2023	FCRB	Revised draft
1.0	20.08.2023	FCRB	Final draft
2.0	30.09.2024	FCRB	Revised final draft

Executive Summary

The purpose of this deliverable is to present all the documentation necessary for the initiation of the MELCAYA work package 4 clinical study Immuno-Ped 1. It contains the final version of the study protocol and corresponding regulatory/ethics approval by the ethical committee of the study sponsor (University of Perugia). The protocol includes an introduction in which a review on relevant literature, the objectives of the study, the design and study procedures are presented. Details on data collection and management are also discussed, as well as ethical considerations such as how incidental or secondary findings will be communicated or how personal data will be processed. The documents presented in this deliverable will be subsequently used by the other clinical sites for approval in their respective ethical committees.

1. General information

1.1. Identification of the study

Title: Impact of anti PD-1 therapy in children, adolescents and young adults melanoma patients (Immuno-Ped 1)

Code or protocol identification number: NCT06281912 (<https://clinicaltrials.gov/>)

Version and date: v3 (03/06/2024)

1.2. Identification of the sponsor/principal investigator

Name: Mario Mandalà

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1.3. Identification of site investigators

Name: Susana Puig

Institute and department: Hospital Clínic de Barcelona, Dermatology service

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1.4. Identification of the principal investigators from participant centers

Researcher 1

Name: Daniela Massi

Institute and department: University of Florence (Department of Health Sciences)

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Researcher 2

Name: Ines Brecht

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Researcher 3

Name: Alexander Eggermont

Institute and department: Prinses Maxima Centrum Voor Kinderoncologie (Clinical and Translational Immunotherapy department)

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Researcher 4

Name: Hildur Helgadóttir

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Researcher 5

Name: Andrea Ferrari

Institute and department: Fondazione Irccs Istituto Nazionale Dei Tumori (Pediatric Oncology Unit)

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Researcher 6

Name: Piotr Rutkowski

Institute and department: Maria Skłodowska-Curie National Research Institute of Oncology (Soft Tissue/Bone Sarcoma and Melanoma department)

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Researcher 7

Name: Daniel Orbach (Pediatrics department)

Institute and department: Institut Curie

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Researcher 8

Name: Josep Maria Borràs Andrés

Institute and department: Catalan Institute of Oncology

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Researcher 9

Name: Ewa Bien

Institute and department: Medical University of Gdansk (Pediatrics, Haematology and Oncology department)

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Researcher 10

Name: Thomas Eigentler

Institute and department: Charité Universitätsmedizin Berlin (Dermato-oncology department)

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Additional organizations:

This study will utilize data from existing datasets, cohorts, registries, and databases, including the European Organization for Research and Treatment of Cancer (EORTC) Melanoma Group, the Italian Intergroup Melanoma (<https://www.melanomaimi.it>), a melanoma dataset from the University of Perugia (IT), the Catalan Melanoma Network and Registry and the Melanomas and Melanocytomas Registry (Clinic Health Corporation).

2. Justification

Melanoma in childhood and adolescence is underestimated, understudied, and as a consequence it lacks adequate diagnostic and therapeutic strategies. The incidence of melanoma is reported to be about 1.3-1.6 per million in children under 15 years of age and 15 per million in 15-19 years, with increasing incidence in adolescents by 4.1% annually since 1997 [1,2]. Furthermore, melanoma is among the most frequent solid tumors diagnosed in young adults, having in Europe an incidence of 6.6 per 100.000 and a mortality of 4 per million [3].

Immunological therapies based on anti PD-1 antibodies represent one of the standard immunological therapies in the advanced and early-stage melanoma [4]. This kind of treatment has been highly developed during the past decade based on the comprehensive understanding of the role of tumor microenvironment and immune cells in melanoma, and has highly improved patient outcomes both in advanced and adjuvant setting. Despite these advances, metastatic melanoma remains incurable in the majority of patients at any age and a major clinical challenge. Clinical trials are ongoing to develop novel and more effective targeted therapies and

immunotherapies in order to overcome resistance and lead to a further improvement in long term prognosis.

One challenge in this therapeutic trajectory development is that, because melanoma in childhood and adolescence is rare, the management of pediatric melanoma patients has been extrapolated from the treatment of adults, but specific clinical data are missing [5]. Furthermore, due to limited understanding surrounding the diagnosis and prognosis of childhood melanoma, these patients were excluded from the vast majority of clinical trials offered to adult patients; this strategy has hampered research efforts and access to treatment in this population. Overall, there are only minimal data on the efficacy of systemic therapy in children and adolescents with early-stage or advanced melanoma. Some explorative, phase I/II trials have been designed to evaluate therapies for pediatric cancer patients that included subsets of patients with advanced melanoma, and the only drug approved by the Food and drug administration in this population is Ipilimumab based on a phase I/II clinical study, and more recently anti PD-1, based on very limited data in small, selected patient population. Hence no data are available in unselected, routinely treated childhood and adolescence melanoma patients.

3. Study hypothesis

This clinical study is aimed at providing the most extensive data on anti-PD-1 therapy in the adolescent and pediatric population, which has already been widely approved and tested in the adult population. Activity data will be integrated by evaluating the toxicity profile. Furthermore, exploratory translational analyses may be instrumental in selecting patients who may primarily benefit from clinical benefits.

4. Objectives and purpose of the study

The primary objective is to evaluate the activity, effectiveness as well as the acute and long-term toxicity of anti-PD-1 antibodies in adolescents, children, and young adults with early and advanced melanoma. The secondary objective is to evaluate the acute and long-term toxicity of anti PD-1 antibodies in the aforementioned population.

5. Study design

This is a multicenter translational retrospective European observational study aimed at evaluating the activity and efficacy of anti-PD-1 antibodies in adolescents, children, and young adults with early and advanced melanomas.

Clinical outcomes will be retrospectively retrieved starting from the primary diagnosis of melanoma. Clinical outcomes related to anti-PD-1 therapy will be evaluated retrospectively from the beginning of treatment until the most recent follow-up. The collected data will include demographic information, disease history, concomitant pathologies, treatment response, progression-free survival, and overall survival. Data collection period ranges from January 2000 to November 2023.

6. Participant selection

Children, adolescent and young adult population affected by melanoma treated with anti-PD-1

6.1. Subject inclusion criteria

Patients of either sex over 12 years old with histologically confirmed melanoma, treated with anti-PD-1 immunotherapy (Ipilimumab plus Nivolumab) and with clinical and follow-up data available.

6.2. Subject exclusion criteria

Patients that have not received immunotherapy, with no melanoma or age over 30 years old.

7. Treatment and study calendar

Not applicable to this study.

8. Statistics

8.1. Sample size

Around 70-80 pediatric patients and 400 adolescent and young adults will be included in this study.

8.2. Statistical analysis

Continuous variables will be reported as mean and standard deviation, or median and range where appropriate. Categorical variables will be summarized as number and proportion of the total study population, and by subgroups where appropriate. Frequencies will be presented as *n* (%), with percentage calculated based on the total study population and by subgroups where

appropriate. Proportions will include all patients in a specified group in the denominator and the number of these patients with an outcome of interest in the numerator. The corresponding 95% CI will be calculated using the Pearson- Clopper binomial proportion method. Non-parametric Mann-Whitney Test will be performed to compare continues variable with no normal distribution. Categorical variables will be evaluated by chi-square analysis or Fisher's exact test were appropriate.

9. Ethical and legal aspects

9.1. Legal and ethical basis

The partners have a lawful basis for the re-use of health data for scientific purposes under specified conditions and with adequate safeguards i.e., legitimate interests (article 6.1 (f) GDPR), combined with 'scientific research' article 9.2 (j) GDPR. In the cases that the subjects could be re-identified, the guidelines on registry-based studies (EMA/426390) will be followed to ensure that access and use of the proposed data poses minimum to no risk to the study subjects or their fundamental rights and freedoms. In the cases where pre-existing ethics approvals are currently not in place, an authorization (or an amendment in the case of existing approval) to access and use this data will be requested from each partner's respective local ethics committee or national competent body prior to study start-up.

All study materials, including clinical and laboratory protocols, will be submitted to pertinent Institutional Review Boards (IRBs) for review and approval. Approval of the study protocol will be obtained prior to participant/case selection. Any changes to the study protocol, materials, etc. will be subjected to ethics review and approval before the changes are implemented into the study. All participating institutions will comply with international ethical standards regarding principles for medical research involving human subjects and data (Declaration of Helsinki, 2013). In the particular case of Hospital Clínic de Barcelona, compliance at the Spanish level with the Ley 14/2007 de 3 de julio, de Investigación biomédica will be ensured. On top of that, the guidelines set out in the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) and the following EMA/426390/2021 (Guideline on registry-based studies) regulation will be followed.

9.2. Communication of incidental/secondary findings

In the event that incidental/secondary finding occur during the study, the researcher is expected to inform an officer from his or her local Ethics Committee and coordinate a consultation with

the medical professionals involved in the study from their participating institution to review and evaluate if the finding is relevant and how it should be communicated to the participant. In case of doubt, consultation can be made with other medical experts within the consortium. Contact with the patient would be done through the practitioner that generally attends the patient, using the available data recorded in the clinical history (if any). For minors, the general practitioner would contact with the parents or legal representatives (signatory of the informed consent). Ideally, a medical appointment would be scheduled when sharing this information to reassure the patient and avoid unnecessary stress.

The general conditions that must be always met to communicate an incidental/secondary finding are the following:

- It may affect a participant's health and welfare.
- It is scientifically and clinically valid.
- Ethical approvals have been obtained and the participant or their legal representative has opted in to receiving such results through their clinician(s) in the informed consent form.

Incidental and secondary findings will not be communicated:

- When the clinical information is anonymized, as it will be justifiably impractical or impossible to contact the research participant.
- When the participant has indicated that he/she does not want to be informed about such findings.

9.3. Supervision of legal-ethical issues

The institutions involved in this study will establish an Ethical Monitoring Board (EMB) that will act as liaison between them and local competent IRBs. This will be done to ensure that data collection methods and clinical aspects of the study protocol are efficacious and in agreement with competent IRBs policies and procedures, as well as to oversee the process of obtaining scientific advice and regulatory guidance from the appropriate regulatory agencies. In addition, access to regulatory expertise will be ensured through each institution ethics committee. Communication between the partners and competent IRBs will be continuous in order to verify that the study is in compliance with European and national regulatory guidelines.

10. Data management

10.1. Data storage

All data will be stored in a secured electronic database known as Xarxa Melanoma approved by the Ethical Committee of the Hospital Clínic de Barcelona on the 14/04/2015 (Reg. HCB/2015/0298). This database is routinely used by dermatology medical professionals of our hospital and complies with international standards on data protection and offers a consistent, auditable and integrated electronic database environment. Each institution involved in the clinical studies will count with a local data protection officer (DPO) to advice on highly complex, sensitive or large-scale data processing. Upon completion of the study, data will be preserved for a minimum of 10 years to guarantee continued accessibility and data discovery. Personal data information will only be kept for updating follow-up by the local center investigator. The sponsors will only use the data collected for other scientific purposes if participants have given prior consent and if the legal basis for processing is still in place (see section 9.1). After that, paper and electronic records will be destroyed or erased per institutional/University policy.

10.2. Data codification

Before uploading the collected patient data to the database, a codification procedure will be implemented at each local data source center. The procedure will be carried out in the following way: a researcher from our center will assign a code to the clinical information of each patient, which will be kept in a separated database to which only the Principal Investigator or authorized personnel in his research team will have access to. In that way, without knowledge of the respective assignment of code and patient, no re-identification of individual persons is possible. Data processing will be carried out exclusively by persons who had no direct patient contact during data collection.

10.3. FAIR data

All data will be identified by a digital object identifier (DOI) to ensure that it is findable and made available through scientific publications and publicly accessible data repositories such as Zenodo. Priority will be given to open access high impact journals. The Directory of Open Access Journals or a similar index will be used to determine the most appropriate one for submission of the study data and results to ensure immediate and unrestricted access to new knowledge. Open data formats (such as XML, PNG, HTML) will be used to increase data interoperability. The data will be released under an open access license, for instance, Creative Commons Attribution

International Public Licence (CC BY) or similar. This will facilitate the reuse of data and ultimately maximize the overall impact.

11. Treatment of data, record keeping and data confidentiality

The processing, communication and transfer of personal data of all participants shall comply with 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 data and the Organic Law 3/2018 of December 5 on the Protection of Personal Data and guarantee of digital rights. The legal basis that justifies the processing of your data is the consent you give in this act, in accordance with the provisions of article 9 of EU Regulation 2016/679. The data collected for these studies will be only identified by a code, so no information will be included that would allow to identify the participants. Only the study physician and his collaborators with the right to access the source data (medical history) could relate the collected data with the patient's medical history. The identity of the participants will not be available to any other person except for a medical emergency or legal requirement. Health authorities, Research Ethics Committee and personnel authorized by the study sponsor may have access to the identified personal information when necessary to verify data and procedures of the study, but always maintaining confidentiality in accordance with current legislation.

Only the encrypted data will be transferred to third parties and other countries, which in no case will contain information that can directly identify the participant (such as name and surname, initials, address, social security number, etc.). In the event that this transfer was to occur, it would be for the same purpose of the study described and guaranteeing confidentiality. If encrypted data is transferred outside the EU, whether to entities related to the hospital where the patient participates, to service providers or collaborating researchers, the data of the participants will be protected by safeguards such as contracts or other mechanisms established by the data protection authorities.

Data processing will be done in accordance with EU Regulation 2016/679. As a result, a record of all the processing activities will be kept and a risk assessment of those activities will be performed to know what measures will be needed and how to implement them. In addition to the rights already provided for in the previous legislation (access, modification, opposition and cancellation of data, deletion in the new Regulation), participants can now also limit the

processing of data collected for the project that is incorrect, request a copy or transfer them to a third party (portability). To exercise these rights, they should contact the principal investigator of the study or the Data Protection Officer of the Hospital Clínic de Barcelona through protecciodades@clinic.cat. Likewise, they have the right to contact the Data Protection Agency if they are not satisfied. Data cannot be deleted, even if a patient leaves the study, to ensure the validity of the research and comply with legal duties and drug authorization requirements. The Investigator and the Sponsor are obliged to keep the data collected for the study for at least 25 years after its completion. Subsequently, personal information will only be retained by the health care facility and by the sponsor for other scientific research purposes if the patient has consented to do so, and if permitted by applicable law and ethical requirements.

12. Management of biological samples

Not applicable to this study.

13. Financing

Immuno-Ped 1 study was conceived independently of any commercial organization and will be coordinated, managed and analyzed in independent form. The costs related to the analyses envisaged on the samples, for research purposes only, will be supported by research fundings of MELCAYA project (HORIZON-MISS-2021-CANCER-02, Proposal number: 101096667).

14. Publication policy

The transmission or dissemination of the data, through scientific publications and/or presentation in congresses, conventions, and seminars, may be carried out only after each Principal Investigator's written authorization. Accordingly, the Principal Investigator of the study undertakes to produce a report on the study, publish all data collected as described in the protocol and ensure that the data are reported responsibly and coherently. In particular, the publication of the data deriving from this study will be independent of the results obtained. The transmission or dissemination of data, through scientific publications and/or presentation in congresses, conventions and seminars, participation in Multicentric studies, will take place only following a purely statistical elaboration of the same, or otherwise in anonymous form.

15. References

[1] Ferrari, A. et al. European Journal of Cancer 110, 120–126 (2019)

- [2] de Vries, M., Vonkeman, W. G., van Ginkel, R. J. & Hoekstra, H. J. *European Journal of Surgical Oncology* 32, 785–789 (2006); 3. Bleyer, A., Budd, T. & Montello, M. *Cancer* vol. 107 1645–1655 (2006)
- [3] Steininger, J. et al. *Cancers* vol. 13 1–28 (2021)
- [4] Kottschade, L. A. et al. *American Journal of Clinical Oncology: Cancer Clinical Trials* vol. 37 635–641 (2014)

Prot. N. 27138/23/OV del 17/04/2023

Al responsabile dello studio
Mandalà prof. Mario
U.O. Oncologia Medica
Ospedale S. Maria della Misericordia
06156 Perugia

e p.c.

Al Direttore/Responsabile
del Reparto/Unità Operativa
Al Direttore Generale
Alla Direzione Sanitaria
Azienda Ospedaliera di Perugia
LORO SEDI

OGGETTO: Parere del CER Umbria

Studio osservazionale: MELCAYA STUDY
Sponsor: A.O. di Perugia - Univ. degli Studi di Perugia
Registro CER N.: 4504/23

Con riferimento alla richiesta di autorizzazione a condurre lo studio clinico in oggetto, si informano le SS.VV. che il Comitato Etico Regionale dell'Umbria, riunitosi in data **29/03/2023**, ha emanato il parere di competenza, ai sensi della normativa vigente e del proprio Regolamento Interno, che si allega alla presente unitamente al foglio delle presenze.

Si fa presente:

- che lo studio dovrà essere condotto nel rispetto della Circolare del Ministero della Salute n. 6 del 02/09/2002 e dei principi della Determinazione AIFA del 20/03/2008 "Linea guida per la classificazione e conduzione degli studi osservazionali sui farmaci";
- che è necessario:
 - o comunicare al Comitato Etico ogni modifica al protocollo di studio e ogni informazione che possa incidere negativamente sulla sicurezza dei soggetti o sulla conduzione dello studio,
 - o dare seguito agli adempimenti relativi all'interruzione e/o conclusione dello studio;
 - o inviare al Comitato Etico la comunicazione della data effettiva di inizio studio, la revisione annuale dello studio e il consuntivo scritto al termine dello stesso.

Si dichiara che il CER Umbria opera nel rispetto della Dichiarazione di Helsinki, delle Norme di Buona Pratica (D.M. 15/07/1997 e D. Lgs. 200/2007), del D. Lgs. 211/2003, del D.M. 21/12/2007, della Legge n. 189 del 08/11/2012 e di tutta la normativa vigente in materia di sperimentazione clinica.

Si dichiara infine che non hanno partecipato alla decisione, al parere ed al voto lo sperimentatore o i componenti del Comitato per i quali sussista un conflitto di interessi diretto o indiretto con la presente sperimentazione.

Distinti saluti.

IL SEGRETARIO GENERALE
Dott. Alessandro D'Arpino



Allegato alla lettera prot. N. 27138/23/OV del 17/04/2023

STUDIO

Impatto della terapia con anti PD-1 nella popolazione pediatrica e giovane adulta affetta da melanoma: studio osservazionale retrospettivo.

CODICE: MELCAYA STUDY

SPONSOR: A.O. di Perugia - Univ. degli Studi di Perugia

TIPO DI PROMOTORE:

SPERIMENTATORE: Mandalà prof. Mario

U.O. ONCOLOGIA MEDICA

OSPEDALE S. MARIA DELLA MISERICORDIA

06156 PERUGIA

DOCUMENTAZIONE:

(Legenda: X = presente, -- = non presente, np = non pertinente)

- Lettera di trasmissione del promotore del 15/02/2023
- Delega CRO
- Dichiarazione studio osservazionale
- Parere favorevole espresso da: nella seduta del
- Foglio informativo/Modulo per il consenso: per il/i genitore/i o tutore legale vers 2.0 del 13/04/2023
- Nota informativa/Consenso tutela dati personali: vers 01 del 15/02/2023
- Materiale per il paziente: Assenso informato minore di età compresa tra 12 e 17 anni vers 2.0 del 13/04/2023
- Lettera per il medico curante:
- Scheda Raccolta Dati:
- Sinossi del protocollo:
- Protocollo di studio: vers 0.1 del 15/02/2023
- Lettera dello sperimentatore
- Dichiarazione conflitto di interessi dello sperimentatore
- Elenco centri partecipanti 15/02/2023
- Bozza di contratto economico
- Dichiarazione di pubblicazione dei risultati
- Altro:
 - email di trasmissione integrazioni del 13/04/2023

PARERE DEL CER UMBRIA DEL 29/03/2023 :

Favorevole

Precisazioni:

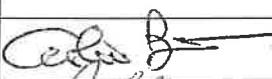
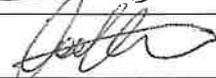
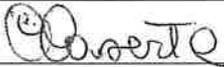
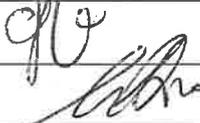
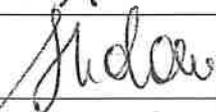
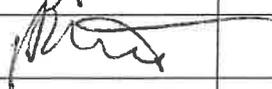
Parere rilasciato il 17/04/2023 a seguito di richiesta di modifiche/integrazioni.

- Lo Sponsor è impegnato, ai sensi della C.M. del 02/09/2002 n. 6, a rendere pubblici e in maniera tempestiva i dati sulle sperimentazioni cliniche consentendone di conseguenza il libero accesso agli sperimentatori;
- Lo sperimentatore, ai sensi del Regolamento del CER Umbria, può pubblicare e diffondere i risultati delle ricerche condotte, previa comunicazione allo Sponsor.

Si ricorda che lo studio potrà essere avviato solo dopo aver ricevuto l'autorizzazione all'attivazione da parte dell'Autorità Competente individuata ai sensi della normativa vigente.

COMITATO ETICO REGIONALE DELL' UMBRIA

Nominato con D.G.R. n. 35 del 20/01/2021

PRESENZE SEDUTA DEL 29/03/2023	FIRMA	IN ORARIO DI LAVORO	FUORI ORARIO DI LAVORO
Prof.ssa Becattini Cecilia - PRESIDENTE Clinico di area medica internistica – Università degli studi di Perugia			
Dr. Prontera Paolo – VICE-PRESIDENTE Esperto di genetica - Azienda Ospedaliera di Perugia			X
Dr. D'Arpino Alessandro - SEGRETARIO GENERALE Farmacista del servizio sanitario regionale - Azienda Ospedaliera di Perugia	A		
Dr. Bartolini Fausto Esperto in dispositivi medici – Azienda USL Umbria 2	A		
Dr. Bucaneve Giampaolo Clinico di area internistica con competenze in materia di Farmacologia Clinica – Centro Regionale di Farmacovigilanza	Presente on line		
Dr.ssa Caserta Claudia Clinico di area medica specialistica – Azienda Ospedaliera di Terni			X
Dr. Cochetti Giovanni Clinico di area medica chirurgica - Università degli studi di Perugia	Presente on line		
Dr. Farinelli Edoardo Specialista in pediatria - Azienda USL Umbria 1	Presente on line		
Dr. Gili Alessio Biostatistico - Università degli studi di Perugia			X
Dr. Mariotti Claudio Medico di medicina generale con competenze in scienze dell'alimentazione			
Prof.ssa Martelli Maria Paola Clinico di area medica specialistica - Università degli studi di Perugia	A		
Prof.ssa Morresi Assunta Esperto in bioetica - Università degli studi di Perugia	A		
Dr. Prestipino Marco Rappresentante del volontariato o dell'associazionismo di tutela dei pazienti	A		
Prof. Sidoni Angelo Esperto clinico di nuove procedure tecniche, diagnostiche e terapeutiche invasive o semi invasive - Università degli studi di Perugia			X
Dr. Tarducci Roberto Fisica sanitaria - Azienda Ospedaliera di Perugia	Presente on line		
Dr. ssa Verdelli Anna Maria Medico legale - Azienda Ospedaliera di Perugia	Presente on line		
Dr. Zucconi Marco Rappresentante dell'area delle professioni sanitarie			X
Dr. Arturo Pasqualucci Direttore Sanitario – Azienda Ospedaliera di Perugia	A		
Dr. Pietro Manzi Direttore Sanitario – Azienda Ospedaliera di Terni			
Dr. Lugi Sicilia Direttore Sanitario f.f. – Azienda USL Umbria 1	A		
Dr. Zampolini Mauro Delegato permanente Direttore Sanitario – Azienda USL Umbria 2	Presente on line		
Dr.ssa Rossi Mariangela Delegata dal Dirigente Servizio Regionale Umbria			