In Memory of Natale Cascinelli

MEETING CHAIRMAN

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Istituto Europeo di Oncologia,
Milano

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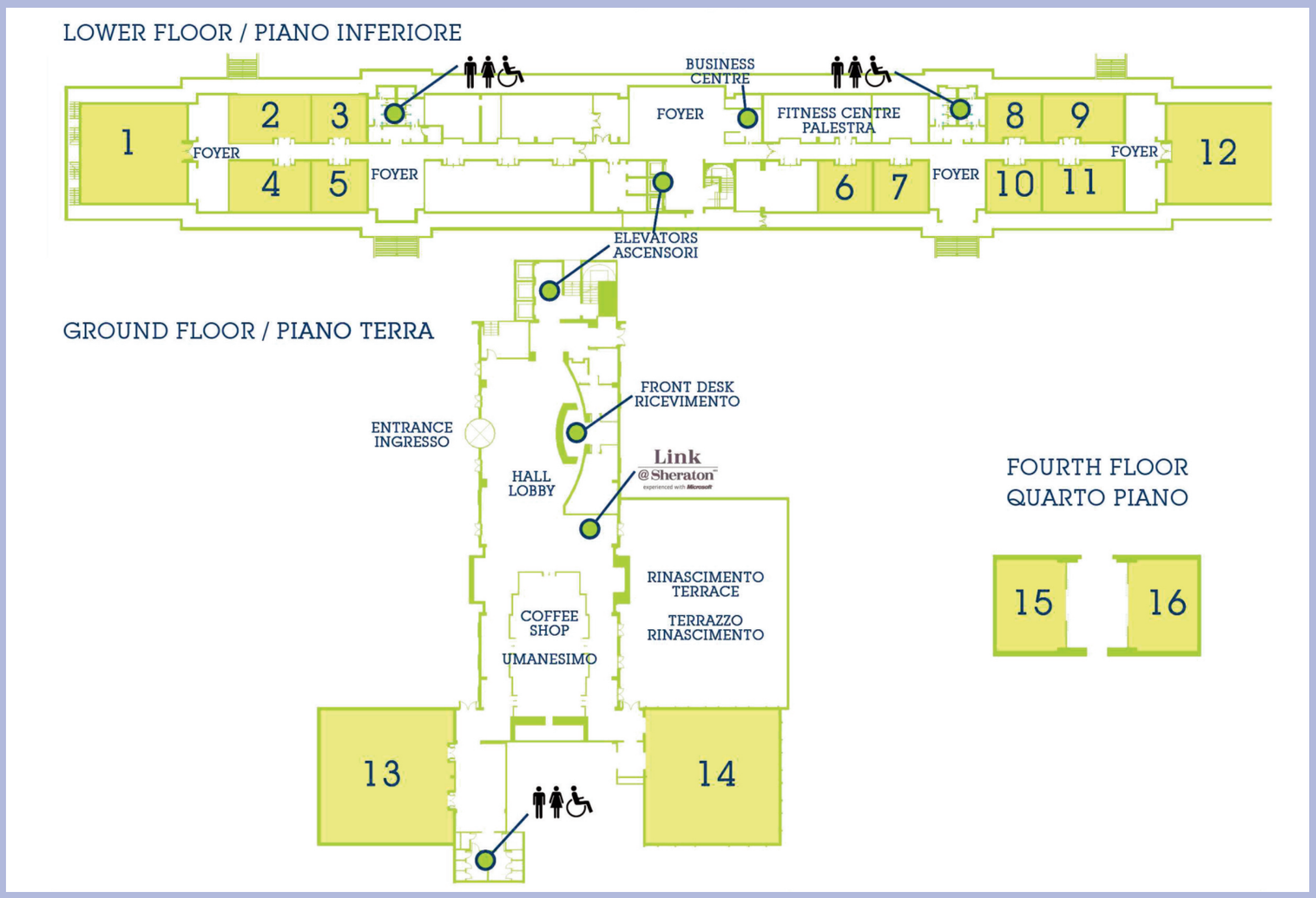

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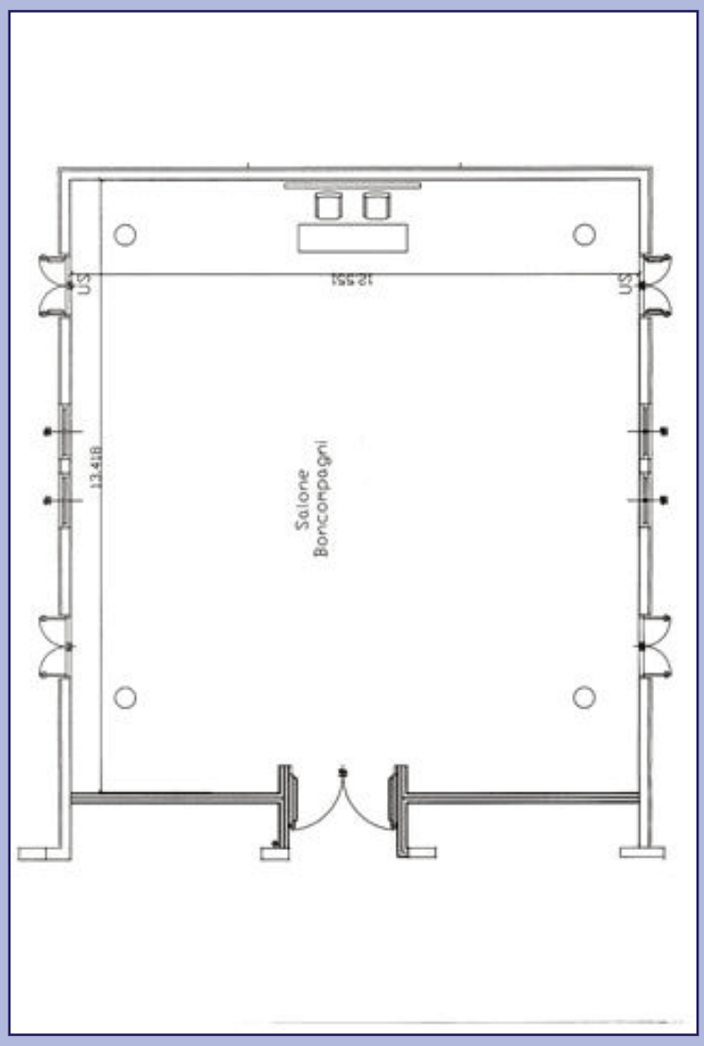
Salone
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CONTENT

Alessandro Testori

Istituto Europeo di Oncologia, Milano

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Francesco de Lorenzo

President European Cancer Patients Coalition (ECPC)

Carlo Riccardo Rossi

Istituto Oncologico Veneto Padova

WELCOME MESSAGE

Melanoma Independent board
SECOND MELANOMA MIB CONFERENCE 2014 October 27-28
on INNOVATION AND SUSTAINABILITY

The second edition of the Melanoma Independent Board will discuss two main aspects between the melanoma scientific issues which are actual and of new definition. Firstly the concept of innovation of the various developments of cure of this disease, of how the new single drugs and integrated therapeutic approaches available may in future develop in combination modalities and how we may improve the ability in selecting the best treatment proposals to obtain the highest chances to cure the specific disease entity of a single melanoma patient and secondly the concept of sustainability will discuss on organizational aspects with specific attention to the regulatory pathways, the budget applications, the interaction with payers and the point of view of patients not only in the situation of requiring the best available treatment when discovered, but also in terms of managing their lives once cured from a melanoma.

Innovation

The vast majority of research is conducted by pharma and from a pipeline of thousands of drugs, only few reach the market: this is a crucial aspect in the definition of the difficulty from one side to develop new drugs and explains why this kind of research is in the hands of big companies, while from the other side justifies only in part the increase in prices shown during the last 10 years by new drugs. The total pharmacological expenditure for oncological drugs is anyway a real minority of the global balance of sanitary costs in Italy, where a large amount of spending review can be obtained by rationalizing several inefficient costs like the those linked to the excessive number of little hospitals distributed in the national territory and the unexplainable difference of costs of similar devices in different Italian regions.

Molecular medicine is developing a concept of individualizing the best treatment to be offered to cure the cancer of a single person: it is more than clear that a single drug will not be effective on all patients affected by a specific disease and the most important task will be the selection of the drug to be offered to cure a single patient. Moreover it is becoming more and more clear that the molecular pathways involved in the development and progression of cancer cannot be controlled by a single drug, so the association of different compounds will be a strategic task for the next 10 years of cancer research. This aspect brings the discussion to a very delicate but fundamental aspect which is the necessity that different companies will have to play a common job and activate strategies of cooperation within specific collaborative clinical trials. The proposal to create cooperation within different companies on the target to accelerate the projectuality on new drugs and improve the quality on conduction of clinical trials is of great interest: “Transcelerate” has been proposed to reach ambitious results.

Immunology and molecular medicine will represent the future of cancer cure when we shall be able to predict the response and we shall make the investment behind a cure proposal really beneficial, making the treatment proposal to a patient unavoidable: if you are proposing a cure to a cancer patient with a probability of success as high as it is now the cure rate of an antibiotic towards a bacterial infection, no price limitations will ever be present, firstly because you select the patient to whom a certain therapy is most probable to be effective, secondly because the selection of the patients will limit the number of patients to whom a certain therapy will be offered. Targets of immune response and pharmacological interaction pathways of molecular medicine drugs are the milestones of cancer cure and require all our efforts to be efficiently discussed and finalized.

Sustainability

The organizational aspects are requiring a new methodology concerning the level of discussion and the rational to guide the decision making processes: new effective treatments are coming available to melanoma patients and we all agree that all new effective therapies should be offered to patients but on the opposite site the NHS budget has to be sustainable as it is not unlimited. This brings the discussion to a setting where different figures should be involved starting from medical experts, pharm company representatives, economists, regulatory agency representatives patients association representatives and media and communication experts; such a panel could be the best scenario to obtain an agreement on the selection of the targets of new therapies, but also on the identification of the characteristics of the centers where a certain treatment could be offered to patients with both the goal of efficacy but also efficiency in terms of costs control.

Patients with melanoma have a 85-90% probability to be cured from this disease. Are we sure that this aspect is well considered in a life time project concerning a melanoma patient? In reality there is a discrimination in various environments in which a cured melanoma patient may be involved every day and where instead this individual person is instead excluded as previously affected by a melanoma. What about if a melanoma patient wants to obtain a health insurance or a life insurance or wants to buy a house with a bank loan and he receives a refusal due to the melanoma history? We may cure biologically and clinically a melanoma patient, but our legislation permits to this person to be cured also from the juridical point of view?

Two general sessions

This meeting will discuss the topics within two main frameworks which appear very different only from a superficial analysis:

- Scientific issues
- Strategic issues

In the next future we shall not be able to offer everything to every patient, but we must be able to offer the best available therapies to the patients who may benefit from it.
Science and cancer care can no more improve without a discussion which involves different roles, and the target of this meeting will be to create a productive evaluation where strategic and scientific issues should be put together.
An important role has to be dedicated to the validation of diagnostic and therapeutic pathways with the identification of certified regional institutions where both the quality of care and the economical sustainability will be guaranteed. To reach this objective of auditing and survey the discussion needs to identify precise markers of quality through validated methods of cost-benefit evaluation.
This approach needs to be proposed by recognized groups (IMI, AIOM, SICO, SIAPEC etc.) and ultimately be approved by national and regional health authorities from whom this activity has been formally devoted.

The topics listed below represent the background of the discussion of this second melanoma independent board meeting, from which new topics will be proposed for future discussions and meetings.

FINAL PROGRAM AT A GLACE

OCTOBER 27th

8.00-9.30 Registration Sheraton Parco de' Medici building N° 2
First session 9:30 chair Alessandro Testori, Saverio Cinieri, Gordon Mcvie, Maria Teresa Baldini

09:30 "The Melanoma Independent Board as a model for clinical research: the mile stone trials from WHO Melanoma programme in memory of Natale Cascinelli". Vodafone EORTC Melanoma Group project to sensibilise the population on skin tumors early detection" ***Alessandro Testori***

10:00 "Welcome message from representative of health Ministry" ***Aldo Morrone***

10:20 "Welcome message from Regione Lombardia" ***Maria Teresa Baldin***

10:30 "Welcome message from Regione Lazio" ***Antonello Aurigemma***

10:40 "Welcome message Federlab Italia" ***Pierpaolo Cavallo***

10:50 "Melanoma socio-economic epidemiology" ***Sara Gandini***

11:10 "Ecancermedical science: a new way to manage a scientific journal" ***Gordon McVie***

11:15 "The role of ISS in supporting Italian clinical research projects" ***Enrico Proietti***

11:25 Welcome message from AIOM ***Saverio Cinieri***

11:35 "Sustainability of new drugs in a global vision of NHS costs" ***Maurizio de Cicco***

11:55 Comments ***Francesco de Lorenzo***

12:00 "Patients associations: the collaboration is on going" ***Francesco de Lorenzo***

12:20 "Sustainability of innovation in Medical Device Industrial offer" ***Claudio Viola***

12:30 Comments ***Eugenio Morsiani***

12:35 Discussion
13:20

13:20 **abstract oral presentation**
13:30 ***(chair Ruggero Ridolfi and Anna Maria Di Giacomo)***

13:30 **Lunch**

14:00 Second session chair Nicola Pimpinelli, Francesco De Lorenzo, Mario Mandalà, Michele Del Vecchio

14:00 "Adoptive immunotherapy: past, present and future"
Vincenzo Russo

14:15 Comments ***Anna Maria Di Giacomo***

14:20 "Communication with patients the goal of ethical journalism health"
Maria Emilia Bonaccorso

14:40 Comments ***Francesco de Lorenzo***

14:45 The point of view of insurance companies in front of oncological patients: when and how to approve a new contract
Giuseppe Gionta

15:00 Comments ***Mario Mandalà***

15:05 Discussion
15:40

15:40 Third session chair Armando Santoro, Francesco Cognetti

15:40 "Ipilimumab and PD-1: pipeline to clinical practice"
Cosimo Paga

16:00 "T-VEC: oncolytic immunotherapy platform for the tratment of melanoma"
Zsolt Szabo

16:10 "PD-1 and new drugs projects"
Loredana Orsini

16:20 "The management of new melanoma drugs in Italian hospitals:"

16:20 "Pharmacy Istituto Europeo di Oncologia Milano"
Costantino Jemos

16:30 "Innovation in melanoma: from BRAF to multiple targets"
Federico Pantellini

17:00 "Clinical research plans in melanoma"
Alessandra Aloe

17:10 "Clinical research plans in melanoma"
Eugenio Morsiani

17:20 "Planning Ipilimumab therapy in a single institution"
Ruggero Ridolfi

17:40 Comments ***Vanna Chiarion Sileni***

17:50 "Planning anti B-Raf and anti mek therapy after the end of theraputical use"
Massimo Guidoboni

18:05 Comments ***Michele Guida***

18:10 ***Evening lectures chair Alessandro Testori***

18:25 "The frontiers of National NHS should have been opened throughout Europe and patients able to choose the country where to be treated"
Marianna Cavazza

18.45 Discussion
19:10

20:30 ***"Transfer to Group dinner"***

FINAL PROGRAM AT A GLACE

OCTOBER 28th

8.15 forth session chair Vanna Chiarion Sileni, Michele Del Vecchio, Francesco Cognetti

08:15 Morning lecture. Support to cancer patients: the new frontier of patient empowemen
Claudio Lucchiari

08:30 Living from Melanoma: a direct experience
Hein Jambroers

08:40 Comments ***Ruggero Ridolfi***

08:45 "Quality of life projects at different stages of melanoma patients"
Paola Arnaboldi

08:55 Comments ***Mario Mandalà***

09:00 "Cancer Center certification program in Germany"
Claus Garbe

09:20 Comments ***Michele Maio***

09:30 "Cancer center certification in Italy"
Silvia Basso

09:40 "What to do when the hospital budget is spent with new patients to be treated? How to integrate "File F" and hospital budget?"
Michele Del Vecchio

10:05 Comments ***Francesco Cognetti***

10:10 Discussion
10:30

10:30 Where to be cured? What are the aspects that help patients to choose the hospital/doctor to cure his/her disease. 3 slides to introduce the discussion
Hein Jambroers

10:45 Fifth session
First Round table: 3 slides each presentation to introduce the topic and to start a general discussion
The word to patients
Clinical and juridical aspects towards a better quality of life
Chair: Massimo Giudoboni, Sergio Chimenti

10:45 "When can we consider a melanoma patient clinically cured?" 3 slides to introduce the discussion
Nicola Mozzillo

10:50 "Cured melanoma patients and everyday life experiences: are they considered from a juridical point of view normal persons?" 3 slides to introduce the discussion
Sara Vigna

10:55 "Insurance companies approach on cured oncological patients: can we help these people not to be discriminated?" 3 slides to introduce the discussion
Elisabetta Iannelli

11:00 "The role of patients associations to support a new mentality for bank loans and insurance approvals on cured oncological patients." 3 slides to introduce the discussion
Francesco de Lorenzo

11:05 "Clinical trials as an opportunity both for patients and Institutions: clinical trials management and financial resources. 3 slides to introduce the discussion"
Paolo Ascierto

11:10 "Risk management and quality of therapeutical outcomes. Is the concept of Excellency a self referral issue?" 3 slides to introduce the discussion
Carmen Verrengia

Round table lectures

11:15 Discussion
11:50

11:50 Sixth session
Second Round Table: 3 slides each presentation to introduce the topic and to start a general discussion
Scientific issues: the word to laboratory experts
Chair Ruggero Ridolfi, Massimo Guidoboni,
Massimo C.P. Barberis

11:50 "Prognostic biomarkers for target therapies in melanoma patients: the point of view of molecular pathology." 3 slides to introduce the discussion
Massimo C.P. Barberis

11:55 "Genetic profiling in melanoma: a step to identify patients susceptibility to target therapy." 3 slides to introduce the discussion
Giuseppe Palmieri

12:00 "B raf Inhibitors efficacy differencies." 3 slides to introduce the discussion
Mario Mandalà

12:05 "Identifying susceptibility to immunotherapy: the preclinical point of view." 3 slides to introduce the discussion
Massimo Guidoboni

12:10 "Identifying patients susceptibility to immunotherapy: the clinical point of view." 3 slides to introduce the discussion
Michele Maio

12:15 "Target therapy molecular identification: role of quantitative evaluation." 3 slides to introduce the discussion
Gerardo Botti

12:20 "Molecular evaluations for target therapy: different results with different methods?" 3 slides to introduce the discussion
Daniela Massi

12:25 "Mechanisms of resistance to target therapy." 3 slides to introduce the discussion
Paolo Ascierto

Round table lectures

12:35
13:20 ***Discussion on the following topics: combination therapies: immunotherapy plus target therapy and conventional therapies can be effective cocktails? Target therapy and immunotherapy: rational for toxicity when combined and sequential combination approaches***

13:20 ***Lunch***

14:10 ***Melanoma white paper (chair Sara Vigna, Francesco de Lorenzo, Alessandro Testori, Hein Jambroers, Paolo Ascierto)***

14:40 Seventh session
Technology supporting health practice
Chair Carlo Riccardo Rossi, Sergio Chimenti, Ignazio Stanganelli, Lorenzo Borgognoni, Corrado Caracò

14:40 "Performance and cost-effectiveness analysis of the "ReteMela" project (Veneto Region)".
Carlo Riccardo Rossi

14:50 Comments ***Corrado Caracò***

14:55 "Who cures melanoma patients? The cooperation of Regional authorities and hospital management in certification and validation of "melanoma cancer centers"
Michele Maio

15:05 Comments ***Claus Garbe***

15:10 Mole mapping in early detection programs of high risk patient
Alessandro Di Stefani

15:20 Comments ***Ignazio Stanganelli***

15:25 "Confocal microscopy: actual role and future developments"
Caterina Longo

15:35 Comments ***Giuseppe Spadola***

15:40 "Hyperthermic antiblastic perfuion in the treatment of limb melanoma: analysis of efficacy, cost and reinbursement."
Franco di Filippo

15:50 Comments ***Nicola Mozzillo***

16:00 "The experience of Istituto Tumori Toscano on melanoma programs"
Lorenzo Borgognoni

16:10 ***Closing lecture***
"Collaboration with patients associations: a must for the future."
Francesco de Lorenzo

16:20 Comments ***Michele Maio***

16:30 Discussion

Conclusions and Planning of next meeting (Rome November 09-10, 2015)
Alessandro Testori

Roma
27th-28th October 2014

AGENDA

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12.00 "Patients associations: the collaboration is ongoing"
Francesco de Lorenzo
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Claudio Viola
12.30 comments
Eugenio Morsiani
12.35-13.20 discussion

13.20-13.30 abstract oral presentation (chair Ruggero Ridolfi and Anna Maria Di Giacomo)

"The PI3K/mTOR inhibitor GSK-2126458 and the NF-kB inhibitor NEMO-binding domain peptide inhibit invasiveness of melanoma cells with acquired resistance to dabrafenib"
Simona Caporali

"The terapeutical effect of timing of Snb"
Cristina Fortes

Session 1 (preparation of the report by Sara Gandini and Anna Maria Di Giacomo)

Second session chair Nicola Pimpinelli, Francesco de Lorenzo, Mario Mandalà, Michele Del Vecchio

14.00 "Adoptive immuno therapy: past, present and future"
Vincenzo Russo
14.15 Comments
Anna Maria Di Giacomo
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Maria Emilia Bonaccorso
14.40 Comments
Francesco de Lorenzo
14.45 "The point of view of insurance companies in front of oncological patients: when and how to approve a new contract"
Giuseppe Gionta
15.00 Comments
Mario Mandalà

15.05-15.40 discussion

Session 2 (preparation of the report by Giuseppe Palmieri)

15.40 ***Third session chair Andrea Messori, Armando Santoro, Francesco Cognetti***
15.40 "Ipilimumab and PD-1: pipeline to clinical practice"
Cosimo Paga
16.00 "T-VEC: oncolytic immunotherapy platform for the tratment of melanoma"
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18.05 Comments
Michele Guida
18.10 ***Evening lectures chair, Alessandro Testori***

18.25 "The frontiers of National NHS should have been opened throughout Europe and patients able to choose the country where to be treated" ***Marianna Cavazza***

18.45-19.10 discussion

Session 3 (preparation of the report by Vanna Chiarion Sileni and Michele Guida)

20.30 Transfer to Group dinner

October 28th

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08.15 Morning lecture. Support to cancer patients:
"The new frontier of patient empowemen"
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Michele Del Vecchio

10.05 Comments
Francesco Cognetti

10.10-10.30 discussion

10.30 "Where to be cured? What are the aspects that help patients to choose the hospital/doctor to cure his/her disease."
3 slides to introduce the discussion
Hein Jambroers

Session 4 (preparation of the report by Mario Madalà and Paola Arnaboldi)

10.45 Fifth session

First Round table: 3 slides each presentation to introduce the topic and to start a general discussion

The word to patients

Clinical and juridical aspects towards a better quality of life
Chair: Massimo Giudoboni, Sergio Chimenti

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3 slides to introduce the discussion
Nicola Mozzillo

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11.10 "Risk management and quality of therapeutical outcomes. Is the concept of Excellency a self referral issue?"
3 slides to introduce the discussion
Carmen Verrengia

Round table lectures

11.15-11.50 discussion

Session 5 (preparation of the report by Sara Vigna and Corrado Caracò)

Sixth session

Second Round Table: 3 slides each presentation to introduce the topic and to start a general discussion

Scientific issues: the word to laboratory experts

11.50 Chair Ruggero Ridolfi, Massimo Guidoboni, Massimo C.P. Barberis, Armando Santoro

11.50 "Prognostic biomarkers for target therapies in melanoma patients: the point of view of molecular pathology."
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Daniela Massi

12.25 2Mechanisms of resistance to target therapy." 3 slides to introduce the discussion
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Round table lecture

12.35-13.20 **Discussion on the following topics:**
"Combination therapies: immunotherapy plus target therapy and conventional therapies can be effective cocktails?"
"Target therapy and immunotherapy: rational for toxicity when combined and sequential combination approaches"

Session 6 (preparation of the report by Massimo C.P. Barberis and Massimo Guidoboni)

13.20 Lunch

14:10 ***Melanoma white paper (chair Sara Vigna, Francesco de Lorenzo, Alessandro Testori, Hein Jambroers, Paolo Ascierto)***

14.40 Seventh session

Technology supporting health practice

Chair Carlo Riccardo Rossi, Sergio Chimenti, Ignazio Stanganelli, Torello Lotti, Lorenzo Borgognoni, Gordon Mcvie

14:40 "Performance and cost-effectiveness analysis of the "ReteMela" project (Veneto Region)".
Carlo Riccardo Rossi

14.50 Comments
Corrado Caracò

14.55 "Who cures melanoma patients? The cooperation of Regional authorities and hospital management in certification and validation of "melanoma cancer centers"
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Francesco de Lorenzo
16.20 Comments
Michele Maio
16.30 Discussion

Conclusions and Planning of next meeting
(Rome November 09-10, 2015)
Alessandro Testori

Adjourn

At the end of each session the selected rapporteurs will record a summary of the presentations:

Session 1
(preparation of the report by Sara Gandini and Anna Maria Di Giacomo)

Session 2
(preparation of the report by Giuseppe Palmieri)

Session 3
(preparation of the report by Vanna Chiarion Sileni and Michele Guida)

Session 4
(preparation of the report by Mario Mandalà and Paola Arnaboldi)

Session 5
(preparation of the report by Sara Vigna and Corrado Carracò)

Session 6
(preparation of the report by Massimo C.P. Barberis and Massimo Guidoboni)

Session 7
(preparation of the report by Giuseppe Spadola and Ignazio Stanganelli)

Reports from the seven sessions will focus specifically on:

- Italian Regional authorities definition of the authorisational pathway of each treatment by stage and by dedicated institutional contracts: DRG recognized to specific Institutions.
- Pharmacological industrial research and cooperation with scientific groups
- Patients associations: national and European perspectives
- Interaction between patients, doctors, politicians (payers) and regulatory agencies
- Interaction of Big Pharma and academic research towards:
- Activation of collaborative "spontaneous studies"
- Guide lines of research in molecular therapies
- Consolidation of immunotherapy in melanoma
- The management of the contractual "privilege" of treating melanoma patients
- Clinical & diagnostic and therapeutical pathways
- Juridical situation of cured melanoma patients
- Long term side effects of oncological therapies on cured patients
- COLLABORATION WITH PATIENTS ADVOCACY GROUPS: specifically the discussion will be oriented towards the creation of an active collaboration with the federazione italiana delle associazioni di volontariato in oncologia (FAVO) and associazione italiana malati di cancro parenti e amici (AIMaC) and a link at an European level with associations of patients and relatives like European Cancer Patients Coalition (ECPC, prof De Lorenzo), the European Alliance for Personalised Medicine (EAPM) and with the scientific societies like ESMO.
- First step should be to involve all Italian melanoma associations with the goal of creating a consortium of melanoma patient associations which may bring to the coexistence of the single identities but obtaining the de finition of common strategies within the FAVO.

The 7 reports will be the basis for the preparation of a publication on the topics of the meeting.

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Vice Presidente Commissione
"Politiche Sociali e Sanità"
Consiglio Regionale del Lazio

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Federlab Italia

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PROF. FRANCESCO DE LORENZO
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GENERAL INFORMATION

Congress Venue

Sheraton 2 Parco De' Medici
Viale Salvatore Rebecchini. 39 – 00148 Roma Italia
T. +39 06 65287105

Congress Date

October 27th – 28th, 2014

Registration and Information Desk

The registration desk is situated at the ground floor of the Sheraton 2 Parco De' Medici

Hotel Accommodation

The DEA EVENTI SRL will make a reservation for the speakers at the Sheraton 2 Parco De' Medici ,the same
place where the convention is held.
DEA EVENTI SRL
Piazza Cavallotti, 2 – 00040 Castel Gandolfo (RM)
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E – Mail: ladeaeventi@gmail.com

CME Credits

Speakers partecipants at the Conference will be able to request the CME Credits

Registration Fee

200 € (inclusive of social events)

Abstract

Abstract insertion inside the congress website. The speakers are invited to use

The site www.mib-roma.com to enter their abstract.

Inside the site will find the specific instruction about the question.

Deadline Abstract Submission: October 5th

Insurance

The Organizer does not accept liability for individual medical, travel or personal insurance and partecipants are strongly advised to make their own arrangements in respect to health and travel insurance.

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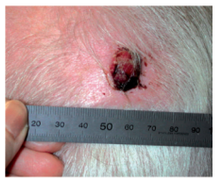
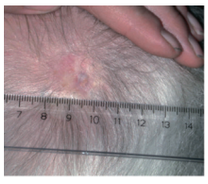


10 weeks after electrochemotherapy



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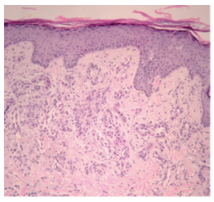
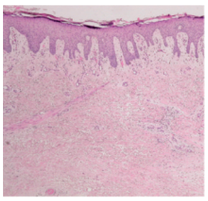
Before electrochemotherapy



60 days after electrochemotherapy



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dead line for abstract selection is 21th September; abstract should be 600 words max, one single A4 format,
inclusive of figures, 12 character dimension, times new roman character type.

Notes of the Speaker

From each session, 2 rapporteurs will make a summary and record an inteview
for a publication of the meeting highlights on Ecancermedicalscience.

Notes of the Participant

Each accepted abstract will permit a free registration for one person to participate to the meeting; no hotel or travel costs will be covered by the organizers for abstracts acceptance. Registration fee 200 € (inclusive of social events.

Type of Submit

☐ Speaker ☐ Participate

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.....

Family Name

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Qualification

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Type of Activity

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