

**In Memory of Natale Cascinelli**

Melanoma Independent board

**THIRD MELANOMA MIB CONFERENCE  
INNOVATION AND SUSTAINABILITY**

Rome - 9 November 2015



**MEETING CHAIRMAN**

**Alessandro Testori**

Istituto Europeo di Oncologia, Milano

**MEETING BOARD**

**Paola Queirolo**

Ospedale San Martino Genova

**Nicola Mozzillo**

Istituto Tumori di Napoli

**Pascale Francesco de Lorenzo**

President European cancer patients coalition (ECPC)

**Carlo Riccardo Rossi**

Istituto oncologico Veneto Padova



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**Carlo Riccardo Rossi** – Istituto oncologico Veneto Padova

Communication and Organizing Secretary:

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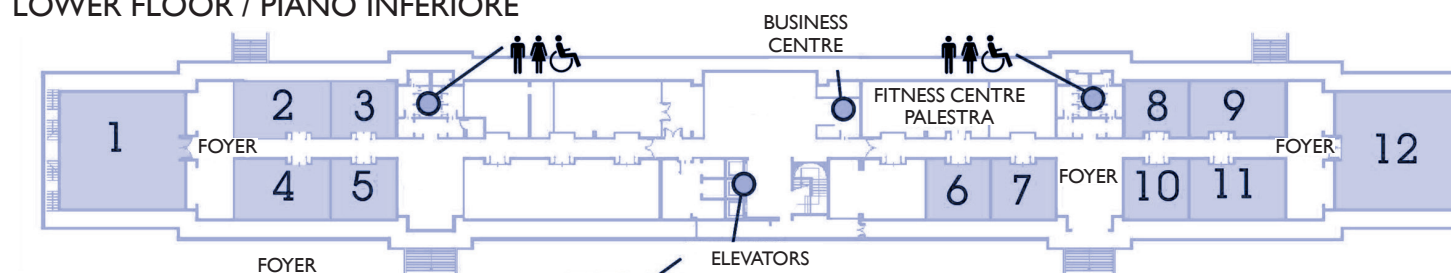
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### LOWER FLOOR / PIANO INFERIORE



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### FOURTH FLOOR QUARTO PIANO

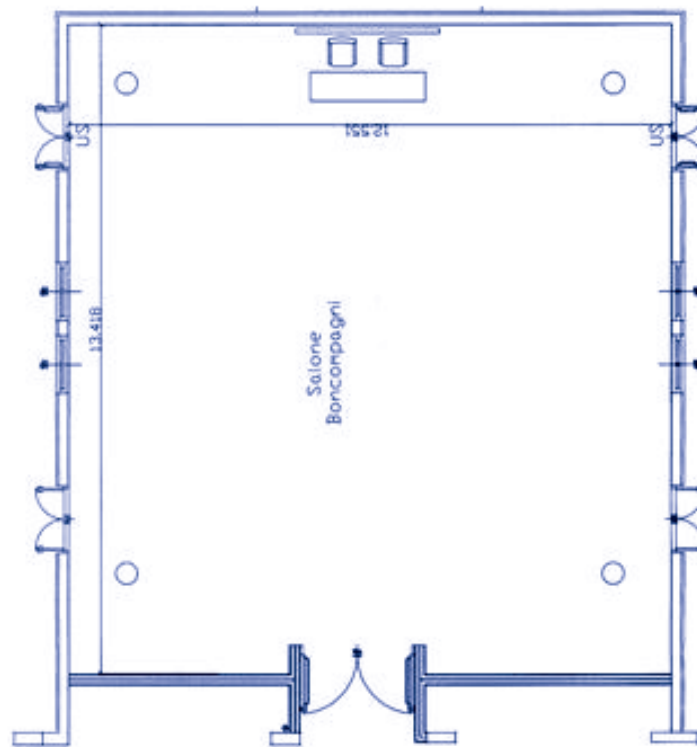


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## SALONE BONCOMPAGNI





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## WELCOME MESSAGE

Melanoma Independent board

### THIRD MELANOMA MIB CONFERENCE 9

November 2015

#### INNOVATION AND SUSTAINABILITY

**A**fter the success of the previous two meetings, the third edition of the Melanoma Independent Board will discuss three main aspects between the melanoma issues which are actual and under new and continuous development. Firstly the concept of innovation of the various proposals 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; consequently, together with the requisite of innovation, the concept of sustainability will focus 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. Second topic will be the preparation of the national diagnostic and therapeutical pathways to be proposed to our melanoma patients; this project will be characterized by inviting a selected network of melanoma experts in the different fields and involving representatives from the most important scientific societies directly or indirectly dedicated to diagnosis and cure of melanoma patients. The third topic will be dedicated to the newborn associazione italiana malati di melanoma (AIMAME) that will organize the first general assembly and plan the priority activities for next year.

#### 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 and the combination of the drugs to be offered to cure a single patient. In-fact 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.

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 high probability of success, 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.

## **Discrimination**

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 his 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?

## **Diagnostic and therapeutical pathways**

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 Italian scientific societies (IMI, AIOM, SICO, SIAPEC etc.) and ultimately be approved by national and regional health authorities from whom this activity has been formally devoted.

## FINAL PROGRAM AT A GLANCE

8.30	Registration Sheraton Parco de' Medici building N° 2	
10.00	<i>The Melanoma Independent Board as a model for integrating clinical research and the society</i> - Alessandro Testori	
10.15	<i>Melanoma socio-economic epidemiology</i> - Sara Gandini	
10.30	<i>Cancer Center certification program in Germany: strengths and weaknesses</i> Claus Garbe	
10.45	<i>Welcome messages from representatives of Health Ministry</i> - Aldo Morrone	
10.55	<i>The role of ISS in supporting Italian clinical research projects</i> - Enrico Proietti	
11.05	Welcome messages from Italian Regions representatives <i>Regione Lombardia</i> - Maria Teresa Baldini <i>Regione Lazio</i>	
11.15	<i>Innovation and sustainability from the point of view of an economist</i> Americo Cicchetti	
11.45	<i>The frontiers of National NHS should have been opened throughout Europe and patients able to choose the country where to be treated</i> Alessandro Testori	
12.00	<i>Comments/ Discussion on the developed subjects</i> - Carmine Pinto	
12.10	<i>E-cancer medical science: a new way to manage a scientific journal</i> Gordon McVie	
12.20	<i>Conclusions</i>	

12.20	<i>BMS melanoma projects</i> Maria Almerica Gaudino	
12.30	<i>T-VEC: oncolytic immunotherapy platform for the treatment of melanoma</i> Emerenziana Marturano	
12.40	<i>Clinical research plans in melanoma</i> Eugenio Morsiani	
12.50	<i>Insurance companies approach on cured oncological patients: can we help these people not to be discriminated?</i> Elisabetta Iannelli	
13.00	<i>How the point of view on insurance companies is moving on oncological patients</i> Giuseppe Gionta	
13.10	<i>Roche: Innovation in melanoma: from BRAF to multiple targets</i>	
13.20	<i>Research plans from Fidia Pharmaceuticals</i> Barbara Bellei	
13.30	<i>lunch break</i>	
14.00	<i>PV-10: a new opportunity in Europe from Provectus</i> - Eric Wachter	
14.10	<i>Electrochemotherapy: Sustainability of innovation in Medical Device Industrial offer</i> Claudio Viola	
14.20	<i>PD-1, PD-L1 and IFN with new combinations</i> Loredana Orsini	
14.30	<i>Sustainability of new drugs in a global vision of NHS costs</i> - Massimo Visentin	
14.40	Alessandro Testori/Ignazio Stanganelli <ul style="list-style-type: none"> <li>• Dermatologic area</li> <li>• Management of pigmented lesions</li> <li>• Dermatologic and pathologic areas</li> <li>• From clinical diagnosis to histological confirmation of melanoma/nevi</li> <li>• Global network</li> <li>• Management of atypical tumoral melanocytic lesions</li> </ul>	

- Management of melanocytic lesions presenting from 50% to 100% regression

#### 15.00 Alessandro Testori/Ignazio Stanganelli

- Dermatologic and surgical area
- Stages I & II
- Instrumental preoperative staging
- Laboratory tests
- Molecular mutations and receptorial analysis therapy oriented
- Therapeutical indications on the basis of each T parameter: Tis, T 0-1 mm, T 1.1-2 mm, T 2.1-4 mm, T > 4 mm, +/- ulceration and mitosis or microsatellites
- Surgery
- Adjuvant therapy
- Neoadjuvant approaches for locally advanced primaries
- Surgical indications for primaries on extremities or face

#### 15.30 Alessandro Testori/Ignazio Stanganelli

- Surgical and oncological areas
- Stage III
- N+ any
- N- with in transit metastases (or satellites)
- N+ any with in transit metastases (or satellites)
- Instrumental preoperative staging
- Laboratory tests
- Molecular mutations and receptorial analysis therapy oriented Surgery
- Adjuvant therapy
- Locoregional /intralesional treatments

#### 16.00 Alessandro Testori/Ignazio Stanganelli

- Surgical and oncological areas
- Stage IV
- M1a, M1b, M1c
- Instrumental staging
- Laboratory tests
- Molecular mutations and receptorial analysis therapy oriented
- Surgery
- Medical therapies
- Radiotherapy
- Locoregional/Intralesional treatments

- 16.30 Alessandro Testori/Ignazio Stanganelli
- *Dermatologic, surgical and oncological areas*
  - *Follow up at any stages*
  - *Rehabilitation and management of long term complications*

17.00 *Introduction and presentation of the Assembly agenda*  
Sara Vigna

*Membership approval, finances, approval of the scientific committee members and chairman*

*Primary goals to be reached by the association, AIMAME projects*

Sara Vigna

18.30 *Discussion and Conclusion*  
Alessandro Testori

19.00 *Learning Test and ECM Educational Activity Test*

## AGENDA

### Roma 9 November 2015

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

8.30-10.00 Registration Sheraton Parco de' Medici building N° 2

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#### **First session 10.00 – 11.30** **chair Alessandro Testori**

#### **Introduction (epidemiology and numbers, the authorities)**

- |       |  |
|-------|--|
| 10.00 | “The Melanoma Independent Board as a model for integrating clinical research and the society”<br><b>Alessandro Testori</b>   |
| 10.15 | “Melanoma socio-economic epidemiology”<br><b>Saverio Caini</b>   |
| 10.30 | “Cancer Center certification program in Germany: strengths and weaknesses”<br><b>Claus Garbe</b>   |
| 10.45 | “Welcome messages from representatives of Regione Lazio”<br><b>Antonio Aurigemma</b>   |
| 10.55 | “The role of ISS in supporting Italian clinical research projects”<br><b>Enrico Proietti</b>   |
| 11.05 | Welcome messages from Italian Regions representatives<br>Regione Lombardia - <b>Maria Teresa Baldini</b><br>Regione Lazio  |
| 11.15 | “Innovation and sustainability from the point of view of an economist”<br><b>Americo Cicchetti</b>   |
| 11.45 | “The frontiers of National NHS should have been opened throughout Europe and patients able to choose the country where to be treated”<br><b>Alessandro Testori</b> |
| 12.00 | “Comments/ Discussion on the developed subjects”<br><b>Del Vecchio Michele</b>   |
| 12.10 | “E-cancer medical science: a new way to manage a scientific journal”<br><b>Gordon McVie</b>  |
| 12.20 | Conclusions<br><br><b>end of first session</b>   |

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## MEETINGS NOT PART OF THE ECM EDUCATIONAL ACTIVITY

### Optional and not included in the ECM Educational Program

- 12.20 “BMS melanoma projects”  
**Maria Almerica Gaudino**
- 12.30 “T-VEC: oncolytic immunotherapy platform for the treatment of melanoma”  
**Emerenziana Marturano**
- 12.40 “Clinical research plans in melanoma”  
**Eugenio Morsiani**
- 12.50 “Insurance companies approach on cured oncological patients: can we help these people not to be discriminated?”  
**Elisabetta Iannelli**
- 13.00 “How the point of view on insurance companies is moving on oncological patients”  
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**Barbara Bellei**
- 13.30 lunch break
- 14.00 “PV-10: a new opportunity in Europe from Provectus”  
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- 14.10 “Electrochemotherapy: Sustainability of innovation in Medical Device Industrial offer”  
**Claudio Viola**
- 14.20 “PD-I, PD-LI and IFN with new combinations”  
**Loredana Orsini**
- 14.30 “Sustainability of new drugs in a global vision of NHS costs”  
**Massimo Visentin**



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## **Second session 14.30-16.30**

**Chairmen Ignazio Stanganelli, Alessandro Testori**

### **Italian diagnostic and therapeutic path of melanoma: panel discussion**

Ignazio Stanganelli; Giovanni Pellacani ; Giuseppe Spadola; Carlo Riccardo Rossi; Nicola Mozzillo; Daniela Massi; Massimo Barberis; Paolo Ascierto; Michele Maio; Sara Vigna (presidente AIMAME, associazione italiana malati melanoma); Francesco De Lorenzo (presidente FAVO e ECPC) dott. Gian Marco Tomassini delegato ADOI; dr Domenico Piccolo Presidente e delegato AIDA; Dott Alessandro Di Stefani presidente e delegato AIDNID; dr. Pierluigi Zanco delegato AINM; Alessandro Minisini e Virginia Ferraresi delegati AIOM; Andrea Riccardo Filippi delegato AIRO; dr Marco Simonacci Coordinatore e delegato GIPME; Giuseppe Palmieri delegato IMI; Anna Maria di Giacomo delegata NIBIT; Antonino Di Pietro delegato ISPLAD; Claudio Clemente, Gerardo Botti, Stefania Staibano delegati SIAPEC; Dr. Ettore Capoluongo delegato SIBIOC; Achille Lucio Gaspari delegato SICO; Corrado Caracò delegato SICO; Corrado Caracò delegato SICO; Maria Giuseppina Onesti delegato SICPRE; Dott. Fabrizio Fantini e Dott. Antonio Ascari Raccagni delegati SIDCO; Ketty Peris e Giuseppe Argenziano delegati SIDEMAST; Franco di Filippo Responsabile Chirurgia Generale e della Mammella Istituto Nazionale Tumori Regina Elena IRCCS – Roma; Dott. Nicola Solari Delegato SIC; Dr.ssa Giovanna Pescatore della Direzione Tecnico Scientifica di Farindustria; Dott.ssa Paola Ghorzo, Dott. Andrea Anichini e Dott.ssa Maria Pizzichetta delegati della IMI.

#### **14.40 Alessandro Testori/Ignazio Stanganelli**

- Dermatologic area
- Management of pigmented lesions
- Dermatologic and pathologic areas
- From clinical diagnosis to histological confirmation of melanoma/nevi
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**16.30 Alessandro Testori/Ignazio Stanganelli**

- Dermatologic, surgical and oncological areas
- Follow up at any stages
- Rehabilitation and management of long term complications

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**Third Session 17.00-19.00**

**Chairmen Sara Vigna, Francesco de Lorenzo, Psico - Oncologo**

**General assembly of the associazione italiana malati di melanoma (AIMAME)**

**17.00 Introduction and presentation of the Assembly agenda**

**Sara Vigna**

Membership approval, finances, approval of the scientific committee members and chairman  
Primary goals to be reached by the association, AIMAME projects

**Sara Vigna**

**18.30 Discussion and Conclusion**

**Alessandro Testori**

**19.00 Learning Test and ECM Educational Activity Test**

## **Adjourn**

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

## **MEETING CHAIRMAN**

Alessandro Testori

Istituto Europeo di Oncologia, Milano

## **MEETING BOARD**

Nicola Mozzillo

Istituto Tumori di Napoli Pascale

Francesco de Lorenzo

President of the European Cancer Patients Coalition (ECPC)

Carlo Riccardo Rossi

Istituto oncologico Veneto Padova

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Università Tor Vergata, Roma

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Istituto Europeo di Oncologia, Milano

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Responsabile Unità di Genetica dei Tumori  
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**Proff.ssa KETTY PERIS**

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Professore di Chirurgia Dermatologica,  
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**Dr. CARMINE PINTO**

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**Avv. SARA VIGNA**

Libera Professione

**Dr. LUIGI ZANCO**

Az. ULSS 6, Vicenza

## SPECIFIC ORGANIZATIONAL ASPECTS

### **Congress Venue**

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

### **Congress Date**

November 9th , 2015

### **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)

Tel. 06. 9360565 – Fax 06. 93590149

Cell. 340. 1835524

Email: ladeaeventi@gmail.com

### **CME Credits**

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

### **Invited Faculties**

Each invited speaker is kindly requested to send an abstract of the presentation by October 16th

### **Participants:**

Registration fee: € 200,00

### **Abstracts Submission:**

Abstracts will be submitted by October 16th; abstracts should be of maximum 600 words, on 1 (one) A4 Format (inclusive of figures), character used will be Times New Roman, dimension 12.

Accepted abstracts will allow a free registration for one person only; no hotel or travel costs will be covered by the organizers of the event.

Two delegates per session will write a summary per each session; summaries will be published on the e-cancermedicalscience (ecancer.org) of the European Institute of Oncology.

### **Insurance**

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

**Passaport and Visa**

For most nationalities visas are not required for entering Italy. For further information about visa and passport please contact the Italy embassy in your country.

## MAIN SPONSOR







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**Dea Eventi Srl**

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