

# **Immuno-oncology: a policy action framework**

19 November, 2014 - Brussels

## **The role of immuno-oncology in the future of cancer treatment**

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**SIENA, ITALY**

# Evolution of cancer immunotherapy

**118  
years**

1893

**William Coley's toxin induces tumour regression in some patients<sup>1</sup>**

1909

**Paul Ehrlich predicts immune system represses tumour growth<sup>1</sup>**

1950s

**Frank Burnet proposes acquired immunological tolerance**

1960s

**and tumour immunosurveillance theories<sup>1</sup>**

1985

**Administration of IL-2 results in regression of tumours<sup>2</sup>**

1991

**Molecular characterisation of first human cancer antigen<sup>3</sup>**

2011

**Immunotherapies shown to improve overall survival in patients with metastatic melanoma and hormone-resistant prostate cancer<sup>4,5</sup>**

1. Parish C. Immunol Cell Biol 2003;81:106–13
2. Rosenberg SA, et al. N Engl J Med 1985;313:1485–1492
3. van der Bruggen P, et al. Science 1991;254:1643–1647
4. Hodi FS, et al. N Engl J Med 2010;363:711–723
5. Kantoff PW, et al. N Engl J Med 2010;363:411–422

# Breakthrough of the Year 2013



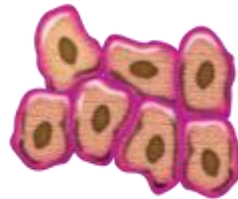
**CANCER**  
IMMUNOTHERAPY

*Science* 2013

# Cancer-Cell Directed vs Immune-System Directed Cancer Treatment: a Matter of Time



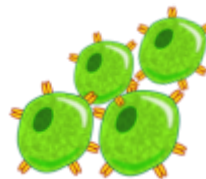
**Chemotherapy/  
Target Therapy**



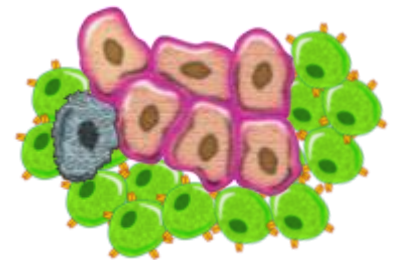
**Tumor Cell  
Destruction**



**Immunotherapy**

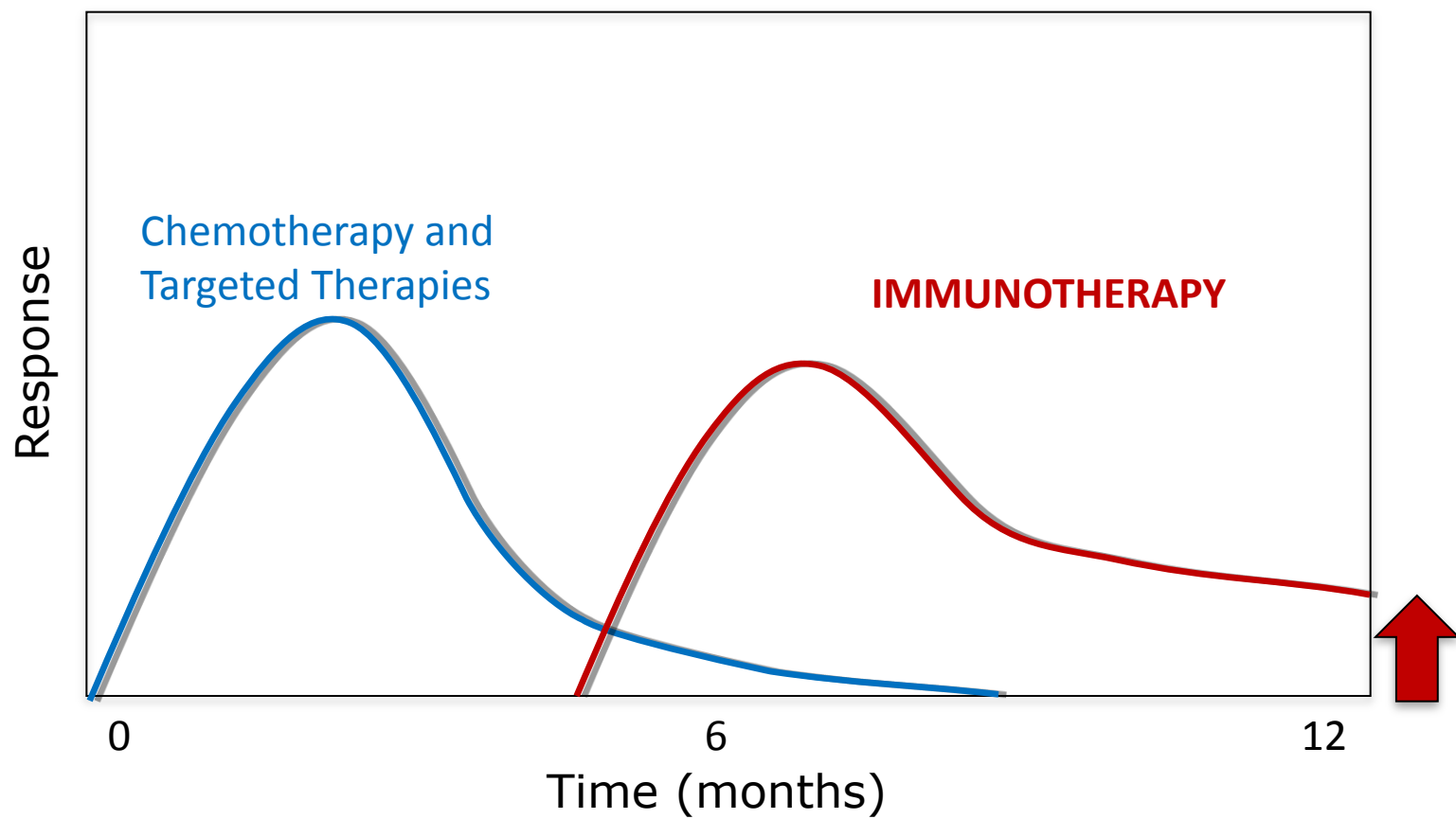


**Immune System  
Activation**



**Tumor Cell Destruction**

# Chemotherapy/Targeted Agents and Immuno-therapy Differ in Action and Outcome

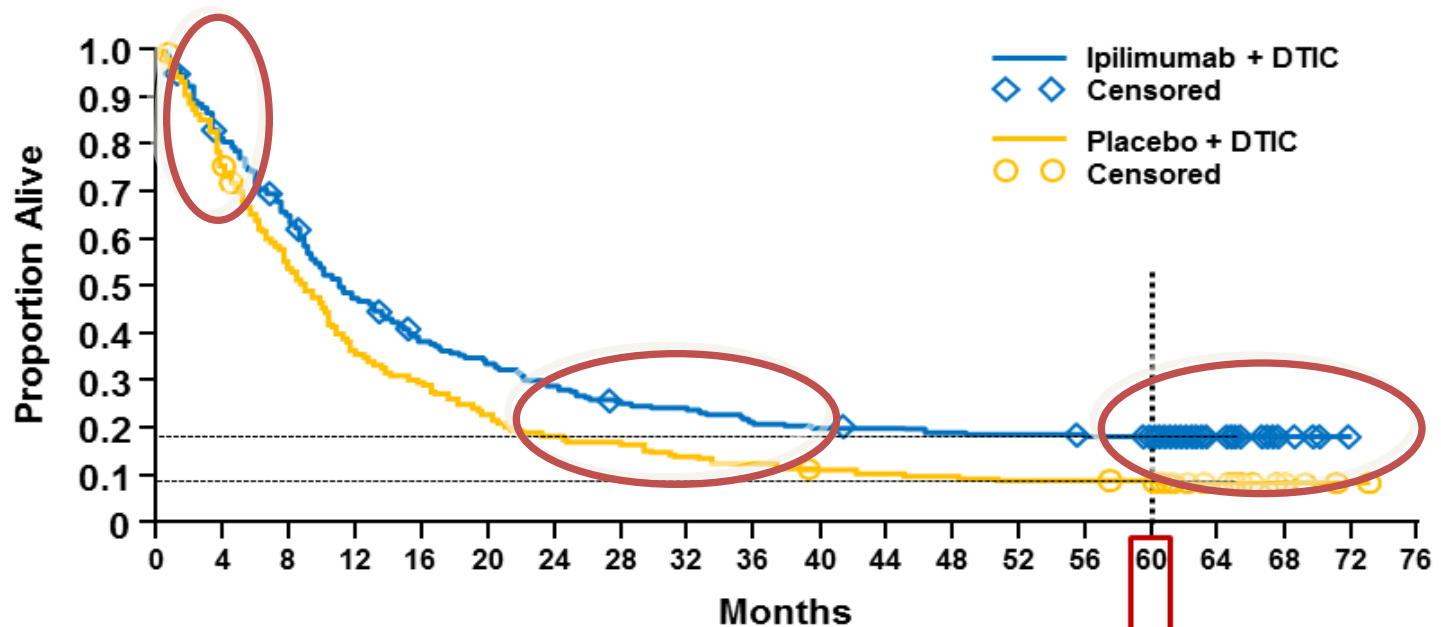


# Melanoma as a tool for cancer research

- ✓ **Tissue samples readily accessible**
- ✓ **Adaptable to tissue culture**
- ✓ **Amenable to testing of novel therapies**



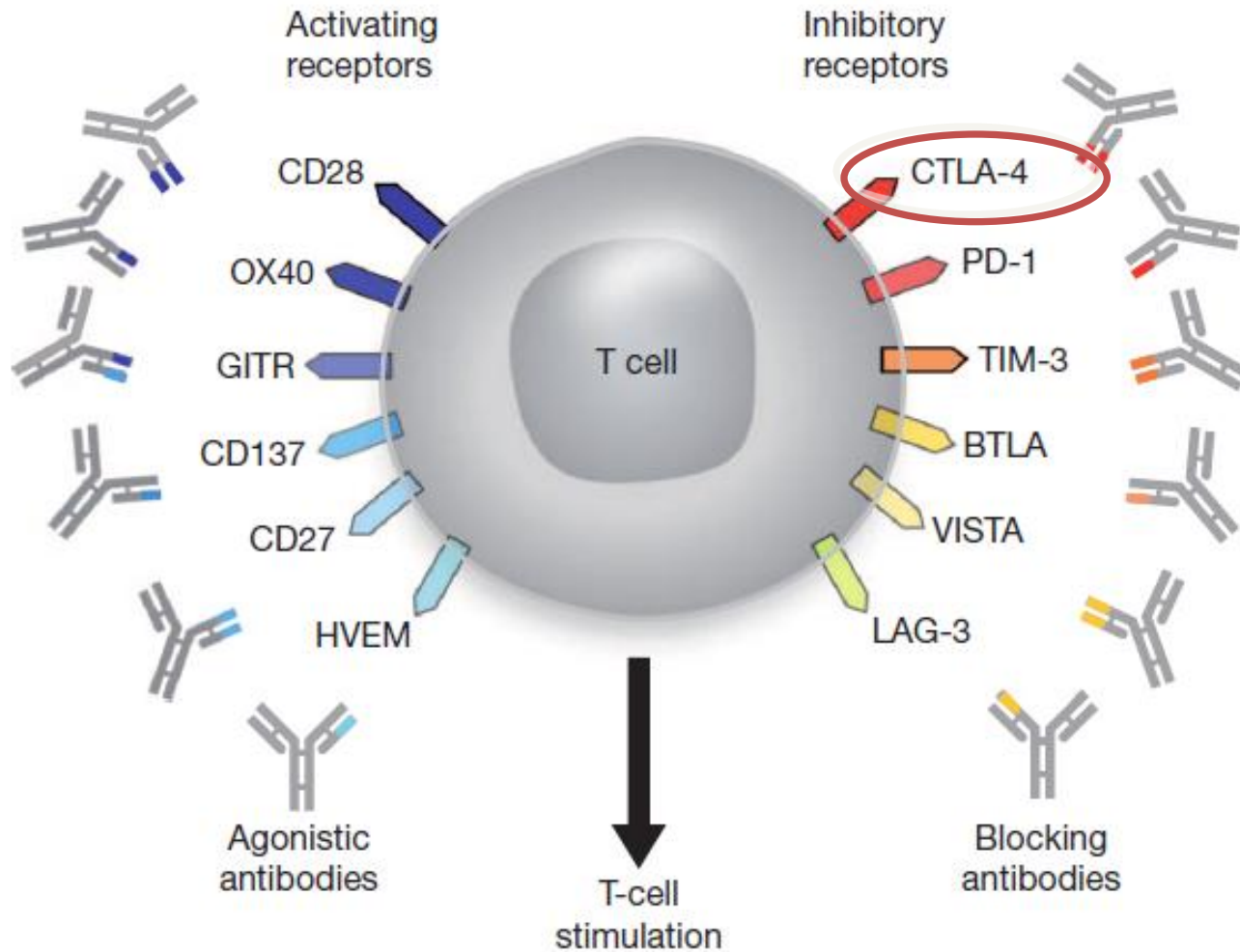
# Kaplan-Meier Plot of Overall Survival BMS CA184024



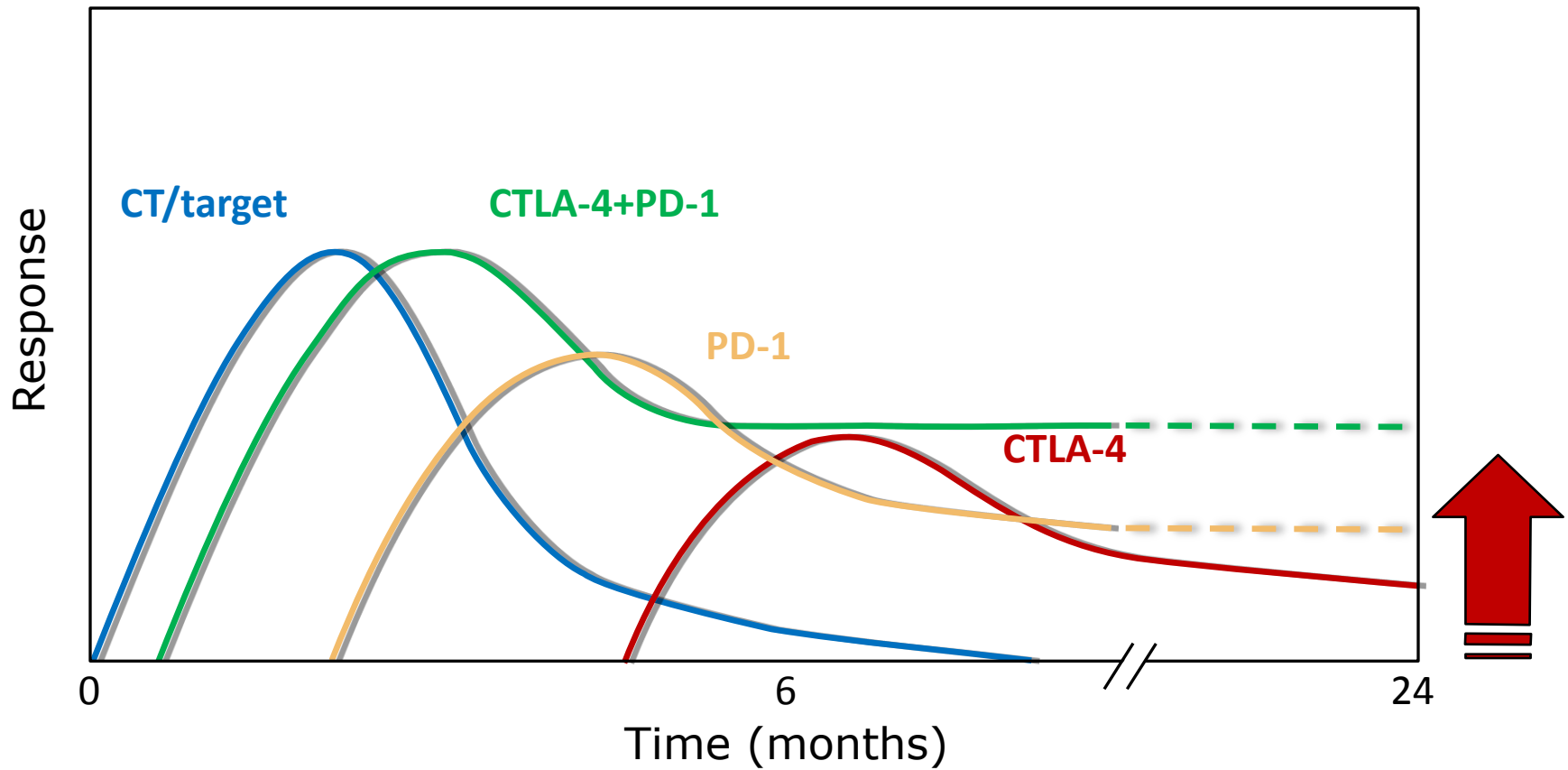
## Patients at Risk

Ipilimumab + DTIC	250	200	159	116	92	80	69	60	57	50	47	46	44	43	42	40	17	6	0	0
Placebo + DTIC	252	192	136	90	73	56	44	42	34	30	26	24	23	21	21	20	9	4	1	0

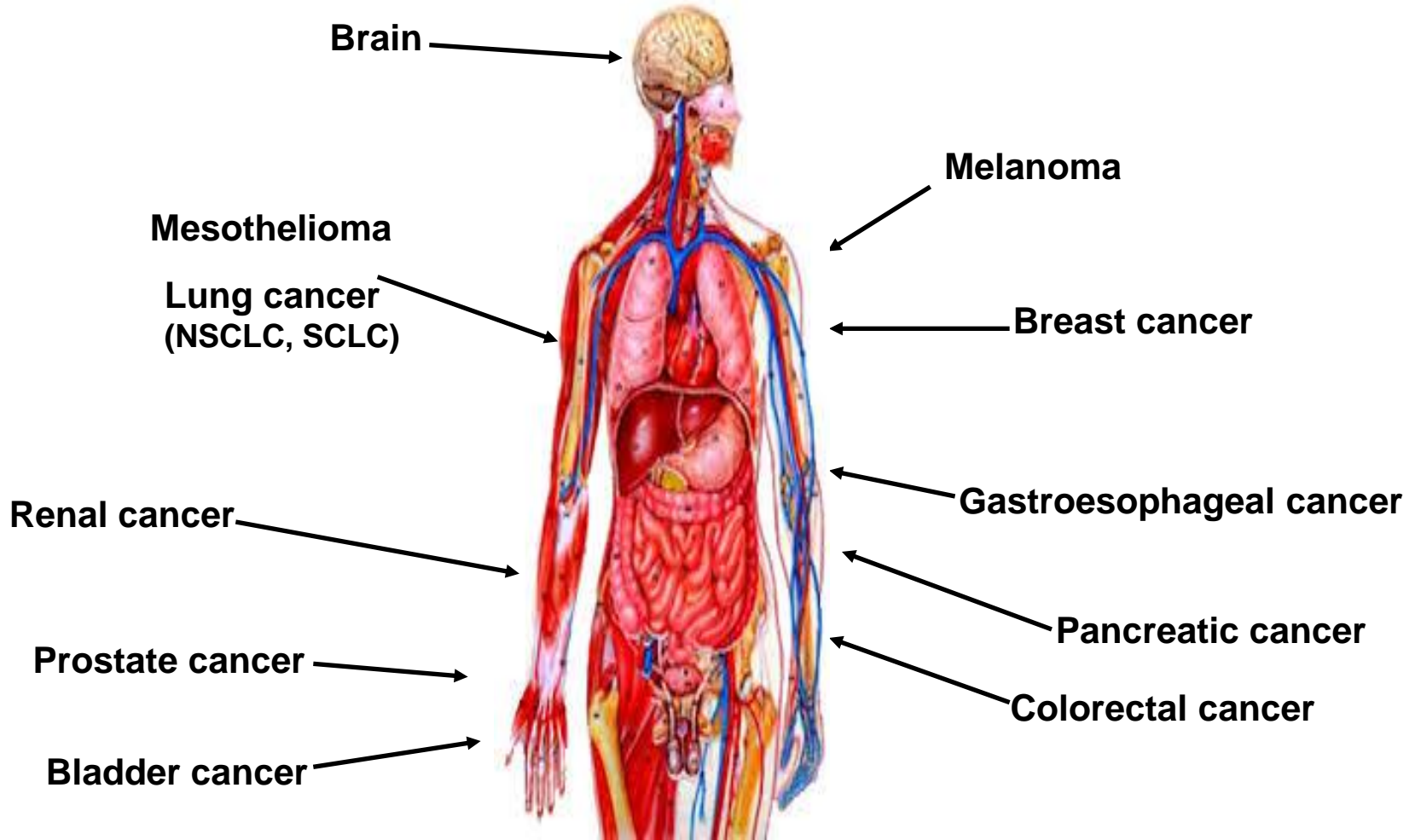
# T-cell costimulatory receptors



# Chemotherapy/Targeted Agents and Immuno-therapy Differ in Action and Outcome



# Immunotherapy in solid tumors with immunomodulating antibodies



# **Certosa di Pontignano ( Siena ) 24 Giugno 2004**



**2006 Associazione no-profit**

# NIBIT

Network Italiano per la Bioterapia dei Tumori





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Luana Calabrò  
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*U.O.C. Immunoterapia Oncologica  
Azienda Ospedaliera Universitaria Senese*

per il  
Network Italiano per la Bioterapia  
dei Tumori



### CORSO NIBIT DI FORMAZIONE SULLA IMMUNBIOTERAPIA DEI TUMORI UMANI:

basi teoriche, risultati clinici  
e tossicità delle più promettenti  
strategie terapeutiche in oncologia

**Bari, 16 dicembre 2011**

Istituto Tumori "Giovanni Paolo II"  
IRCCS Ospedale Oncologico – Sala Conferenze  
Viale Orazio Flacco, 65

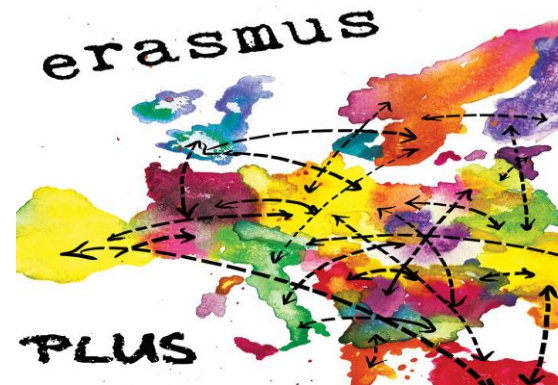
Presidente: Michele Maio  
Coordinatore: Michele Guida

L'iscrizione al corso è gratuita  
Sono previsti 7 crediti E.C.M.

Ospedale Le Scotte  
**SIENA**



## 1° Master Nazionale NIBIT in immunoncologia



Key Action 2: Cooperation for innovation and the exchange  
of good practices

# THE LANCET **Oncology**

Volume 13, Issue 9; September 2012, Pages 879-886

Articles

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## **Ipilimumab and fotemustine in patients with advanced melanoma (NIBIT-M1): an open-label, single-arm phase 2 trial**



*Anna Maria Di Giacomo, Paolo A Ascierto, Lorenzo Pilla, Mario Santinami, Pier Francesco Ferrucci, Diana Giannarelli, Antonella Marasco, Licia Rivoltini, Ester Simeone, Stefania VL Nicoletti, Ester Fonsatti, Diego Annesi, Paola Queirolo, Alessandro Testori, Ruggero Ridolfi, Giorgio Parmiani, Michele Maio*

# Nibit Foundation



FONDAZIONE  
**NIBIT**

Network Italiano per la Bioterapia dei Tumori

# NIBIT Foundation



Established in 2012 by the NIBIT Board of Directors to best focus the comprehensive activities connected with the conception, planning and implementation of clinical trials.

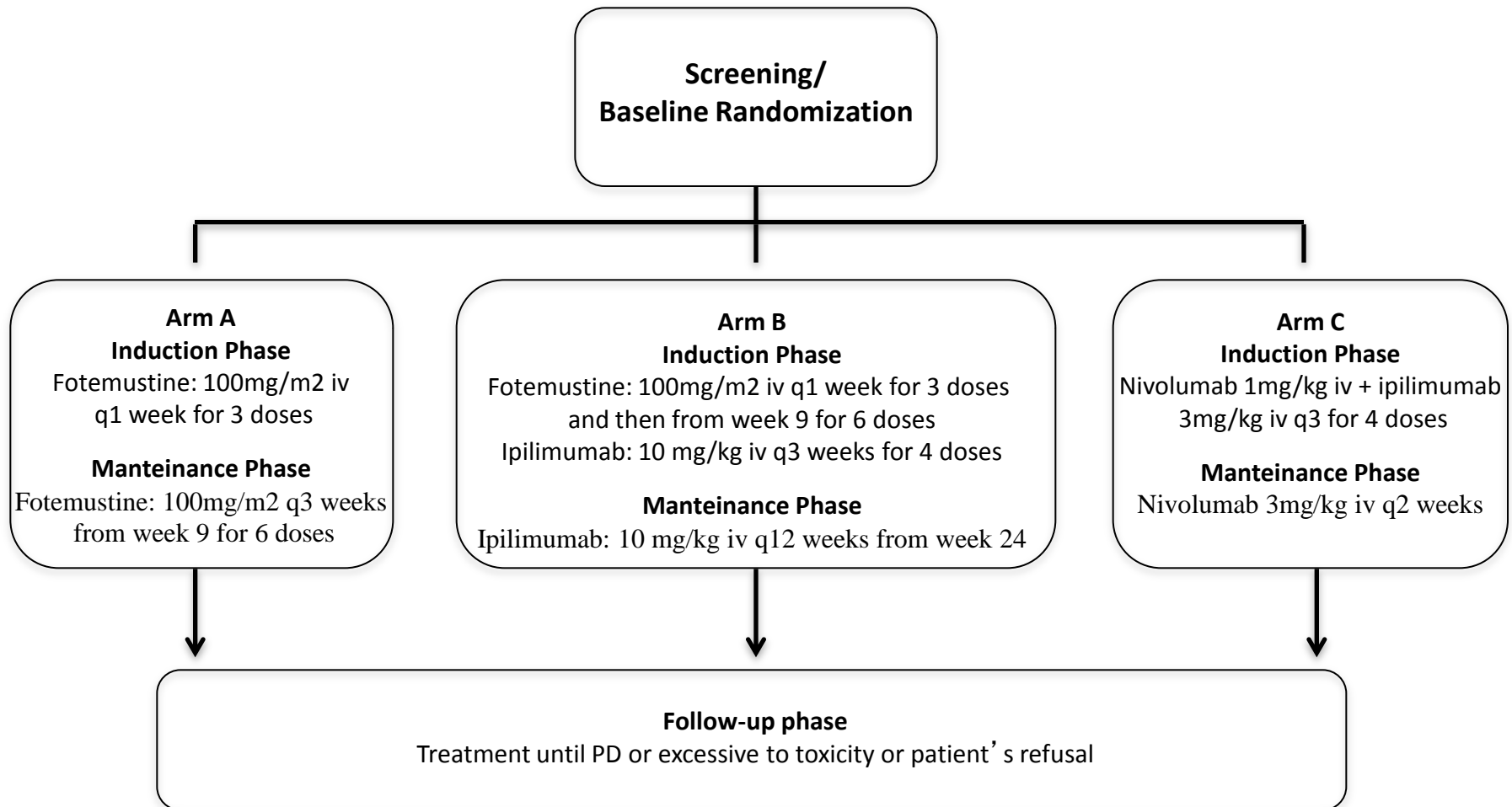
## **Main goals:**

- **To design, develop and implement phase I-IV clinical trials.**
- **To coordinate and/or to cooperate at multicenter clinical studies.**
- **To promote and/or implement scientific initiatives in the field of cancer bio-immunotherapy.**
- **To support basic or translational research projects.**

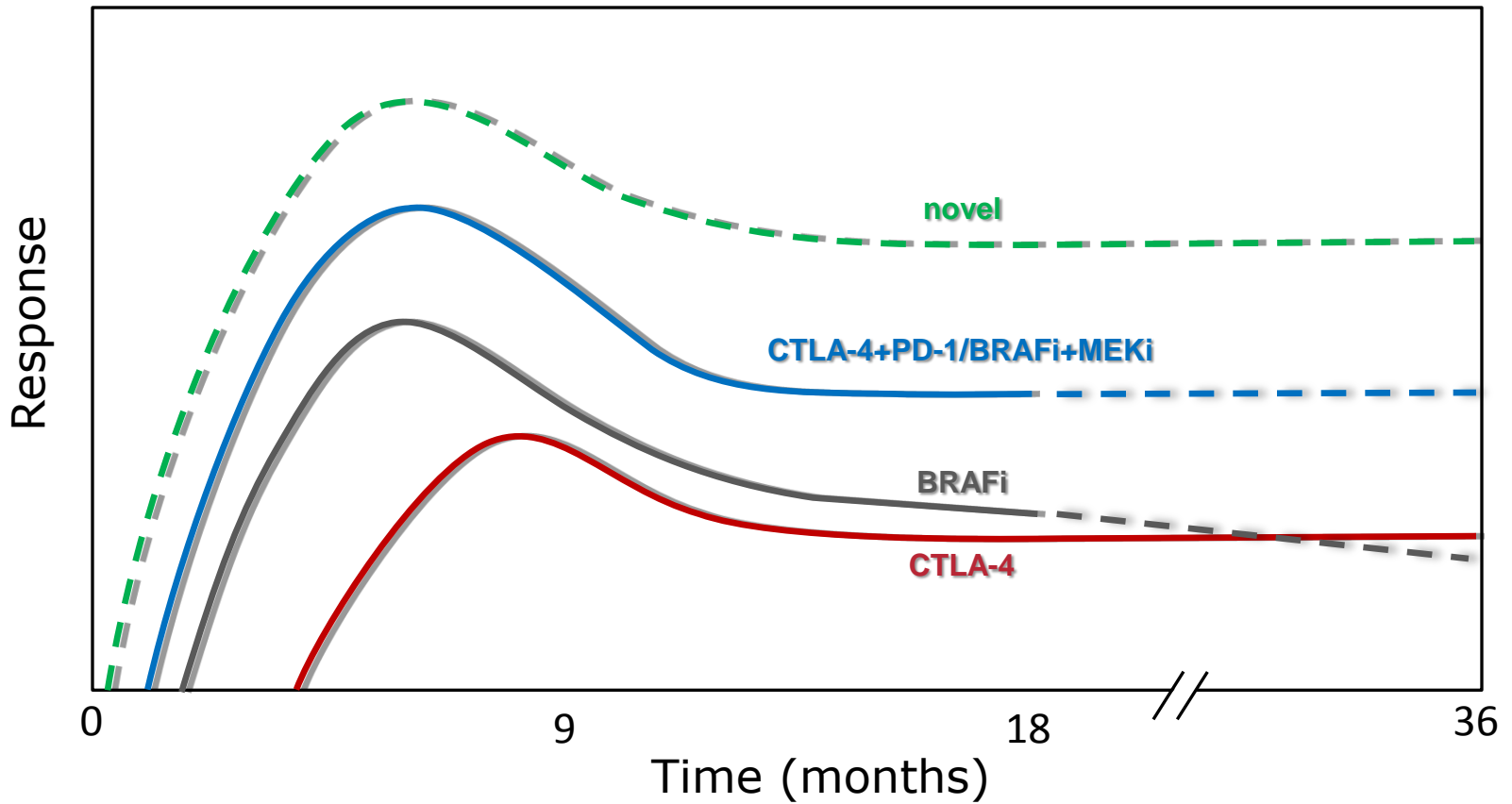
## **Main scientific yearly events:**

- **The International meeting "Cancer Bio-Immunotherapy in Siena"**

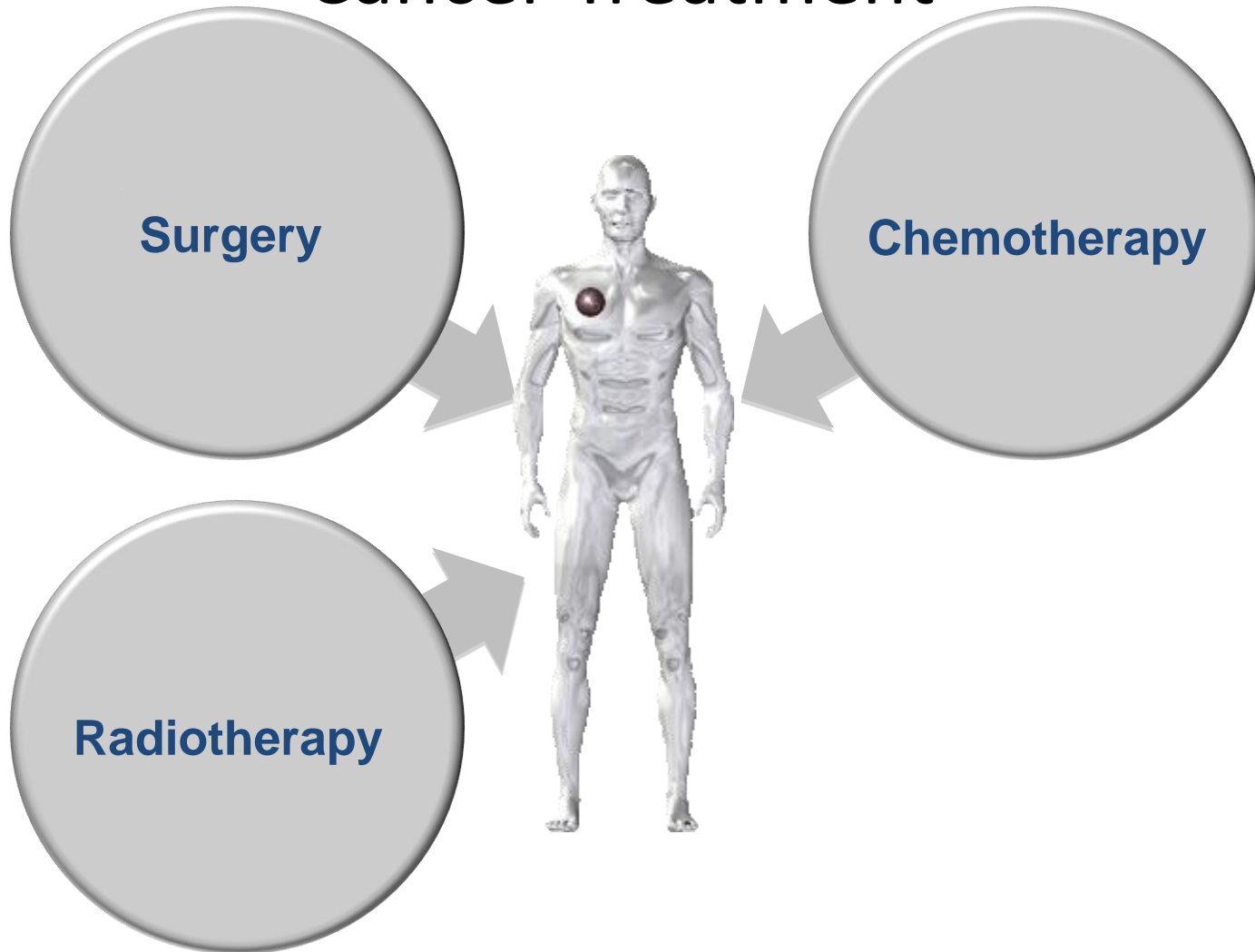
# The NIBIT-M2 study design



# Aiming to an even better future with novel combinations



# Evolving Therapeutic Options for Cancer Treatment



# Evolving Therapeutic Options for Cancer Treatment

