HUMANITAS
RESEARCH HOSPITAL

# SCIENTIFIC REPORT 2014 › 2015

RESULTS & PERSPECTIVES

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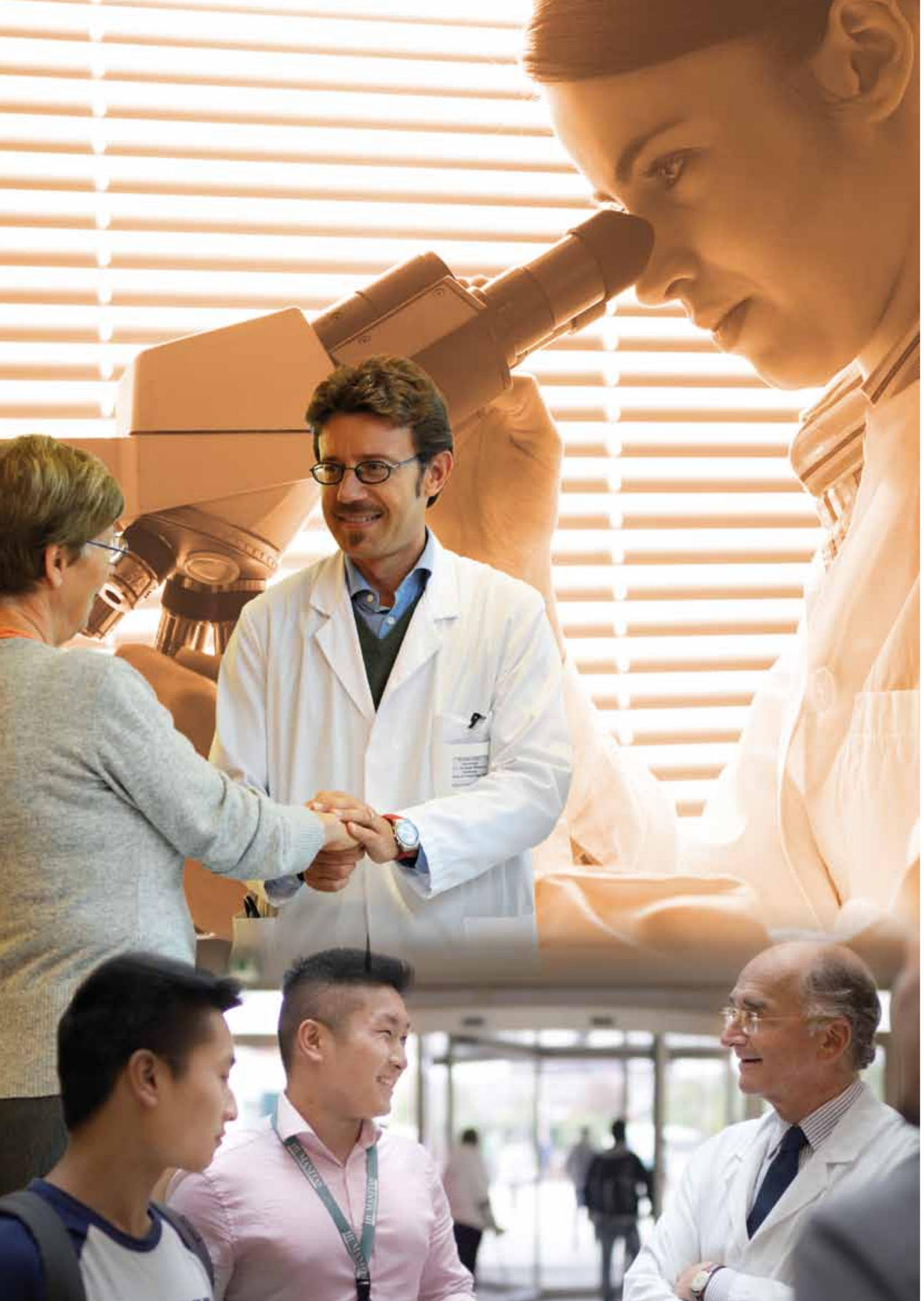
RESEARCH HOSPITAL

# SCIENTIFIC REPORT 2014 ›2015

## RESULTS AND PERSPECTIVES



The yearly Scientific Report is an opportunity to reflect on the position occupied by modern Medicine in the context of biomedical sciences, and to illustrate how Humanitas is prepared to face Medicine's fast changes and challenges.

The last year has been marked by two significant events. In 2014 Humanitas University was born to address the true challenge represented by students' education, however in consistency and continuity with our broad spectrum commitment in education.

Let me remind that Humanitas has hosted international academic courses, including a Medicine course and, in addition, has a broad educational mission ranging from high school students – with open lessons – up to postgraduate students, e.g. residents or PhD students. The beginning of Humanitas University is both a challenge and an asset: educating future physicians and researchers able to combine management of the most advanced technologies with dedication and care to the patient as a human being. Not only: they are trained to do this in an international scenario, and this represents a unique breeding ground for Italian talents.

At Humanitas University, the close integration among medical education, research and bedside healthcare draws the so called triangle of knowledge and healthcare. Enrolment and nurturing of new talents has already begun and will be the challenge for the years to come.

The other relevant event in the past year I mentioned is another challenge, completely out of our control, but still involving the entire scientific community. I am referring to the Precision Medicine Project launched by president Obama, who just reminded how modern medicine will be increasingly based on tailored rather than ready-to-wear. The huge investment on Precision Medicine starts exactly from this premise. The Precision Medicine Plan clearly has oncology at its core, where genomics and immunomics have radically changed the approach to patients. We can state that this is just the beginning of a great revolution.

I believe that our institution is well equipped with all that is needed to participate – and anticipate – the challenge of a medicine based on the care for the human being and to precision, according to its newest definition.

**Alberto Mantovani**
Scientific Director of Humanitas

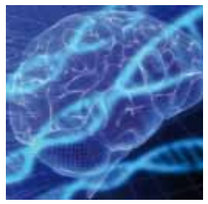
# Contents













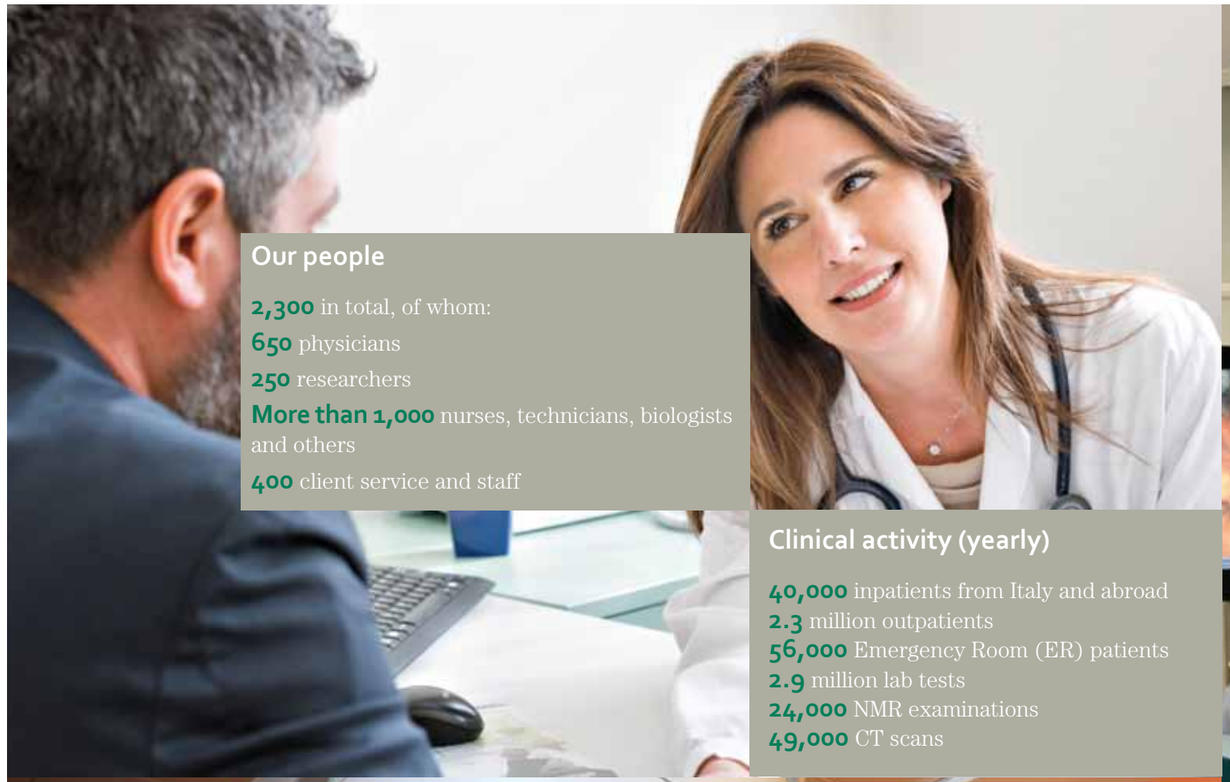
# Humanitas
# Research & University Hospital


## Who we are

Humanitas is a highly specialised hospital, research and teaching center and hosts Humanitas University.
Built around centers for the prevention and treatment of cancer, cardiovascular, neurological and orthopedic disease – together with an Ophthalmic Center and a Fertility Center – Humanitas also operates a highly specialised Emergency Department.
First Italian hospital quality certified by Joint Commission International, Humanitas is accredited by the National Health System.

Humanitas promotes health, prevention and early diagnosis by means of innovative and advanced outpatient healthcare facilities.
Appointed as IRCCS by the Ministry of Health (an accreditation in the Italian system that acknowledges institutions focused on excellence in clinical care and research), Humanitas is a world-famous center of excellence for immune system related diseases, from cancer to rheumatoid arthritis.
Humanitas Research Hospital is the flagship of a hospital group also present in Bergamo, Turin, Catania, and Castellanza (Varese).

# Humanitas at a glance



## Our people

**2,300** in total, of whom:
**650** physicians
**250** researchers
**More than 1,000** nurses, technicians, biologists and others
**400** client service and staff

## Clinical activity (yearly)

**40,000** inpatients from Italy and abroad
**2.3** million outpatients
**56,000** Emergency Room (ER) patients
**2.9** million lab tests
**24,000** NMR examinations
**49,000** CT scans

## Our facilities

**90,000** sqm, of which:
- **75,000** are devoted to clinical activity
- **6,000** to scientific activity
- **4,000** to training and teaching
- **3,000** to facilities for patients and relatives

**747** beds, of which:
- **75** in the medical, surgical, and oncological day-hospital
- **28** in the intensive care unit
- **154** in cardiopulmonary, orthopedic and neuro-motor rehabilitation

**36** operating theatres

**5** rooms for minimally invasive cardiology interventions

**more than 200** outpatients clinics


## Our cutting-edge technologies

**5** NMR, of which 3 Tesla and open-bore with ambient light

PET-CT

Da Vinci Robot

EOS imaging system

3D Ultrasound Scan

Genetic diagnostics and molecular tests

Stereotaxis for cardiac arrhythmias treatment

Digital mammography with tomosynthesis

Excimer laser

Femtosecond laser

**5** linear accelerators for radiotherapy, of which **1** TrueBeams

**1** Gamma Knife

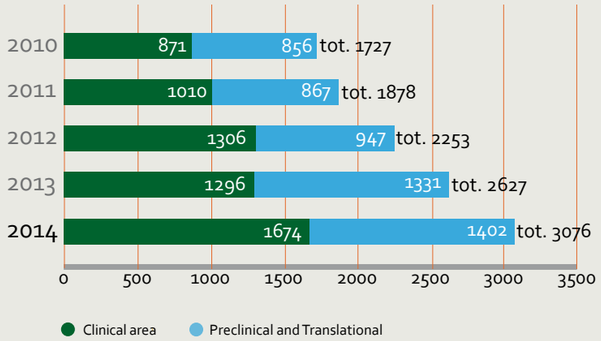
# Humanitas at a glance

## Scientific activities

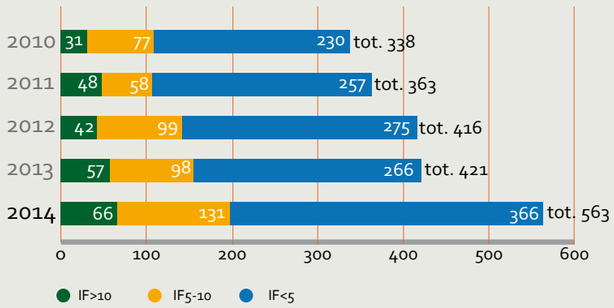
**3,076** = Impact Factor in 2014
**More than 300** professionals involved into research, of whom:
- **200** researchers (PIs, Junior PIs/Staff scientists, Postdocs and PhD students, technologists/technicians)
- **more than 100** clinicians involved into research

**20** labs
**20,000** sqm dedicated to research and education

### Raw Impact Factor*




### Papers classified according to their raw IF*




* The raw IF is the sum of the IFs of each journal that publishes the paper with at least one author from Humanitas.
The Impact Factor (IF) of a journal reflects the average number of citations to its recent articles.

# Our history

**1989** Design and construction of Humanitas are assigned to Techint based on James Gowan's project.

**1996** The hospital construction terminates and – on March 4, 1996 – Humanitas opens its doors and welcomes its first patient.

**1997** Humanitas is subsidized by the National Health System for inpatient services.

**1999** Humanitas Foundation is established for psychological and practical support to patients and caregivers.

**2000** Humanitas becomes a teaching center of the Università degli Studi di Milano for the Nursing Degree, followed by Medicine and Biotechnology.

**2002** Humanitas becomes a case-study for the Master in Business Administration at Harvard University and also receives excellence accreditation by the Joint Commission international, becoming the first Italian hospital to be acknowledged by one of the most important bodies for hospital quality certification worldwide.

**2003** Humanitas opens the ER and the Radiotherapy Unit.

**2005** The Ministry of Health accredits Humanitas as IRCCS. Fondazione Humanitas per la Ricerca is launched.

**2007** Inauguration of the Research and Teaching Center.

**2010** Humanitas launches the International Medical School in collaboration with the Università degli Studi di Milano.

**2013** Scientific output from Humanitas reaches a total Impact Factor of 2,627, an outstanding result that positions the IRCCS among the first Italian Institutions for quality of research.

Diagnostic services enlargement with new available facilities.

**2014** Humanitas University, a new international institution dedicated to the medical sciences, is established.



# Our philosophy

**Our mission is to:**

- improve our patients' lives by offering increasingly effective treatments based on an innovative and sustainable organization
- invest in research that ultimately improves clinical management and outcomes
- train a new generation of professionals for clinical skills, research and academia.

## Humanitas and prevention

Being proactive is the winning strategy to maintain good health. Even the most serious diseases can be prevented (primary prevention) or improved (secondary prevention) with physical activity and correct lifestyle.
Humanitas is actively involved in campaigns to promote healthy lifestyles and focuses on prevention and early diagnosis thanks to daily investments in expertise and technologies.

## On the patients' side

Humanitas cooperates with Fondazione Humanitas and Fondazione Ariel to provide support to patients and their families. In particular, Fondazione Humanitas supports patients with chronic diseases and their families by means of dedicated programs and properly trained nursing volunteers, while Fondazione Ariel supports children affected by cerebral palsy and their families through orientation activities, psychological and social support and assistance.

# Clinical innovation

## Patient centered care

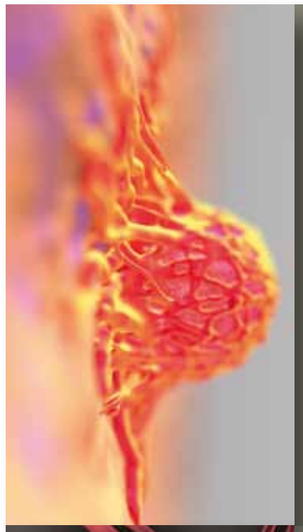
Humanitas is committed to integrating care, research and education in order to offer our patients the world's best affordable care. Hundreds of professionals – physicians, researchers, nurses, technicians, and other team staff – stand every day at the frontline to achieve this ambitious aim.

## Research Hospital

Humanitas in Milan is an IRCCS (an accreditation in the Italian system that acknowledges institutions focused to excellence in clinical care and research).
Humanitas is accredited by the Italian National Health System. Its diagnostic and therapeutic activities meet patients' needs at a local, national, and international level.

## Specialized Centers of excellence and care pathways

Healthcare, supported by the best specialist expertise and integrated by a multidisciplinary approach, is sustained by continual research activities for care improvement and personalization. Humanitas developed its clinical organization by establishing excellence centers for cancer, cardiovascular, neurological, orthopedic and ophthalmic diseases – in addition to a Fertility Center – where patients are assisted by multidisciplinary teams and dedicated organizations.

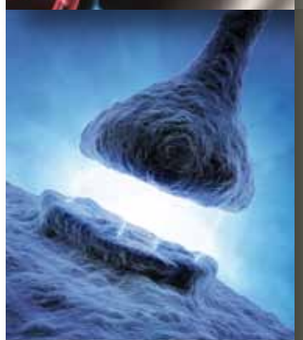


### Cancer Center

Oncology
General, hepatic and pancreatic surgery
Thoracic surgery
Gynecology
Urology
Breast unit
ENT
Nuclear Medicine
Radiotherapy
Dermatology

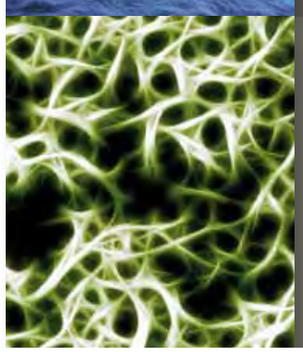
### Cardio Center

Heart surgery
Cardiology
Vascular surgery
Electrophysiology
Hemodynamics
Ecocardiography
Cardiac care unit
Rehabilitation



### Neuro Center

Brain and spine neurosurgery
Functional neurosurgery
Neurology
Stroke unit
Rehabilitation



### Ortho Center

Prosthetics

Specialised equipes in surgery of: shoulder, knee, hand, foot

Traumatology
Rehabilitation



### Humanitas' Eye Center

HUMANITAS
CENTRO OCULISTICO

Humanitas' Eye Center combines state-of-the-art technologies – such as latest laser techniques to ameliorate visual impairment (myopia, astigmatism, hypermetropia) increasingly accurately and rapidly, and with progressively less invasive procedures – with its experienced professionals, who constantly innovate in the field of refractive surgery. This highly specialised center, led by **Paolo Vinciguerr**a, is located in the heart of the Policlinic:
23 professionals, 797 sqm, an expert team able to assist each day more than 200 patients.

## The following health professionals have joined Humanitas' team in the current year:

**Alberto Albanese**
Director of the Division of Neurology

**Savino Bruno**
Director of the Department of Internal Medicine and professor at Humanitas University

**Efrem Civilini**
Director of the Division of Vascular Surgery

**Stefano Duga**
Principal Investigator of the Laboratory of Medical Genetics and RNA biology and professor at Humanitas University

**Giorgio Guazzoni**
Director of the Division of Urology and professor at Humanitas University

**Giulio Maira**
Division of Neurosurgery

**Giuseppe Marinari**
Director of the Division of Bariatric Surgery

**Piero Picozzi**
Gamma Knife Unit

**Giulia Veronesi**
Division of Thoracic Surgery

# Clinical innovation

HUMANITAS
FERTILITY CENTER

## Fertility Center

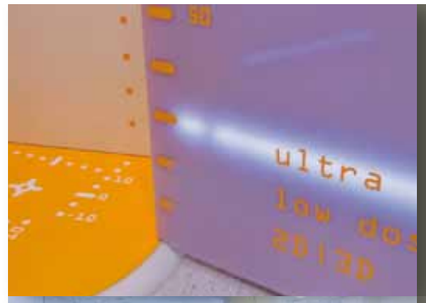
Helping couples make their dream of having a child come true, supporting them with humanity and scientific expertise. This is the aim of the team managed by **Paolo Emanuele Levi Setti** at Humanitas Fertility Center. The team is made up of doctors, nurses, biologists and staff personnel. The Center – one of the most important reference points for infertile couples in Italy and Europe, and one of those with the highest number of IVF cycles – provide couples with personalized treatments, supporting them throughout the whole intervention, and not only during medically assisted procreation (MAP) procedures: starting from prevention to thorough diagnostics, from minimally invasive surgery to cryopreservation, for instance for oncologic patients.

| Figures of MAP at Humanitas | |
|---|---|
| **Over 25,000** | assisted couples since 1996 |
| **Over 5,000** | babies born until 31.12.2014 |



# Our technology

Humanitas is considered one of the technologically most-advanced hospitals in Europe. Among the most significant examples, last generation linear accelerators (TrueBeam) for radiotherapy, robotic surgical systems (the new frontier in minimally invasive surgery), next generation laser for ophthalmology, 5 Nuclear Magnetic Resonance, including a 3 Tesla and an open-bore NMR, 2 PET-CT.
Humanitas is also equipped with an EOS, a newly-designed imaging system susceptible to 3D reconstruction with a sharply reduced X-ray exposure dose.




### EOS

EOS is a newly-designed imaging system that allows to study spine and lower limbs in standing position (loaded condition).

### NMR

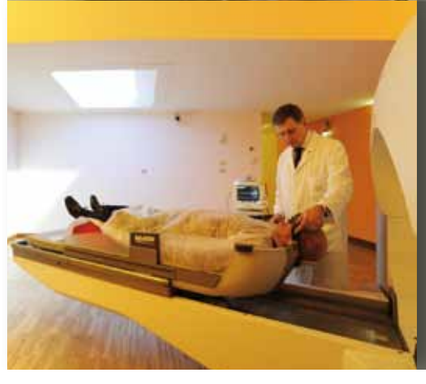
The 3 Tesla Magnetic Resonance provides higher resolution images in few seconds (favoring breath-held acquisition), with the advantage of minimizing the patient's permanence time in the machinery.

### TRUEBEAM

The linear accelerators TrueBeam and TrueBeam STX adapt to the motion of internal organs due to breathing and deliver the highest possible radiation dose to the targeted cancer tissue within millimeter precision, thus sparing healthy surrounding tissue.


### DA VINCI

The Da Vinci robot is a state-of-the-art surgical system, with 3D high-definition vision and four robotic arms.



### GAMMA KNIFE AND EDGE

Gamma Knife and Edge are dedicated, fully integrated systems for brain radiosurgery, often an alternative to the normal surgery. Gamma Knife and Edge are known for exceptional dose conformity and precision, limiting radiation to the surrounding brain tissue and critical structures.

# Scientific research

## Research at Humanitas

In recent years, Humanitas' scientific productivity has been constantly increasing in quality, achieving very high levels, as indicated by bibliometric indexes: over 3,000 Impact Factor points in 2014 (ranking among the first IRCCS Institutions in scientific output), with particular focus on the immune system. The latter is crucial for contemporary research in medicine because of its strong impact on different clinical areas, from cancer to cardiovascular diseases, inflammatory and autoimmune diseases.

## From labs to patients, rapidly

More than 300 researchers work at the University Research and Teaching Center – which is fully integrated with the hospital – utilizing cutting-edge technologies, such as the recently acquired two-photon microscope.
The group operates in close collaboration with the 650 physicians from the hospital, in order to facilitate translation, i.e. the direct application of the most recent advances in healthcare through a systematic and ongoing process of innovation. Scientists and researchers from 16 countries spanning over four continents carry out innovative research in immunology, and are involved in studies on high impact non-communicable diseases, e.g. cancer, myocardial infarction, stroke, and autoimmune diseases.

## Evaluation of Humanitas' scientific output

Every year Scimago Research Group analyzes the publication of more than 5,000 research centers. According to the "Excellence Rank" indicator (which represents scientific output), Humanitas ranks among the top 10% worldwide (315th out of 4,849 institutions) and in Western Europe (141st out of 1,535 institutions), and among the top 5% in Italy (8th out of 163).

**In Italy among the Top 10%**

**In Western Europe among the Top 10%**

**In the World among the Top 10%**

### Certified excellence

Progress and growth during the last 3 years has been outstanding. (...)

The recruitment of translational researchers and physician scientists has been particularly successful and should be further expanded. (...)

The overall increase in scientific productivity is particularly impressive. (...)

Progress in education has been outstanding. (...)

The establishment of the International Medical School and the M.D.-Ph.D. program is viewed as a major strength of the HRI, which positions the Institute as a leader in the training of the next generation of physician scientists in Europe. (...)

The ranking of Humanitas is also very impressive (...): it is now top 10% in Italy and Western Europe worldwide (SCImago ranking)".



## Prizes awarded to Humanitas for Research

**Eduardo Bonavita,** Best presentation Award, *PTX3 acts as an extrinsic oncosuppressor by regulating complement-dependent tumor-promoting inflammation*, SIICA PhD students retreat, Bari October 10-11 2014

**Angela Ceribelli,** 2014 Young Researchers Award, Fondazione Eli Lilly per la Ricerca Medica

**Fabia Filipello,** FISM (Fondazione Sclerosi Multipla) Award

**Giuliana Fossati,** Immunotools Special Award 2014, Italian Society of Pharmacology and Novartis Award for participation to "Clinical trials and young investigators: hit the target", Roma; participation in Novartis Biocamp Italia 2014

**Maria Rosaria Galdiero,** First Prize Winner, Oral Presentation Competition for Junior Scientists "The trainees' session honouring the memory of Pierre Borgeat, PhD (1947-2013)", International Symposium Neutrophil 2014, Montreal, QC, Canada, May 31-June 3 2014

**Elsa Ghirardini,** Workshop "Young Researchers Training in scientific communication: Debating techniques", Prion 2014

**Carolina Magdaleine Greco,** Best poster, PhD course, Università Bicocca

**Silvia Locatelli,** Italian Lymphoma Foundation Young Investigator Award in memory of Ercole Brusamolino, MD

**Enrico Lugli,** Fondazione Lorini Award

**Sonia Mazzitelli,** 2014 Fondazione Veronesi Award

**Raffaella Morini,** 2014 Fondazione Veronesi Award

**Andrea Ponzetta,** participation in Novartis Biocamp Italia 2014

**Chiara Raggi,** Full Bursary EASL HCC SUMMIT, Geneva, Switzerland, February 13-16 2014

**Marco Rasile,** LERU (League of European Research Universities) Award for the participation in the Fifth LERU Summer School "Doing the right things right – Research integrity in a complex society"; EFIS fellowship for participation to the Workshop "The Maternal Immune System in Pregnancy", Castellammare di Stabia, Napoli

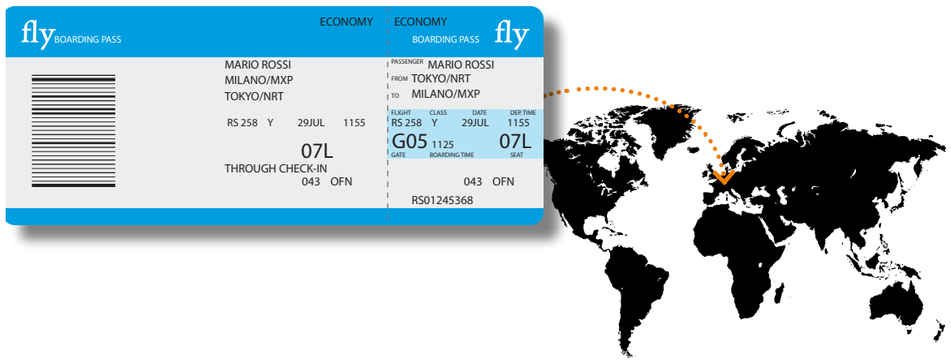
**Giuliana Roselli,** VIBes Biosciences travel Grant, International PhD Symposium, Antwerp, Belgium, September 17-19 2014

**Giulio Giuseppe Stefanini,** Morgagni Lecture, Società Italiana di Cardiologia, Roma, 2014

**Giuliano Giuseppe Stirparo,** Best Poster Award, Frontiers in Cardiovascular Biology (FCVB), European Society of Cardiology 2014, Barcelona

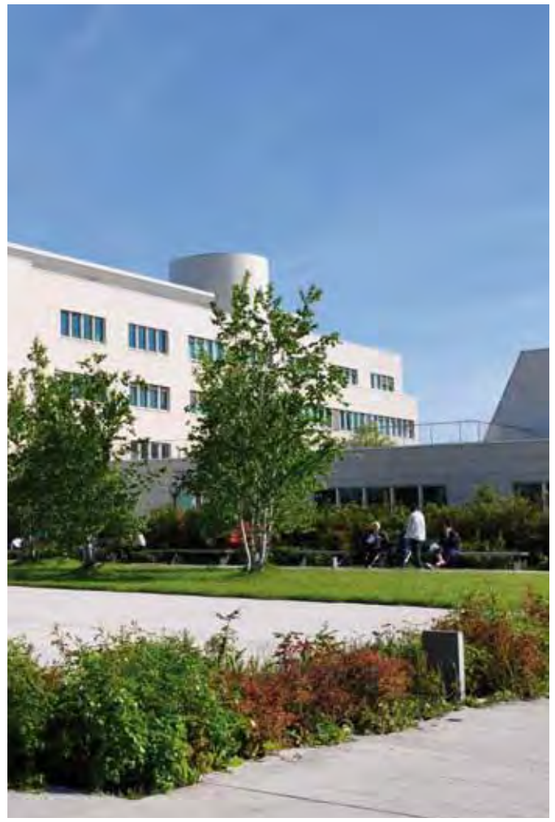
**Alessandro Vacchini,** EFIS (European Federation of Immunological Societies) Grant, Immunology Letters Short Term Fellowship Award


## Italian researchers who returned after an experience abroad **Total 23**




## International Advisory Boards

Humanitas firmly believes in the evaluation process. For this reason, an Advisory Board for pre-clinic research headed by the Nobel Prize awardee **Rolf Zinkernagel** has been appointed. Another International Advisory Board assesses and evaluates Humanitas Cancer Center research and clinical activities on a continuous base.



HUMANITAS
FONDAZIONE PER LA RICERCA

Fondazione Humanitas per la Ricerca is involved in supporting clinical and basic studies on pathophysiology of immunological defense mechanisms and of risk factors for several diseases, among which chronic inflammatory, cancer, cardiovascular, and neurological diseases.
The research activity of Fondazione Humanitas is monitored by an Advisory Board whose chairman is the Nobel Prize awardee Rolf Zinkernagel.

**The Advisory Board of Fondazione Humanitas per la Ricerca:**

**Rolf Zinkernagel**, MD/PhD (President)
University of Zurich and University Hospital of Zurich
Institute of Experimental Immunology
Zurich, Switzerland

**Fabio Cominelli**, MD/PhD
University Hospital
Dept. of Medicine-Gastroenterology
Cleveland, Ohio, USA

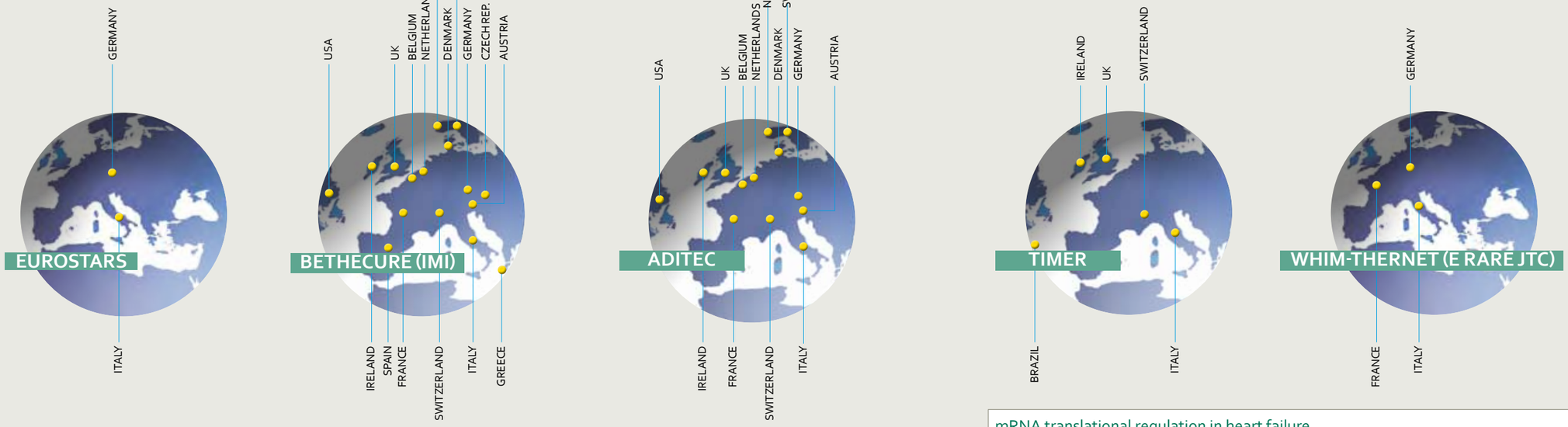
**Charles Dinarello**, MD
Professor of Medicine
Division of Infectious Diseases
University of Colorado Health Sciences Center
Denver, Colorado, USA

**Pietro De Camilli**, MD
Eugene Higgins Professor of Cell Biology and of Neurobiology
Director, Yale Program in Cellular Neuroscience and Neurodegeneration and Repair
New Haven, Connecticut, USA

**Napoleone Ferrara**, MD/PhD
Genentech Inc.
South San Francisco, USA

**Lorenzo Moretta**, MD
Research Director Giannina Gaslini Pediatric Institute
Professor of General Pathology
University of Genova
Genova, Italy

**Göran K. Hansson**, MD/PhD
Karolinska University Hospital
Stockholm, Sweden




**The network of the EU-sponsored research projects**

| | |
|---|---|
| mRNA translational regulation in heart failure | Marie Curie IIF |
| Epigenetics and microRNAs in Myocardial Function and Disease | ERC Advanced grant |
| Structured International Post Doc Programme 2 | Marie Curie COFUND program |
| Global microRNA profiling of normal and Pbx1-null hematopoietic stem cells and progenitors for the identification of new regulators of the balance between self-renewal and differentiation | Marie Curie CIG |
| Characterization of NK cell distributions and functions in human tissues in HIV-1 pathogenesis | |
| Improving adoptive T cell transfer immunotherapy for cancer with T memory stem cells | |
| ICT-enabled, cellular artificial liver system incorporating personalized patient management and support | FP7 ICT UK, France, Germany, Switzerland, Italy, Norway, Spain |
| Generation and maintenance of long-lived memory T cells in humans | ERC Starting grant |
| Role of microRNAs 143 and 145 in cardiovascular physiology and disease: from bench to bedside | Marie Curie IRG |

## The Ethical Committee

Since 2005, an Ethical Committee has been active at Humanitas. This is an independent body which protects the rights, security and well being of the parties involved, within the realm of clinical research.
Any experimentation process, be it carried out industrially or within the Institute, depends on the Committee's decision, which takes into account the correctness and the compliance to ethical standards of new therapeutic methods, or diagnoses, that involve human beings directly.
Key priorities for the Ethical Committee are independence (granted by the fact that its personnel does not work for the same hospital as the one where the Committee operates), and a multifaceted approach, where different professional competencies and skills are indispensable for ensuring critical evaluation of different aspects of experimentation.
According to current regulations, the Ethical Committee must be composed by: two clinicians, a biostatistician, a pharmacologist, a chemist, the Medical Director, the Scientific Director and an expert in law.
In addition, the hospital where the Committee is based may appoint other members among general practitioners and local doctors, nurses and people committed to voluntary work, provided that the independence – and multifaceted-approach criteria above are met.

## Humanitas' biobank

Advanced research increasingly needs to be supplied with biological samples (small amounts of blood and other biological fluids, or small sections of tissue removed during surgery) to be analyzed. These samples come from donors who suffer from different diseases, and are helpful to understand how patients differ from one another and – in perspective – to develop personalized treatment.
In order to cater for this need, Humanitas has established a biobank. A biobank can be compared to a "current account" where donors "deposit" their own biological material, and obtain "interest" in return, in the form of knowledge of their disease.
By signing an Informed Consent form, and under absolute confidentiality, donors authorize Humanitas to take samples to be used for biomedical research programs which would otherwise be impossible to carry out.

HUMANITAS UNIVERSITY

An international setting, along with innovative educational methods and the close integration with first rate hospital facilities and cutting-edge scientific research are the pillars of Humanitas University, a private nonprofit institution dedicated to the medical sciences and strictly interconnected with the identity of the Humanitas hospital.

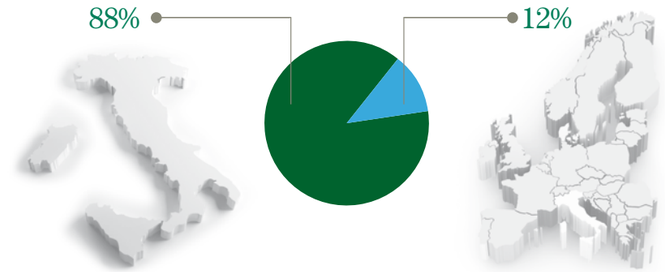
At Humanitas University, the degree courses are based on more than 10-year experience in academic teaching as well as on an active learning approach.

Initially, Humanitas University offers two degree courses:

- MD, in English
- Nursing BD, in Italian

A wider offer of degree, PhD and specialization courses and masters will be available within few years.

Once fully operating, Humanitas University will accommodate over 800 students (starting from 100 a year for the MD course in English and 40 a year for the Nursing BD).




Geographical origin of the students admitted to the first year of the MD course at Humanitas University

# International collaborations and recognitions

Collaboration at international level is fundamental for clinical practice. In the last years, collaborations with national and international top-ranking hospitals and the constant effort in implementing the most advanced technologies have led to outstanding results in the treatment of neoplastic, gastrointestinal, cardiovascular, neurological and immunological diseases.


### Harvard University

Considered by Harvard University one of the four most innovative hospitals worldwide, Humanitas is a case study for its organization model, which combines quality of care with economic sustainability, development and social responsibility.

### Joint Commission

Humanitas was the first polyclinic in Italy, and among the very few in Europe, to have been certified by the Joint Commission International. This acknowledgement of excellence has been confirmed and renewed since 2002 and has required compliance with over 1,300 standards.

### Workers' safety

Humanitas is OHSAS 18001 (Occupational Health and Safety Assessment Specification) certified, an international recognition that highlights the hospital attention to its own workers' safety and health.

### Responsible Payments

Humanitas has joined the Codice Italiano Pagamenti Responsabili (The Italian Code of Responsible Payments), an initiative which has been launched by Assolombarda to promote prompt and timely payments to suppliers and aimed at improving national and international reputation of Italian companies, thus strengthening their competitiveness.

HUMANITAS
LECTURE

### Humanitas Lectures

Humanitas Lectures include a series of top level scientific meetings organised in partnership with the Università degli Studi di Milano.
These lectures represent a focus on the development and the evolution of the biomedical research at the service of human health. Among the speakers, the Nobel Prize awardees Prof. Rolf Zinkernagel and Prof. Françoise Barré-Sinoussi are worth mentioning.



# Humanitas Group in Italy

**Castellanza**
Humanitas Mater Domini
www.materdomini.it

**Bergamo**
Humanitas Gavazzeni
www.humanitasgavazzeni.it

**Turin**
Clinica Cellini
www.clinicacellini.it

**Milan-Rozzano**
Istituto Clinico Humanitas
www.humanitas.it

**Catania**
Humanitas Centro Catanese di Oncologia
www.humanitascatania.it

**1,450** beds
**155,000** sqm
**more than 1,000** physicians
**114,000 inpatients** (yearly)
**more than 4.6 million** outpatients (yearly)
**107,000** ER patients

# Translational research

Immunity and inflammation
Oncology
Neuroscience
Cardiovascular

## Specific instruments of Humanitas Laboratories

| IMMUNOLOGY, ONCOLOGY, NEUROSCIENCE, CARDIOVASCULAR |
|---|
| Confocal microscopes equipped for FRET analysis, TIRF and fast FRAP |
| CellR for high-quality time-lapse imaging |
| Two-photon microscope |
| Olympus VS120 Virtual Microscopy Slide Scanning System |
| LSR Fortessa cell Analyzer |
| Bio-Plex multiplex system for the detection and quantification of multiple analytes |
| BD FacsAria |
| Automacs Cell Isolation |
| ION TORRENT sequencer |
| Next Seq 500 Sequencing System |
| AB 3500 genetic analyzer |
| IScan System |
| NGS Express |

| NEUROSCIENCE |
|---|
| 2 operating theatres equipped with O-Arm (three-dimensional imaging device) coupled to a neuronavigation system |
| Cavitron Ultrasonic Surgical Aspirator (CUSA) for parenchymal tumor tissues or bone tissues |
| BoneScalpel Ultrasonic Osteotome |
| Neuromonitoring and neuronavigation combined with intra-operative 3D ultrasound for stereotactic excision of deep brain lesions |
| 3D endoscopy tools for skull-base surgery |
| 5 NMR (among which 3-Tesla, 1 open with ambient light) |
| NMR equipment for functional imaging studies |
| Acquisition and processing workstation for diffusion MRI tractography |
| 4 TC (among which 1 64-slice) |
| Inverted microscopes IX71 |
| Perfusion system |
| Electron-multiplying CCD (EMCCD) camera Quantem 512 |
| Patch-clamp amplificatory Multiclamp |
| Analog/ digital converter Digidata 1440A |
| Light-Emission-Diod as source light |
| PatchStar Micromanipulator |
| Metamorph software |

| CARDIOVASCULAR |
|---|
| High-frequency, high-resolution VeVo 2100 digital imaging platform with linear array technology and Color Doppler Mode |
| Mikro-Tip Pressure Volume System (MPVS)-Ultra Foundation System |
| Telemetry for blood pressure and ECG assessment |
| Scanning Ion Conductance Microscopy |
| Optical Mapping for electrical Impulse Propagation |
| IonOptix for Ca2+ transient and contractile assessment |
| Patch-Clamp instruments for studies on action potential |

# Immunity and inflammation

## Treating the right patient with the right treatment at the right time

Interview with
**Alberto Mantovani**

Scientific Director of Humanitas; Professor of General Pathology, Humanitas University

**Bringing lab results to the patient's bed: this is a revolutionary achievement. We are working towards being able to choose what results may benefit each patient according to their needs.**

### How close are we getting to meeting this goal?

In some cases we are there, for instance in some cancers where the genetic alterations dictate treatment, and more in general we are on the right track in that direction, as this topic has now gone beyond scientific debate, reaching the general public: the news of the *Precision Medicine Initiative* that has been described by president Barack Obama as "one of the biggest opportunities for breakthroughs in medicine that we have ever seen" has been reported enthusiastically by *The Wall Street Journal*.
The actual definition of Precision Medicine is "treating the right patient with the right treatment at the right time", and this implies a revolution. Namely, any treatment must (necessarily) consider the whole picture, the entire biology of the patient and of the disease – in our case, with particular reference to tumors. Even if genomics alone may not go far enough.
I would like to point out that a precision-based approach has relevant positive implications on healthcare expenditure, as it clarifies how pointless it is to treat 100 patients if it is well known that just 20 of them – let's say – are going to benefit from treatment. Thus, a short-medium term economic return is expected, which explains the huge investment of 215 million dollars in the US Precision Medicine Initiative.

### What role would you say immunology has in Precision Medicine?

Crucial, speaking about tumors. Immunotherapy is now included among oncologists' therapeutic equipment. According to realiable broadcasts, in a near future – approximately within 4 years – molecules acting via the modulation of the immune system will represent 60% of the cancer drug market.
This means we have to get ready for the challenge, and come prepared.

### At what stage are we at the moment, and – most importantly – where are we heading?

We have recently had an encouraging starting point, as drugs belonging to the class of "checkpoint blockade inhibitors" have been approved in the United States and in Europe. These drugs are antibodies able to remove certain brake points of the immune system, which typically works as a high-powered vehicle: in order to work efficiently, it needs both an accelerator system and a brake system: in other words, the coordination of activation and inhibition mechanisms. Otherwise, the immune system is "out of control" and diseases – mainly autoimmune diseases – occur.
Over the years immunologists have identified and described some of these brakes in depth. In addition, they have proven that the blockade is activated in certain pathologic conditions, e.g. in cancer. This is as if cancer was continuously stepping on the brakes of the immune system, preventing it from launching full-out attacks.
Recently we have had the proof of principle when the first monoclonal antibody acting through the above mentioned removal of the brake whose name is CTLA-4 (Cytotoxic



T-Lymphocyte Antigen 4) was approved for the treatment of metastatic melanoma. Ipilimumab – this the name of the antibody – was proven long-term effective in a substantial number of cases after a success story. CTLA-4 was initially described and characterized in Europe, by the French research group led by Pierre Goldstein. Then its development up to the clinical use has been carried on by James Allison, a US immunologist.
Since then, the list of the checkpoint blockade inhibitors has progressively increased.

### Shall we list some examples, including Humanitas' contribution?

Research has reached an advanced stage in the development of those antibodies able to remove a further brake, acting as ligands of the molecule named PD-1 (Programmed Death 1) or PDL1, which exerts an immunosuppressive effect on T-cells. Since anti PD-1 antibodies are possibly endowed with a broader *spectrum* of activity than anti-CTLA-4 antibodies, immunotherapy with these molecules is associated with encouraging results.
Our Cancer Center is actively engaged in translational research on these innovative therapeutic strategies, a research which is halfway between the bench lab and the bedside. In particular, we are trying to identify clinical parameters which enable us to predict responsiveness to immunotherapeutic strategies.
When speaking about cancer and immunity, another big issue is the capacity of a the tumor, once settled, to progressively deploy tactics to escape or to circumvent immunity or even use it to its advantage, e.g. as a mechanism promoting tumoral progression. I usually explain the case of tumor-associated macrophages (TAMs) with the metaphore of the good cops turned corrupted policemen. TAMs' M1 phenotype is normally devoted to killing microrganisms, presenting antigens to killer T cells, and engulfing the tumor cell, but in the cancer microenvironment it can shift to an M2 phenotype, able to receive signals from tumors to promote tumor cell growth, angiogenesis, and metastasis.
In a recent past, research at Humanitas has made a considerable contribution in developing drug-targeting key molecules involved in macrophage M2 polarization and reorienting them towards M1 phenotype, that is "redeeming" the bad cops. In addition, studying a compound approved for clinical use in Europe (trabectedin) **Paola Allavena** in our Institute showed that it acts by targeting and reducing the number of "corrupted policemen", thus providing a proof of principle with a clinically approved drug of the potential value of this approach. Moreover, **Antonio Sica** and colleagues were part of an international study showing that a monoclonal antibody that inhibits the receptor of CSF-1 (Colony-Stimulating Factor 1) – a key survival factor for TAMs – strongly reduces their number both in experimental models and in tumor tissues of patients and has antitumor activity in certain forms of sarcoma.
We owe most results of this considerable effort to translational research conducted at Humanitas, in particular by Antonio Sica (see the highlight) and Paola Allavena whose results have been published on the prestigious journal *Cancer Cell*.

### Has progress been made mainly for cancer, or are there promising results in other medical fields as well?

Another field in which we have been making progress, is autoimmune diseases, another example of how genomics and clinical investigation cooperate and enhance mutually. The project, carried out by **Pietro Invernizzi** (see the highlight) who participates in an international research group, showed that one of the gene candidates in primary biliary cirrhosis – an autoimmune disease seriously affecting the liver – encodes IL-12 (Interleukin 12), a protein that modulates immune response. This finding prompted a clinical trial aimed at evaluating the effect of anti-IL-12 antibody. As yet, even though we are far from enjoying the benefits of the outcome, this is another good example of Precision Medicine, ranging from the identification of genetic risk factors to the clinical application of targeted therapy.
Another interesting research activity refers to white blood cells – more specifically lymphocytes – trafficking. These cells act as the body's "patrols" and guard tissues. If the wrong number of lymphocytes reach the wrong place at the wrong moment however, they may determine a pathologic condition. Humanitas' scientists have long been involved in the study of the molecular mechanisms driving white blood cells trafficking. This issue has been extensively investigated in intestinal bowel diseases and last year the results of the multicenter international clinical trial conducted by the GEMINI study group, in which **Silvio Danese** took part (see the highlight) have been published on *The New England Journal of Medicine*. According to these findings, vedolizumab, a monoclonal antibody exerting a gut-selective blockade of lymphocyte trafficking is able to hide a digit in the zip code addressing white blood cells to the gut. Thus, it has been proven effective in patients with ulcerative colitis in different phases of the treatment of the disease, and in both induction and maintenance. Another case of significant progress advance supported by a considerable amount of preclinical work which is being translated into clinical benefit.

### We started out with genetics, but we have seen many other fields where transactional research plays a relevant part.

Let us go back to genome to deal with another field of research: the one that showed that the most prevalent fraction of DNA – considered for quite a long time useless and hence named junk-DNA – is at least as important as the approximately 20-30,000 protein-encoding genes which account for a very small fraction of the double strand not exceeding 1-2%. Actually, junk-DNA includes a large percentage of sequences coding for small RNA molecules including microRNA (miRNAs) which regulate the programs of gene expression.
To understand their role suffice it to say that humans are not so different from plants or animals in terms of gene

HIGHLIGHT

**Silvio Danese**

Director of the Division of Inflammatory Bowel Disease

### New antibodies for the induction and maintenance therapy for ulcerative colitis

The aetiology of Crohn's disease (CD) and ulcerative colitis (UC), both known as inflammatory bowel disease (IBD), remain poorly understood. Also the therapeutic approach is currently limited to steroids, immunomodulators and the blockade of tumor necrosis factor α (TNF-α). Recently, the role of leukocyte recruitment into the gut thorugh the binding between α4β7 integrin and adhesion molecules, mainly mucosal addressin-cell adhesion molecules (MAdCAMs) has been found to play a key role in maintaining active chronic inflammation into the bowel. Thus, a new therapeutic approach has been successfully investigated. The development of vedolizumab, a gut-selective antibody against α4β7 integrin, represents a novel drug class, with different mechanism than anti-TNFs, that results to be effective and safe both in Crohn's disease and ulcerative colitis. The multicenter clinical trial GEMINI 1 and 2 conducted on subjects with active moderate-to-severe ulcerative colitis and Crohn's disease has led to establish the efficacy of this new class of drugs.
Based on the results of the GEMINI trials, vedolizumab has been approved by the European Medicines Agency and Food and Drug Administration for both Crohn's disease and ulcerative colitis. It represents a novel and effective therapeutic alternative to anti-Tumor Necrosis Factor agents in patients who fail conventional therapy, with expected similar efficacy and a good safety profile, due to the gut-selective mechanism.
Next challenges are to adapt more selectivity and to understand the patients that might benefit most from such terapies, in order to personalize medicine.



HIGHLIGHT

**Pietro Invernizzi**

Principal investigator of the Laboratory of Hepatobiliary Immunopathology

## Implications of genome-wide association studies in novel therapeutics in primary biliary cirrhosis

Genome-wide association studies have revolutionized the search for genetic influences on complex disorders, such as primary biliary cirrhosis. To date, four genome-wide association studies and two Illumina® immunochip studies of this condition have confirmed associations at the human leukocyte antigen (HLA) locus and identified 27 non-HLA risk loci. The tertiary referral center for autoimmune liver diseases at Humanitas is one of the largest centers in Europe and gave a fundamental contribution on current knowledge on the genetic architecture of primary biliary cirrhosis.
Within its very active program of genetic research in primary biliary cirrhosis, the center coordinates a national multicentric effort that allowed to collect DNA from about 1,500 Italian patients. Overall, these studies highlighted the remarkable contribution of key immunological pathways in the disease that may be involved in the initial mechanisms of loss of tolerance and the subsequent inflammatory response and chronic bile duct damage. Results from genome-wide association studies have the real potential to be translated in biological knowledge and, hopefully, clinical application. There are a number of immune pathways highlighted in genome-wide association studies that may have therapeutic implications in primary biliary cirrhosis and in other autoimmune diseases, such as the anti-interleukin-12/interleukin-23, nuclear factor-kb, tumor necrosis factor, phosphatidylinositol signaling and hedgehog signaling pathways. It is remarkable how the demonstration by Humanitas researchers in the past years that primary biliary cirrhosis is associated with a genetic variant of the interleukin 12 gene has stimulated an active clinical program to evaluate the efficacy of an anti-IL-12 monoclonal antibody. Further areas in which genome-wide association studies findings are leading to clinical applications both in primary biliary cirrhosis and in other autoimmune conditions, include disease classification, risk prediction and drug development.



HIGHLIGHT

## Clinical translation of strategies targeting myeloid cell accumulation in cancer patients

**Antonio Sica**

Principal investigator of the Laboratory of Molecular Immunology

Preclinical data show that selected myeloid cell populations orchestrate tumor promoting conditions, indicating these cells as attractive therapeutic targets. We and others have previously demonstrated that myeloid-derived suppressor cells (MDSCs) and tumor-associated macrophages (TAMs) are the predominant myeloid populations arising during tumor development and expressing tumor promoting functions. Their generation is tightly associated with the altered hematopoietic output occurring in cancer bearers, defined as "emergency hematopoiesis". Hence, targeting pathways that drive MDSCs and TAMs accumulation may provide new therapeutic opportunities against cancer. The macrophage-colony stimulating factor 1 (MCSF-1) is a major survival factor of macrophages. Together with other groups, we have recently observed that administration of an anti-MCSF receptor antibody in vivo prevents TAMs accumulation in preclinical tumor models, as well as in tumor tissues of cancer patients across various tumor types. Administration of the anti-MCSF receptor antibody in patients with neoplastic disorder characterized by CSF-1 overexpression (diffuse-type giant cell) resulted in a striking tumor inhibition (70%), proving this pathway as a new therapeutic option. We also identified a member of the retinoid-related orphan receptor γ (RORC) family of transcription factors as a key driver of tumor-associated emergency hematopoiesis leading to MDSCs expansion, and validated this observation in colorectal cancer patients. Inhibition of RORC-mediated emergency hematopoiesis resulted in inhibition of tumor growth in preclinical models (fibrosarcoma and mammary carcinoma). Development and clinical translation of specific inhibitors of this pathway is a now a major effort of our research group.

TOP PAPER

Jaillon S, Moalli F, Ragnarsdottir B, Bonavita E, Puthia M, Riva F, Barbati E, Nebuloni M, Cvetko Krajinovic L, Markotic A, Valentino S, Doni A, Tartari S, Graziani G, Montanelli A, Delneste Y, Svanborg C, Garlanda C, Mantovani A.

### The humoral pattern recognition molecule PTX3 is a key component of innate immunity against urinary tract infection.

*Immunity. 2014* Apr 17;40(4):621-32. doi: 10.1016/j.immuni.2014.02.015.

Immunity in the urinary tract has distinct and poorly understood pathophysiological characteristics and urinary tract infections (UTIs) are important causes of morbidity and mortality. We investigated the role of the soluble pattern recognition molecule pentraxin 3 (PTX3), a key component of the humoral arm of innate immunity, in UTIs. PTX3-deficient mice showed defective control of UTIs and exacerbated inflammation. Expression of PTX3 was induced in uroepithelial cells by uropathogenic Escherichia coli (UPEC) in a Toll-like receptor 4 (TLR4)- and MyD88-dependent manner. PTX3 enhanced UPEC phagocytosis and phagosome maturation by neutrophils. PTX3 was detected in urine of UTI patients and amounts correlated with disease severity. In cohorts of UTI-prone patients, PTX3 gene polymorphisms correlated with susceptibility to acute pyelonephritis and cystitis. These results suggest that PTX3 is an essential component of innate resistance against UTIs. Thus, the cellular and humoral arms of innate immunity exert complementary functions in mediating resistance against UTIs.

Cunha C, Aversa F, Lacerda JF, Busca A, Kurzai O, Grube M, Löffler J, Maertens JA, Bell AS, Inforzato A, Barbati E, Almeida B, Santos e Sousa P, Barbui A, Potenza L, Caira M, Rodrigues F, Salvatori G, Pagano L, Luppi M, Mantovani A, Velardi A, Romani L, Carvalho A.

### Genetic PTX3 deficiency and aspergillosis in stem-cell transplantation.

*New England Journal of Medicine.* 2014 Jan 30;370(5):421-32. doi: 10.1056/NEJMoa1211161.

sequences, but the difference stems from fine tuning of gene-regulation mechanisms.
Humanitas has made a substantial contribution to the advances in miRNAs in various research activities, from cardiovascular (see the interview with **Gianluigi Condorelli**) to innate immunity and inflammation. At the moment we are evaluating these molecules as biomarkers in different human conditions.
As it can be seen, bench-to-bedside is a continuous return journey: this back and forth process is vital in biomedical research. ■

# Oncology

# Innovation through continuity

Interview with
**Armando Santoro**

Director of Humanitas Cancer Center

**Our fight against cancer at Humanitas is taking on new challenges, encouraged by the positive results so far.**

### How does cancer research at Humanitas affect – and improve – patients' lives?

Let us now examine thoroughly our already existing research activity: it is carried out in a wide variety of areas and not only does it follow up from continuous positive results, but also renovates – and innovates – year by year. Innovation runs throughout all fields of the fight against cancer: medical therapies, surgical interventions, radiotherapy. This year we have focussed our efforts on tumors of the genitourinary system and of the gastrointestinal system (see the highlight of **Guido Torzilli** and **Alessandro Zerbi** and the highlight of **Carlo Carnaghi** and **Lorenza Rimassa**).
Thanks to our wide range of equipment, we continue to be able to offer the most modern and precise diagnostic pathways in oncology. Imaging techniques are impressively expanding the potentiality in the diagnosing and in the evaluation of the response to treatment.
In addition, we have increased robotic surgery which – being less demolitive – allows for a sharp reduction of both the postoperative phase and postsurgical complications.
In radiation therapy, we have invested in the most advanced technologies to provide accurate, selective and effective therapeutic plans (see the highlight of **Paolo Zucali**, **Marta Scorsetti** and **Giorgio Guazzoni**).
All in all, the clinical advantage results from the combination of several improvements and innovations in the therapeutic approach from different fields, namely sophisticated and precise radiation therapy or surgery, whose association to targeted therapy allows us to be optimistic about the capacity to control cancer.

### You mentioned targeted therapy. What progess has been made in this area and in medical oncology in general?

Well, we can describe progress looking at three different research areas: not only targeted terapies, but also development of new anticancer drugs, and immunological therapies. Let us begin with an area where Humanitas remains a key player, the area of targeted drugs – also named molecular drugs or biological drugs – can be properly considered Precision Medicine (see also the interview with **Alberto Mantovani**). This approach implies a precise profiling of cancer in order to optimize the appropriateness of the treatment since the therapy is targeted against a given molecular alteration.

### Has any further progress been made in this area?

Development of targeted therapies has substantially contributed to enforce the role and relevance of translational research, and to change the way we face cancer treatment.
New developments regard two mutually supporting conditions: on one hand, the increasing possibility to characterize genetic alterations responsible for the disease, thanks to next-generation sequencing techniques which have been activated at Humanitas, and on the other, the availability of a huge number of biological molecules able to target those mutations (see also the highlight of **Carmelo**



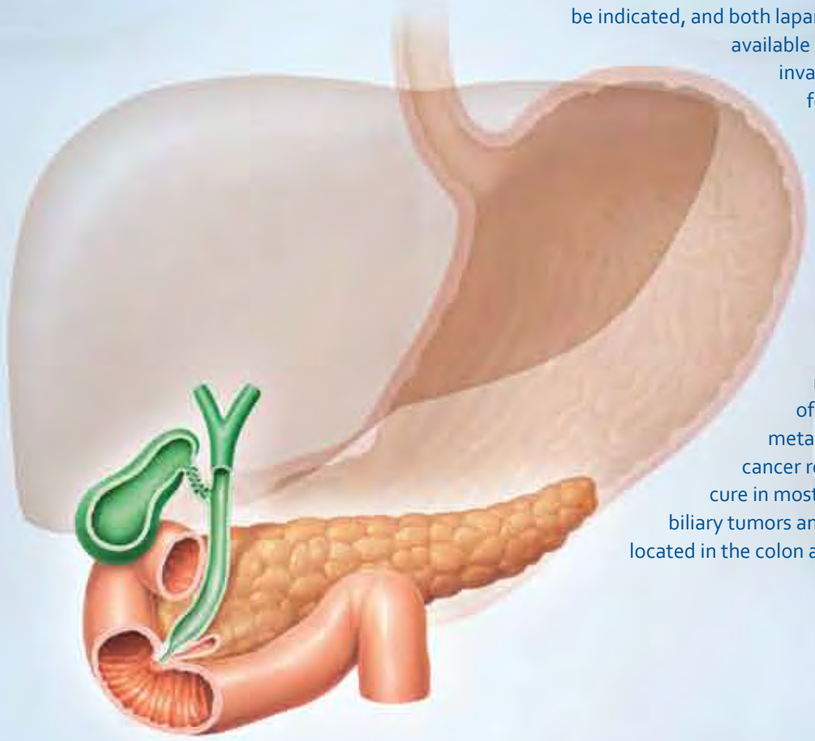
**Guido Torzilli**
Director of the Division of Hepatobiliary Surgery

**Alessandro Zerbi**
Director of the Division of Pancreatic Surgery

HIGHLIGHT

## New concepts and techniques in pancreatic and hepatobiliary surgery

Pancreatic cancer is the fourth cause of cancer death and it is characterized by a late diagnosis and poor survival. In the last years results have been slowly improving, thanks to the availability of new chemotherapic regimens, better patients selection, and improved surgical outcome. Patients with pancreatic cancer at Humanitas are managed by a multidisciplinary team including dedicated surgeons, medical oncologists, radiation oncologists, gastroenterologists, radiologists and pathologists.
When feasible, surgical resection remains the cornerstone of treatment, always integrated in multimodal approaches with adjuvant or neoadjuvant radio-chemoterapic regimens. Surgery of pancreatic cancer is highly demanding, requiring sometimes multivisceral resections and vascular reconstruction. In selected cases a mini-invasive approach can be indicated, and both laparoscopic and robotic procedures are available at Humanitas. More often mini-invasive approaches are recommended for pancreatic tumors different from cancer, such as cystic and neuroendocrine tumors. Multicenter clinical trials on postoperative pain control and enhanced recovery after surgery are available, and contribute to the improved surgical outcome. Hepatobiliary surgery has been widely implemented in the recent years to meet a request of treatment for both primary and metastastic liver tumors , which still have cancer removal as a key factor for patients' cure in most types. Hepatocellular carcinoma, biliary tumors and metastases from primaries located in the colon and rectum, whenever resectable, have surgery as one of the best therapeutic options. Then – being resectability a clue for patients' management – the hepatobiliary surgical team in HRH has concentrated its efforts towards improving this aspect, getting an internationally recognized leadership as promoter of a new concept in terms of surgical technique. Original operations have been for the first time described and reported in medical literature. An English textbook on the peculiar surgical approach has been released. Reports on long-term clinical results confirming the relevant impact of Humanitas Research Hospital's hepatobiliary surgical team approach on patients' safety and prognosis, and on operability on otherwise non-treatable subjects, have been published or are going to appear in indexed medical literature. Advanced hapatocellualr carcinoma, and multiple liver metastases from colorectal cancer represent the type of diseases on which these techniques have provided the best advantages, and have resulted in an expansion of the indication for surgery. This leadership has brought Humanitas Research Hospital to function as headquarter of a new Scientific Society (EWALT) devoted to the study of liver tumors and endorsed by many prestigious institutions scattered worldwide.
Finally, a translational approach to liver tumors to improve the patients selection for local treatment and to better tailor surgical treatment to those who may get more benefit from its application has been started with the activation of a new laboratory within the layout of the hepatobiliary surgical department: monthly based meetings involving clinicians and scientists, and close cooperation with national and international groups of scientists have been successfully promoted. Furthermore, application for several grants has been submitted within the few months from the lab's activation.





**Carlo-Stella** and **Matteo Simonelli**), due to the advances in clinical pharmacology.
A meaningful example is represented by malignant melanoma, a cancer that had a poor prognosis until not so long ago, and has seen promising perspectives in terms of improvement in survival. In a large number of cases ranging from 40% to 50%, a BRAF mutation can be found and anti-BRAF drugs, i.e. ipilimumab, have been used with quite positive results. The greatest interest however, comes from the sequential or combined use of several targeted drugs with different mechanisms of action – in the case of melanoma ipilimumab and another biologic agent whose name is antiMK – in order to attack cancer on multiple fronts, and strengthen the possibility to overcome it, or reach longer survival.
Targeted therapy has brought about new opportunities and presented considerable advantages for the treatment of breast cancer, especially for HER (Human Epidermal Growth Factor) 2-positive cases which account for a 20-25% of all breast tumors. Very recently, another two molecules have been added to the list, beside trastuzumab. The first is pertuzumab which has been shown able to significantly improve the survival of patients with metastatic disease. The other is trastuzumab-emtansine (T-DM1), an antibody-drug conjugate which seems to fulfill the requirements for optimal targeted therapy, that is maximizing efficacy while minimizing toxicity. Notably, an amazing and promising improvement in the therapeutic outcomes has been registered in the field of haemato-oncology, an area of excellence at Humanitas, but which had few therapeutical options until recently, in terms of target therapy.
A series of promising drugs – e.g. monoclonal antibodies – for chronic lymphocytic leukemia, non-Hodgkin lymphomas, myelodysplastic syndromes and myeloproliferative neoplasms, is at the moment in an advanced experimental phase.
For instance, international research studies which Humanitas Cancer Center has conducted or taken part in, have shown the high efficacy of ibrutinib and idelalisib in certain forms of lymphomas.

### And this is the second aspect you mentioned: the development of new drugs.

For the development of new drugs and due to its pivotal role in this activity, Humanitas has expanded the laboratory of Clinical Pharmacology, where phase I studies are carried out, and which supports basic and translational research in the



development of new drugs tailored on molecular and genetic characteristics of the disease. Its activity was at first focused on solid organ tumors, which progressed towards increasing research on haematological malignancies.
This means that, thanks to our active participation in international clinical trials – we seldom took part as coordinators – we have gained expertise in the whole process of the development of new drugs: from phase 1 (evaluation of safety and dose-finding of new drugs) to phases 2 and 3 (evaluation of drug-effectiveness and/or comparison to other therapeutic options available in a large group of patients).

HIGHLIGHT

**Luca Castagna**
Division of Medical Oncology and Haematology

**Enrico Lugli**
Laboratory of Clinical and Experimental Immunology

**Domenico Mavilio**
Principal Investigator of the Laboratory of Clinical and Experimental Immunology

## Haploidentical hematopoietic stem cell transplantation as new frontier in the cure of hematologic malignancies

Allogeneic stem cell transplantation is currently the gold standard therapeutic approach to cure several hematological malignancies given the ability of alloreactive immune cells of the donor to eliminate cancer cells in the recipient. In the absence of HLA-identical donor, there are three possible sources of stem cells: 1. from mismatched unrelated individuals; 2. From cord blood; 3. from mismatched related donors (mainly haploidentical).
While the first two choices require an extensive search in the currently available banks for such biological specimens worldwide, the third one is often immediately available within the families of the aff ected patients. Hence, this procedure highly improved the availability of a compatible stem cell source, remarkably shortened the intervals between the diagnosis and the transplant and made it possible for patients lacking compatible donors to have access to a cure.
In 2009, we adopted a novel approach of haploidentical hematopoietic stem cell transplantation (haplo-HSCT) based on infusion of unmanipulated stem cells from T-repleted bone marrows and post-transplantation cyclophosphamide (PT-Cy) to deplete alloreactive T cells and reduce the immunological complications such as graft versus host disease (GvHD) and host versus graft reaction (HVG). In collaborations with the Institute Paoli Calmettes in Marseille (France), we transplanted more than 200 patients and we experienced surprising high rates of positive clinical outcomes in term of disease free survival (47%) and overall survival (51%).
Among all hematologic malignancies treated, patients affected by Hodgkin lymphomas, as well as those suff ering from non-Hodgkin lymphomas showed the best prognosis. Moreover, the presence of a reduced conditioning regimen before the infusion of haploidentical stem cells allowed us to cure aged patients (up to 70 years old) that before were not eligible for bone marrow transplants.
Our team analyzed the patterns of immune reconstitution following haplo-HSCT and revealed that a population of T cells with stem cell-like properties and superior reconstitution capacity (as revealed by preclinical models) is extremely frequent in the early days following transplantation. These T memory stem cells, or TSCM, along with conventional memory T cells present in the graft, allow the transfer of tumor- and virus-specific immunity from the donor to the patient.
We are currently evaluating whether the composition of lymphocytes present in the graft influence the clinical outcome of the transplanted patients in the short and the long term as far as infectious reactivations and disease recurrence are concerned. Ongoing laboratory experiments aim to identify the molecular mechanisms at the basis of the functional recovery of Natural Killer (NK) cells, a population of lymphocytes specialized in the anti-tumor immune response. In the future, we expect to manipulate the immune system to increase its protective capacity following haplo-HSCT.



HIGHLIGHT

**Carmelo Carlo-Stella**
Principal Investigator of the Laboratory of Cancer Therapeutics; Division of Medical Oncology and Haematology

**Matteo Simonelli**
Division of Medical Oncology and Haematology

## Early-phase trials at Humanitas Cancer Center

Over the last decade, a better understanding of the molecular biology of cancer, along with the identification of DNA mutations which determine cancer onset and progression led to the clinical development of novel therapeutics that specifically target oncogenic DNA mutations, thereby interfering with pivotal signaling pathways dysregulated in tumor cells. Cancer genomics has revolutionized the way we think about and treat cancer, enabling a shift from an empirical strategy based on the clinical-pathological profile of the tumor to biomarker-driven, therapeutic algorithms based on the molecular profile of distinct tumor types. We are moving from the traditional "one size fits all medicine" to the new paradigm of "personalized medicine" that delivers the right care to the right patient at the right time. Personalized oncology includes the concept that every single solid or hematological malignancy in each person is unique in cause, rate of progression and responsiveness to treatments. In order to reach its goals, successful personalized oncology requires several essential steps: selecting optimal drug targets and dosage, predicting which individuals will respond to specific drugs at high rates and who will be less likely to suffer toxic side effects, selecting and monitoring patients for shorter and less expensive advanced clinical trials, improving and providing more effective healthcare for patients. This new approach requires a global collaborative effort between research groups and industry so that diverse populations of cancer patients have the opportunity to participate in innovative clinical trials. For these reasons, along with the birth of our Cancer Center, we have set up a unit for the development of new drugs in Oncology and Haematology with a dedicated team of physicians, research nurses and data managers who work together at early-stage clinical trials. In these type of studies we evaluate the safety, identify the best dose and schedule and define pharmacokinetic and pharmacodynamic properties of new biological agents. Thus, cancer patients who do not respond to standard treatments can take advantage of the opportunity to be treated with these advanced and innovative molecules. In the last few years we have conducted and completed several studies either as a single institution or in collaboration with other cancer centers worldwide, contributing proactively to the clinical development of various molecules. Results from these trials have been presented in international conferences and published in peer-reviewed journals. Currently, we are testing different classes of drugs: small molecules inhibiting signal transduction pathways (e.g. inhibitors or PI3K or BTK) or targeting oncogenic drivers; angiogenesis inhibitors designed to prevent the formation of new blood vessels; immunotherapies allowing the immune system to work harder and/or smarter against cancer cells; monoclonal antibodies targeting tumor-associated antigens. We are also working on the discovery and application of novel biomarkers that can predict which patients will most likely benefit from a specific treatment. Finally, we are exploring strategies to overcome the resistance mechanisms developed by tumor cells against these new compounds, where resistance may result from secondary genomic events, genomic instability or intratumor heterogeneity.



**Carlo Carnaghi**
Division of Medical Oncology and Haematology

**Lorenza Rimassa**
Division of Medical Oncology and Haematology

## Clinical and translational research on hepatocellular carcinoma, biliary tract cancer and neuroendocrine tumors

Humanitas Cancer Center participates actively in clinical and translational research on liver cancer. Here, the patients with liver cancer are offered a multidisciplinary approach and may receive the standard treatment as well as new biological targeted therapies. We are actively involved in conducting phase I, II, III national and international clinical trials, evaluating new agents that block cancer cell growth by interfering with specific target molecules that play a role in different steps of the carcinogenesis process. These new agents can represent new therapeutic options for patients with liver cancer, especially hepatocellular carcinoma (HCC), a disease for which a single drug (i.e. sorafenib) has been approved. At present, the most interesting drug is tivantinib – an orally administered small molecule inhibitor of c-Met, which has been implicated in cancer cell proliferation and metastasis – for the treatment of pretreated advanced HCC. We had a principal role in international phase I and II clinical trials with this new agent, and we published very interesting clinical and translational results, based on which, we are currently running an international phase III trial with the aim to confirm them and to offer a new therapeutic option to patients with this disease. We are also involved in international clinical trials with other new targeted agents, e.g. multi-kinase inhibitors and anti-angiogenetic drugs. Furthermore, we participated in an Italian translational research evaluating the predictive role of microRNAs (miRNAs) in patients treated with sorafenib and we identified a miRNA, miR-425-3p, associated with the trend of time-to-progression and progression-free survival.

With regard to biliary tract cancer, we conducted a national multicenter clinical and translational study evaluating the role of vandetanib, an orally active anti-angiogenetic and anti-EGFR drug, as single agent or in combination with chemotherapy, in patients with advanced disease untreated with chemotherapy. We recently published the clinical results of this trial.

Neuroendocrine tumors (NETs) are an heterogeneous and rare group of diseases characterized by several specific clinical and biological features. Our interest was based on preclinical and clinical trials that investigate the main aspects of these tumors. We evaluated the efficacy of telotristat, a new tryptophan hydroxylase inhibitor in patients with severe diarrhea (carcinoid syndrome) uncontrolled by somatostatin analogs. In this field we are also evaluating a new formulation of long acting octreotide (somatostatin analog).

Recent data showed that everolimus, an mTOR inhibitor, improves progression-free-survival of pancreatic NETs. We were the Italian coordinators for Radiant4 study that evaluated the efficacy of everolimus in "non-pancreatic" NETs. Morover we are involved in the SEQTOR study, an European randomized trial comparing everolimus vs chemotherapy in order to identify the best first line treatment in metastatic pancreatic NETs.  Immunotherapy is one of the most promising frontier of the cancer treatment and we participated in a phase II clinical trial focused on the new antibody anti PD-L1 in patients affected by pretreated Merkel cell carcinoma, a rare skin NET.

The integration of translational research into clinical trials will improve clinical outcomes, and will identify potential markers of response and prognosis, to transform care into a more selective and personalized management based on the individual patient's cancer biology, allowing patients who are likely to respond positively, to receive optimal care, while sparing those with a low probability of a benefit from unnecessary toxicity and cost.

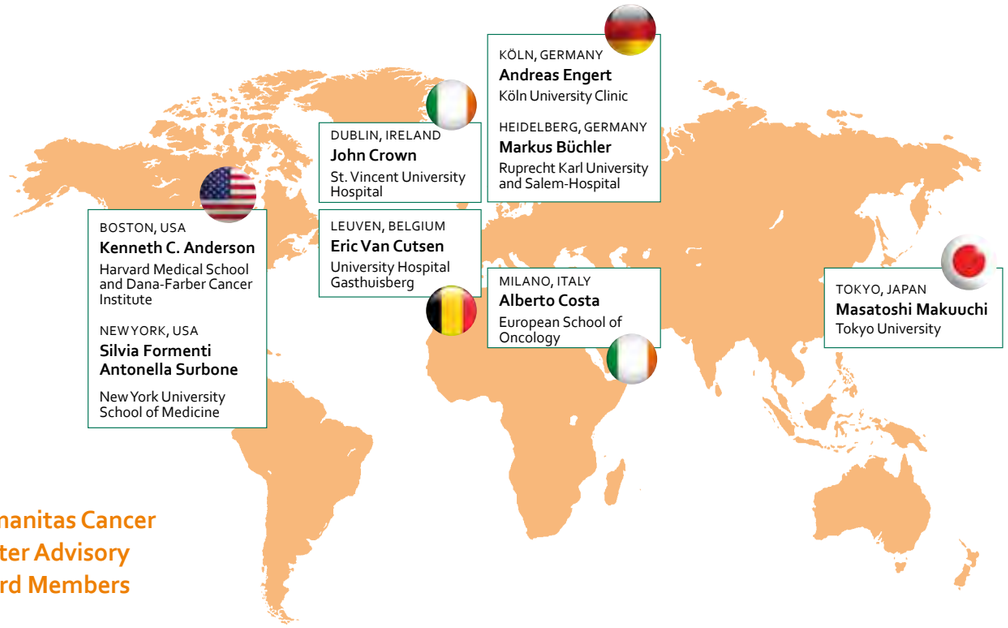
This is true for all classes of anticancer drugs, from traditional chemotherapy to biological therapy.
We have participated in the development of phosphoinositide 3-kinase (PI3K) delta inhibitors, emerging among several other drugs as the ones which would be able to change our approach to treat a variety of haematologic diseases.
Besides, we participated in the development of an anti-cancer drug acting as an ALK (anaplastic lymphoma kinase) inhibitor, which is impressively more effective than previously available options in inducing tumor shrinkage or stabilization, and was recently approved for the treatment of patients with non-small cell lung carcinoma carrying the ALK fusion gene.

### And, there have been important developments in immunotherapy as well...

No doubt. This the third field we have been deeply involved in, with a leading position at an international level. In the next 5 to 10 years, immunotherapy will make great progress in the fight against cancer. I am referring to the modern vision of immunotherapy, as opposed to the classical concept of immunotherapy which has basically failed, at least in terms of fighting the cancer. In fact, the latter was based on finding antigens on cancer cell surface against which specific antibodies or a vaccine could be addressed. Modern immunotherapy has a new and different strategy: releasing T lymphocytes which play a major role in individual defense with the purpose of triggering immune cascades which inhibit cancer progression. Relevant improvements in outcomes have been observed for malignant melanoma, lung cancer, breast cancer, kidney cancer and bladder cancer. Notably, results that I would define impressive have been reported also in relapsing Hodgkin's lymphoma.
Actually this class of drugs, precisely because of their mechanism of action, is quite promising for a large variety of oncologic conditions at different stages, either early or metastatic. In addition, they are being tested as adjuvant options after surgery in order to increase the probability of a disease-free life guaranteed by surgery.

### This kind of reasearch seems quite interesting, and yet demanding.

One of the key aspects is collaboration both within our own Cancer Center and between research centres in Italy and abroad.




**Humanitas Cancer Center Advisory Board Members**



In fact Humanitas is actively engaged in several international studies and at the moment 7-8 research protocols are being fine-tuned. Within our Center we strongly encourage full cooperation with teams of preclinical and translational research in order to develop experimental models. The main research questions we are investigating are:

1. better understanding of the mechanisms of action of immunotherapy
2. identifying parameters and biomarkers predictive of the therapeutical response.

### Parameterers and biomarkers: does this imply that thus immunotherapy is not the same for any patient?

We are committed to providing assistance geared around patients' needs and characteristics, with the patient as a person.
This is particularly necessary for complex patients, a growing subpopulation among oncologic patients, as a consequence of incident comorbidities and longer survival. To accomplish this task we rely on a multidisciplinarity and multispecialty approach, which allows us to provide integrated and personalized assistance.
Making treatment recommendations for patients taking into account age-related and tumor-related issues can be challenging. Notably, these subgroups of patients are usually excluded from clinical trial. But it is mandatory to take into account this increasing number of oncologic patients with specific needs and being able to decide which strategy is appropriate.
We are developing research protocols in this field which attains to public health, more specifically public health in oncology. Among these, one of our strengths is the management of long-term survivors.
Patients who have overcome cancer are increasing year by year. This positive fact is supported by our attention to their special needs, not necessarily due to cancer itself or related interventions, rather to the physical and psychological burden they underwent. Even if after the fifth disease-free year the risk of recurrence is quite low and similar to that of an otherwise healthy person to develop a first onset disease – and may be considered

**Giorgio Guazzoni**
Director of the Division of Urology

**Marta Scorsetti**
Director of the Division of Radiotherapy and Radiosurgery

**Paolo Zucali**
Division of Medical Oncology and Haematology

## We can deploy many weapons against prostate cancer, and many of these are new and innovative

Prostate cancer is the most common solid neoplasm and the second cause of death by cancer in men, representing a major medical problem for the male population. The natural history of the disease from an asymptomatic, organ-confined disease to a locally advanced, metastatic, and hormone-refractory disease describes the complexity of its biology and justifies the need for a smooth collaboration between physicians with competence in different fields. An early diagnosis is mandatory to improve the outcomes. The optimal management for localized prostate cancer considers several options including active surveillance, surgery, radiation therapy and focal therapies. Management of the progressive disease after first-line treatments needs an integrated approach that includes radiation therapy, focal therapy, hormone therapy, chemotherapy or other novel target treatments. A multidisciplinary team approach is crucial to achieve advantages throughout all the phases of prostate cancer management in order to improve survival and life quality.
At Humanitas, a multidisciplinary prostate cancer team (urologists, oncologists, radiation oncologists, andrologists, pathologist, physiologists, physiotherapists, nurses) manages patients with prostate cancer. All these specialists organize and participate in multidisciplinary weekly meetings to discuss the cases and propose appropriate patients-oriented options. Our institution offers the most modern technologies in terms of diagnostics (new molecular biomarkers, multiparametric magnetic resonance, choline C11 PET-CT scan, target fusion biopsy) surgery (robotic surgery), radiation therapy (IMRT, Intensity-Modulated Radiation Therapy; SBRT, Stereotactic Body Radiation Therapy), support and rehabilitation (andrology examinations, counseling, pelvic floor muscle exercises). Humanitas participates in national and international collaborative working groups, and is involved in basic science and several multicentric clinical trials.
The evolution of radiation therapy, the progress in surgical techniques, as well as the introduction of new drugs designed to target specific molecular alteration, has revolutionized the treatment of prostate cancer. These are all examples of how our institution promotes continuous close collaboration of the multidisciplinary prostate cancer medical team with different research labs.

HIGHLIGHT



"cured" – long term survivors should be regularly followed up according to a personalized plan tailored to their cancer type, the treatments received, the characteristics and severity of long-term negative effects that potentially occurred, and the risk of a consequent cancer.

**And that means patients who return to normal life once they leave the hospital, but at the same time need to be followed. It is important that these patients do not feel ill in any way.**

We have been investing considerably on this aspect. In the last few weeks, we have launched the cancer-free platform (see the highlight of **Elena Lorenzi**) an informatic tool which implies participation and interaction of both doctors and patients. The idea behind this is that, after the fifth year disease-free and with no therapy, the patient is referred to his/her primary care physician rather than followed by the Cancer Center care-provider. Each patient is provided with an individual passport gathering not only previous interventions, but specific needs, in order to draw his/her individual profile, so as to guide and facilitate the management by the primary care physician. In this way, patients are never left to their own devices or bound to hospital.
The most relevant advantage is the psychological relief deriving from the awareness of being looked after and feeling well.
This approach has important socio-economic implications. It emphasises the role of community medicine, while repositioning that of the hospital, where acute conditions have to be selected and addressed.
Moreover, a reduction in health expenditure is expected, which is certainly appreciated at times of crisis and resource shortage. It attains to public health and research in public health, a promising and farsighted field the world over, and where Humanitas has to be a playmaker.
A good example of this is the Horizon 2020 European Research project, which has a dedicated section on public health, thus promoting and empowering research and development on healthcare management models able to provide advantage for the vast majority of the population.
Still in relation to cured or long-surviving patients, we are launching a quite challenging investigation, starting from the well-known assumption that they have a high probability of second or subsequent malignancy in their lifespan. Our study protocol is aimed at understanding molecular mechanisms underlying the onset of multiple tumor types in the same patient (e.g. certain mutations). If this hypothesis was confirmed in well-characterized subgroups of patients, an intense and extended (to familials) screening should be performed. ■

**Elena Lorenzi**
Division of Medical Oncology and Haematology

## Cancer-free Program

As the number of cancer survivors increases, the importance of understanding the unique needs of this population also grows. Cancer treatment is associated with long-term effects that can influence patients' quality of life as cardiotoxicity, lung toxicity, metabolic disorders, sexual dysfunction, pain, fatigue, cognitive dysfunction, and psychological distress. This population also faces other issues that can prevent their return to everyday-life as infertility and planning of pregnancy.
Few publications have described the outcome of different survivorship care models, or even defined what constitutes a model of cancer survivorship care. Ideally, a shared-care model, using a risk-stratified approach, can take advantage of the expertise of the cancer team and the primary care provider in coordinating survivor follow-up.
The economic impact of cancer survivorship is considerable also years after diagnosis. Efforts to reduce the economic burden caused by cancer will be increasingly important. The current organization of follow-up leads to redundant and unnecessary testing, using limited economic resources.
The Cancer-free Project tries to facilitate effective collaboration between oncologists and primary care providers and to implement, where appropriate, the transition of survivorship care from the specialist provider to the primary care physician, without abandoning patients from the medical, psychological and social point of view. The project will use the following tools:

1. release of treatment summaries (cancer-free passport)
2. release of individualized care plans (cancer-free program) where exams, timing of assessment and individualized components of care will be specified
3. release of a decalogue with suggestions for patients to reach psycho-physical health
4. creation and updating of a computer platform both for patient and primary care providers that will be used for direct communication with the oncologist and as a source of scientific information about survivorship
5. presence of a dedicated oncologist that will address doubts and questions both from patients and PCP.

HIGHLIGHT

**TOP PAPER**

Shaw AT, Kim DW, Mehra R, Tan DS, Felip E, Chow LQ, Camidge DR, Vansteenkiste J, Sharma S, De Pas T, Riely GJ, Solomon BJ, Wolf J, Thomas M, Schuler M, Liu G, Santoro A, Lau YY, Goldwasser M, Boral AL, Engelman JA.

### Ceritinib in ALK-rearranged non-small-cell lung cancer.

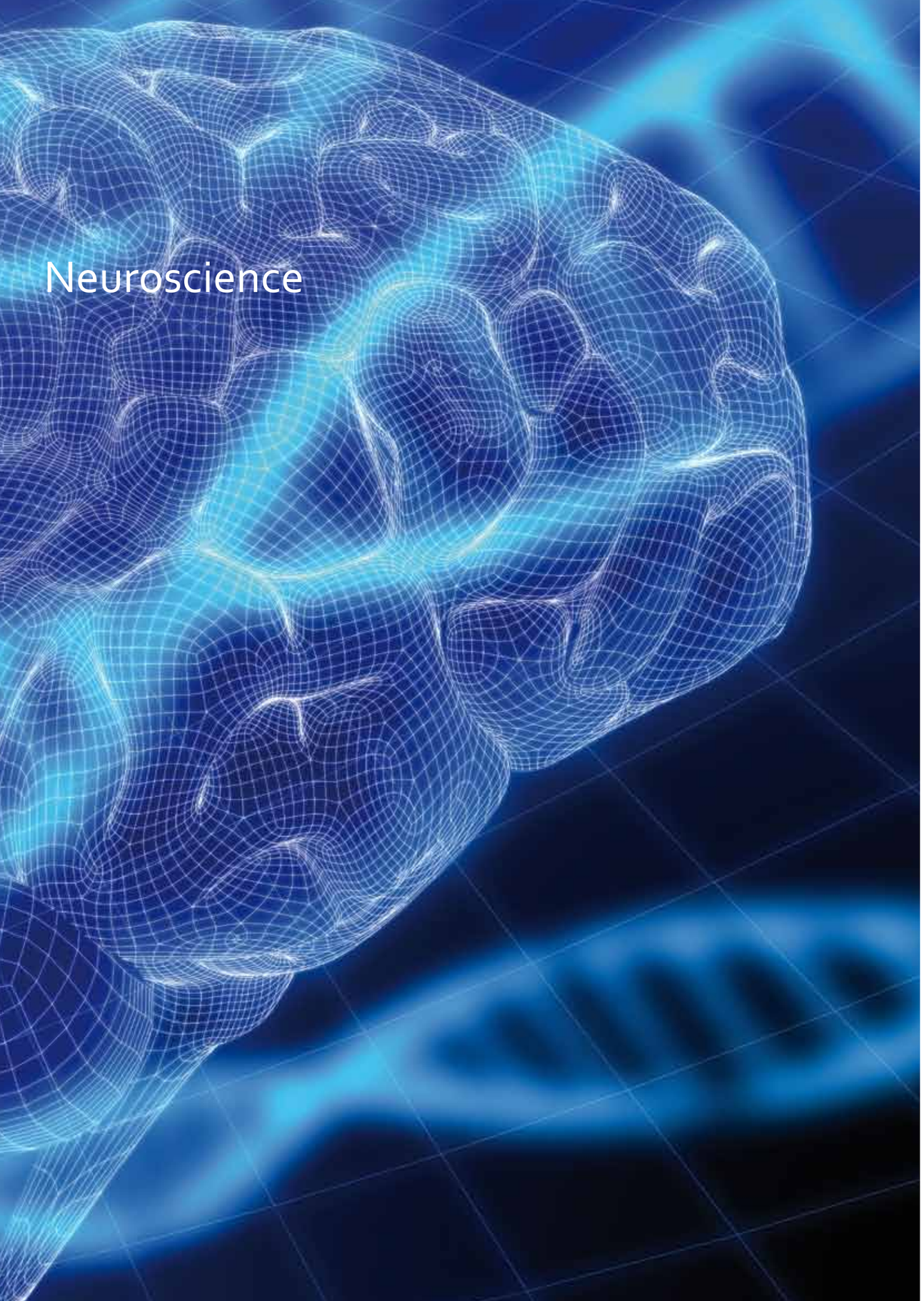
*New England Journal of Medicine.* 2014 Mar 27;370(13):1189-97. doi: 10.1056/NEJMoa1311107.

**Background:** Non-small-cell lung cancer (NSCLC) harboring the anaplastic lymphoma kinase gene (ALK) rearrangement is sensitive to the ALK inhibitor crizotinib, but resistance invariably develops. Ceritinib (LDK378) is a new ALK inhibitor that has shown greater antitumor potency than crizotinib in preclinical studies.

**Methods:** In this phase 1 study, we administered oral ceritinib in doses of 50 to 750 mg once daily to patients with advanced cancers harboring genetic alterations in ALK. In an expansion phase of the study, patients received the maximum tolerated dose. Patients were assessed to determine the safety, pharmacokinetic properties, and antitumor activity of ceritinib. Tumor biopsies were performed before ceritinib treatment to identify resistance mutations in ALK in a group of patients with NSCLC who had had disease progression during treatment with crizotinib.

**Results:** A total of 59 patients were enrolled in the dose-escalation phase. The maximum tolerated dose of ceritinib was 750 mg once daily; dose-limiting toxic events included diarrhea, vomiting, dehydration, elevated aminotransferase levels, and hypophosphatemia. This phase was followed by an expansion phase, in which an additional 71 patients were treated, for a total of 130 patients overall. Among 114 patients with NSCLC who received at least 400 mg of ceritinib per day, the overall response rate was 58% (95% confidence interval [CI], 48 to 67). Among 80 patients who had received crizotinib previously, the response rate was 56% (95% CI, 45 to 67). Responses were observed in patients with various resistance mutations in ALK and in patients without detectable mutations. Among patients with NSCLC who received at least 400 mg of ceritinib per day, the median progression-free survival was 7.0 months (95% CI, 5.6 to 9.5).

**Conclusion:** Ceritinib was highly active in patients with advanced, ALK-rearranged NSCLC, including those who had had disease progression during crizotinib treatment, regardless of the presence of resistance mutations in ALK. (Funded by Novartis Pharmaceuticals and others; ClinicalTrials.gov number, NCT01283516.).




# Studies on gene-environment interactions in brain hold the key for translation to clinics

Interview with
**Michela Matteoli**

Director of Neuroscience Program and Principal investigator of the Laboratory of Pharmacology and Brain Pathology, Director of the CNR Institute of Neuroscience

**When neurosciences shed a light on the complexity of their molecular network, interesting data arise and indicate that not only the interactions between cells, but also those between genetics and the environment need to be addressed: this approach to neurodevelopmental diseases allows surprising and encouraging analogies between important conditions to emerge.**
**Since its early days, research on brain diseases has been following two main tracks: the interaction between genes and the environment, and communication between brain cells. Both pathways have showed since the very beginning how apparently diverse neurological conditions share common factors, with potential effects in clinical practice.**

### Neurodevelopmental disorders: where has research started from, and where is it heading? We are somehow witnessing a revolutionary approach to these conditions.

For several years our research on psychiatric and neurodegenerative disorders has been focusing on the nerve cells and in particular on the synapses – the brain structures that mediate information transfer between neurons. One may say that neurons, communicate "kissing" each other – this kiss is referred precisely to synapses. Through this communication, our brain controls all body functions and all aspects of cognition, including attention, perception, learning, decision making, as well as mood and emotions. More recently, however, evidence has emerged that environmental influences can also heavily contribute to alter synapse function, modifying the risk and the severity of a variety of brain diseases.

### Can you tell us more about how gene-environment interactions affect central nervous system diseases/ disorders?

Since the neurodevelopmental hypothesis of schizophrenia was proposed – which suggests that a disruption of brain development during early life underlies the later emergence of psychosis during adulthood – the pathophysiological origins of many neuropsychiatric diseases are increasingly recognized to associate with environmental influences. Among these, inflammation is a key factor influencing physiology and pathology in the immature and mature brain.
This perspective has gone beyond the idea that the central nervous system and the peripheral immune system act independently, and only recently has inflammation emerged as an important factor operating in the nervous system. At the moment, we are trying to define the extent to which the immune system activation and inflammation – alongside with genetic factors – play a part in the occurrence and progression of neurological and psychiatric diseases.

### What kind of processes have you identified?

Inflammation may resolve without any harmful effects on the brain, even contributing to reparative processes,



or can be shifted to a chronic inflammatory state, thus contributing to injury, enhancing central nervous system vulnerability and/or adversely affecting brain development. In the last years, evidence mainly based on behavioral or epidemiological studies, raised the possibility that inflammation may not represent the mere consequence of a degenerative process occurring in the adult brain, but could itself modify the risk or severity in a variety of brain diseases. And indeed we are getting to the demonstration that inflammation modifies synapse structure and function.

### And how would this process work?

A number of molecules involved in inflammation has been found to regulate specific neuronal processes raising the possibility that inflammatory cascades, either alone or in combination with a susceptible genetic background, may impact synapse formation and plasticity, thus leading to a disease condition. Certainly, given these background conditions, it is necessary to identify these molecules as systematically as possible, and this is what we have been working on in the last years at our laboratory: such a complex project is an inevitably elaborate process made up of several stages.

### What would you describe as the most important stages?

The first step was to provide evidence about specific molecular mechanisms through which proteins involved in psychiatric disorders negatively affect the structure and function of synapses. Our laboratory has identified two proteins involved in the control of dendritic spine (i.e. the small membranous protrusion from a neuron's dendrite that typically receives input from presynaptic terminals and represents the site for controlling synaptic strength and memory storage morphology) and showed that a reduction in their levels of expression results in spine abnormalities due to a reduced synaptic plasticity. Notably, these morphological alterations were associated to learning and memory defects. Among these proteins, Eps8, when expressed at lower levels, as is the case with the brain of autistic patients, makes the spine immature and disables the morphological changes that are typical of learning. Another protein, called SNAP-25, is reduced in schizophrenia and in ADHD, affecting short-term presynaptic plasticity and spine morphology. Indeed we have shown in the current year that SNAP-25 is a central protein of the synapse which binds several partners, that crucially operate at the synapse.

More recently, we have started novel lines of investigation aimed to define whether and to what extent environmental influences, such as immune activation and inflammation, affect the synaptic structure and function and cooperate with a susceptible genetic background, possibly leading to psychiatric and neurodegenerative diseases.

### Could you fill us in a bit more about these promising news?

We are investigating whether immune challenges, prenatally or postnatally delivered, impact on synaptic protein networks and function, thus resulting in psychiatric, neurodevelopmental diseases. As an example we "simulated" a bacterial or viral infection, using specific stimuli delivered at selected times during the prenatal period, and unexpectedly found that this results in alteration of brain functionality in the offspring. We are now investigating the synaptic components which are specifically involved. In parallel, by using genetic models of immune deregulation, we are gathering evidence for the existence of a direct correlation between an abnormal activation of the immune system and important defects at the synaptic level.

### And would you say that these correlations are at last a starting point for treatment at this stage?

Actually, the results from our studies are already opening the road to novel forms of treatment of neurodevelopmental diseases through modulation of the immune system, using pharmacological approaches which are already in use for the treatment of immune diseases.
Along the same line, in a parallel line of research, we are investigating whether the inflammatory process at early stages of neurodegenerative diseases triggers a cascade of events that may eventually lead to neuronal damage.
In this respect, we have evidence for a crucial role of microglia, the immune component in the brain, in driving the neurodegenerative events through the metabolism of the beta amyloid protein, the main component of plaques in Alzheimer's disease. Notably, this process occurs even in the absence of genetic mutations. A crucial contribution of inflammation and microglia activation to the development of sporadic forms of Alzheimer's disease thus emerges, providing novel targets suitable for innovative therapeutic intervention.

### Schizophrenia, ADHD, Alzheimer disease, learning disabilities... are all examples of heterogeneous and



HIGHLIGHT



## Brain diseases: from biomolecular characterization to the identification of diagnostic and prognostic markers

**Giulio Maira**
Division of Neurosurgery

At the moment, research in neurosurgery outlines two main directories.
The first attains the management of glioblastomas, the most frequent and deadliest among brain tumors, with an incidence rate of 6 per 100,000 person-years in Europe. Despite decades of research, the standard treatment, which consists of surgical resection followed by adjuvant chemotherapy and radiation, still results in a dismal mean survival time of only 14-16 months.
Glioblastoma, like the majority of cancers, is characterized by an heterogeneity of biomolecular events, possibly targets on which therapy might be directed. It has been many years now, that together with **Ruggero De Maria, Angelo Vescovi, Gigliola Sica, Roberto Pallini** we have conducted a research project funded by the Ministero dell'Università e della Ricerca Scientifica, investigating some peculiar aspects of tumor biology, in particular the role of neural cancer stem cells in its origin and progression, with the aim to identify new diagnostic/prognostic markers and develop innovative treatment. We were able to show that the tumor vascularization is realized via endothelial differentiation of glioblastoma stem-like cells, to describe the gene expression profile of glioblastoma peritumoral tissue, and to identify a receptor protein, the EphA2 receptor (Ephrin type-A receptor 2) in the membrane of cancer stem cells crucial for the development of glioblastoma. Together with **Michela Matteoli,** we are now starting a new European project that will study the human glioma tumor heterogeneity in order to overcome recurrence and resistance to therapy.
Another interesting field of research is related to the identification of biomarkers predicting the rupture of intracranial aneurysms, the most common cause of subarachnoid hemorrhage, which represents a life-threatening emergency with high fatality, mortality, and morbidity. In fact a quarter of patients with subarachnoid hemorrhage die, and roughly half of survivors are left with some persistent neurological deficit and will depend on others for activities of daily life. Luckily, unruptured intracranial aneurysms are incidentally discovered more and more often, and the possibility to cure even the most complex situations has significantly increased. However, surgical procedures still present some degree of morbidity and mortality, thus raising questions about the necessity of treating incidentally discovered intracranial aneurysms.
Our goal is to identify possible molecular markers in pathologic tissues from intracranial aneurysms and in peripheral blood of patients, allowing to characterize this pathology from a molecular point of view, but also to predict the aneurysm rupture risk. Markers identified in this study may become potential target for non-invasive screening and therapeutic intervention for aneurysms at high risk of rupture. Preventing its occurrence might have a tremendous social, medical, and economical impact.



HIGHLIGHT

**Maurizio Fornari**

Director of
the Division of
Neurosurgery

## New frontiers in neurosurgery

At the moment, research in neurosurgery is focused on three main areas: cancer-related neurological conditions, an increased reduction of surgical invasivity and tackling the degenerative spine condition.
As far as the first area is concerned, the crucial point is developing and assessing innovative surgical interventions for brain malignant tumors. Secondly, a continuous effort is being made towards reducing surgical invasivity, especially when the intervention is performed on central nervous system vessels (i.e. to treat brain aneurysmatic or angiomatous lesions). To this aim, interventional radiology techniques are being increasingly used, as they allow to reach brain vessels and treat vascular lesions through peripheral arterial access.
In terms of the third research activity, degenerative spine was simply not described 30 years ago, while it is currently a considerable challenge for neurosurgical research. Degenerative spine is closely related to ageing in the general population. In other words, to increased life expectancy.
Over time, the spine is involved in a gradual loss of normal structure and function of intervertebral discs and vertebral bodies, with a progressive imbalance that ultimately results in impairment when standing upright and walking.
Preserving the ability to stand upright is the starting point towards tackling human ageing. Our researchers are working both on technologies and surgical techniques, as well as on innovative therapeutic options that are able to prevent the occurrence of the disease, and to control its progression.



TOP PAPERS

Agosta F, Dalla Libera D, Spinelli EG, Finardi A, Canu E, Bergami A, Bocchio Chiavetto L, Baronio M, Comi G, Martino G, Matteoli M, Magnani G, Verderio C, Furlan R.

### Myeloid microvesicles in cerebrospinal fluid are associated with myelin damage and neuronal loss in mild cognitive impairment and Alzheimer disease.

*Annals of Neurology.* 2014 Dec;76(6):813-25. doi: 10.1002/ana.24235. Epub 2014 Oct 16.

**Background:** We have described cerebrospinal fluid (CSF) myeloid microvesicles (MVs) as a marker of microglia activation during neuroinflammation in Alzheimer disease (AD), and characterized their ability to produce toxic amyloid β1-42 (Aβ1-42) oligomers from aggregated or soluble substrate. The aim of this study is to investigate the association of CSF myeloid MVs with neuroimaging, clinical, and paraclinical data in AD and mild cognitive impairment (MCI).

**Methods:** We collected CSF from 106 AD patients, 51 MCI patients, and 29 neurologically healthy controls. We examined CSF myeloid MV content and AD markers. A subgroup of 34 AD and 21 MCI patients underwent structural and diffusion tensor MRI.

**Results:** Higher levels of myeloid MVs were found in the CSF of AD patients and MCI patients converting within 3 years relative to controls, but also, at a lower level, in MCI patients not converting to AD. CSF myeloid MVs were associated with Tau but not with Aβ1-42 CSF levels. CSF MVs levels correlated with white matter (WM) tract damage in MCI, and with hippocampal atrophy in AD.

**Interpretation:** Microglial MVs are neurotoxic and myelinotoxic in the presence of Aβ1-42 . CSF myeloid MVs, mirroring microglia activation and MV release, are associated with WM damage in MCI and hippocampal atrophy in AD. This suggests that hippocampal microglia activation, in the presence of Aβ1-42 in excess, produces neurotoxic and oligodendrotoxic oligomers that, through WM tract damage, spread disease to neighboring and connected areas, causing local microglia activation and propagation of disease through the same sequence of events.

Joshi P, Turola E, Ruiz A, Bergami A, Libera DD, Benussi L, Giussani P, Magnani G, Comi G, Legname G, Ghidoni R, Furlan R, Matteoli M, Verderio C.

### Microglia convert aggregated amyloid-β into neurotoxic forms through the shedding of microvesicles.

*Cell Death & Differentiation.* 2014 Apr;21(4):582-93. doi: 10.1038/cdd.2013.180. Epub 2013 Dec 13.

Ruiz A, Joshi, Mastrangelo R, Francolini M, Verderio C, Matteoli M.

### Testing Aβ toxicity on primary CNS cultures using drug-screening microfluidic chips.

*Lab on a Chip.* 2014 Aug 7;14(15):2860-6. doi: 10.1039/c4lc00174e. Epub 2014 Jun 10.

**diverse diseases or disabilities. Yet, from what you are saying, they appear to share common features…**

Investigations of synapses hold the key to understanding brain processing and function, and shading a light on synaptic defects called “synaptopathies”, involved in major psychiatric, neurological and childhood developmental disorders (including autism, schizophrenia, ADHD), depression, intellectual disabilities. It is indeed becoming more and more evident that different neurodevelopmental conditions share common biological pathways, and that certain brain diseases with similar phenotypes and symptom spectra may arise from disruption of partially overlapping complexes and interacting proteins, in most cases located at the level of the dendritic spine. On the other hand, understanding a given synaptopathy at the level of its genetic, molecular, and synaptic dysfunction is typically insufficient to explain the whole picture which may in fact depend on additional genetics, epigenetics, and environmental factors, which remain to be outlined. Generally speaking, it is reasonable to hypothesize that putative environmental factors that have an impact on these networks during development, may modify their correct organization, possibly leading to a psychiatric phenotype.

**What consequences do you think these considerations may have?**

By working extensively and constantly on such a specific and crucial area, we are hoping to find innovative therapies for intellectual disability-related problems and for the different pathologies of the central nervous system, including neurodegenerative diseases. We need to start from the knowledge of the mechanisms at the basis of these diseases in order to find a cure, which is still missing for most brain disorders. This is the next challenge, and this is the direction in which we are moving now. ■

Cardiovascular

# Bench-to bedside: putting research findings to good use for everyday health

Interview with
**Gianluigi Condorelli**

Director of Cardiovascular Research at Humanitas Research Hospital; full professor of Cardiology, Università degli Studi di Milano

**Translational research in cardiovascular diseases shows promising perspectives in traditional "niches" of research (e.g. cardiomyopathy or rare diseases), but also in conditions alarmingly frequent in the general population (e.g. coronary artery disease or metabolic disorders), called multifactorial diseases.**

### What has been the role of translational research in the yearly account for cardiovascular research?

Cardiovascular research at Humanitas is progressing and constantly meeting objectives of our multiannual plan. Humanitas is in line with the most advanced academic centres in the world. For these high standards to be met, a significant amount of preclinical and clinical research is required, a *conditio sine qua* for performing cutting-edge translational research.
Translating knowledge from basic science to the clinic today is possible through the exploitation of technologies traditionally used for preclinical studies, particularly those within the realm of "omics" sciences (genomics, proteomics, metabolomics, etc.), of human diseases. This approach has been defined "Precision Medicine" and is the focus of a major effort by the US Government. In other areas of investigation, nowadays the gap between the identification of a molecular pathway of disease and the development of a new drug can be bridged much faster than before.

### Could you tell us more about Humanitas' activity within this plan?

At Humanitas, we have set up technologies and skills necessary and sufficient for "genotyping" rare, inherited myocardial diseases (primary cardiomyopathies) through next-generation DNA sequencing and, more importantly, bioinformatics analysis, which allow to identify rare mutations by scanning the genome of a diseased individual and their family members. Our team of bioinformaticians helps investigators, not only in the cardiovascular field but also in other areas, in data mining and interpretation, a task fundamental in "omics" sciences in which the output of a typical experiment generates thousands of data. In addition, we have created a facility for generating iPS cells, embryonic-like cells generated from mature cells of any individual and that can be genetically modified so as to acquire the potential to proliferate indefinitely and to differentiate in a specific *milieu* into any cell type of the human body – in our case, into cardiomyocytes. These cells can be used to reproduce human disease in a test tube. The combination of the two technologies – high-throughput DNA sequencing with bioinformatics analysis of billions of base pairs of DNA for the identification of disease-related mutations and the study of iPS-derived cardiomyocytes – can help us not only identify with certainty the specific disease-causing mutation but also gain further insight into the underlying mechanisms of cardiac malfunctioning in these pathologies, and could lead to the development of better diagnostic procedures and therapeutic interventions (see also the highlight of **Elisa Di Pasquale**).
Another example of the results derived from the application



of basic science technologies to cardiovascular diseases comes from the identification of circulating levels of microRNAs (miRNAs) – small non-coding RNA sequences that regulate gene expression at a post-transcriptional level – in hypertrophic cardiomyopathy, a disease state in which the heart undergoes severe hypertrophy following mutations of specific cardiac genes. We have identified distinct miRNAs involved in different aspects of myocardial remodelling, a pathological process common to many cardiac diseases and which has many biological components, such as enlargement of cardiomyocytes and increased fibrosis. We analysed levels of 21 miRNAs known to be involved in different, specific aspects of myocardial remodelling and found significant correlations between some of them and the degree of ventricular hypertrophy; more importantly, we found that only one of them, miR-29a, correlated with the degree of myocardial fibrosis, a pathological component typical of this disease state with a bad prognostic value. Circulating levels of miR-29a did not increase to the same extent in control patients with severe aortic stenosis, in which left ventricular hypertrophy usually results from pressure overload.

### What can we assume from this study?

The most striking finding of this study is the correlation between miR-29a and cardiac hypertrophy, as measured by echocardiographic parameters on one hand, and fibrosis, as measured with cardiac magnetic resonance, on the other. Notably, miR-29a is produced mostly by fibroblasts, and its family members are key regulators of fibrosis, modulating levels of collagen and other extracellular matrix genes. An increase in the circulating level of miR-29a is apparent when hypertrophy and fibrosis are not yet clinically evident; thus, we may hypothesize that it is released into the bloodstream from intact myocardial cells undergoing stress. In this way, miR-29a can be considered a biomarker for the early prediction of myocardial remodelling, whose assessment can provide prognostic and therapeutic indications. These results suggest that the measurement of circulating miRNAs may be a simple method for following up patients with hypertrophic cardiomyopathies, potentially providing also indications on the prevalence of specific pathological components of the disease and possibly enabling specific therapies.

### Do you think it will be possible to extend miRNA research findings to other conditions?

As said, “omics” sciences are fundamental for translational research when it comes to predicting the risk of a disease or evaluating the activity of an ongoing pathology by means of specific biomarkers. Circulating miRNAs share many of the essential characteristics of a good biomarker e.g. noninvasive measurability, stability in the extracellular *milieu*, high sensitivity and specificity, early detection of a pathological state and the time-related changes during its course, and rapid and cost-effective laboratory detection. Research on miRNAs is gradually being extended to other forms of cardiovascular and metabolic conditions. On the basis of distinctive profiles of circulating miRNAs, several groups have proposed these molecules as biomarkers for diagnosis and prognosis of cardiovascular pathologies ranging from heart failure, acute myocardial infarction and cardiomyopathies to atherosclerosis and diabetes mellitus. At the moment, miRNAs have not yet entered the clinical

HIGHLIGHT

**Elisa Di Pasquale**
Laboratory of Immunology and Inflammation in Cardiovascular Diseases

## Induced pluripotent stem cells (iPSC) technology for studying and treating cardiac diseases

Understanding the molecular mechanisms underlying human diseases is vital for a rational development of new therapeutics. Our laboratory is mainly devoted to the investigation of inherited forms of cardiomyopathies and arrhythmias through the analysis of human cardiomyocytes derived from induced pluripotent stem cells (iPSCs). iPSCs technology allows to revert somatic cells from patients back to a pluripotent state, which means that potetially any cell type can generate from them. In the last years, our laboratory has developed skills to generate and analyze cardiomyocytes derived from iPSCs by integrating multiple techniques including molecular biology, next-generation sequencing, electrophysiology, imaging and epigenetics, and we are continuously working on improving protocols to differentiate human cardiomyocytes able to reproduce the physiology of an adult cardiomyocyte accurately. Having at hand in vitro models that recapitulate human diseases has given us the possibility to study the molecular mechanisms of human cardiomyopathies and congenital arrhythmias. Results from these studies have contributed in proving the reliability of iPSCs technology in the study of cardiovascular diseases.
Our research is now moving toward the development of genome editing strategies to generate an isogenic iPSC-based cardiac platform. A step forward in this direction is fundamental for studying the contribution of genetic mutation in polygenic diseases. The accomplishment of this goal is also expected to have a positive impact on the discovery and testing of new drugs and increasingly personalized therapies.
Importantly, these model systems will allow us to study drugs for specific molecular targets without the need of big clinical trials, a crucial step for improving therapeutic options for rare diseases.

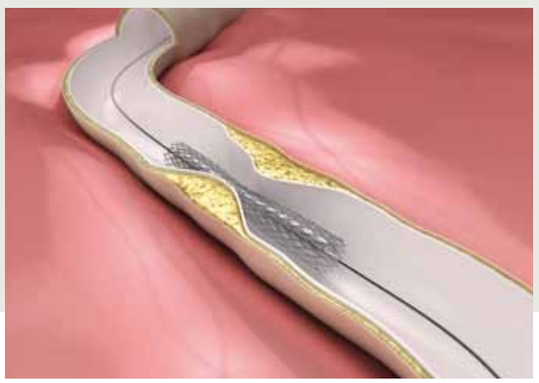


HIGHLIGHT

**Giulio Stefanini**
Division of Haemodinamics, Invasive Cardiology and Coronary Care

## Myocardial revascularization: the impact of technological progress on clinical outcomes

Drug-eluting stents represent a cornerstone in the treatment of coronary artery disease and are used in approximately 2 million patients every year. My scientific interest has been focusing on the clinical impact of technological advances in coronary artery stents technology. In two large-scale clinical investigations concluded in 2013 we found important improvements in both safety and efficacy outcomes with device iteration, showing that contemporary drug-eluting stents provide excellent clinical outcomes in a broad spectrum of patients with coronary artery disease.
Nevertheless, the persistence of these metallic prostheses in the treated vessel may result in foreign body responses and a risk of thrombosis. Moreover, long-term follow-up studies of patients treated with new generation drug-eluting stents showed that more than 50% of adverse events are not related to the initially implanted device but rather to progression of disease at new coronary sites.
In order to address these remaining challenges, at Humanitas Research Hospital we intend to evaluate coronary artery disease progression over time and to investigate the predictive value of novel biomarkers on disease progression in high-risk patients. In addition, in the same setting, we will evaluate the use of fully bioresorbable coronary scaffolds – which are novel coronary devices providing transient vessel support and site-specific drug delivery followed by complete device resorption.
Overall, understanding the pathogenetic mechanisms of coronary artery disease progression and exploring novel treatment strategies is crucial to improve prediction, prevention and treatment in our patients.





scenario, simply because of the limited number of large cohort studies conducted to date, but we expect that that this gap will soon be filled.

### Could you clarify such an outstanding shift from bench to bedside with an example?

The "contamination" between basic and clinical research is touching many aspects of cardiovascular disease, from aortic stenosis to heart failure to myocardial ischemia; this is being conducted in parallel by different teams at Humanitas. I would like to mention the relevant contribution of **Giulio Stefanini** (see the highlight), a young but already authoritative researcher at the European level. Basic scientists are interacting with clinical cardiologists to integrate circulating biomarker analysis and imaging technologies for diagnostic and prognostic purposes in coronary artery disease.
Whilst on the subject of miRNAs, another important long-term effort has been to assess their role as biomarkers of myocardial stress. We have generated large amounts of data on miRNAs released by myocardial cells under stressful conditions and detectable in the bloodstream either "free"– i.e. only bound to proteins – or within membrane bodies called exosomes, in particular in aortic stenosis, a condition in which the aortic valve undergoes a degenerative process that leads to pressure overload hypertrophy of the myocardium. In addition, at this very moment, we are conducting a project co-funded by AIRC (Associazione Italiana per la Ricerca sul Cancro) to determine whether measuring their level could reliably predict impairment of myocardial function during the course of chemotherapy, a condition in which the heart is frequently hit by the so-called off-target effects of anti-cancer drugs, which frequently lead to heart failure. Positive results can lead to enacting protective measures.

### What can you tell us about the metabolic diseases affecting cardiovascular function you mentioned earlier?

Diseases affecting vessel walls include hypertension, diabetes and atherosclerosis, and they can all be considered metabolic disorders. Recent studies indicate that the heart releases messages which target metabolic tissues, such as white adipose tissue. Molecular biology and "omics" technologies are generating more and more results in this exiting area of investigation. We are also verifying that changes in myocardial metabolism are reflected in the major epigenetic features of cardiomyocytes and, in turn, in gene expression. To study these modifications we are using experimental models that reliably reproduce what happens in humans. Lastly, we are determining whether microRNAs and other non-coding RNAs could be employed as predictors of disease in many instances, including myocardial infarction. The leading concept is thus to trace a *continuum* from preclinical to clinical research for the most common diseases.

### Would you say your remarks can extend the scope of translational research to common cardiovascular diseases?

Certainly. One example relates to the role of molecular medicine in the detection of biological processes implicated in diseases. Modern approaches are aimed more and more at spotting the signs of cardiovascular disease as early as possible. Results of translational research are able to meet the needs of clinical research on high-burden disorders, such as coronary artery disease and metabolic disorders. Thus, studying the heart and the vascular system with a translational approach is not only challenging, but also of great public interest, considering the high prevalence of cardiovascular disease and its socio-economic impact.
A second instance relates to the shortened path from the identification of key pathological molecules to therapy: this opens a new perspective for a more targeted and efficient approach to cardiovascular disease therapy. ■

**TOP PAPERS**

Ricci RP, Pignalberi C, Landolina M, Santini M, Lunati M, Boriani G, Proclemer A, Facchin D, Catanzariti D, Morani G, Gulizia M, Mangoni L, Grammatico A, Gasparini M; ClinicalService cardiological centres.

## Ventricular rate monitoring as a tool to predict and prevent atrial fibrillation-related inappropriate shocks in heart failure patients treated with cardiac resynchronisation therapy defibrillators.

*Heart.* 2014 Jun;100(11):848-54. doi: 10.1136/heartjnl-2013-305259. Epub 2014 Mar 28.

**Objective:** Inappropriate implantable cardioverter defibrillators (ICD) therapies have been associated with multiple adverse effects, including worse quality of life and prognosis. We evaluated the possibility of predicting atrial fibrillation (AF)-related inappropriate ICD shocks through continuous monitoring of device diagnostics.

**Methods:** 1404 ICD patients were prospectively followed in an observational research by 74 Italian cardiology centres. Device diagnostics stored daily information on AF duration and ventricular rate (VR) during AF. Uncontrolled VR was defined as mean VR>80 beats per minute (bpm) and maximum VR>110 bpm. Expert electrophysiologists reviewed the ventricular tachycardia/ventricular fibrillation (VT/VF) episodes electrograms, stored in the device memory, and classified appropriate detections, inappropriate detection mechanisms and ICD therapy outcomes.

**Results:** Over a median follow-up of 31 months, 511 (36%) patients suffered spontaneous VT/VF, which were treated by ICD shocks in a subgroup of 189 (13%) patients. Inappropriate detections occurred in 232 (16%) patients, and inappropriate ICD shocks in 101 (7%) patients. AF was the cause of inappropriate shocks in 60 patients. AF caused 144 inappropriate shocks: 53% of all inappropriate shocks. The likelihood of experiencing AF-related inappropriate shocks was 2.4% at 1 year and 6% at 5 years. Uncontrolled VR during AF proved to be an independent predictor of AF-related inappropriate shocks (OR=3.02, p=0.006); an alarm set at a VR>90 bpm or 100 bpm was associated with prediction of AF-related inappropriate shocks with a sensitivity of 73% or 62%, respectively.

**Conclusions:** AF is the most common cause of inappropriate shocks in ICD patients. Continuous remote monitoring of VR during AF would promptly and efficiently predict AF-related inappropriate shocks.

**Clinical Trial Registration:** http://clinicaltrials.gov/ct2/show/NCT01007474.



Castaldi A, Zaglia T, Di Mauro V, Carullo P, Viggiani G, Borile G, Di Stefano B, Schiattarella GG, Gualazzi MG, Elia L, Stirparo GG, Colorito ML, Pironti G, Kunderfranco P, Esposito G, Bang ML, Mongillo M, Condorelli G, Catalucci D.

## MicroRNA-133 modulates the β1-adrenergic receptor transduction cascade.

*Circulation Research.* 2014 Jul 7;115(2):273-83. doi: 10.1161/CIRCRESAHA.115.303252. Epub 2014 May 7.

**Rationale: T**he sympathetic nervous system plays a fundamental role in the regulation of myocardial function. During chronic pressure overload, overactivation of the sympathetic nervous system induces the release of catecholamines, which activate β-adrenergic receptors in cardiomyocytes and lead to increased heart rate and cardiac contractility. However, chronic stimulation of β-adrenergic receptors leads to impaired cardiac function, and β-blockers are widely used as therapeutic agents for the treatment of cardiac disease. MicroRNA-133 (miR-133) is highly expressed in the myocardium and is involved in controlling cardiac function through regulation of messenger RNA translation/stability.

**Objective:** To determine whether miR-133 affects β-adrenergic receptor signaling during progression to heart failure.

**Methods and results:** Based on bioinformatic analysis, β1-adrenergic receptor (β1AR) and other components of the β1AR signal transduction cascade, including adenylate cyclase VI and the catalytic subunit of the cAMP-dependent protein kinase A, were predicted as direct targets of miR-133 and subsequently validated by experimental studies. Consistently, cAMP accumulation and activation of downstream targets were repressed by miR-133 overexpression in both neonatal and adult cardiomyocytes following selective β1AR stimulation. Furthermore, gain-of-function and loss-of-function studies of miR-133 revealed its role in counteracting the deleterious apoptotic effects caused by chronic β1AR stimulation. This was confirmed in vivo using a novel cardiac-specific TetON-miR-133 inducible transgenic mouse model. When subjected to transaortic constriction, TetON-miR-133 inducible transgenic mice maintained cardiac performance and showed attenuated apoptosis and reduced fibrosis compared with control mice.

**Conclusions**: miR-133 controls multiple components of the β1AR transduction cascade and is cardioprotective during heart failure.

# Gerry Scotti supports 4 talented young researchers in the fight against cancer, infections and neurodegenerative diseases



It's been the fourth time that the famous TV presenter has funded research projects for four talented researchers. Thanks to these one-year- grants **Francesca Faggioli, Sébastien Jaillon, Sonia Mazzitelli,** and **Monica Zuradelli** will be able to carry out their studies in Italy, either returning from abroad or in our country.

## Finding the link between ageing, immunity and cancer

**Francesca Faggioli**, 36, started out as a researcher at Milan's CNR. After taking part in research on new therapeutic approaches to breast carcinoma and on liver biology, she moved to New York in 2010, where she studied (the relationship between) ageing and cancer at the Genetics Department of the Albert Einstein College of Medicine for three years.
She returned to Italy to work at Humanitas, at the CNR laboratory led by **Paolo Vezzoni**. Here, she started a research project which investigates the interaction between cellular ageing (senescence), the activation of the immune system, and its role played in liver cancer development.
In chronic stress conditions, cells age earlier and favour an inflammatory microenvironment, which can modulate the immune system response to inflammation and tumoral growth. Francesca Faggioli's research, supported by Gerry Scotti, has two objectives: the first is to check if pro-inflammatory signals (aka SASP) coming from ageing cells enhance tumor growth, and the second is to investigate the molecular mechanisms underlying this process, with particular reference to liver cancer.

## A precious weapon against urinary tract infections

**Sébastien Jaillon**, 35, born in Metz, France, has a degree in Immunology, and has specialised in Cell Biology and Immunology at Angers University in France, where he worked as a researcher before moving to Humanitas at the Laboratory of Experimental Immunopathology, directed by **Cecilia Garlanda**.
Sébastien Jaillon's research group studied pentraxin 3 ($PTX_3$), a molecule belonging to a family of proteins highly conserved during evolution, usually referred to as an "ancestor" of antibodies.
Thanks to Gerry Scotti's research grant, Sébastien Jaillon is staying in Italy at Humanitas to carry out a study on the role of $PTX_3$ in infection resistance in general, and with particular reference to urinary tract infections. The aim of the project is to verify whether $PTX_3$ levels can be associated to infections, and therefore whether this marker may represent a valid diagnostic tool.
In addition, Sébastien Jaillon in cooperation with a Swedish team has started investigating the relationship between susceptibility to infections and $PTX_3$ genotype (i.e. small nucleotide polymorphisms).



## Alzheimer's disease: new perspectives for diagnostics and therapy

**Sonia Mazzitelli**, 33, graduated in Molecular and Cell biology at Roma Tor Vergata University, and has then obtained a PhD in Molecular Biology and Neurosciences at the University of Manchester in the UK, followed by 2 years' post-Doc at Boston's Harvard Medical School.
Thanks to Gerry Scotti's research grant, Sonia Mazzitelli returned to Italy to join Humanitas' Neurosciences program, led by **Michela Matteoli**.
Sonia Mazzitelli's research focus is Alzheimer's disease, which represents a serious social and medical problem – with particular reference to the role of inflammation in the development of this condition.
There are some specialized brain cells (microglia), which actually belong to the immune system, and act as the primary active defense of the central nervous system.
The objective of the project supported by Gerry Scotti is to verify whether these cells are able to release neurotoxic A-beta proteins, and how this release may contribute to the development of Alzheimer's disease.
This study might in fact lead the way to new perspectives and discover different strategies for Alzheimer's diagnostics and therapy.

## Breast and ovary cancer: when genetics supports prevention

**Monica Zuradelli**, 38, graduated in Medicine at the Università di Milano in 2001, and specialized in Medical Oncology at the Università di Genova in 2005. Since then, she has been working as a medical oncologist at Humanitas Cancer Center, led by **Armando Santoro**. She has also worked for the department of medical oncology at Saint Vincent's University Hospital in Dublin, where she co-conducted experimental clinical studies. Her dedication to clinical research has been primarily focused on breast cancer.
BRCA1 and BRCA2 are the genes most directly involved in breast cancer development and play a role in DNA reparation processes during cellular replication. When either of these genes is mutated, the stability of the cell's genetic material is impaired, leading to an increase in risk of cancer disease. That is why counselling with an onco-genetic approach allows for a more personalized and effective prevention and treatment plan.
Thanks to Gerry Scotti's research grant, Monica Zuradelli will develop a project based on oncogenetics aimed at investigating the biological meaning – which is unknown at the moment – of a few genic variants of BRCA1 and BRCA2, as well as their role in guiding the response of new target drugs, such as Parp [Poly-(ADP-ribose)-polymerase], an enzyme responsible for the tumor's resistance to chemotherapy.

HUMANITAS
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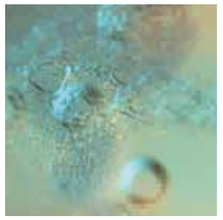
Updated as of 28th February 2015

(*) Phisycian dealing with activity in the Research laboratories too
(**) Research Staff
(***) Research Nurse
(•) Head of unit
(°) Consultant
(§) Vicarious

■ Divisions that join in the Humanitas Cancer Center



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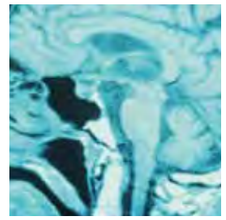

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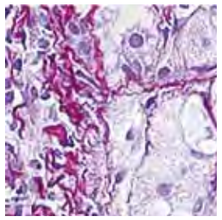

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Federico Arturo Villa
Paola Cosma Zito

(*) Phisycian dealing with activity in the Research laboratories too
(**) Research Staff
(***) Research Nurse
(•) Head of unit
(°) Consultant
(§) Vicarious

■ Divisions that join in the Humanitas Cancer Center



# General Surgery Department

DIRECTOR: **Marco Montorsi**

## GENERAL AND DIGESTIVE SURGERY

DIVISION DIRECTOR:
**Marco Montorsi**

Fabio Baticci (°)
Stefano Bona (•)
Michele Maria Carvello
Martina Ceolin
Hayato Kurihara (•)
Alessandra Marano
Matteo Sacchi
Antonino Spinelli (•)
Giuseppe Spinoglio (°)

### Pancreatic Surgery

DIVISION DIRECTOR:
**Alessandro Zerbi**

Giovanni Capretti
Francesca Gavazzi
Cristina Ridolfi

## GENERAL AND ONCOLOGIC SURGERY

DIVISION DIRECTOR:
**Vittorio Quagliuolo**

Antonella Ardito
Pietro Francesco Bagnoli
Andrea Brocchi
Ferdinando Carlo Cananzi
Luca Cozzaglio (•)
Chiara Erminia Mussi
Ombretta Nucca

### Gastroesophageal Surgery

DIVISION DIRECTOR:
**Uberto Fumagalli Romario**

Pietro Dante Museli
Matteo Porta

## HEPATOBILIARY SURGERY

DIVISION DIRECTOR: **Guido Torzilli**

Matteo Maria Cimino
Daniele Del Fabbro
Matteo Donadon
Barbara Franceschini (**)
Angela Palmisano
Fabio Porcopio
Cristiana Soldani (**)
Luca Viganò

# Gynaecology Department

DIRECTOR: **Paolo E. Levi Setti**

## FERTILITY CENTER

DIVISION DIRECTOR:
**Paolo Emanuele Levi Setti**

Elena Albani
Annamaria Baggiani
Renzo Benaglia
Valentina Caccavari
Luca Cafaro
Valentina Canevisio
Raffaella De Cesare
Alessia De Mita
Alessandra Drovanti
Valeria Liprandi
Luciano Negri
Maria Rosaria Parisen Toldin
Laura Sacchi
Valeria Scolaro
Cristina Specchia
Elena Zannoni
Irene Zerbetto

## GYNAECOLOGY

DIVISION DIRECTOR:
**Domenico Vitobello**

Antonio Accardi
Gianluigi Bresciani
Cinzia Bulletti
Nicoletta Iedà
Costantino Mangioni (°)
Fabrizio Romano
Gabriele Siesto

# Internal Medicine Department

DIRECTOR: **Salvatore Badalamenti** (§)

## ACCIDENT & EMERGENCY UNIT

DIVISION DIRECTORS:
**Salvatore Badalamenti**
**Antonio Voza**

Alessandro Barraco
Giuseppe Biancofiore
Alessandro Bottani
Gianluigi Citterio
Giuseppe Civitavecchia
Luca Contu
Carlo Fedeli
Giovanni Giorgino
Elisabetta Lavezzi
Alfonso Maiorino
Silvia Oldani
Stefano Ottolini
Silvia Paiardi
Maria Gioia Lea Pich
Marta Ripoll Pons

## DERMATOLOGY

DIVISION DIRECTOR:
**Marcello Monti**

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Francesco Sacrini
Federica Sanna
Francesca Savalli
Luca Speroni

## ENDOCRINOLOGY AND DIABETOLOGY

DIVISION DIRECTOR:
**Andrea Lania**
Paolo Colombo

## GENERAL MEDICINE AND PNEUMOLOGY

DIVISION DIRECTOR:
**Michele Ciccarelli**

Benedetta Campolo
Massimo Crippa
Alessandra Ibba
Alessia Marseglia (°)
Francesca Puggioni
Lucia Testoni

## INTERNAL MEDICINE

DIVISION DIRECTOR: **Raffaello Furlan**
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Franca Barbic (°)
Enrico Brunetta
Mara Bulgheroni
Franca Dipaola
Mauro Podda (°)

## NEPHROLOGY AND DIALYSIS

DIVISION DIRECTOR:
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Paola Arosio
Cesare Berra (•)
Albania Calvetta
Giuseppe Favacchio
Silvia Finazzi
Giorgio Graziani (°)
Marco Mirani
Rosa Pedale
Luisa Persichini
Claudio Ponticelli (°)
Silvia Santostasi
Rossella Valentino
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## RHEUMATOLOGY AND CLINICAL IMMUNOLOGY

DIVISION DIRECTOR:
**Carlo Francesco Selmi**

Angela Ceribelli (**)
Maria De Santis
Maria Rosaria Galdiero (*)
Bianca Marasini (°)
Marco Sergio Massarotti

## THROMBOSIS CENTRE

DIVISION DIRECTOR: **Corrado Lodigiani**
Monica Demarco
Paola Ferrazzi
Luca Librè
Ilaria Quaglia

## OUTPATIENT AREA

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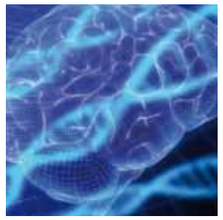
Lara Castagnetti
Giovanni Covini (•)
Bruno Pessano
Vanessa Ronzoni
Vincenzo Tullo
Emanuele Francesco M. Ungaro



# Neuro Center

## EMERGENCY NEUROLOGY AND STROKE UNIT

DIVISION DIRECTOR: **Simona Marcheselli**
Beatrice Albano
Elisa Coloberti
Manuel Corato
Lara Fratticci
Maria Luisa Soardi (°)
Mariacarmela Spinelli
Laura Straffi

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DIVISION DIRECTOR: **Eduardo Nobile Orazio**
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Claudia Giannotta (**)
Fabrizia Terenghi

## NEUROSURGERY

DIVISION DIRECTOR: **Maurizio Fornari**
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Simonetta Beluffi (°)
Massimo Borroni (°)
Andrea Cardia (•)
Paola Carmagnini (°)
Francesca Cortese
Francesco Costa
Giuseppe D'Aviri (°)
Antonio De Santis (°)
Giovanni Battista Lasio (•)
Giulio Maira
Guido Menasce (°)
Davide Milani
Alessandro Ortolina
Armando Pellanda (°)
Piero Picozzi
Alberto Pollini (°)
Stefania Radice
Riccardo Rodriguez y Baena (°)
Giovanni Sabatino
Giorgio Savoia (°)
Massimo Tomei

## ONCOLOGIC NEUROSURGERY

DIVISION DIRECTOR: **Lorenzo Bello**
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Alessandro Comi
Enrica Maria Fava
Federico Pessina

# Ortho Center

## ARTHROSCOPIC SURGERY OF THE KNEE

DIVISION DIRECTOR: **Enrico Arnaldi**
Stefano Bertora (°)
Andrea Bruno
Andrea Bruno Massimo De Donato
Paolo Dupplicato
Alexander Kirienko (°)
Paolo Pesenti (°)

## HAND SURGERY

DIVISION DIRECTOR: **Alberto Lazzerini**
Alessandra Martano
Luciana Marzella
Ilaria Papini Zorli
Pier Luigi Raimondi (°)
Angela Trabucco
Fabiana Zura Puntaroni

## HIP AND KNEE PROSTHETIC SURGERY

DIVISION DIRECTOR: **Guido Grappiolo**
Franco Astore
Andrea Baldini (°)
Giovanna Borello (°)
Emanuele Caldarella
Tiziana D'Amato
Federico D'Aria (°)
Federico Della Rocca
Alessandro Eusebio
Matteo Carlo Ferrari
Antonino Gurgone
Federica Martorelli
Giuseppe Mazziotta
Francesca Meda
Damiano Ricci
Riccardo Ruggeri
Giuseppe Santoro
Marco Scardino
Francesco Traverso
Francesco Verde

## KNEE ORTHOPAEDICS AND SPORT TRAUMATOLOGY

DIVISION DIRECTOR: **Piero Volpi**
Corrado Bait
Matteo Giovanni Maria Denti (°)
Antonio Orgiani
Emanuele Prospero
Alessandro Quaglia

## PAEDIATRIC AND NEURO-ORTHOPAEDICS SURGERY

DIVISION DIRECTOR: **Nicola Portinaro**
Artemisia Panou
Franco Ronchi

## SHOULDER AND ELBOW SURGERY

DIVISION DIRECTOR: **Alessandro Castagna**
Mario Borroni
Silvana De Giorgi (°)
Giacomo Delle Rose
Paolo Renato Rolla (°)

## FOOT SURGERY

DIVISION DIRECTOR: **Leonardo Maradei**
Antonio Giardella
Nikolaos Markopoulos

## TRAUMATOLOGY

DIVISION DIRECTOR: **Marco Berlusconi**
Matteo Cavanna
Davide Cecconi
Lorenzo Di Mento
Davide Marchettini
Mattia Mocchi
Jose Antonio Puchol Incertis
Ivano Scarabello

# Rehabilitation Department

DIRECTOR: **Stefano Respizzi**

## CARDIAC & RESPIRATORY REHABILITATION

DIVISION DIRECTOR: **Stefano Aglieri**
Anna Beretta
Franco Rusconi (°)
Ilaria Viscone

## NEUROLOGIC REHABILITATION

DIVISION DIRECTOR: **Bruno Bernardini**
Giovanna Cerina
Viviana Colantonio
Carla Corsini
Sara Ghirmai
Marco Augusto Pagani

## ORTHOPAEDIC REHABILITATION

DIVISION DIRECTOR: **Stefano Respizzi**
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Gianluca Galimberti (•)
Paolo Maria Parenti (°)
Giuseppe Strangio
Elisabetta Tibalt

## SPORTS AND EXERCISE MEDICINE

Daniela Lucini (•)

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(**) Research Staff
(***) Research Nurse
(•) Head of unit
(°) Consultant
(§) Vicarious

■ Divisions that join in the Humanitas Cancer Center

# Specialised Divisions of Surgery

## EYE CENTER

DIVISION DIRECTOR: **Paolo Vinciguerra**
Elena Albe
Laura Balia
Fabrizio Ivo Camesasca
Carlo Castellani
Marco Criscito (°)
Chiara Cuccaro
Alessandra Di Maria
Marco Gramigna
Emanuela Legrottaglie
Raffaele Piscopo
Grazia Maria Quaranta (°)
Alessandro Randazzo
Mario Romano
Pietro Rosetta
Riccardo Scotti (°)
Adriana Sergio
Maria Ingrid Torres Munoz
Rosario Urso
Jose Luis Vallejo Garcia
Pietro Paolo Vico

## OTORHINOLARYNGOLOGY

DIVISION DIRECTOR: **Arturo Poletti**
Giovanni Colombo
Gioavanni Cugini
Susanna Di Pietro
Luca Malvezzi
Stefano Miceli
Vanessa Rossi

## PLASTIC SURGERY

DIVISION DIRECTOR: **Marco Klinger**
Valeria Bandi
Barbara Banzatti
Barbara Catania
Claudio Cordani
Silvia Giannasi
Luca Maione
Alessandra Veronesi

## SURGICAL DAY HOSPITAL

DIVISION DIRECTOR: **Roberta Monzani**
Marco Aldo Babbini
Benedetta Basta
Francesco Carrera
Aljosa Ciarloni
Barbara Crescimbini
Laura Crozzoli
Michele De Ruvo
Chiara Ferrari
Stefania Gherardi
Fabio Intelligente
Annarita Larocca
Marco Maiola
Oreste Davide Montino
Maria Del Carmen Rodriguez
Beatrice Rossi
Claudio Sacchi
Alessandro Scafella

## UROLOGY

DIVISION DIRECTOR: **Giorgio Ferruccio Guazzoni**
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Luigi Castaldo
Girolamo Fiorini (°)
Guido Giusti (•)
Rodolfo Hurle
Massimo Lazzeri (°)
Giovanni Lughezzani
Luisa Pasini
Roberta Peschechera
Alessandro Pizzocaro
Silvia Proietti
Mauro Seveso
Gianluigi Taverna (•)
Silvia Zandegiacomo De Zorzi

# Departments and teams

## Scientific Research and Laboratories

Updated as of 28th February 2015

### Scientific Superintendence

DIRECTOR: **Nicola Dioguardi**

### Scientific Direction and Research Laboratories

DIRECTOR: **Alberto Mantovani**

### Clinical trials office

DIRECTOR: **Michele Tedeschi**

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Emanuela Morenghi
Silvia Spagnoli

### Innovation Office

Alessandra Orlandi

### Grant office

HEAD OFFICER: **Danilo Petroni**

Simona Pipolo

(•) Group leader

(1) MD-PhD. In addition to research s/he works as a clinician in Endocrinology

(2) MD-PhD. In addition to research s/he works as a clinician in Reumathology

(3) MD-PhD. In addition to research s/he works as a clinician in Inflammatory Bowel Disease

(4) MD-PhD. In addition to research s/he works as a clinician in Epathology

(5) MD-PhD. In addition to research s/he works as a clinician in Medical Oncology and Haematology

#### ADAPTIVE IMMUNITY

JUNIOR PRINCIPAL INVESTIGATOR:
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Giuliana Roselli
Claudia Sardi

#### CELL SIGNALLING INNATE IMMUNITY

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Valeria Corlianò
Matias Soncini

#### CELLULAR AND MOLECULAR ENDOCRINOLOGY

PRINCIPAL INVESTIGATOR: **Andrea Lania** (1)

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Eleonora Vitali

#### CELLULAR IMMUNOLOGY

PRINCIPAL INVESTIGATOR: **Paola Allavena**

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Giovanni Castino
Nina Cortese
Marco Erreni
Mohammad Azhar Kamal
Manuela Liguori
Federica Marchesi
Giulia Marelli
Imran Siddiqui
Fernando Torres Andon

#### CLINICAL AND EXPERIMENTAL IMMUNOLOGY

PRINCIPAL INVESTIGATOR: **Domenico Mavilio**

Francesca Calcaterra
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Kelly Lorraine Hudspeth
Manuela Lo Porto
Enrico Lugli
Joanna Mikulak
Karolina Pilipow
Elena Pontarini
Alessandra Roberto
Paolo Francesco Tentorio
Veronica Zanon

#### CLINICAL IMMUNOLOGY AND AUTOIMMUNITY AND METABOLISM

PRINCIPAL INVESTIGATOR:
**Carlo Francesco Selmi** (2)

Angela Ceribelli (2)
Maria De Santis (2)
Elena Generali
Natasa Isailov

#### EXPERIMENTAL IMMUNOPATHOLOGY

PRINCIPAL INVESTIGATOR:
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Eduardo Bonavita
Louise Felipe Campesato
Maria Rosaria Galdiero
Stefania Gentile
Sebastien Jaillon
Elena Magrini
Martina Molgora
Fabio Pasqualini
Nadia Polentarutti
Marcello Rubino
Federica Riva
Andrea Ponzetta
Valentina Taverniti

#### GASTROINTESTINAL IMMUNOPATHOLOGY

PRINCIPAL INVESTIGATOR: **Silvio Danese** (3)

Carmen Correale
Silvia D'Alessio
Philippe Fonteyne
Marco Genua
Molina Cristina Mascaraque
Luciana Petti
Andrea Piontini
Carlotta Tacconi
Stefania Vetrano
Federica Ungaro

#### HEPATOBILIARY IMMUNOPATHOLOGY

PRINCIPAL INVESTIGATOR: **Pietro Invernizzi** (4)

Francesca Bernuzzi
Ilaria Bianchi (4)
Marco Carbone (4)
Margherita Correnti
Ana Lleo De Nalda (4)
Chiara Raggi
Ilaria Sogno
Hayang Zhang

#### IMMUNOPHARMACOLOGY

PRINCIPAL INVESTIGATOR:
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Kenji Daigo
Antonio Inforzato
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Massimo Messa
Raffaella Parente
Francesca Petroni
Marina Sironi
Sonia Valentino

#### LEUKOCYTE BIOLOGY

PRINCIPAL INVESTIGATOR:
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Elena Borroni
Paolo Buratti
Lorenzo Drufuca
Andrea Ferraro
Matteo Massara
Irene Mattiola
Stefania Recalcati
Tiziana Renzi
Benedetta Savino
Naths Grazia Sukubo
Alessandro Vacchini

#### LEUKOCYTE MIGRATION

PRINCIPAL INVESTIGATOR:
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#### MEDICAL GENETICS AND RNA BIOLOGY

PRINCIPAL INVESTIGATOR:
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Elvezia Paraboschi
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Michela Robusto
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#### MOLECULAR IMMUNOLOGY

PRINCIPAL INVESTIGATOR:
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Chiara Porta
Elena Riboldi
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#### ONCOLOGY EXPERIMENTAL THERAPIES

PRINCIPAL INVESTIGATOR:
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Giuseppa Careddu
Alessandra Inguscio
Silvia Laura Locatelli
Laura Paladini
Luca Rubino

#### PHARMACOLOGY AND BRAIN PATHOLOGY

PRINCIPAL INVESTIGATOR:
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Genni Desiato
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Elisa Focchi
Lucrezia Folladori
Giuliana Fossati
Elsa Ghirardini
Maria Malosio
Cristina Mantovani
Rosa Matrangelo
Sonia Mazzitelli
Elisabetta Menna
Raffaella Morini
Davide Pozzi
Marco Rasile
Matteo Tamborini
Romana Tomasoni
Mauro Valenti
Claudia Verderio

#### PHYSIOLOGY

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#### HUMAN GENOME

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Virginia Maina
Stefano Mantero
Veronica Marrella
Ciro Menale
Eleonora Palagano
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Cristina Sobacchi
Dario Strina

#### MEDICAL BIOTECHNOLOGIES

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Laura Crisafulli
Francesca Faggioli
Michela Lizier
Sharon Muggeo
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Marianna Paulis
Lucia Susani

#### INFLAMMATION AND IMMUNOLOGY IN CARDIOVASCULAR

PRINCIPAL INVESTIGATOR:
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Anna Castaldo
Laura Catarozzo
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Stefano Marzo
Michele Miragoli
Michelle Monasky
Laura Papa
Roberto Papait (•)
Manuela Quintavalle
Pierluigi Rossi
Francesca Rusconi
Lucia Rutigliano
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Chiara Viviani Anselmi

#### SARCOMERS IN CARDIAC PATHOLOGY

PRINCIPAL INVESTIGATOR:
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Giuseppina Mastrototaro
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PRINCIPAL INVESTIGATOR:
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• = Authors equally contributing to the study

# Preclinical Research

## ADAPTIVE IMMUNITY

Anselmo A, Mazzon C, Borroni EM, Bonecchi R, Graham GJ, Locati M*.

Flow cytometry applications for the analysis of chemokine receptor expression and function.

*Cytometry*: Part A 2014;85(4):292-301.

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## CLINICAL AND EXPERIMENTAL IMMUNOLOGY

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*Cell Death and Differentiation* 2015;22(1):58-73.

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*Journal of Cerebral Blood Flow and Metabolism* 2014;34(6):979-88.

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# Translational Research

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## MOLECULAR GASTROENTEROLOGY

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Barbic F*, Galli M, Dalla Vecchia L, Canesi M, Cimolin V, Porta A, Bari V, Cerri G, Dipaola F, Bassani T, Cozzolino D, Pezzoli G, Furlan R.

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Tailoring neurophysiological strategies with clinical context enhances resection and safety and expands indications in gliomas involving motor pathways.

*Neuro-Oncology* 2014;16(8):1110-28.

**Raw IF: 5.286** **Normalized IF: 6**

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# Clinical Research

## ANAESTHESIA AND CARDIOSURGERY INTENSIVE CARE

Barbone A*, Pini D, Ornaghi D, Visigalli MM, Ardino L, Bragato R, Curzi M, Cioccarelli SA, Di Diodoro L, Basciu A, Cappai A, Settepani F, Citterio E, Cappelleri A, Calcagnino M, Mangiavacchi M, Tarelli G, Lettino M, Vitali E.

CircuLite Synergy ventricular assist device: a new approach to end-stage congestive heart failure.

*Giornale Italiano di Cardiologia* 2014;15(2):116-22.

**Raw IF: 0** **Normalized IF: 0**

Settepani F*, Cappai A, Citterio E, Melis LC, Tarelli G.

Unusable radial artery for severe atherosclerosis in a young patient.

*Journal of Cardiac Surgery* Epub ahead of print 2014 May 15.

**Raw IF: 0.617** **Normalized IF: 1**

## BREAST UNIT

Torzilli G*, Procopio F, Cimino M, Donadon M, Del Fabbro D, Costa G, Gatti A, Garcia-Etienne CA.

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Hepatic vein-sparing hepatectomy for multiple colorectal liver metastases at the caval confluence.

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**Raw IF: 3.943** **Normalized IF: 6**

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*Journal of Surgical Oncology* 2014;11(1):61-7.

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## CARDIAC AND RESPIRATORY REHABILITATION

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## CARDIAC SURGERY

Barbone A*, Pini D, Ornaghi D, Visigalli MM, Ardino L, Bragato R, Curzi M, Cioccarelli SA, Di Diodoro L, Basciu A, Cappai A, Settepani F, Citterio E, Cappelleri A, Calcagnino M, Mangiavacchi M, Tarelli G, Lettino M, Vitali E.

CircuLite Synergy ventricular assist device: a new approach to end-stage congestive heart failure.

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An unusual left ventricular apical mass.

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*Journal of Cardiovascular Surgery* Epub ahead of print 2013 Dec 17.

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Rossi ML, Barbaro C, Pagnotta P, Cappai A, Ornaghi D, Belli G, Presbitero P*.

Transapical transcatheter valve-in-valve replacement for deteriorated mitral valve bioprosthesis without radio-opaque indicators: the "invisible" mitral valve bioprosthesis.

*Heart Lung and Circulation* 2015;24(2):e19-22.

**Raw IF: 1.172** **Normalized IF: 2**

Settepani F*, Cappai A, Citterio E, Melis LC, Tarelli G.

Unusable radial artery for severe atherosclerosis in a young patient.

*Journal of Cardiac Surgery* Epub ahead of print 2014 May 15.

**Raw IF: 0.617** **Normalized IF: 1**

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*Journal of Cardiovascular Medicine* 2015;16(4):310-7.

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**Raw IF: 1.407** **Normalized IF: 2**

## CLINICAL CARDIOLOGY

Barbone A*, Pini D, Ornaghi D, Visigalli MM, Ardino L, Bragato R, Curzi M, Cioccarelli SA, Di Diodoro L, Basciu A, Cappai A, Settepani F, Citterio E, Cappelleri A, Calcagnino M, Mangiavacchi M, Tarelli G, Lettino M, Vitali E.

CircuLite Synergy ventricular assist device: a new approach to end-stage congestive heart failure.

*Giornale Italiano di Cardiologia* 2014;15(2):116-22.

**Raw IF: 0** **Normalized IF: 0**

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*Heart Failure Reviews* 2014;19(6):699-708.

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Perioperative management of antiplatelet therapy in patients with coronary stents undergoing cardiac and non-cardiac surgery: a consensus document from Italian cardiological, surgical and anaesthesiological societies.

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Eleven-year trends in gender differences of treatments and mortality in ST-elevation acute myocardial infarction in Northern Italy, 2000 to 2010.

*American Journal of Cardiology* 2014;114(3):336-41.

**Raw IF: 3.425** **Normalized IF: 4**

Nicholls SJ, Kastelein JJ, Schwartz GG, Bash D, Rosenson RS, Cavender MA, Brennan DM, Koenig W, Jukema JW, Nambi V, Wright RS, Menon V, Lincoff AM, Nissen SE; VISTA-16 Investigators. (Collaborator: Corrada E).

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*Journal of the American Medical Association* 2014;311(3):252-62.

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Transapical transcatheter valve-in-valve replacement for deteriorated mitral valve bioprosthesis without radio-opaque indicators: the "invisible" mitral valve bioprosthesis.

*Heart Lung and Circulation* 2015;24(2):e19-22.

**Raw IF: 1.172** **Normalized IF: 2**

Savonitto S, Ferri M, Corrada E.

Fatal bleedings with prasugrel as part of triple antithrombotic therapy.

*Revista Espanola de Cardiologia* 2014;67(3):225-6.

**Raw IF: 3.342** **Normalized IF: 2**

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Chinnici CM, Amico G, Monti M, Motta S, Casalone R, Petri SL, Spada M, Gridelli B, Conaldi PG.

Isolation and characterization of multipotent cells from human fetal dermis.

*Cell Transplantation* 2014;23(1):1169-85.

**Raw IF: 3.570** **Normalized IF: 3**

Gamba C, Schroeder J, Citterio A, Cazzaniga S, Rivolta AL, Vighi G; il Gruppo REACT-Lombardia. (Collaborators: Monti M, Fazio M).

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*Recenti Progressi in Medicina* 2014;15(1):379-84.

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## DIAGNOSTIC RADIOLOGY

Bello L*, Riva M, Fava E, Ferpozzi V, Castellano A, Raneri F, Pessina F, Bizzi A, Falini A, Cerri G.

Tailoring neurophysiological strategies with clinical context enhances resection and safety and expands indications in gliomas involving motor pathways.

*Neuro-Oncology* 2014;16(8):1110-28.

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The urokinase plasminogen activator receptor (uPAR) controls macrophage phagocytosis in intestinal inflammation.

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Molecular heterogeneity and prognostic implications of synchronous advanced colorectal neoplasia.

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**Raw IF: 0** **Normalized IF: 0**

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Peritonectomy and hyperthermic intraperitoneal chemotherapy: cost analysis and sustainability.

*European Journal of Surgical Oncology* 2015;41(3):386-91.

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*World Journal of Gastroenterology* 2014;20(46):17578-87.

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Peritonectomy and hyperthermic intraperitoneal chemotherapy: cost analysis and sustainability.

*European Journal of Surgical Oncology* 2015;41(3):386-91.

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Bellera CA, Penel N, Ouali M, Bonvalot S, Casalli PG, Nielsen OS, Delannes M, Litière S, Bonnetain F, Dabakuyo TS, Benjamin R, Blay JY, Bui BN, Collin F, Delaney TF, Duffaud F, Filleron T, Fiore M, Gelderblom H, George S, Grimer R, Grosclaude P, Gronchi A, Haas R, Hohenberger P, Issels R, Italiano A, Jooste V, Krarup-Hansen A, Le Péchoux C, Mussi C, Oberlin O, Patel S, Piperno-Neumann S, Raut C, Ray-Coquard I, Rutkowski P, Schuetze S, Sleijder S, Stoeckle E, Van Glabbeke M, Woll P, Gourgou-Bourgade S, Mathoulin-Pélissier S.

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Atypical lipomatous tumors: should they be treated like other sarcoma or not? Surgical consideration from a bi-Institutional experience.

*Annals of Surgical Oncology* 2014;21(13):4090-7.

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Bona S*, Molteni M, Rosati R, Elmore U, Bagnoli P, Monzani R, Caravaca M, Montorsi M.

Introducing an enhanced recovery after surgery program in colorectal surgery: a single center experience.

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Cozzaglio L*, Giovenzana M, Biffi R, Cobianchi L, Coniglio A, Framarini M, Gerard L, Gianotti L, Marchet A, Mazzaferro V, Morgagni P, Orsenigo E, Rausei S, Romano F, Rosa F, Rosati R, Roviello F, Sacchi M, Morenghi E, Quagliuolo V.

Surgical management of duodenal stump fistula after elective gastrectomy for malignancy: an Italian retrospective multicenter study.

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*Updates in Surgery* 2014;66(2):121-5.

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The urokinase plasminogen activator receptor (uPAR) controls macrophage phagocytosis in intestinal inflammation.

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*Digestive and Liver Disease* 2014;46(6):479-93.

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**Raw IF: 0** **Normalized IF: 0**

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*Journal of Clinical Gastroenterology* 2015;49(2):174-5.

**Raw IF: 3.186** **Normalized IF: 2**

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Molecular heterogeneity and prognostic implications of synchronous advanced colorectal neoplasia.

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**Raw IF: 4.817** **Normalized IF: 6**

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Atypical lipomatous tumors: should they be treated like other sarcoma or not? Surgical consideration from a bi-Institutional experience.

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Øresland T, Bemelman WA, Sampietro GM, Spinelli A, Windsor A, Ferrante M, Marteau P, Zmora O, Kotze PG, Espin-Basany E, Tiret E, Sica G, Panis Y, Faerden AE, Biancone L, Angriman I, Serclova Z, de Buck van Overstraeten A, Gionchetti P, Stassen L, Warusavitarne J, Adamina M, Dignass A, Eliakim R, Magro F, D'Hoore A; European Crohn's and Colitis Organisation (ECCO).

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*Journal of Cancer Research and Clinical Oncology* 2015;141(3):543-53.

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*Alimentary Pharmacology & Therapeutics* 2014;40(9):1009-22.

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*Catheterization and Cardiovascular Diagnosis* 2014;83(7):E283-6.

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*Heart Lung and Circulation* 2015;24(2):e19-22.

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*Autonomic Neuroscience: Basic and Clinical* 2014;184:46-52.

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*Cnr-Ceris* 2014;12:5-19.

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*Cardiology Clinics* 2013;31(1):27-38.

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*Journal of Clinical Endocrinology and Metabolism* 2014;99(9):3199-207.

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*Autonomic Neuroscience: Basic and Clinical* 2014;184:17-23.

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*European Journal of Internal Medicine* 2014;25(9):847-52.

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*European Geriatric Medicine* 2014;5(5):307-13.

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*Internal and Emergency Medicine* 2014;9(7):723-34.

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*Internal and Emergency Medicine* 2013;8(6):59-2.

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*European Journal of Internal Medicine* 2013;24(8):6-8.

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*Gerontology* 2013;39(4):307-15.

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*Frontiers in Immunology* 2014;5:128.

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*Europace* 2015;17(2):300-8.

**Raw IF: 3.500** **Normalized IF: 4**

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*Annals of Emergency Medicine* 2014;64(6):649-55e2.

**Raw IF: 4.333** **Normalized IF: 6**

## KNEE ORTHOPAEDICS AND SPORT TRAUMATOLOGY

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*Orthopedics* 2014;37(5):321-4.

**Raw IF: 0.977** **Normalized IF: 2**

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*Muscles, Ligaments and Tendons Journal* 2014;3(4):324-3.

**Raw IF: 0** **Normalized IF: 0**

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*Muscles, Ligaments and Tendons Journal* 2014;4(1):95-9.

**Raw IF: 0** **Normalized IF: 0**

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Autologous collagen-induced chondrogenesis technique (ACIC) for the treatment of chondral lesions of the talus.

*Knee Surgery, Sports Traumatology, Arthroscopy* 2014;22(6):1320-6.

**Raw IF: 2.837** **Normalized IF: 6**

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High accuracy in knee alignment and implant placement in unicompartmental medial knee replacement when using patient-specific instrumentation.

*Knee Surgery, Sports Traumatology, Arthroscopy* Epub ahead of print 2013 Dec 4.

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## LABORATORY TESTS

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*Bone Marrow Transplantation* 2015;5(2):282-8.

**Raw IF: 3.466** **Normalized IF: 0.8**

Jaillon S*, Moalli F, Ragnarsdottir B, Bonavita E, Puthia M, Riva F, Barbati E, Nebuloni M, Cvetko Krajinovic L, Markotic A, Valentino S, Doni A, Tartari S, Graziani G, Montanelli A, Delneste Y, Svanborg C, Garlanda C, Mantovani A*.

The humoral pattern recognition molecule PTX3 is a key component of innate immunity against urinary tract infection.

*Immunity* 2014;40(4):621-32.

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Successful treatment of post-neurosurgical multidrug-resistant Pseudomonas aeruginosa meningo-encephalitis with combination therapy of colistin, rifampicin and doripenem.

*Journal of Antimicrobial Chemotherapy* 2014;69(3):857-9.

**Raw IF: 5.439** **Normalized IF: 6**

Ristagno G, Latini R, Vaahersalo J, Masson S, Kurola J, Varpula T, Lucchetti J, Fracasso C, Guiso G, Montanelli A, Barlera S, Gobbi M, Tiainen M, Pettilä V, Skrifvars MB; FINNRESUSCI Investigators.

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*Journal of the American Heart Association* 2014;3(4).

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*European Journal of Nuclear Medicine and Molecular Imaging* Epub ahead of print 2014 Dec 18.

**Raw IF: 5.217** **Normalized IF: 6**

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*American Journal of Nuclear Medicine and Molecular Imaging* 2014;4(4):365-84.

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*Annals of Oncology* 2014;25(2):442-7.

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*Annals of Surgical Oncology* 2014;21(13):4090-7.

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*New England Journal of Medicine* 2014;371(2):107-18.

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*Biology of Blood and Marrow Transplantation* 2014;2(4):51-6.

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*Nature Genetics* 2014;46(8):844-9.

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*Medical Oncology* 2014;31(12):38.

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*Investigational New Drugs* 2015;33(1):159-68.

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*Journal of Clinical Oncology* 2014;32(12):1188-94.

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*Blood* 2015;125(7):161-72.

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*Hepatic Oncology* 2014;1(2):181-8.

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B-cell reconstitution recapitulates B-cell lymphopoiesis following haploidentical BM transplantation and post-transplant CY.

*Bone Marrow Transplantation* 2015;50(2):317-9.

**Raw IF: 3.466** **Normalized IF: 2**

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*Biology of Blood and Marrow Transplantation* 2014;2(9):1444-7.

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*Annals of Oncology* 2015;26(3):542-7.

**Raw IF: 6.578** **Normalized IF: 6**

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*Lung Cancer* 2014;86(1):47-53.

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*Blood* 2014;123(4):e-letter.

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*Annals of Oncology* Epub ahead of print 2014 Dec 8.

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Increased SOX2 gene copy number is associated with FGFR1 and PIK3CA gene gain in non-small cell lung cancer and predicts improved survival in early stage disease.

*PLoS One* 2014;9(4):e95303.

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## SHOULDER AND ELBOW SURGERY

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*Knee Surgery, Sports Traumatology, Arthroscopy* Epub ahead of print 2014 Nov 21.

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*Muscles, Ligaments and Tendons Journal* 2014;4(2):226-31.

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**Raw IF: 2.050** **Normalized IF: 4**

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