# **ISTORETT** *Istituto di Ricovero e Cura a Carattere Scientifico*

Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione











Mission, Vision, and Values Corporate Structure ISMETT Data Our Partners Our Successes, Year by Year	4 5 6 8 9
CLINICAL OUTCOMES ISMETT and Transplantation ISMETT Clinical Activity Data and Values International Patients	12 13 15
SCIENTIFIC RESEARCH ISMETT - The Research Scientific Production at ISMETT in 2021 Research Projects Scientific Collaborations Cardiology Network Precision Medicine Research Infrastructure	18 19 21 22 23 24
INVESTMENTS Fixed Assets Long-Term Cost Composition Detail	30 32
LEVERAGING TALENTS Our Staff DAISY AWARD ROSE AWARD Training Degree in Nursing Master's Degree in Physiotherapy	36 37 37 38 39 39
A QUALITY HOSPITAL Patient Safety is a Priority Lean Thinking to Improve Organization in Health Care Accreditations, Certifications and Acknowledgments	42 45 46
REVIEWS ISMETT's Successes and Achievements	50





Year 2021 was a successful year for ISMETT. Successes in the clinical field, but also in terms of management and innovation. ISMETT was established thanks to an international partnership between the Region of Sicily - through ARNAS Civico Hospital of Palermo - and UPMC (University of Pittsburgh Medical Center). ISMETT is a model for innovative and efficient health management. It is acknowledged as a center of excellence in the field of organ transplantation, cardiothoracic surgery, abdominal surgery, and high specialty therapies.

The partnership with the University of Pittsburgh Medical Center brought the expertise and studies of its world-renowned international hospitals, research centers and universities to Palermo, thus enabling ISMETT to be acknowledged throughout Europe as a high-level facility. More specifically, ISMETT has become a reference point for the treatment of patients suffering from end-stage organ failure, with more than 2,750 transplants performed so far.

2021 was a year marked by good health care. A record number of **211** transplants were performed. This goal was reached thanks to a perfect organization and the use of state-of-the-art techniques - e.g., reconditioning procedures or the use of drugs such as simvastatin - which enabled ISMETT to use marginal organs, that is organs reported as surplus by other Italian regions and therefore rejected. It was a remarkable year **during which ISMETT was on the front line in the fight against the COVID-19 pandemic**. In the first half of 2021, as many as 40 ISMETT intensive care beds were made available to COVID-19 patients requiring high-level intensive care. Significantly, patients were transferred to the facility in Palermo from all over the Region and beyond when in a critical condition and in need of high-specialty therapies such as ECMO - an extracorporeal oxygenation system that puts the lungs at rest and can therefore foster the recovery of lung activity.

But the ISMETT model has also achieved significant outcomes in terms of administrative processes, health technology, and system quality. The facility in Palermo was the first hospital in Southern Italy to be accredited by the Joint Commission International (JCI), one of the most advanced accreditation systems to assess the quality of hospital facilities. The accreditation was confirmed for the fifth time in 2021.

Moreover, last year ISMETT was also acknowledged as the most technologically advanced hospital in Italy and among the first ones in Europe. The technology level achieved was certified by the College of Healthcare Information Management Executives (CHIME) in its annual "Digital Health Most Wired", a ranking that assesses the effectiveness of new technologies in the clinical and management programs of global health care facilities. ISMETT achieved a score of 7 in the "Acute" category, i.e., in the treatment of severe patients - the only facility in Europe together with the Cambridge University Hospitals NHS Foundation Trust. Among the successes of ISMETT there was also the Budget Honor "Felix" Industry Award and the acknowledgment by the European Commission, which certified the "Research Infrastructures" project as one of the most remarkable financed with the PO-FESR Sicily 2014-2020 European funds.



### Mission, Vision, and Values

ISMETT offers top-level patient care and contributes to developing future health care through clinical and management innovation, research, and commitment in theoretical and hands-on training.

### Vision

ISMETT's goal is to be acknowledged at national and international level as the center of reference in the field of transplantation and high specialty therapies at the service of the Region of Sicily and of the countries of the Mediterranean area. By adopting a health care model that testifies how the public and private sectors may successfully coexist, ISMETT implements the philosophy and commitment of the University of Pittsburgh Medical Center as regards collaborating with other regional clinical facilities and with the local medical communities.

### Values

Our values are:

We create a safe environment where quality is our guiding principle. QUALITY AND SAFETY

We treat all people with dignity and respect. **DIGNITY AND RESPECT** 

We listen to and care for our patients, health plan members, fellow staff, doctors, and community. **CARING AND LISTENING** 

We perform our work with the highest levels of responsibility and integrity. **RESPONSIBILITY AND INTEGRITY** 

We think creatively and aim at excellence in everything that we do. **EXCELLENCE AND INNOVATION** 



### **Corporate Structure**

### **Board of Directors**

*President:* Camillo Ricordi

Members: Charles Edward Bogosta Antonino De Lisi Michele Vaira Giuseppe Dell'Acqua

### **Board of Auditors**

*President:* Dario La Marca

*Members:* Daria Beatrice Langosco di Langosco Giuseppe Genco

### Management

*Director:* Angelo Luca

*Director of Health Care Activities:* Cinzia Di Benedetto

*Scientific Director:* Pier Giulio Conaldi

Administrative Director: Giuseppe Alongi

HR Director: Gianfranco Poledda

Nursing & Healthcare Professionals: Giuseppe Arena

### **Clinical Activity Departments**

Clinical activity at ISMETT is organized across multiple departments. There are currently five departments with corresponding units:

- Department of Anesthesia and Critical Care. *Director:* Antonio Arcadipane
- Department for the Treatment and Study of Abdominal Diseases and Abdominal Transplantation. *Director:* Salvatore Gruttadauria
- Department of Pediatrics for the Treatment and Study of Abdominal Diseases and Abdominal Transplantation.
   Director: Jean de Ville de Goyet
- Department for the Treatment and Study of Cardiothoracic Diseases and Cardiothoracic Transplantation.
   Director: Michele Pilato
- Department of Diagnostic and Therapeutic Services *Director:* Angelo Luca





The Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione (ISMETT) is a government-approved research hospital (IRCCS) acknowledged by the Italian Ministry of Health's Decree of September 12, 2014. ISMETT operates in the area of end-stage organ failure care and research.

An example of innovative and efficient clinical management, ISMETT was created with an international partnership between the Region of Sicily, through ARNAS Civico Hospital of Palermo, and UPMC. In June 2017, the Ri.MED Foundation, established by the Presidency of the Italian Council of Ministers, entered ISMETT's governance. ISMETT is a center of excellence in the field of organ transplants, cardiothoracic surgery, abdominal surgery, and high specialty therapies.

### **Our Partners**

**UPMC** (University of Pittsburgh Medical Center) is a \$24 billion health care provider and insurer based in Pittsburgh, Pennsylvania, with over 90,000 employees, 40 hospitals and 700 outpatient clinics. Working in close collaboration with the University of Pittsburgh Schools of the Health Sciences, it develops new models of patientcentered, effective and sustainable care models. UPMC shares its clinical, managerial and technological skills worldwide with UPMC Enterprises and UPMC International.

It has been operating in Italy since 1997, when ISMETT (Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione) was created in Palermo; nowadays the Italian activities of the group include two advanced radiotherapy centers, UPMC Hillman Cancer Center San Pietro in Rome and UPMC Hillman Cancer Center Villa Maria in the Region of Campania; the private hospital Salvator Mundi International Hospital in Rome; and the Institute for Health in the Region of Tuscany, a center specialized in preventive and rehabilitative medicine.

Azienda di Rilievo Nazionale ad Alta Specializzazione (ARNAS) "Civico e Benfratelli – Giovanni Di Cristina – Maurizio Ascoli" in Palermo is the largest hospital in Southern Italy. ARNAS Civico has been successfully involved for many years in developing national and regional programs for emergency medicine, transplantation, maternity and infant care, oncology, and training and research activities, also in the field of biotechnologies. In addition to its clinical and research activity, ARNAS Civico organizes training and refresher courses accredited by the Italian National Commission for Continuing Medical Education.

ARNAS Civico is committed in humanitarian and medical care programs for populations of developing countries and collaborates with the main international organizations. The hospital campus hosts the Pediatrics section of the University Department of Maternity and Infant Care, the Institute for Infectious Diseases and Virology, the postgraduate schools of Pediatrics and Infectious Diseases, and the University of Palermo's Nursing School. ARNAS Civico hosts the Regional Center for Organ Coordination and the "118" Emergency Service for the provinces of Palermo and Trapani. The Ri.MED Foundation, established by the Presidency of the Italian Council of Ministers to encourage the socioeconomic development of Sicily and Southern Italy, is a public-private partnership management model based on a scientific collaboration agreement between the United States of America and Italy.

Ri.MED is a not-for-profit foundation developing biomedical and biotechnological translational research approaches, disseminating scientific know-how, training qualified staff in Life Sciences, and establishing and managing research centers and laboratories. Ri.MED is currently involved in the realization in Carini, near Palermo, of the Biomedical Research and Biotechnology Center (BRBC), a research center that will allow Sicily to become a biomedical research hub in the Mediterranean. The Foundation has its registered offices and its computational biology and chemistry laboratories in Palermo. Ri.MED also has biomedical research and regenerative medicine laboratories at ISMETT, and structural biology laboratories at the ATeN Center of the University of Palermo. The Foundation is involved in major projects with various research centers at the University of Pittsburgh.



Our Successes, Year by Year			
			211 organ transplants performed at
	2021	•	ISMETT, the highest figure since the
			40 ICU beds made available to
Imaging Labs inauguration to launch		2020	COVID-19 patients
COVID-19 ICI Jaunched	, and the second s	2020	
	2019	•	Celebration of the 20th anniversary since
	2017		the first liver transplant in Sicily
Region of Sicily, UPMC and the			
RI.MED Foundation sign the renewal	••	2018	
for the first time, a 10-year-period			
	2017 💿	•	Induguration of the new Pediatrics and
	ľ		fiedit Center dieds
Opening of the new hybrid	•	2016	
operating room at ISMELL	<u> </u>		
	2015	•	First lung transplant using EVLP
	2013		ICI Network Quality Award
ISMELL IS acknowledged as a			Server and the server
hospital (IRCCS) in the area of	•	2014	ISMETT celebrates the 100th lung
end-stage organ failure care			transplant performed
and research	2013 💿	•	ISMETT joins the network of hospitals that
First in the world, a right liver labo			of women, receiving the "Pink Award" for
resection for transplantation was	•	2012	the following two-year periods
performed with the Da Vinci robot	<u> </u>	2012	
	2011		Integration with the Cardiac Surgery
	2011 🦉		program of ARNAS Civico Hospital
1,000 transplants performed			FFAA Quality Awara
ISMEIT achieves stage 6 HIMSS	•	2010	
health record implementation			
	2009 💿	•	ISMETT is the first hospital in Southern Italy
			To receive JCI accreditation
Performance project launched,	•	2008	
18 research tellowships	<u> </u>		First HIV-positive patient lung transplant
	2007	•	ever performed in the world
	2007		Opening of the "Renato Fiandaca"
ISMETT, UPMC and the University		2007	Simulation Center and of the GMP facility
of Palermo sign an agreement		2006	
to encourage training programs	0005		First lung and kidney-pancreas transplant
	2005 🅑	•	ever performed
Induduration of the new clinical facility			
First heart transplant performed	•(•)	2004	
			First padiatric liver transplant performed
	2003 🕥	•	in a Southern Italy facility
First living donor liver transplant	•	2002	
ever performed	Ť	2002	
	2001	•	First HIV-positive patient kidney transplant
			ever performed in Italy
ECF project launched, 37 scholarships		2000	
to train transplant specialists	Ť		
	1999	•	First liver transplant
			performed in Sicily









### **ISMETT and Transplantation**

ISMETT is accredited to perform all types of solid organ transplants. In 2021, 211 transplants were performed (including VAD), i.e., 44 more than in the same period of the previous year. This is the highest figure for ISMETT since the clinical activity was launched. In 2020, a total of 163 transplants were performed. **In 2021, in detail**, the following were carried out: 101 liver, 69 kidney, 16 heart, 16 lung and 3 combined transplants. **22 pediatric transplants** were performed. **36** living donor transplants were performed at ISMETT in 2021, of which 18 were liver transplants.

During the pandemic, ISMETT was the only center where the living donor liver transplant program remained truly active. Since the beginning of the transplantation activity in June 1999, a total of **2,754** transplants have been performed at ISMETT, of which 431 have been living donor procedures (kidney and liver).



### ▲ ISMETT - Transplant data since the activity launch



### **ISMETT Clinical Activity Data and Values**

In 2021, **2,755** inpatients were discharged, with an ALOS of 11.6 days and an average DRG weight of 3.98. Compared to the previous year, there was a 5.9% increase in the number of regular admission patients discharged (2,755 vs 2,601) with a mean DRG weight higher by 6.9% (3.98 vs 3.72) and a mean stay higher by 0.8 (11.6 vs 10.8).

16.8% of patients were admitted as urgent and 17.5% came from other hospitals.

The incidence of patients transferred from other hospitals in 2021 was slightly higher than by 1% as compared to 2020. In 2021, 64.9% of the regular admissions received a surgical DRG.

The average DRG weight in 2021 was higher by 0.6 as compared to 2020 (3.98 vs 3.72).

OR cases were **1,576**. Half of these (50%) were recorded in the Cardiac Surgery and Heart Transplantation session, 31% in Abdominal Surgery and Abdominal Transplantation, 16% in Thoracic Surgery and Lung Transplantation, and 3% in Pediatrics.

Day Hospital admissions were **2,157**, with an overall average DRG weight of 0.96, which marked a 17.9% increase in admissions compared to the year 2020.

A total of **77** COVID-19 patients required ECMO, an extracorporeal oxygenation system that puts the lungs at rest and can therefore foster the recovery of lung activity. Finally, there were **20** non-COVID-19 patients for whom no extracorporeal circulation system was required.





### ISMETT - 2021 in a nutshell



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### **International Patients**

ISMETT attracts many patients from the European and Mediterranean areas coming to Sicily to receive qualified care in a facility owned by the Region of Sicily, created based on a U.S. model and partnership. **95 foreign patients** were treated at ISMETT in 2021.

In total, in 2021 **19** transplants were performed on foreign patients, 15 of which were liver transplants.

According to recent data on pediatric transplants, one out of two patients arrive at ISMETT from abroad. **10** children arrived in Palermo because they needed a transplant. In total, since the international patients' program was launched – i.e., since 2005 – 165 transplants have been performed on foreigners.



### A PATIENTS FROM THE EUROPEAN AND MEDITERRANEAN AREAS

- ROMANIA 48%
- MALTA **19%**
- UKRAINE 13%
- ESTONIA 6%
- ITALY 3%
- PORTUGAL 3%
- REPUBLIC OF POLAND 3%
- SERBIA 3%









### **ISMETT - The Research**

In 2014, with a decree signed by the Minister of Health, ISMETT was acknowledged as a government-approved research hospital (IRCCS) in the area of end-stage organ failure care and research.

ISMETT has 4 active research lines.

Over the course of ISMETT's activity, it has become even more evident that organ transplants cannot be the only therapeutic response to vital organ end-stage failure. Although transplants provide excellent clinical results, the lack of balance between organ availability and necessity is such as to identify other therapeutic strategies. Over the years, ISMETT has intensified its efforts in clinical and basic biomedical research and in developing of new technologies to identify solutions, protocols, and strategies capable of preventing or delaying the endstage disease of vital organs.

In particular, ISMETT invests in advanced therapies as an alternative to transplantation, perfecting surgical techniques aimed at repairing the patient's organ, which could be partially or totally compromised, reserving the complete organ replacement for extreme cases only.



### Scientific Production at ISMETT in 2021

In recent years, there has been a progressive increase in the number of scientific publications of ISMETT. The total of scientific publications raised from 150 in 2018, to **179** in 2021 with a raw Impact Factor (IF) or **888.6**.

An analysis of the works published with ISMETT affiliation shows that part of the carried out scientific activity focused on issues that are additional or not directly related to those of the IRCCS recognition area, but almost always linked to the use of highly specialized surgical, interventional, or diagnostic techniques, they are related to the high-complexity clinical activity of ISMETT.

### Total Scientific Production



### Scientific Production at ISMETT in 2021







The scientific activity carried out by the ISMETT research staff mainly focused on the area of IRCCS recognition, namely end-stage organ failure care and research, which is divided according to four lines of research. In this context, the number of publications has increased from 83 in 2018 to **151** in 2021.

The progressive increase in the number of publications corresponds to a surge of the value both for the overall impact factor (raw if 879.1 in 2021) and of that assigned by the Ministry of Health.

In the three-year period 2018-2020, the normalized impact Factor assigned to ISMETT increased by 147% and in 2021 a further 133% increase over the previous year was registered.

Between 2018 and 2021, the Normalized Impact Factor assigned to ISMETT by the Ministry of Health almost doubled and reached a value above 500, as required to attest to the quality of scientific production by singlefocus IRCCS, as ISMETT is.



### Scientific production for the IRCCS area

### **Research Projects**

During 2021, the value of research projects at ISMETT amounted to over € 20 million. Most of the funding comes from projects financed by the Region of Sicily, followed by the Ministry of Health, and the Ministry for Economic Development.

### Value of active projects in 2021 divided by funding source



### **Scientific Collaborations**

ISMETT has undertaken important scientific collaborations with regional, national, and international partners. One of ISMETT's goals is creating networks that generate competitive research financing for its research lines.

This goal meets what the Ministry of Health fostered in recent years.

As a matter of fact, over the years the Ministry has promoted and financed the establishment of structured networks among IRCCS in order to: share their resources in terms of clinical, scientific, experimental, and biotechnological skills and advanced technologies; optimize the use of resources; strengthen the Italian position in Europe in terms of research and care in different areas.

### Scientific partnership



### **Cardiology Network**

ISMETT is one of the twenty members of the **Cardio Network**, the largest Italian research network in the cardiovascular field promoted by the Ministry of Health to foster cooperation between IRCCS through the creation of an information and collaboration network including public and private IRCCS hat have a cardiovascular specialization and/or are involved in a significant way in the cardiovascular field.

Established in 2017, the mission of the Cardio Network is to facilitate and promote scientific and technological research in the field of cardiovascular diseases and related risk factors, with the aim of improving diagnosis, and treatment. ISMETT is a member of the **Board of Directors**, which is composed of seven scientific directors of IRCCS part of the cardiology network.

Moreover, since November 2020, ISMETT has made available to the network its **own contracting station**, with its own RUP, to carry out public tender procedure in the name and on behalf of the cardiology network. ISMETT, together with the cardiology network, is partner of 9 projects for a total budget of € 872,550.00.

# 20 7 BoD BoD MEMBERS Image: Comparison of the second second

### ✓ ISMETT within the Cardiology Network



### **Precision Medicine Research Infrastructure**

The Research Infrastructure (IR) of ISMETT and the Ri.MED Foundation for Precision Medicine has been strengthened thanks to the "GMP facility, Research Laboratories and Diagnostic and therapeutic Services" project by improving twelve laboratories: Biobank, Structural Biology Laboratory, Molecular Medicine Laboratory, Immunotherapy and Regenerative Medicine Laboratory, Laboratories of Vaccine Development and Experimental Microbiology Laboratories, Virology and Immunology Laboratories, GMP facility, Sensor Technology Laboratory, 3D Laboratory, Imaging Laboratory, Big Data Laboratory, and Neuroscience Laboratory.

The investment, co-financed by the Sicilian Region, Department of Productive Activities, through the resources of the European Regional Development Fund Operational Programme (ERDF OP) Sicily 2014-2020, aims at the strengthening and consolidation of existing IR through the acquisition of new technologies able to improve the infrastructure, organizational, and collaborative component. The enhanced IR is therefore able to improve and increase productivity, develop new devices for advanced therapies, develop new ICT technologies to support clinical and research activities and above all it is an even more credible interlocutor in the national and international scenario of scientific and biomedical research.

The IR, thanks also to the integration of ICT systems, can generate "big data" through numerous high-throughput technologies feeding datasets to accelerate traslational research processes and customize clinical interventions based on automatic analysis of biological profiles and digital phenotype.

The co-existence in the same IR of clinical activities, basic and clinical research, traslational research and, in addition, of a very "evolved" ICT component, is a unique and strongly positive event: it enables researchers and clinicians to have a variety of "structured" data that is now considered essential to translating "bench-tobedside" and "bedside-to-bench" information. Another equally relevant aspect is that such structured data, Big Data, allow to implement personalized and precision medicine.

The main result of IR enhancement is to have a platform that allows the application of the principles of Precision Medicine. The heart of said enhancement lies in the Big Data laboratory, since it contains the database and knowledge useful for the development of predictive models in a variety of fields of application.

The laboratory is characterized by the heterogeneity of the collected, managed, and analyzed information (clinical and laboratory data, but also environmental data, pollutants, sensors, life, and health styles, etc.).

This allows traslating results in the field of Life Sciences by providing products/services for wellbeing, particularly but not only for fragile social categories, such as the elderly and the disabled, through home automation solutions that facilitate living conditions and monitoring systems that reduce the need for hospital care, able to prevent domestic accidents.

It should also be noted that the development of sensor technology associated with the predictive models of outcome can result in the development of new models of assistance (home, local, etc.), which allow a different organization of care by reducing the number and duration of hospitalizations, thus optimizing the use of resources toward other aspects of healthcare and welfare.





### PO-FESR Sicily 2014-2020 European funds

Priority axis 1 - Research, technological development, and innovation Action 1.5.1 "Sostegno alle Infrastrutture della ricerca considerate strategiche per i sistemi regionali al fine dell'attuazione della S3".



### Biobank

The biobank has been improved with the purchase of equipment necessary for a correct collection, classification, and storage of biological material (biological fluids, tissues, primary cell cultures, stem cells, and their products) for research, diagnostic, prognosis and therapeutic purposes.

### Structural Biology

The Structural Biology Laboratory, dedicated to research activities in the field of neurodegenerative, oncological, and infectious diseases, has been enhanced through the purchase of an NMR spectrometer operating at 800 MHz. Thanks to the purchase of said device, it is possible to carry out structural characterization of pathological targets, study their metabolic pathways, and provide key information for the development of potential drugs.





### **Molecular Medicine**

The laboratories dedicated to research activities in the field of molecular medicine have been enhanced thanks to the purchase of the latest generation of molecular biology equipment (Next Generation and Single Cell Sequencers, Digital PCR, etc.), allowing for sequencing single cells and the entire genome, or to quantify and characterize nucleic acids and nanoparticles more accurately.

### Immunotherapy and Regenerative Medicine

The laboratories dedicated to research activities in the field of immunotherapy and regenerative medicine have been enhanced with the acquisition of a Single Cell Sorter and a mass cytometer, which allow the separation of specific cell populations and a single cell proteomics analysis, providing simultaneous information on phenotype and cell function.





### Vaccine Development and Experimental Microbiology

The laboratory dedicated to research activities for vaccine development and experimental microbiology has been enhanced with the purchase of incubators dedicated to growing bacteria and yeasts, a microcentrifuge, and an ultracentrifuge.

### Virology and Immunology

The laboratories dedicated to the research activities of Virology and Immunology have been enhanced with equipment allowing handling viruses (level of biological safety BLS2), as well as to isolate and maintain primary cell cultures derived from different tissues and biological fluids.





### **GMP** Facility

The production and quality control laboratories according to Good Manufacturing Practice (GMP), dedicated to the production and control of Advanced therapy medicinal products (ATMPs), underwent a substantial restructuring that has rationalized the environments and made them more versatile, hence allowing for the concurrent production several products and have optimal control of your activities and areas.

### Sensor Technology -

A sensor technology laboratory was created to collect data from structured sensors in the context of wearable devices or mobiles that can communicate directly with analytics platforms for point-of-care monitoring or diagnostic purposes.





### 3D

A 3D printing laboratory was created with the aim of developing models from data imaging to help clinicians plan interventions, surgical access, and maneuvers with the purpose of avoiding complications.

### Imaging

The radiology, interventional radiology, pathology, endoscopy laboratory has been enhanced with the purchase of a multi-slice CT scanner, echocolor doppler, portable digital radiography system, coronary flow meter, and digital system for pediatric endoscopy.





### Big Data

The Big Data laboratory has been enhanced for the collection, integration, and management of heterogeneous data (clinical, preclinical, experimental, bioinformatics, homic, epidemiological, and environmental) to develop new knowledge in the field of precision medicine and to support research activities and clinical decisions.

### Neurosciences

The neuroscience laboratory is already equipped with spaces (rehabilitation gym) and state-of-the-art devices (RM 3T, TMS ECG, etc.) and will benefit from specific consults for the development of research activities on neurodegenerative diseases with cognitive disorders.











### **Fixed Assets**

In ISMETT, the fixed assets amounted to € 10,336,559 in 2021.

An overall increase of € 709,716 was recorded, of which € 408,681 related to the "Research Infrastructure Enhancement – Research Infrastructure National Project (PNIR)".

Both the works relating to the "Heart Institute Project" and the works under the "Research Infrastructure Enhancement" project have been included within this item. In the first case, they are 100% financed, in the second case they are 50% financed.

Costs of  $\notin$  4,200 were incurred in 2021 for the two patents filed and registered.

With reference to concessions, licenses, trademarks and similar rights, the main increases (of which  $\notin$  74,000 for the PNIR project and  $\notin$  38,000 for one of the capital account research projects) are:

- Mimics Innovation Software for € 44,700
- BioBanking program for € 29,900
- COMSOL MultiphysicsCPU c2 software € 12,000.
- Interfacing with Dedalus S management system for € 6,700.

With regard to current fixed assets and advances, no increase was recorded, the balance as at 31 December 2020 was fully reclassified as it went into production in 2021.

The item of other intangible fixed assets mainly includes the realization of the so-called "improvements" on the ISMETT clinical site, carried out during the year for a total value of approximately  $\notin$  584,479, correlated to the PNIR project for  $\notin$  334,761, to the construction of the Research building for  $\notin$  175,024, and other improvements on various systems and equipment for  $\notin$  74,693.



### ▲ ISMETT intangible fixed assets

	Industrial patents and intellectual property rights	Concessions, licenses, trademarks, and similar rights	Current intangible fixed assets and advances	Other intangible fixed assets	Total intangible assets
FY initial value					
Cost	-	2,409,338	3,149,582	22,681,914	28,240,834
Depreciation (Depreciation fund)	-	2,152,424	-	13,782,365	15,934,789
Book value	-	256,914	3,149,582	8,899,549	12,306,045
FY variations					
Increases due to acquisitions	4,253	120,985	-	584,478	709,716
Riclassifiche (del valore di bilancio)	19,012	-	(3,149,582)	3,130,570	-
Depreciation for the year	5,095	202,251	-	2,471,856	2,679,202
Total variations	18,170	(81,266)	(3,149,582)	1,243,192	(1,969,486)
FY end value		-		· · ·	
Cost	23,265	2,530,323	-	26,396,962	28,950,550
Depreciation (Depreciation fund)	5,095	2,354,675	-	16,254,221	18,613,991
Book value	18,170	175,648	-	10,142,741	10,336,559

### Long-Term Cost Composition Detail

### **Tangible fixed assets**

Tangible fixed assets also include supplies relating to the "Heart Institute Project" for a total original value gross of the depreciation fund of  $\in$  5,298,343 as well as the equipment and machinery relating to the "Research Infrastructure Enhancement" project for a total gross value of  $\notin$  6,674,569 (AP. 6,019,215) with an increase of  $\notin$  655,354.

Tangible fixed assets acquired during 2021 free of charge gross of the related depreciation funds amount to € 25,909.

### Changes in tangible assets

Tangible fixed assets before the relative depreciation reserve amount to € 33,903,270; the depreciation reserve totals € 25,058,144. The value of the new investments in tangible fixed assets was therefore approximately € 1.822 million (of which € 655,000 related to the "Research Infrastructure Enhancement" project, € 248,500 related to capital projects, € 63,000 related to the Research Building Construction and € 98,000 for ATMP projects financed by UPMC Overseas).

This increase was mainly due to the acquisition of equipment for  $\notin$  1.58 million (of which  $\notin$  575,000 related to the PNIR project),  $\notin$  236,000 related to other tangible fixed assets. Healthcare equipment paid by means of ISMETT's ordinary funds amounted to  $\notin$ 522,984, this without considering  $\notin$  78,000 relating to equipment intended for the management of the COVID-19 pandemic.

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### Tangible fixed assets: handling

	Lands and buildings	Systems and equipment	Industrial and commercial equipment	Other tangible fixed assets	Total tangible fixed assets
FY initial value				-	
Cost	572,233	1,148,956	24,750,966	5,608,943	32,081,098
Depreciation (Depreciation fund)	138,929	204,755	17,802,015	4,140,085	22,285,784
Book value	433,304	944,201	6,948,951	1,468,858	9,795,314
FY variations					
Increases due to acquisitions	-	-	1,586,578	235,594	1,822,172
Depreciation for the year	23,146	88,720	2,260,518	399,976	2,772,360
Total variations	(23,146)	(88,720)	(673,940)	(164,382)	(950,188)
FY end value					
Cost	572,233	1,148,956	26,337,544	5,844,537	33,903,270
Depreciation (Depreciation fund)	162,075	293,475	20,062,533	4,540,061	25,058,144
Book value	410,158	855,481	6,275,011	1,304,476	8,845,126







### Our staff

**945** people work at ISMETT (this figure also includes permanent UPMC staff at ISMETT).

ISMETT has a dynamic and growing work environment. In fact, **61** people started collaborating with the center of Palermo in 2021.

ISMETT is a dynamic and multicultural working environment with integrated dignity and respect. UPMC Italy provides opportunities for personal development, oriented towards continuous improvement and outstanding healthcare and research. More than half of ISMETT's staff are women. In fact, there are as many as **525** women working in the Institute in different sectors.

Thanks to the partnership with UPMC, the ISMETT staff has the possibility of a continuous confrontation with an international reality. The collaboration with UPMC brought to Palermo the expertise and professionalism of its worldwide-renowned centers.

### ▲ ISMETT staff



average age of employees





\* Including UPMC staff permanently assigned at ISMETT

ISMETT pays great attention to the issues of diversity and inclusion. ISMETT aims to ensure that diversity, inclusion, dignity, respect, and cultural awareness are core components of the employee, patient, and community experience.

Differences can make a difference, be they of gender, culture, ethnicity, skills, geographic origin, age, physical ability, sexual orientation etc.

IN 2021, the GEDI (Gender, Equality, Diversity & Inclusion) Committee was established as an organizational tool for identifying and implementing corporate strategies and measures in this sector, which sees close collaboration between the HR, Scientific Director / Grants & Project Management, Director of Health Care Activities and Medical Director.

### **DAISY AWARD**

ISMETT is part of the **DAISY AWARD** program, an international award that aims to reward and recognize so-called extraordinary nurses. An alternative way to thank them for their hard work. ISMETT was the first hospital in Italy to start the program in spring 2019, with the precise aim of leveraging the nursing profession.

THE DAISY (diseases attacking the immune System) Award is **an international award** that pays tribute to, and celebrates, the professional and generous care provided daily by health workers.

The award was born from an idea of the family of J. Patrick Barnes, a North American boy who died in 1999 due to complications from an autoimmune disease: Idiopathic Thrombocytopenic Purpura (ITP). The care and compassion shown by the nursing staff to Pat and his family during the hospitalization and even after the death of their son made the family feel the need to find a special way to thank them.

### **ROSE AWARD**

ROSE (Raising Our Standard of Excellence: Improving the Standards of Excellence) is an award that aims to enhance and reward health personnel who do not belong to the nursing categories who stand out for their human and personal aspects.

At ISMETT, the program was launched in late 2019 to highlight the work of non-nursing staff and to highlight their extraordinary efforts for patients and their families.

Three are the key features of the ROSE award winner:

- Quality and service: offering excellent services of which quality is the guiding principle.
- **Dedication and respect**: listening and paying attention to the needs of patients, guaranteeing the highest levels of dignity and respect.
- Integrity and collaboration: giving priority to teamwork and aiming at excellence in all daily activities.





### Training

ISMETT is a reference point for health care training at regional and national level. ISMETT contributes to the development of the Regional Health System, through the dissemination of UPMC's know-how and develops training courses for doctors and external health professionals. ISMETT has the ISO 9001:2008 certification for training and accreditation activities as a regional CME provider.

In 2021, a total of **540 training events** were organized within ISMETT involving **5,765 participants**, of which 323 were outside ISMETT.

The training activities provided in 2021 refer to:

- On-site activities for employees, carried out in suitable premises to ensure the necessary distancing between the parties involved.
- On-site activities for external operators, carried out in suitable premises to ensure the necessary distancing between the parties involved.
- CPR maneuvers (BLS/ACLS/PALS) simulations
  organized in small groups and carried out in suitable
  premises to ensure the necessary distance between
  the subjects involved.

- **Remote activity**, in asynchronous mode (remote training) or synchronous (live streaming).
- Training on-the-job for orientation of newly-hired nurses and/or transferred from another department and to training on newly introduced procedures / policies / equipment.

In particular, for 2021, compared with 2020, there is an increase in the number of:

- Training events (+ 165%)
- Courses in synchronous remote mode (+ 450%)
- Participants in remote courses (+ 270%)
- On-the-job training events (+ 200%)

Finally, **160** traineeships were activated in 2021, 170% more than in the previous year. The internships concerned university students enrolled in health professions study courses, those enrolled in administrative study courses and those of postgraduates from UPMC.



### University degree in nursing in English

Thanks to the collaboration between ISMETT and the University of Palermo, a degree in Nursing was launched in English. Nursing graduates will be well-rounded professionals who will be able to work in all EU and non-EU countries.

ISMETT's nursing staff are among the "professors".

The course is divided into three years and is organized with theoretical and practical parts. Both theory and practice are exclusively in English. There is an internship period which is carried out entirely at ISMETT. Throughout this period, undergraduates are supported by a tutor.

The first edition of the course will end in 2022, when there will be the first graduates.

### Master's Degree in Physiotherapy

ISMETT is among the promoters of the Master's Degree in Physiotherapy organized by the University of Palermo.

The aim of the Master is to implement specialized skills for physical and respiratory rehabilitation therapists through the study of basic sciences, physiopathological mechanisms, and clinical sciences useful for understanding the rational, indispensable for acquiring new specialized skills, both functional evaluation and rehabilitation techniques in the field of physiotherapy and respiratory rehabilitation, in line with the current trends and prospects of the international scientific world.

The curriculum is equivalent to 60 university training credits (CFU). Participants will be trained at ISMETT.











### **Patient Safety is a Priority**

Improving patient safety involves a precise and joint effort of the management, department heads, doctors, nurses, and all clinical and administrative staff.

The success of this effort depends on the choice to learn from mistakes to prevent the events from recurring.

The participation of each employee in the patient's quality and safety program is crucial. At ISMETT, staff contribute to strengthen the culture of safety in the hospital by sharing information, reporting dangerous events, and collaborating in the development and implementation of procedures to improve the performance of the entire organization.

## The ISMETT Quality, Environment and Safety System involves the entire organization and takes into account:

- Clinical results through a robust clinical outcome monitoring system, including organ transplantation, cardiothoracic surgery, abdominal surgery, anesthesia and resuscitation.
- Patient safety through the analysis and monitoring of preventable adverse events reported by the staff.
- Standards and regulations of several voluntary certification models, including Joint Commission International, ISO 9001:2015 and the Safety and Environment Integrated System according to UNI EN ISO 14001:2015 and UNI ISO 45001:2018 regulation.
- Standards and regulations provided for by accreditations to scientific societies, such as the Italian Society of Digestive Endoscopy (SIED), by which the ISMETT digestive Endoscopy Service has been accredited since 2017.
- Patient experience through patient satisfaction monitoring, complaint analysis and claims assessment.

The tools used to promote the ISMETT clinical governance include a systematic evaluation of process and outcome indicators collected through information systems, such as electronic medical records, the provision of clinical protocols based on efficacy data, ongoing training, and the program for quality improvement and clinical risk management.



### The Program for Quality Improvement and Clinical Risk Management includes:

- Dedicated and permanent risk management and patient safety role pursuant to regional legislative decree of 23 December 2009.
- Periodic external audits such as JCI, ISO and other voluntary audits.
- Definition and use of internal policies and procedures: ISMETT has developed a manual containing about 300 procedures consistent with JCI standards, ISO standards, which are periodically reviewed and updated, and collectively approved by the Corporate Policy Committee. Once approved, the procedures are published in the corporate infonet and their compliance is constantly monitored.
- Training sessions, with differentiated programs, on the principles and methods of quality improvement and Just Culture are periodically held for all clinical coordinators, area managers and organization management.
- Internal audits are conducted to assess compliance with the procedures implemented to meet the standards and regulations set by certifying bodies.
- Definition of diagnostic-therapeutic guidelines and development of order sets in the electronic medical records as well as monitoring of their correct application.

### Patient Satisfaction is our #1 priority

At ISMETT, patient satisfaction is monitored on a continuous basis. Thanks to an agreement with Press Ganey, a world leader in the development and distribution of patient satisfaction surveys, the analysis of the results obtained from the questionnaires is uploaded to the PGFusion platform. Press Ganey annually collects feedback from more than 40 million patients from 2,000 healthcare organizations, mainly located in the U.S.A.

This gave ISMETT the opportunity to compare its results and find that overall patient satisfaction levels are among the highest ones in all hospitals of the PGFusion database, ranging from 98th to 99th percentiles. This means that only ½% of hospitals worldwide are better than ISMETT in terms of patient satisfaction.

43

### **Quality monitoring**

Indicators are monitored according to internationally recognized criteria (intra-hospital mortality, 24-hour and 30-day mortality, CDC criteria for SSI, etc.).

The program for active monitoring of quality indicators is not meant to establish causal relationships. It is a tool for monitoring macro levels of very complex phenomena (such as hospital mortality), which has the advantage of identifying areas requiring further analysis in order to determine whether corrections are needed, by assessing individual cases and comparing them with homogeneous patient groups comparable due to the presence of risk factors, age, associated diseases, etc. Some indicators used as alerts for the verification of preventable complications, such as readmissions to the OR and ICU, pulmonary embolisms (PE) and deep vein thrombosis (VTE), are also subject to review/validation by a physician experienced in the specialty/area in order to establish appropriateness and inclusion criteria (Quality of Care Review Program).

The trend of the hospital-wide indicators was analyzed using the RAGB methodology, the criteria of which are reported below. The purpose of the evaluation is to monitor processes pro-actively and identify areas of improvement:

### **ZERO HARM**

0 HARM or 100% COMPLIANCE

ON TARGET (year)

YEAR TARGET ACHIEVED

IMPROVING

IMPROVEMENT ≥ 5% vs. PREVIOUS YEAR

NOT IMPROVING

VARIATION (+/-) <5% vs. PREVIOUS YEAR

### WORSENING

WORSENING ≥ 5% vs. PREVIOUS YEAR

Excellent results (100% compliance or ZERO harm) are marked in **blue**.

Indicators for which the target set at the beginning of the year was achieved are marked in **green**.

When the target has not been achieved, results are compared with those of the previous year and, given a threshold of 5%, improving results are marked in **orange**.

Worsening results are marked in **red**.

Results that, although not worsening, do not reach the threshold of >5% to be counted as improving indicators are marked in **gray**.

# Lean Thinking to Improve Organization in Health Care

The first lean projects were launched at ISMETT. Lean is a management approach that includes methods, procedures, and tools to understand what the patient identifies as important and to reorient organizational processes, whether primary or secondary, toward achieving the best value performance.

The origins of Lean thinking date back to the late 80's and early 90's. The guiding principles of the Lean model include getting rid of overloads and wastes, while promoting continuous quality improvement.

### Projects started according to the LEAN methodology

### Project "LEAN on hands hygiene issues to fight carerelated infections"

The team project identified the WHO multimodal hand hygiene improvement strategy (a combination of actions to address different obstacles and behavioral barriers) as a series of hospital-sustainable countermeasures to improve the company's performance.

The strategy was designed by the WHO to translate their hand hygiene guidelines into clinical practice. It consists of five essential elements: 1) system change (e.g., availability of alcohol-based hand rub at the point of patient care and/or access to a safe, continuous water supply and soap and towels;) 2) training and education of health care professionals; 3) monitoring of hand hygiene practices; 4) performance feedback; 5) creation of a hand hygiene safety culture with the participation of both operators, leadership, and finally patients.

The monthly blind observation program, which has been launched for many years, provides ongoing feedback on the compliance with the company's guidelines. In 2021, a total of 9,500 observations have been carried out, with a compliance of 87.3%, which rises to 91.1% if only hospitalization is considered (excluding services). Data is monthly shared with department/service leadership and all staff through Quality bulletin boards.

The project implementation is still ongoing and proceeds according to the program.

# Project "Learning from your falls" LEAN on decreasing hospital falls

The project, which started in April 2021 in the CTU pilot department, aims to reduce falls and falls with damage by at least 45% in 9-12 months. The creation of a multidisciplinary task force was preliminary to the development of the project, which strictly followed the LEAN methodology.

The preliminary results show an encouraging trend in fall reduction, especially falls with damage. The project implementation is still ongoing and proceeds according to the program.

The target of 45% reduction for the overall fall rate will be measured in March 2022 by comparing the preimplementation rate to the post-implementation rate. The project was submitted at the 2021 Lean Healthcare and Life Science Award and ranked among the 16 finalists selected from more than 100 competing projects.



### Accreditations, Certifications and Acknowledgments

### JCI Accreditation

In 2021, for the fifth time, ISMETT received reaccreditation from **Joint Commission International (JCI)**, one of the most advanced accreditation systems to assess the quality and safety of hospital facilities. In 2009, ISMETT was the first hospital in Southern Italy to receive accreditation, a symbol of quality reflecting the commitment of an organization to providing safe and effective care to patients. Today only 16 hospitals in Italy are JCI accredited.

### ISO 1400-2015 certification

ISMETT's commitment for the environment and safety in the workplace has been confirmed. The Occupational Health, Safety and Environment system certifications have been renovated according to the UNI EN ISO 14001:2015 and UNI ISO 45001:2018 standards. Safety and environment are essential elements for ISMETT and UPMC management.

### College of Healthcare Information Management Executives (CHIME) Level 7 accreditation

In 2021, ISMETT has been recognized as one of the most technologically advanced hospitals in the world. The technology level achieved was certified by the College of Healthcare Information Management Executives (CHIME) in its annual "Digital Health Most Wired", an annual global survey to assess how effectively health care organizations apply core and advanced information technology in their clinical and business programs. The advanced technologies adopted by ISMETT allowed the hospital to score Level 7 in the "acute" category, i.e., the treatment of severe patients. Across Europe, only two hospitals have achieved Level 7, ISMETT and the Cambridge University Hospitals NHS Foundation Trust, which achieved one higher point (Level 8). The evaluation was conducted on infrastructure, safety, privacy, supply chain, analytics and data management, interoperability, patient engagement, clinical quality, and safety and, starting this year, COVID-19 response.

### **HIMSS Stage 6 accreditation**

HIMSS is a leading not-for-profit global advisor in health information and technology that has awarded ISMETT with a score 6 out of 7, which was only achieved by other 5 facilities in Italy. The average Italian score is 3.3 (3.7 for facilities of our size). In Europe, only 28 out of 1,134 facilities have been awarded with a level 6. Only 5 facilities in Europe have achieved level 7 (none in Italy). Level 7 provides for a totally computerized management of clinical processes, including health governance and continuity of care to third-party facilities. The evaluators found and stressed: "Excellent governance arrangements are in place to successfully manage a programme of this type together with strong clinical engagement and visible leadership from all members of the senior management team. This is a good hospital where practices in the main are consistent and standardized. Clinicians and managers alike have a real sense of ownership and belonging and are rightfully proud of all that has been achieved here" e "The absolute highlight that we observed on the day is the state-of-the-art Pharmacy, without doubt one of the best systems and associated workflows that I have ever seen".

### ISMETT certified as Phase I Unit

In 2021, ISMETT has submitted to AIFA the autocertification stating its possession of Phase I requirements for the clinical center and the laboratory, according to circular 809/2015, and since October it has been included in the AIFA list of active centers conducting phase I trials. Before auto-certification, ISMETT passed a system audit and is now preparing for the second one. External promoters can already propose to ISMETT profit studies on patients or healthy volunteers, to test drugs for treating end-stage organ failure for the first time on humans.

Phase I unit includes about thirty trained professionals constantly updated. Following the auto-certification, the AIFA inspection is expected to confirm the possession of the requirements and absence of any critical deviations.

### Toward the authorization of the Cell Factory

The GMP production premises for advanced therapies and dedicated quality control laboratory have recently been renovated at ISMETT. The new Cell Factory, which was delivered at the end of 2021, guarantees flexible types of production and functional premises. Based on specific user requirement specification, layouts of production and control areas for the three types of advanced therapies (gene therapy, somatic cell therapy, tissue engineering) have been developed (and approved by AIFA during a scientific advice meeting). Four class B laboratories were built, one of which with larger containment (with a pre-inlet negative pressure well and an autoclave for waste processing). The other 3 class B laboratories can be used totally independently, allowing the simultaneous preparation of three different products, or they can communicate in pairs so that part of the operations (e.g., organ cleaning) are carried out in a first laboratory and other manipulations (e.g., isolation and culture) are carried out in the second laboratory (with the intermediate production via passbox). In addition, a class C room has been built to hold cell preparation systems. Technical rooms contain the instrument engines and allow maintenance without accessing the production areas. Large quality control laboratories have been equipped to conduct all tests on raw materials, intermediate and final products necessary for the release of the product, as well as to receive and store reagents, materials, and products appropriately. Both the production area and the QC laboratory are equipped with a monitoring system for remote control of critical parameters. The activities necessary to achieve AIFA authorization are currently being carried out.

The new Cell Factory will produce advanced therapies developed by the Ri.MED Foundation and ISMETT researchers, to be used in clinical trials and in hospital specific patient.

Moreover, thanks to specific agreements of Technology Transfer with the University of Pittsburgh or with other Cell Factory/companies in Italy and Europe, externally developed products will be produced in the Cell Factory for clinical use at ISMETT or in other hospitals.

### **Research Infrastructure Award**

The Research infrastructures project has been awarded by the European Commission. The project, realized by ISMETT-Ri.MED-UPMC thanks to an investment cofinanced by the Sicilian Region — Department of Productive Activities, through the PO-FESR Sicily 2014-2020 European funds, was considered as "one of the most significant projects supported with the PO-FESR Sicily 2014-2020 European funds".

### **Research Fund allocated by EHDEN**

The European Health Data & Evidence Network (EHDEN), has assigned a research fund to ISMETT to develop a clinical data warehouse model. The EHDEN project is a public-private partnership established under the IMI2 program (www.imi.europa.EU). EHDEN's mission is to provide a new paradigm for the discovery and analysis of clinical data by creating a large-scale network of partner data across Europe.

### **Excellence of the Year Award**

In 2021, ISMETT received the Excellence of the Year Innovation & Hospital Technology Leadership award by LeFonti AWARDS<sup>®</sup>, which each year recognizes the best Italian organizations for being a state-of-the-art reference point in end-stage organ failure care and research. For clinical and management innovation, and for the recent CHIME certification as the most technologically advanced hospital in Europe and among the first ones in the world.

### Industria Felix Award

ISMETT received the High Budget Honor of the Felix Industry Award, based on a competitiveness algorithm, the Cerved Group Score Impact, a financial reliability indicator of one of the most important rating agencies in Europe.

ISMETT was awarded in the category "Subsidiary company with a majority public shareholder".









### **ISMETT's Successes and Achievements**

Successes and achievements of ISMETT in 2021 were reported by local and national newspapers and media.

The media focused on the clinical results obtained by ISMETT, including the first organ transplants performed with COVID-19 positive donors, the 200th heart transplant, and recognition by AGENAS (the Italian Agency for Regional Health Services) for abdominal cancer surgery, and the new immersive reality used in endoscopy.



Much emphasis was also given to the award for the most-technologically advanced hospital and JCI reaccreditation.

**ISMETT reaches 200** 

heart transplants

5 March 2021

Sicilia





