

**VISMEDERI**  
ANALYSES FOR LIFE IMPROVEMENT

*We prove. You improve*



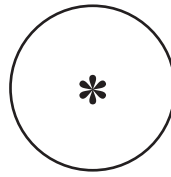
2 We prove. You improve

Our mission is to provide Biopharmaceutical Companies with the analytical services required by the “EMA”, “FDA” and “PMDA” for the development and marketing of new vaccines.



**VISMEDERI**  
ANALYSES FOR LIFE IMPROVEMENT

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## THE PRESIDENT & CHIEF SCIENTIFIC OFFICER

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**President Emanuele Montomoli is the founder and CSO of VisMederi Srl, the innovative Sienese Company established in June 2009 by the Department of Molecular Medicine of the University of Siena. Within a few years, the Company has integrated in the field of Life Sciences and Public Health, gaining the role of a highly qualified and reliable partner at an international level.**



**Emanuele  
Montomoli**

*Non-Executive  
President and  
Scientific Director  
of VisMederi*

“2016 and 2017 has been years of major changes within VisMederi’s governance. The acquisition of all the business units, an economically and strategically relevant chapter in VisMederi’s history, allowed me to implement my will to continue investing in an entrepreneurial, dynamic, innovative and successful reality such as VisMederi and to go on with my determination in the commitment I had undertaken since the Company’s birth. VisMederi is today a solid reality that grew year after year in credibility, customer portfolio, human resources and economic results. These are the results of the fruitful work carried out by a motivated, young and highly competent group, who in VisMederi has found not only a job but also a great opportunity of professional growth. Together with the new management, we will continue this journey, strengthened by our international positioning in the development of experimental protocols for the study of vaccines and the provision of qualified food and environmental analysis services.

LIFE SCIENCE

# THE COMPANY PROFILE

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**VisMederi is a globally skilled, well-resourced Research and Service Company that supports businesses and big pharma industries in improving public health through the development and optimization of safer and more effective drugs and vaccines.**

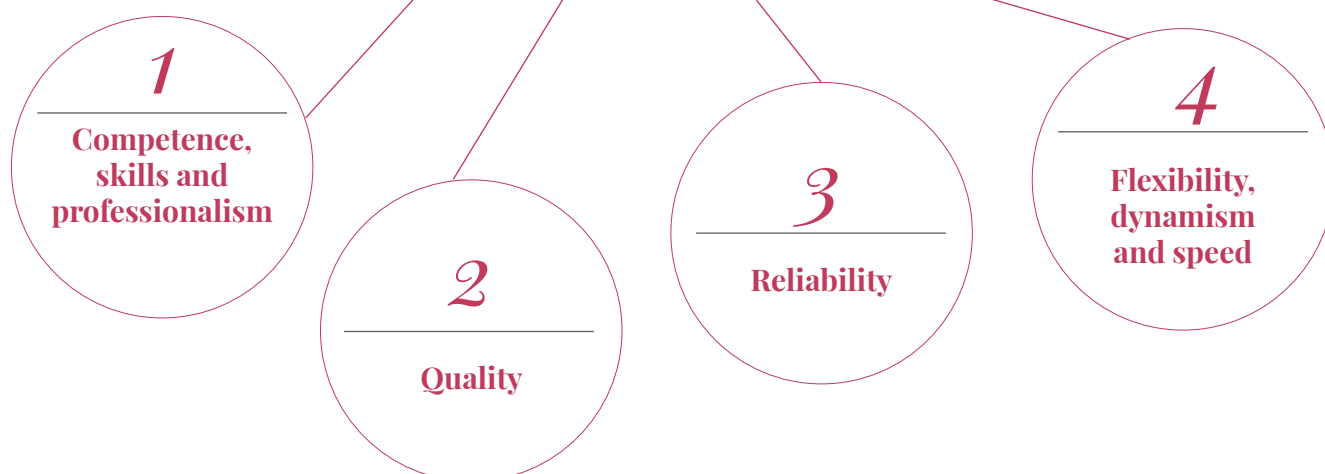
Thanks to the profound scientific expertise and experience of its management and staff, VisMederi conducts and perfects serological tests to evaluate the immunogenicity of vaccines, creates and validates bioanalytical methods and experimental protocols for the release of therapeutic molecules and vaccines in development phases and performs quality control during the intermediate stages of vaccine production.

VisMederi has its headquarters in Siena, Italy, a city strengthened by its research tradition dating back to the early 20th century and a reference point of international excellence in the field of vaccines and Life Sciences, as well as home to one of the most prestigious Italian universities.

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## *Why VisMederi?*

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## CORE BUSINESS

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**The Company fits within that complex path that leads to the release on the market of a new vaccine or new medication through the optimization of analytical tests on biological samples and its application on clinical studies.**

VisMederi aims at assisting pharmaceutical companies in the development path of their own products. The logic driving VisMederi's collaboration with key customers is based on creating a long-term partnership based on continuity, trust and stability relationships embodied in the sharing of objectives and instruments to identify professional winning solutions. All the implemented activities are very high quality and internally validated in order to ensure maximum customization upon customer request. VisMederi is thus capable of offering an accurate analytical result.

The tests carried out by VisMederi always require a validation process consistent with international guidelines such as "Validation of Analytical Procedures: Text and Methodology (ICH)" and as required by leading international regulatory bodies such as EMA (European Medicines Agency), FDA (Food and Drug Administration) and PMDA (Pharmaceuticals and Medical Devices Agency).



# VACCINE DEPARTMENT

In the year 2017, VisMederi continued to develop and consolidate the main serological tests for the validation of immunogenicity of pandemic and seasonal influenza vaccines, such as Haemagglutination Inhibition (HAI), Single Radial Hemolysis (SRH) and Virus Neutralization (VN), already existing in the Company's portfolio.

The experience gained over the years, the scientific and methodological accuracy in this field of action represent a guarantee in terms of quality of results and times of execution and delivery.

In the philosophy of VisMederi, innovation means making changes in order to produce improvements through a gradual but continuous path of research, planning and transformation that permeates every aspect of corporate life.

In this area, important results concerning **the dosage of IgA flu antibodies** were achieved in 2017, also from "difficult samples" such as saliva or nasal washings. Up to date, vaccine efficacy was assessed solely through the serum antibody

response and it was extremely difficult to devise methods for the dosage of IgA immunoglobulins partly because of the difficulty of finding human standard controls on the market. VisMederi has worked on standardizing an innovative method based on the ELISA technique for achieving this goal.

Influenza vaccination is gradually deviating towards new types of vaccines: from traditional intramuscular and intradermal vaccines, to live attenuated vaccines administered by nasal sprays and sublingual inactivated vaccines. It is expected that these new vaccines can further stimulate a local (mucosal) response, which is not easily detected

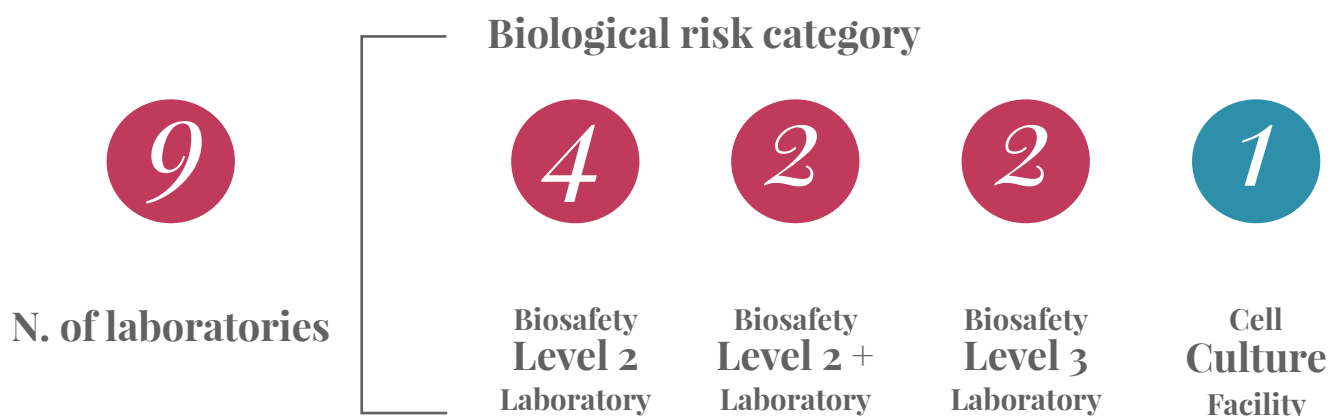
through classic serological tests. In the frame of serological tests, VisMederi also implemented the development of immunoassays for the evaluation of the response to the second antigenic protein (neuramidase) present in the vaccine based on international guidelines and implementing its features. Among the various methods developed for this purpose, the ELLA Test was the most reliable, fast and functional. The platform of flu **pseudotypes**, which has already been part of the corporate portfolio in the last few years, has been further developed thanks to the support by the Tuscany Region through the "Innoviral" project. With this test, the measurement of functional antibodies can be performed without using any living virus.

The **growth activity of influenza viruses in cell cultures and embryonated chicken eggs** represented an important sideline in order to reproduce influenza viruses on a large scale usable in conventional serology. Conventional serology tests represent the gold standard of VisMederi's analysis portfolio; however, the growing interest in **Cell Mediated Immunity (CMI)** pushed VisMederi to invest in this area by adopting appropriate equipment. The Company's experience has been focused on flow cytometry testing in order to evaluate the expression of cytokines and interleukins immune cells, after vaccination. Recently the industry has been further enhanced with a platform devoted to type-B cell response, focusing attention on the "ELISPOT" procedure.

In addition, VisMederi continued to carry

out experimental works also on the immune evaluation of bacterial vaccines, both through traditional immunoenzymatic assays and through the development and qualification of ad hoc methods. One of these methods is MATS (Meningococcal Antigen Typing System), which is aimed at screening and classifying meningococcal strains circulating and coming from various countries around the world and at evaluating their "reaction" against the strains included in the vaccines. To meet the growing request relating to vaccine testing, VisMederi has designed a platform for preclinical studies using animal models in the course of the past year. Alongside ferrets, already used in previous years, we have introduced another species exceptionally suited to infection with influenza virus and with clinical consequences very similar to human ones: "cotton rats". With these animals, VisMederi took up the exciting challenge to be able to study the pathogenesis of influenza and immune response in humans, testing next generation vaccines also through "**challenge studies**".

VisMederi has finally decided to optimize its "**biological material storage**" capacity, no longer limited to the retention of serum samples related to ongoing studies, but also geared towards a genuine customer service. To this end, three new temperature-controlled storage areas have been created, with a 24-hour monitoring system. The service is designed to be customized according to the needs of partners including the ability to manage services and shipping material.





# QUALITY

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**Investing in quality is a strategic choice that can make a difference in terms of competitive advantage. VisMederi performs all its activities in accordance with the European UNI EN ISO 9001:2008 certification system, operates according to the UNI CEI EN ISO/IEC 17025:2005 regulation regarding the food sector and is one of the few private companies in Italy to be accredited as a medical laboratory in accordance with UNI EN ISO 15189:2013.**



The objectives and suitability to the quality policy are constantly reviewed and adapted to the evolution of scientific and technological research, thus ensuring a constant attention to the customer.

The implementation and optimization of the entire business management system of laboratory activities and human resources is a strategic process involving the Company, its customers and suppliers, as well as all the different contributions from academia and science.

The adoption and continuous updating of a specific and complete quality system provide our clients with a quality assurance of the

processes and in particular of the effectiveness and reliability of the services provided at all stages.

VisMederi is annually subjected to auditing by customer companies and pharmaceutical companies with which it collaborates in order to guarantee the highest levels of production and the highest effectiveness of results.

In VisMederi, the quality policy goes through staff training, ranging from the most modern analysis methods to the use of advanced technological equipment, always placing the focus on customer satisfaction. The result of these activities takes the form of a Company led by a solid and shared system of values that makes quality and efficiency the pillars of all activities, continually aiming at the achievement of even higher standards of excellence.

Furthermore VisMederi increased its quality system getting accreditation as serological laboratory operating in accordance with the international guidelines of the Good Clinical Laboratory Practices (GCLP, ISBN 978-1-904610-00-7), essential recognition for laboratories conducting tests on samples from clinical studies, indicator of compliance with the international standards of ethics and scientific quality.



# Certifications and accreditations

## Accreditation for test laboratories

**UNI CEI EN ISO/IEC  
17025:2005**

**Accreditation Body: Accredia  
Release Date: December 2013**

*VisMederi is registered into the Tuscany regional list of laboratories that carry out analysis in the context of self-monitoring procedures for the food industry with N. 065. In 2013, the Company obtained at Accredia (Italian Agency for accreditation) accreditation as a laboratory that operates in compliance with UNI CEI EN ISO/IEC 17025:2005 for the food industry. Accreditation checks and guarantees the competence and professionalism of a test laboratory, according to objective criteria. Gaining accreditation means for the company to see its seriousness and its professional expertise as internationally and officially recognized.*

## Accreditation for Good Clinical Laboratory Practices (GCLP)

**ISBN 978-1-904610-00-7  
Accreditation Body: Qualogy  
Release Date: January 2017**

*In January 2017, VisMederi obtained serological laboratory accreditation from the independent British company Qualogy that operates in accordance with the international guidelines of Good Clinical Laboratory Practices (GCLP, ISBN 978-1-904610-00-7). These guidelines, also included in the processes of the World Health Organization (WHO), identify the requirements and the procedures to be followed inside the laboratories conducting tests on biological samples from clinical studies.*

## Accreditation for medical laboratories

**UNI EN ISO 15189:2007  
Accreditation Body: Accredia  
Release Date: May 2015**

*In May 2015, VisMederi obtained Accredia's accreditation as a medical laboratory operating in compliance with UNI EN ISO 15189:2007. The standard specifies requirements concerning the quality and competence of the only medical laboratories in terms of methodologies, scientific, technical and technological, organizational and procedural elements, as well as the specialization of the staff. The management system requirements of ISO 15189 naturally meet the principles of ISO 9001:2008 Quality Management System – Requirements.*

## Quality Management System

**UNI EN ISO 9001:2008  
Certification Body: TUV Austria  
Release Date: March 2010**

*In the year 2010, VisMederi obtained the certification in accordance with UNI EN ISO 9001:2008 regulation. The "Quality Management System" Certificate guarantees on the quality management systems' requirements a company must meet to demonstrate its ability to deliver products and services that meet customer requirements in regulated areas. Quality according to ISO 9001:2008 is the degree to which a set of inherent characteristics fulfill the requirements in a process of continuous improvement.*





# VISION AND MISSION





## VISION

Our Vision defines the universe of values inspiring VisMederi for our work in the present and our objectives and goals that will guide our business decisions in the future. VisMederi was created to contribute to the improvement of the system of public health through methods of analysis and assessment on the effectiveness of vaccines, medicines and molecules for therapeutic purposes. A goal that finds a solid foundation in the quality and professionalism of the services and researchers that make up the working group. Quality and professionalism are VisMederi's "polar stars", the two values that allow us to act coherently with our business goals and their natural evolution.



## MISSION

VisMederi's Mission is to contribute to the development of vaccines and better and safer medications, ensuring maximum attention to the quality of the system and resulting analytical data. The name itself, VisMederi, is intrinsically tied to this primary goal: from the Latin word "Vis" (strength) and "Medeor" (to cure). In particular, VisMederi works to offer a thorough and documented analytical result and a highly qualified service in the interpretation of the data provided, towards the overall satisfaction of the customer. In the field of vaccines, VisMederi aims at becoming a leading provider of qualified services for pharmaceutical companies.





# **HUMAN RESOURCES**

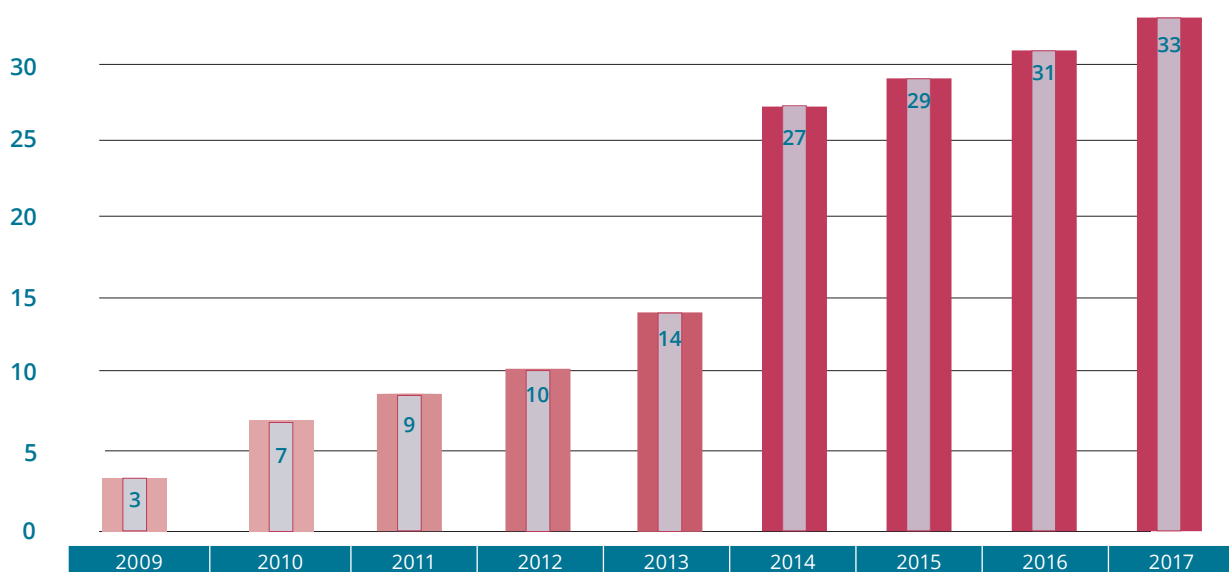
*People are the most important asset for VisMederi today and for its growth and development tomorrow. The success of VisMederi originates from the human capital investing its own skills and professionalism in this Company: strongly motivated women and men sharing the ideal of the Company, its steady rooting on the territory combined with its international perspectives.*

Over the years, the workgroup has been enriched by highly qualified professional technical figures who have recognized VisMederi as a stimulating reality and an opportunity to test and deepen their knowledge.

The two main business areas are alongside an administrative area, a finance and management control area, a legal area and a communications area

that play an important role in supporting research activities.

In line with a growth trend that has never stopped since the foundation year of the company, VisMederi has continued to increase its human resources and to stabilize existing jobs, achieving excellence in a forward-looking perspective of sharing its goals and preserving its values.



*The growth of the staff from 2009 to 2017*

# RESEARCH PROJECTS

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**Innovation and technological development represent for VisMederi two important goals, which the Company daily pursues.**

The current market environment is featured by high technology transnationality and increasingly accelerated development cycles. It is therefore crucial to support the corporate growth by investing continuously in R&D activities aimed at increasing its intellectual property, enhancing its intangibles and increasing more and more the Company's technological level of competitiveness. The ultimate goal is to meet the trend of major pharmaceutical companies to outsource the routine research phases to highly specialized and efficient individuals, taking on an increasingly important role in the business model of their customers, in a more "district-centered" logic of Research in Life Sciences. In the wake of this tendency by large pharmaceutical companies to move more and more towards a collaborative approach to research, it is estimated that the market size of outsourcing services in research will reach \$ 64.58 billion by 2021 (Source: Global CRO Market 2016). The Company's attention to these issues is reflected in its wide participation in research projects strongly linked to the territory's financing policies. VisMederi successfully completed the research, development and innovation project identified with the acronym INNOVIRAL, first presented at Smau Firenze 2015 and co-financed by the Tuscany

Region under the FESR Por-Creo 2014-2020 programming, focusing on the development and implementation of a new process that improves efficiency and security within analytical laboratories, while expanding the Company's production capacity. The results obtained were perfectly in line with the expected results, and the technology developed is currently fully involved in the Company's production process. Also underway is the INSIDE project, involving the subsidiary VisMederi Research in partnership with large companies and public research organizations in the territory of the Tuscany Region, co-funded also in the Por-Creo 2014-2020 programming. At a national level, the Company is also involved, in collaboration with various Universities and Tuscan research organizations, in S-Afrivac and Unavir projects, co-funded through the FAS Health 2014 call and both aimed at the development of vaccines and antiviral agents against rare diseases. Great commitment is then devoted to seeking European prominence. VisMederi has also committed to important projects in partnership with organizations and companies throughout Europe. ADITEC and BioVacSafe undoubtedly represent the two most important projects for which the Company proudly carries out research activities.



## International Projects

### ADITEC

ADITEC's goal (Advanced Immunization Technologies), which involves scientists from 43 different countries and 13 research institutes, is the development of innovative technologies to be used in human vaccines immunization of next generation. ADITEC, the largest project on vaccines funded by Europe with 30 million euros, involves prestigious European universities and research institutes together with the most relevant US groups in the field of system biology and adjuvants. The Consortium also involves numerous pharmaceutical and biotechnology companies in Europe, engaged in the study of innovative technologies for the development of more effective and safer vaccines.

[www.aditecproject.com](http://www.aditecproject.com)

### BIOVACSAFE

BioVacSafe aims at developing innovating tools to improve analysis and monitoring of vaccine safety before and after their launch on the market. The project, lasting 5 years, is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), totaling over 30 million euros of public and private investment.

[www.biovacsafe.eu](http://www.biovacsafe.eu)

## National Projects

### INNOVIRAL

Influenza is a top priority in the field of public health for its impact on overall wellness and for the threat of pandemic events. Serologic tests currently in use, used for licensing of vaccine flu shots, are outdated and are becoming obsolete and unsatisfactory. The last update of the guideline of the EMA (European Medicines Agency, the European regulatory body) for the influenza vaccine has stressed the need to introduce innovative tests for the evaluation of vaccines. The micro-neutralization (MN) test, for which live virus is used, and cell-mediated immunity analysis (CMI) are some examples of new tests. The INNOVIRAL project is focused on the development and validation of a new and innovative test to evaluate pandemic and non-pandemic influenza vaccines, quickly and reliably, using pseudo viral particles (PPN) that will be prepared in the laboratory of VisMederi according to the procedures described in the literature. This test has every prerequisite to be a suitable replacement for the virus micro-neutralization test. This new technology, that is, the use of synthetic viral pseudo particles, has considerable advantages:

- 1) Replacement of the use of live virus in the analyses that can be performed even in low containment laboratories.
  - 2) The test is more versatile, adaptable to different types of viruses and easier to standardize using synthetic particles.
- The innovative test developed by VisMederi, is then performed on a very large number of samples, allowing its validation and the determination of its strength and effectiveness, in comparison with classical tests.

### INSIDE

The project, in which VisMederi Research is a partner, is aimed at developing diagnostic and theranostic targeting based on nanosystems and/or engineered lymphocytes for the early detection and treatment of melanoma, and multiple sclerosis. With its participation in the INSIDE project, VisMederi Research aims at entering the wider market of contract research in the pharmaceutical sector, linked to the development of drugs in a broad sense, broadening the scope beyond the vaccines segment.



**Belgium**

**UK**

**Canada**

**USA**

**Brazil**

**Italy**





**|** *Netherlands*

**|** *Germany*

**|** *Switzerland*

**|** *Japan*

**|** *Vietnam*

**|** *Austria*

# GLOBAL PRESENCE



SYNERGIES

## PARTNERSHIPS

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**The synergy with the University of Siena has continued in both within the framework of European projects and with the Molecular Epidemiology Research Laboratory directed by Prof. Emanuele Montomoli. Intense collaboration has continued with the Toscana Life Sciences incubator in Siena.**

### UNIVERSITÀ DEGLI STUDI SIENA

Collaborating to various research projects, the University of Siena is for VisMederi also an important think tank, in the form of PhD studies in business. The Company contributed to a PhD in Life Sciences funding supporting the project. Several researchers have carried out their PhD in VisMederi, helping to enrich the knowledge and skills of the Company. VisMederi has also contributed to various initiatives promoted by the University, from scientific dissemination activities to activities supporting active job search and introduction of high school students to the world of sciences and research.

VisMederi is also part of the Institute for Global Health that is the natural evolution of the University of Siena's tradition in

science, infectious diseases, its prevention and treatment, vaccines and public health. The IFGH offers internationally recognized programs delivered by global academic and industry leaders in select areas of global health, equipping program participants with the practical and professional expertise they need to lead the next generation of scientists, researchers, and health practitioners across the globe.

### FONDAZIONE TOSCANA LIFE SCIENCES

Since setting their headquarters in the Bioincubator, VisMederi has been collaborating in science projects promoted by the TLS Foundation with the aim to introduce people to the world of research, science, innovation and business culture.



## CORPORATE HOLDINGS

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### **MH – SINGLE MEMBER COMPANY**

MH is the Holding Company of the Group exercising a management activity and controlling the capital of the subsidiaries VisMederi, VisMederi Research and Accurange.

### **VISMEDERI RESEARCH**

Founded in 2014, VisMederi Research Srl, is an innovative startup company established to conduct both basic and applied research, on behalf of the parent VisMederi in order to supplement the R&D sector. During its activity, the Company has focused on the development of new experimental protocols to support the development of natural and synthetic molecules and biological processes in order to ensure greater personalization of tests.

### **ACCURANGE**

The Company specializes in the calibration, maintenance and regulation of laboratory instruments, with particular reference to micropipettes and volume dispensers in general. Accurange guarantees, through the adoption of ISO 9001 quality system and validated procedures, high qualitative standards providing all GLP compliance documentation. The Company provide services to other companies using new innovative equipment and employing highly qualified personnel, in compliance with EN ISO 8655.

## SCIENTIFIC PUBLICATIONS 2016/2017

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Vaccines (Basel). 2017 Jul 18;5(3). pii: E18. doi: 10.3390/vaccines5030018. Review.  
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Expert Rev Anti Infect Ther. 2017 Jul;15(7):689-701. doi: 10.1080/14787210.2017.1333422. Epub 2017 May 29.  
PMID:28524748

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J Prev Med Hyg. 2017 Mar;58(1):E48-E52. Review.  
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PMID:28515628

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**Retrospective Study Evaluating Seroprevalence of Hepatitis E Virus in Blood Donors and in Swine Veterinarians in Italy (2004).**

Zoonoses Public Health. 2017 Jun;64(4):308-312. doi: 10.1111/zph.12332. Epub 2016 Dec 2.  
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 Expert Rev Vaccines. 2016 Nov;15(11):1393-1407.

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 Expert Rev Vaccines. 2016 Aug;15(8):967-76. doi: 10.1586/14760584.2016.1164046.

# ECONOMIC AND FINANCIAL INDICATORS

Index	2017	2016	2015	2014	2013
EBITDA / Net Sales	13,27%	18,42%	42,48%	22,15%	59,80%
ROE	16,21%	10,84%	42,38%	16,99%	86,46%
ROI	8,60%	11,82%	38,67%	17,82%	75,82%
ROS	10,53%	16,40%	41,42%	20,73%	59,33%
ROA	18,04%	22,29%	59,79%	37,14%	148,78%
ROCE	10,90%	14,13%	53,01%	24,02%	127,11%
Capitalization rate	0,50	0,84	0,73	0,74	0,60
Operating Profit Margin Normal (OPM)	10,53%	16,40%	41,42%	20,73%	59,33%
Net Profit Margin (NPM)	9,96%	9,19%	33,11%	14,67%	40,36%
Debt ratio	49,83%	16,29%	27,04%	25,75%	38,30%
Debt To Equity	0,9930	0,23	0,40	0,36	0,70
Leverage	1,9930	1,19	1,37	1,35	1,68
Total solvency ratio	2,01	5,25	3,49	4,39	2,52
Current Ratio	8,06	3,17	2,66	1,95	2,07
Acid Test	6,230	2,94	2,59	1,80	2,05



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