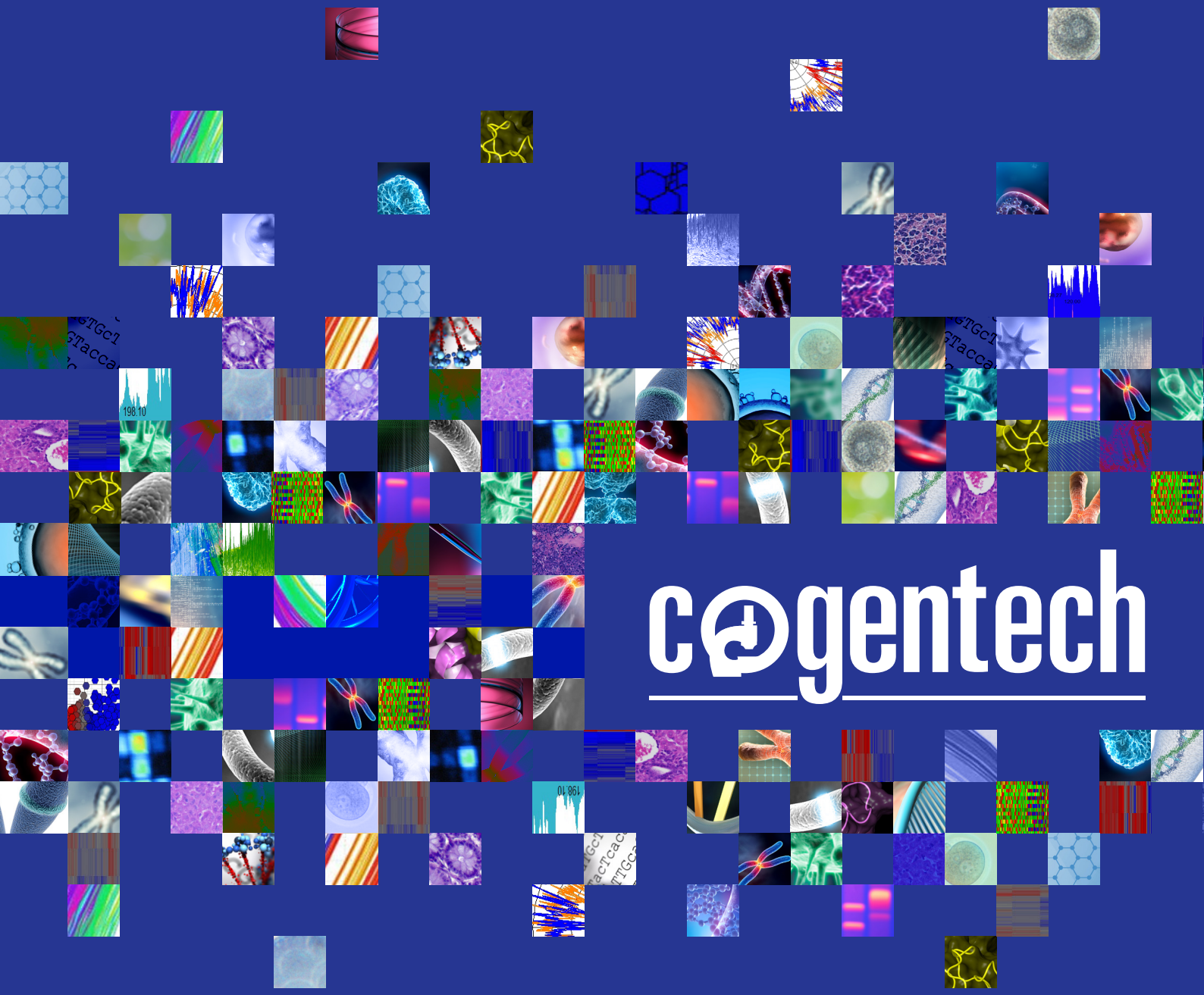

cogentech

IMPACT REPORT 2022

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Letter from the President

Dear stakeholders,

it is with great honor and responsibility that I address you as the new president of Cogentech, the Benefit company that provides technology services for research and molecular diagnostics in cancer.

First, I would like to thank the outgoing president, Marco Pierotti, for his work at the helm of Cogentech. Thanks to his vision and commitment, Cogentech has achieved excellent results and established itself as a strategic partner for AIRC and the world of oncology research.

The year 2022 was a year of transition, with major organizational changes in AIRC and IFOM that brought Cogentech ever closer to AIRC and its mission. We strengthened our collaboration with AIRC-funded researchers, providing them with innovative and quality technology services. We have also expanded our molecular diagnostics offering, making available to physicians and patients the most advanced technologies for molecular characterization of tumors.

One of the most significant milestones of 2022 was the successful conclusion of the BILIGECT research project, funded by the Ministry of Health's PON. Among several goals achieved, this project developed a new methodology for early cancer diagnosis based on the analysis of circulating DNA in blood. This methodology has important practical applications on molecular cancer diagnostics, as it allows the presence and evolution of tumors to be detected noninvasively and accurately.

For 2023, our goals are to grow increasingly in synergy with AIRC and at the service of patients. We want to consolidate our leading position in the field of technological services for oncology research by investing in new equipment and expertise. We also want to expand our molecular diagnostics offering, developing new tests based on the latest scientific discoveries. Finally, we want to enhance our status as a Benefit company by promoting an ethical and responsible corporate culture.

Cogentech is a reality of excellence on the Italian scene, combining scientific and social excellence. I am proud to be part of it and to lead it towards new challenges and opportunities. I count on your support and trust to continue to make Cogentech a company at the forefront of the fight against cancer.

Sincerely,

The President

Methodological note

In line with Italian regulations on Benefit Societies, Cogentech is preparing the Impact Report for the fourth consecutive year, adopting the year 2022 (Jan. 1-Dec. 31) as the reference period.

In this document, Cogentech reports on its social, environmental and economic performance and, in line with regulations, describes the specific goals set and actions implemented in pursuit of the Company's common benefit goals.

The Impact Report was prepared according to an external evaluation standard, developed by an independent third party, which meets the transparency and credibility requirements of the regulations. Based on the industry analysis and its own specifics, Cogentech chose to prepare its Impact Report based on the "Global Reporting Initiative Sustainability Reporting Standards" defined in 2021 by the GRI - Global Reporting Initiative ("GRI Standards") under the "with reference to the GRI Standards" mode.

The general principles applied in preparing the Impact Report are those set forth in the GRI Standards: Accuracy, balance, clarity, comparability, completeness, sustainability context, timeliness and verifiability.

In line with the recommendations of the new GRI Standards published in 2021 and on the basis of what it has already done as a Benefit Corporation-which pursues, as such, purposes of common benefit to its stakeholders-Cogentech has carried out a preliminary analysis of the negative or positive, actual or potential impacts generated in order to validate the material issues supporting the drafting of this Impact Report, i.e., those aspects reflecting the most significant economic, environmental and social impacts-including human rights impacts-generated by the organization towards its stakeholders such as general management, employees and external collaborators, customers, suppliers, end users and the local community.

Downstream, therefore, of an initial investigation of the context in which Cogentech operates and of an internal analysis of the organization carried out taking into consideration what has already been analyzed in past reports, the following were confirmed as the pivotal themes on which to focus its efforts:

- Training and professional development of employees;
- staff welfare;
- relationship with the community;
- customer satisfaction and service quality;
- research and innovation;
- environmental sustainability;
- occupational health and safety.

For details of the impacts related to each material issue and the related management and mitigation actions taken, see the Appendix at the end of the Report.

For reporting on each theme specific GRI-defined Standards significant to the organization were selected. For material issues for which specific GRI Standards are not available, ad hoc indicators (hereafter "No GRIs") have been developed that are representative of the specific business reality and sector within which Cogentech operates.

It is also specified that, for the 2023 Impact Report, the process of updating the materiality analysis will also be further structured in order to include, more extensively, the instances and insights from stakeholder involvement in the analysis activity.

Any use of estimates will be appropriately reported within the text with reasons.

Data collection followed a structured process with the involvement of the organization's internal contacts. The Impact Report 2022 was subjected to Limited Assurance by PricewaterhouseCoopers Business Services S.r.l.

The Impact Report is published on the Company's institutional website at https://www.cogentech.it.

More information about the document can be obtained by contacting the following e-mail address:
press-desk@cogentech.it

About Us

Our history and mission statement

Cogentech is a Sole Proprietorship Limited Liability Benefit Company under the direction and coordination of IFOM - Molecular Oncology Foundation Institute ETS based in Milan, Italy. Active since 2005, Cogentech is dedicated to providing technologically advanced and high quality services both to researchers engaged in the development of basic research in oncology and Translational Medicine and to hospital facilities for the diagnosis and treatment of cancer pathologies.

The Society is based at the IFOM-IEO Campus in which there are numerous other organizations involved in research and clinical applications in the field of oncology. The mission of the Society is to provide innovative and personalized services for the diagnosis and treatment of cancer, with the goal of improving the quality of life of patients.

Cogentech created the Cancer Genetic Test ("CGT Lab") laboratory to offer modern diagnostic solutions. The CGT Lab is a point-of-care Laboratory Medicine Service (SmeL) accredited by the National Health Service since 2011 and registered in the Regional Register of Accredited Facilities in the sub-branch of Cytogenetics and Medical Genetics. This means that the facility possesses both technical-professional and organizational, structural and relational quality requirements necessary for the protection of rights and user satisfaction.

Since 2019, Cogentech has opened a new facility at the Science and Technology Park of Sicily in Catania, Italy. Here, new laboratories have been set up for the development of a scientific project entitled "BiLiGeCT - Liquid Biopsies for Clinical Management of Tumors." This project is funded by the PON/FSC of the Ministry of Education, University and Research (MIUR) and aims to provide a opportunity for development of the area and for highly specialized scientific personnel.

Cogentech has adopted a Code of Ethics since 2014, which defines core ethical values and governs all spheres of the company's activities, from promoting fairness and transparency, to relations with the community, public administration and internal staff.

Cogentech interacts with two broad categories of actors: customers and suppliers. Customers fall into four types. Hospitals that require Cogentech to conduct genetic testing; "internal campus" customers; external academic customers; and external commercial customers who use the research services offered by Cogentech.

An important aspect of the Society's business is its collaboration with different types of suppliers, who offer both innovative technological solutions for research development and quality and reliable services.

The composition of corporate governance

Cogentech's organizational model is inspired by principles of quality and professionalism. The fundamentals on which it is based are:

- The equality of users' rights;
- The impartiality of the staff, inspired by criteria of objectivity and justice;
- Continuity, effectiveness and efficiency in service delivery.

Cogentech is a company whose mission is to promote scientific-technological development, ensure the quality of the service provided, and create value for the target community of workers, medical-scientific professionals, and civil society.

This mission, consistent with the corporate charter, is declined in the quality policy, which establishes the objectives that the organization aims to achieve. Management is committed to constantly monitoring the level of quality achieved, integrating the analysis of the context in which Cogentech operates, the evaluation of the expectations of the various stakeholders, and the assessment of risks related to the specific activities carried out.

Through continuous checks, with the support of staff functions, management thus identifies corrective and improvement actions, which are promptly implemented and communicated internally. Conducting an in-depth SWOT analysis enables management to highlight the strengths (Strenghts) of the system, as well as the weaknesses (Weaknesses), opportunities (Opportunities) and risks (Treaths): these parameters constitute the key elements on which future planning is based.

A significant change in Cogentech's Governance marked the year 2022. Prof. Alberto Bardelli, assumed the position of President, succeeding Dr. Marco Alessandro Pierotti.

The organizational structure consists of a Chairman, a Chief Executive Officer, and a Board of Directors, composed as follows:

Since 2014, Cogentech has had an Organizational Management Model pursuant to Legislative Decree No. 231/01, legislation that introduced the administrative liability of entities into the Italian legal system. In 2020, Cogentech's Organizational

CONSIGLIO DI AMMINISTRAZIONE

ALBERTO BARDELLI
PRESIDENTE

LUCIANO BAIELLI
AMMINISTRATORE DELEGATO

ALESSANDRA DELLA PORTA
CONSIGLIERE

CDA members	Women	Men	Total
Less than 30 years old	0	0	0
Between 30 and 50 years old	0	0	0
More than 50 years	1	2	3
Total	**1**	**2**	**3**

and Management Model pursuant to Legislative Decree No. 231/2001 was updated by providing for the new types of crimes introduced in the catalog of 231 offenses, and in January 2021, the updated version of the Model was published on Cogentech's website.

The services we offer

Cogentech is a provider of high-level technological solutions for the scientific community and clinical entities, which want to use these technologies for diagnostic purposes. Cogentech's personnel are highly qualified and possess highly sophisticated expertise, the technologies are state-of-the-art, and the instruments are numerous and versatile. These are the factors that make it possible to meet the demands of both the researcher and the clinician.

Diagnostic services for the clinic: Cancer Genetic Test Lab

CGT Lab (Cogentech Cancer Genetic Test Laboratory) is a center of excellence in molecular diagnosis of oncological diseases, certified according to UNI EN ISO 9001:2015 and SIGUCERT standards and accredited UNI EN ISO 15189:2013.

Our mission is to provide physicians and patients with quality, innovative and reliable service based on research, development and application of new diagnostic techniques.

Our laboratory, equipped with state-of-the-art technology and registered in the Regional Registry of Accredited Facilities, deals exclusively with genetic testing for cancer prevention and treatment. The laboratory mainly performs germline genetic testing in the genes of predisposition to the development of both adult and pediatric cancers, but also analyses for prognostic and/or therapeutic purposes on DNA extracted from tumor tissues.

The CGT Lab performs molecular genetic testing on behalf of Oncology Genetic Counseling Services (CGOs), which are internal to the Hospital Facilities, who then interface with the patient.

Thanks to the professionalism and experience of a highly specialized team, which has performed more than 17,000 genetic tests, the CGT Lab assures its academic and clinical partners of accurate and effective results, following a rigorous and documented quality management.

The diagnostic protocol uses OncoPan® and OncoPed panels, developed by the Laboratory, with Next Generation Sequencing (NGS) technology. Analysis with the SOPHiA DDM™ Dx HRD Solution diagnostic kit for evaluation of genomic instability in

ovarian cancers and predictivity of response to PARP inhibitors is also available.
New projects were initiated in several areas, demonstrating the ability of the laboratory and its staff to adapt and respond to new and very challenging situations.

Tumors for which service is available

Hereditary Breast & Ovarian Cancer
Lynch syndrome
Familial adenomatous polyposis (FAP)
Li-Fraumeni syndrome
Hereditary Diffuse Gastric Cancer
Peutz-Jeghers syndrome
Cowden disease
Familial Melanoma
Juvenile Polyposis syndrome (JPS)
Polymerase Proofreading Associated Polyposis (PPAP)
Colorectal Cancer and Polyposis (rare hereditary conditions)
Hereditary Prostate Cancer
Hereditary Pancreatic Cancer
DICER1 syndrome
Gorlin syndrome (Nevoid basal cell carcinoma syndrome)
Retinoblastoma
Carney Complex (CNC)
Atypical teratoid/rhabdoid tumor (AT/RT)
Von Hippel-Lindau syndrome (VHL)
Wilms tumor
Birt-Hogg-Dubé syndrome (BHD)
Hereditary papillary renal cell carcinoma (HPRCC)
Hereditary leiomyomatosis and renal cell cancer (HLRCC)
BAP1 tumor predisposition syndrome (BAP1-TPDS)
POT1 tumor predisposition (POT1-TPD)

Outlook for the development of CGT Lab

CGT Lab has started the CE-IVDR certification pathway for OncoPan® and OncoPed gene panels, related to in vitro diagnostic medical devices, in order to be able to continue using said panels, as a "service provider" having recognized the status of a "health institution." The panels may be updated with the inclusion of new genes that should gain relevance for cancer risk assessment based on new data collected by the scientific community, increasing their diagnostic potential.

The OncoPan® Panel contains 313 SNPs for the determination of the Polygenic Risk Score (PRS), which can be used for the purpose of personalizing breast cancer prevention strategies. Currently, the data obtained from the analyses are being provided free of charge to geneticists for research purposes, pending the results of an international clinical validation study of a new breast cancer screening strategy that includes PRS assessment. We expect that, on the basis of this study, PRS analysis may be introduced into clinical practice and result in an increase in the number of analyses conducted with the panel.

Increased molecular testing may also come from analysis for prognostic and/or therapeutic purposes on DNA extracted from tumor tissues. In this area, which is certainly expanding, the laboratory has begun to enter with the offering of somatic testing of BRCA1 and BRCA2 genes with OncoPan® and the SOPHiA DDM™ Dx HRD Solution test on ovarian carcinoma for predictivity of response to PARP inhibitor therapy, but the prescription of the drug will probably be extended to other types of tumors, with a potential increase in testing requirements.

Certifications obtained by CGT Lab

- Accreditation with the National Health Service with entry in the Regional Register of Accredited Facilities in the sub-branch of Medical Genetics with Molecular Genetics activities;
- UNI EN ISO 9001:2015 certification;
- SIGUCERT certification from the Italian Society of Human Genetics;
- UNI EN ISO 15189:2013 accreditation with ACCREDIA for Medical Genetics examinations.

Market impact of CGT Lab

The trend toward increased testing required at the CGT Lab, already highlighted at the end of 2021, continued throughout 2022 and resulted in an overall increase in performance of about 22%. A significant increase in NGS testing on probands (+30%), and a slight increase in ascertainment testing on collaterals (+3%) was noted. It should be noted that a share of the tests performed on probands (9.3%) concerns the opportunity offered to clients to perform additional analysis of one or more genes, compared to a previously performed analysis, without having to repeat the NGS experiment. This is an excellent opportunity, allowing for increased informativeness of the test with reduced use of time and resources. Compared with last year, the requests for all extended panels (> 8 genes analyzed) and also the requests for tumor analysis and prediction to the use of the drug Olaparib in ovarian carcinomas with the OncoPan® panel (+63%) have greatly increased.

Research and technology

Cancer research is the main field of study of IFOM scientists, who for years have been dedicated to discovering the biological mechanisms that cause and promote disease. The goal is to find new ways to prevent and tailor therapies to the characteristics of cancers. Among the most innovative lines of research are those dealing with the genomic instability of cancer cells and the influence of the mechano-biological microenvironment on the development and spread of metastases.

Cogentech offers technological support to oncology research, providing advanced tools for the identification of neoplastic molecular targets (genes, proteins, or mechanisms involved in cancer that can be pharmacologically modified to counteract the disease). Translational Medicine, which makes use of Cogentech's expertise and technologies, also plays an increasingly important role.

Technology services for scientific research

Thanks to the synergy with scientific institutions of excellence, the Cogentech team has acquired enough expertise to offer clients a complete and personalized service in research, from the definition of an appropriate experimental design to the implementation of targeted analyses and the evaluation of the data obtained.

Genome Editing Unit

The facility is involved in genomic editing for various types of scientific projects. Procedures have been developed and validated to generate gene knock-outs in the most common cell lines. The Unit offers gene knock-out and gene knock-in services (e.g., point mutation insertion, revertant mutations, gene tagging, gene/exonic deletions).

The Unit also offers Genetic Screening services, which, through the use of whole-genome CRISPR KO libraries, allow identification of, for example, synthetic lethal genes, or genes involved in drug resistance and sensitivity.

The service offered includes experimental design, a feasibility check, genomic editing, clonal selection and characterization of the modified cell line by sequencing or Western blot. Cas9 can be introduced in plasmid form or as a purified protein in complex with synthetic RNA guides.

Through the use of several alternative methods for Cas9 delivery, the Unit is able, in many cases, to introduce the desired genomic alterations, even in cell lines that transfect with low efficiency.

CRISPR/Cas9 is still a young technology that is constantly evolving. The Unit is constantly updating itself in order to always offer the most efficient and innovative solution to customers' scientific needs.

The service implements quality controls at various levels at different stages of work. Only certified and controlled reagents are used. Specific protocols are developed and validated in-house for the purpose of optimizing genomic editing efficiency. Good laboratory practices for sample handling and data traceability are constantly implemented to ensure reproducibility and quality at all levels of the workflow.

Genomic Unit - Microarray

The Unit performs gene expression profiling on total RNA, miRNA, mRNA from cells or tissues of human, murine, and other species origin. In addition, the Unit offers a human genome analysis service that allows the study of molecular karyotype, genotyping, and identification of Copy Number Variations using very high resolution Affymetrix® arrays.

The Unit can provide comprehensive support for different research projects, from experimental design to data analysis. Customized amplification and labeling protocols can also be performed for difficult samples such as FFPE samples or those with low amounts of starting RNA.

Protocols are periodically revised to ensure optimal performance at all times. New applications available on the market are also implemented to keep up with advances in biotechnology.

The laboratory has been using microarrays technologies since 1999. Various quality checks are performed on the samples throughout processing, providing results in accordance with MIAME guidelines.

Genomic Unit - Next Generation Sequencing (NGS)

The staff of the Genomics Unit has 15 years of experience in Next Generation Sequencing technologies and puts their expertise to work in support of customer research projects. State-of-the-art technology platforms are used, providing comprehensive support in applications including RNA-seq, DNA-seq, ChIP-seq, exome sequencing (WES) and gene panel sequencing, Single Cell and Space Transcriptomics-based studies. Support for Clinical Trials is also offered.

The Unit provides professional support for the different stages of the research project, from the optimization of the experimental design to the functional interpretation of the obtained result. Identification of the ideal methodological approach to achieve the experimental objective, quality control of nucleic acids, generation of indexed fragment libraries, sequencing, and analysis of results for selected applications is provided. The Unit is available to customization of protocols for specific needs. Delivery of sequencing results is done via the Web, using a platform with an intuitive interface and password-protected access.

Understanding of how the genome works is progressing rapidly, in part due to the development of methodologies using NGS sequencing, which are being developed at an ever-increasing pace. Staying current with technological advances requires constant effort. The Unit is dedicated to the constant implementation of new approaches to keep expertise up-to-date and make it available to the scientific community. Nanopore-based sequencing (Oxford Nanopore), single-cell 'omics' applications performed on Chromium instrumentation (10X Genomics) as well as supporting Space Transcriptomics projects are offered.

The Genomics Unit has a decade of experience in genomic technologies, which began in 2008 with an Illumina Genome Analyzer II sequencer, and expanded over the years through the use of Illumina HiSeq2000, MiSeqDx, and NextSeq550Dx sequencers, with the last two currently in use. Quality controls are performed throughout the entire workflow, and the Unit operates according to GLP (Good Laboratory Practice) criteria. Operating procedures and protocols are updated periodically to ensure maximum efficiency. Cogentech is an ISO9001/2015 Certified company.

Histopathology Unit

The mission of the Unit is to provide a service with high quality standards for histological evaluation of normal and pathological tissues from different experimental models. Optimization of new experimental protocols and data verification/ analysis performed by certified Pathologists are an integral part of the activities.

A complete service is offered, ranging from analyzing your needs to trimming tissues, paraffin embedding, slide preparation and staining, and photographic documentation of samples and data analysis.

The staff is continuously engaged in developing new experimental protocols according to the needs of researchers. The service operates under high quality standards: through the monitoring of laboratory activities and staff training, the Unit delivers certified services.

Mouse Genetics Unit

The mission of the Mouse Genetics Service is to provide researchers with the ideal environment in which to do research with laboratory mice.

The Service is responsible for the management of the animal house where mice are maintained and bred for different research programs, with a strong commitment to the application of the 3Rs (Replace, Reduce, Refine) principles. Special attention is paid to the protection of animal welfare. Two veterinarians who specialize in Laboratory Animal Science and Medicine are in charge of animal welfare, and highly qualified staff take care of animal care and breeding. Animal care, breeding, and experimental procedures are carried out in accordance with Legislative Decree No. 26 of March 4, 2014, which implements Directive 2010/63/EU of the European Parliament and of the Council of September 22, 2010, on the protection of animals used for scientific purposes. Cogentech enclosures are facilities authorized by the Ministry of Health.

The animal house is equipped with individually ventilated cages (IVCs) that provide an ideal environment for both animals and operators. In fact, IVC cages are designed both to prevent the spread of microorganisms from the cage to the outside environment (biocontainment) and to prevent the entry of dust/microorganisms from the outside environment to the cage (bioexclusion). Environmental enrichment is present in each cage and consists of a Mouse HouseTM (Tecniplast), which provides a complex three-dimensional environment, and soft bedding that promotes nest construction.

All activities are carried out in accordance with detailed operating procedures and instructions. The enclosure is UNI EN ISO 9001:2015 certified. The staff consists of highly qualified personnel who are constantly updated.

Proteomics Unit

The Proteomics and Mass Spectrometry Unit provides a comprehensive facility for protein identification and characterization, including various platforms for protein and peptide separation and state-of-the-art MS and LC-MS/MS techniques.

Activities can be divided into:

- Mass Spectrometry Services
- Proteomics Services
- Data analysis

All services include scientific advice from Unit staff, pre and post analysis assistance to establish study design and type of analysis, interpretation of data, and an explanatory report of the results obtained.

The fleet of machines is maintained and renewed machines with the latest tools. The protocols are constantly updated, as are the software and technologies to ensure the high quality of the work. We constantly optimize the most widely used protocols in proteomics and develop our own methods, then make them available for collaborations with researchers and clients.

The Unit works in accordance with the guidelines recognized by the scientific community for ascertaining the quality of proteomics data, such as:

- “Universal Metrics for Quality Assessment of Protein Identifications.”
- “Recommendations for Mass Spectrometry Data Quality Metrics for Open Access Data.”

Quantitative PCR (QPCR) Unit

The Unit was founded in 2003 with the aim of supporting researchers in the analysis of nucleic acids, supporting them from the early stages of the project to the analysis of the results. Always attentive to technological innovations, over time it has implemented its portfolio by also introducing digital PCR, a highly innovative technology with high sensitivity, so as to enable it to offer a complete and competitive service for both internal and external users. To date, the Unit offers analysis of gene expression (mRNA and miRNA), copy number variation (CNV), and gene variants for any target sequence (SNP), both with real time QPCR and digital PCR technology. It currently has two QPCR instruments (QS12K Flex with 96-384 well e card block and 7500 Fast Real Time PCR System) and one digital PCR (QS3D).

The Unit has always developed and optimized protocols to ensure reliable and reproducible results and to meet the pressing needs of research and diagnostic activities. Should there be a need to analyze certain regions of the genome, target sequences of particular uncommon species, or meet user requests for specific research studies or diagnostic needs, the Unit is involved in the feasibility study, design, and development of custom Taqman probes. Specifically, the staff designed 2 TaqMan assays for a gene expression study of two alleles of the NF1 gene. Each allele carries a mutation that results in an amino acid change, one on exon 2 and one on exon 5. The project was commissioned by the University of Brescia and conducted in digital PCR.

Thanks to the expertise of the qualified staff, with 20 years of experience, and its continuous updates, the facility guarantees reliable and reproducible results and use of innovative technologies.

Cogentech's QPCR Facility services are performed following UNI EN ISO 9001:2015 No. IT256850 certified procedures. Data analysis is provided in accordance with MIQE guidelines.

DNA Sequencing Unit - Sanger Method

The DNA Sequencing Unit uses automated technology using fluorescent terminators (Sanger's method) to ensure high quality reads from the different types of templates provided by users. The most requested protocols are those related to the verification of cloning of DNA fragments into a vector, screening of introduced mutations by CRISPR genome editing in specific genomic regions, detection of single nucleotide variants (SNVs) in PCR fragments, and validation of mutations found by diagnostic Next Generation Sequencing (NGS) (also at the somatic level, up to a mutated allele frequency of 10-20%). The Unit also makes available fragment analysis technology, which supports both the research side, through analysis of fragments obtained by Multiplex PCR for genotyping samples (microsatellite analysis, i.e. STR or short tandem repeat), and diagnostics, using the MLPA (Multiplex-ligation dependent probe amplification) technique that evaluates allele copy number variants in the human genome (CNV). In more than 20 years of experience in the field of Sanger method sequencing, the facility has provided technical and scientific support to numerous basic and translational research projects, as well as collaborating at the forefront of the diagnostic activities of Cogentech's CGT lab.

The Sequencing Unit is able to offer:

- DNA sequencing of different templated types;
- The possibility of using fragment analysis technology for various applications;
- Assistance with project design and data analysis related to the technology provided by the service.

The Unit is responsible for keeping the protocols up-to-date and optimized with new tests all the time, based on the technologies and reagents coming out on the market, as well as the needs of Clients. In fact, over time there have been requests for DNA sequencing and fragment analysis services concerning not only the human genome, but also murine, canine and other animal species, which the Staff has been able to fulfill thanks to expertise and study. In addition, the availability of a robotic station in the laboratory creates the possibility of working on projects with a medium to high number of samples.

The Unit can guarantee a sequencing read capacity of 600-800 high-quality base pairs. Our customers can also request performance through the Cogentech website, having at their disposal a constantly updated and optimized list of free universal primers. The instrumentation used is based on capillary technology, periodically serviced by trained technicians. Finally, the DNA Sequencing laboratory holds the UNI ISO 9001:2015 certificate of conformity.

Integrated Genomics Unit (Catania office)

The unit consists of three state-of-the-art components: Molecular Biology and Sequencing, Histopathology, and Bioinformatics. Researchers have implemented, in a short period of time, innovative experimental protocols and methods, which they make available to customer needs (research projects and services). In particular, the molecular biology unit boasts the development of protocols aimed at the analysis of cfDNA, obtained from liquid biopsy. The use of state-of-the-art equipment and constant refinement of protocols allows the Unit to offer services with high standards of quality and innovation. In addition, the team of bioinformaticians is supported by tools in the field of Artificial Intelligence to offer solutions in line with advanced technological development.

The Molecular Biology group provides expertise in several application areas: nucleic acid extraction from different matrices, ddPCR, and various types of sequencing (custom gene panels, Lowpass WGS, WES, WGS, RNA-Seq, tcR-Seq, genome-wide DNA methylation). The Bioinformatics unit provides pipelines for analysis of data produced by all sequencing workflows. It also provides its expertise for the implementation and development of custom pipelines. Finally, the Histopathology unit offers services in slide preparation and staining, image digitization, and laser-capture microdissection.

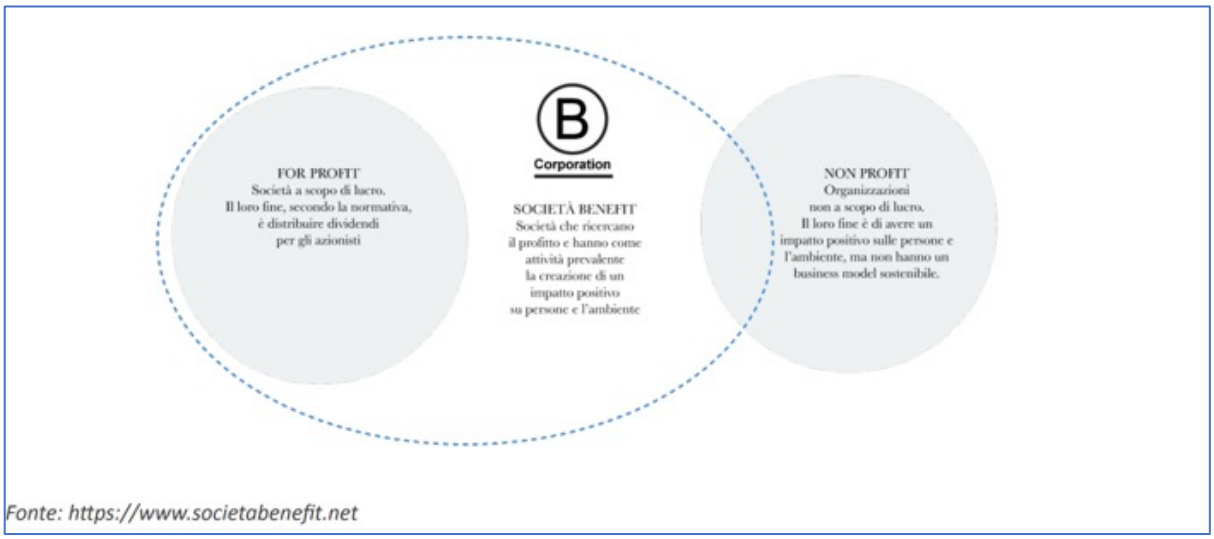
The development of new protocols, the refinement of previously initiated protocols, and the updating of the team's skills and knowledge represent daily challenges that enable the Unit to keep up with scientific progress in the field of biotechnology and to ensure reliability and reproducibility of data. Contributing to the achievement of these results is the use of instrumentation of innovative technological development such as Illumina's NextSeq 2000 sequencer, BioRad's Digital Droplet PCR and Leica's Laser Microdissector.

The Unit staff works by performing quality control at every stage of the workflow. It also constantly updates procedures and protocols to achieve maximum experimental yield.

Our commitment

Benefit societies

A new business model has emerged in Italy thanks to Law No. 208 of Dec. 28, 2015: the Benefit Societies. These are companies that not only pursue profit, but are also committed to creating value for society and the environment. Benefit Societies include in their bylaws a mission of common benefit, which guides them in strategic and operational decisions. In this way, Benefit Societies stand out in the marketplace as responsible, sustainable and transparent businesses that want to contribute to the well-being of people, communities, territories and cultural and social goods and activities. Benefit Societies represent a virtuous and innovative legal form that responds to the needs of entrepreneurs, managers, shareholders, and investors who believe in a more equitable and inclusive capitalism.



Fonte: https://www.societabenefit.net

Cogentech decided to change its legal status in 2018, becoming a Benefit Society s.r.l. with IFOM as its sole shareholder. This choice implies that Cogentech is committed to pursuing and achieving common benefit purposes, which are made explicit in its Articles of Incorporation. To demonstrate its commitment, Cogentech prepares and publishes an annual Impact Report, which shows how the Society is achieving its common benefit goals. The goal is to use an increasingly effective evaluation model that allows for a concise, clear and comprehensive Report. The Impact Report is a transparency and accountability tool, accounting to stakeholders for Cogentech's activities and results as a Benefit Society.

The purposes of common benefit

Cogentech is a Benefit Society whose mission is common benefit through personalized medicine. Our activities are based on four fundamental pillars:

- Harnessing the potential of genomics to offer therapeutic, diagnostic, and preventive solutions tailored to each person's genetic profile, with the goal of improving health and quality of life.
- To educate and raise awareness of healthy lifestyle and disease prevention by providing useful information and tools for managing one's health.
- Participate in the national and international scientific debate, collaborating with scientific entities and realities of excellence, and carry out basic and applied research in the diagnostic field, with the aim of developing innovative models for people's health.
- Promote social and environmental sustainability among all stakeholders, encouraging their commitment to the common good.

Cogentech is a Benefit Society that believes in personalized medicine as a social and scientific model for the future of health.

Scientific research and innovation

A country's social and economic growth depends largely on its ability to produce and transfer scientific knowledge and innovation. In this context, the value of both the generation of new knowledge and its application and dissemination must be recognized. The recent health emergency and the related crisis in some sectors of the NHS have dramatically highlighted the country's lack of autonomy in the design and implementation of health diagnostic devices. This situation is the result of a historical gap in the national biomedical system, which fails to transform research excellence, often globally competitive, into concrete applications.

Cogentech has always been committed to bridging this gap, and its mission is to offer technologically advanced, innovative, and high-quality services, both to researchers engaged in basic research (in oncology and other fields) and to hospital facilities, for the diagnosis and treatment of cancer diseases.

Cogentech's research and development projects and investments, which accounted for 32.9 percent of total investments for the year in 2022 (compared to 38.7 percent in 2021), were geared toward creating an original and innovative proprietary position that enables the company to maintain:

- one's competitive role
- develop new tools
- develop new analysis techniques.

Cogentech is a company dedicated to designing and implementing innovative solutions in the field of hereditary disease diagnostics and prevention. Thanks to its high professional quality, derived from long experience and constant training of its staff, Cogentech is able to offer timely and customized interventions to its clients.

Cogentech collaborates closely with IFOM, its scientific and technical partner, which provides it with ideas to be turned into concrete applications. Together, Cogentech and IFOM conduct cutting-edge research to discover the genes, proteins and molecular mechanisms involved in the development of various diseases, particularly neoplastic ones. These can then be exploited to develop new drugs that can combat or cure diseases.

Cogentech therefore aims to transfer scientific knowledge generated in the laboratory to the health services market, creating added value for the community. Cogentech also has a strong Benefit vocation, which is expressed in promoting clinical and translational research in oncology, thus allowing scientific advances obtained in the laboratory to be rapidly applied in clinical practice. This is especially true in those areas that do not receive sufficient attention and investment from commercial companies.

Goals achieved in 2022

A fundamental aspect of Cogentech's mission is to always be at the frontier with respect to scientific and technological innovations that affect its field of work. This translates into constant Research activity and leading to innovative discoveries both at the level of knowledge of biological processes and at the level of Development of new technological, diagnostic and therapeutic solutions.

Evolution of the OncoPan® panel and introduction of the OncoPed panel

During the year, Cogentech's diagnostic offerings were enriched with two new products that are based on Next Generation Sequencing (NGS) sequencing technology.

The former actually represents a further development of OncoPan®, our flagship product. OncoPan® is a gene panel (42 genes, 313 SNPs) for the identification of genomic risk variants for the most common hereditary adult cancers, including breast and ovarian cancer, Lynch Syndrome Familial Adenomatus Polyposis (FAP), Li-Fraumeni Syndrome, Hereditary Diffuse Gastric Cancer, Peutz-Jeghers Syndrome, Cowden disease, Familial Melanoma, Juvenile Polyposis Syndrome (JPS), and Polymerase Proofreading Associated Polyposis (PPA).

Compared with other solutions available in the market, the OncoPan panel is cost effective in that it combines the answer to three diagnostic questions in a single device:

I. Risk determination for the most common hereditary cancers mentioned above. The latest version of the panel (v4) has been enriched with some new melanoma susceptibility genes (BAP1, POT1, MITF, MC1R, ACD, TERT, TERF21P), a colon cancer susceptibility gene (AXIN2) and a prostate cancer susceptibility gene (HOXB13). Contextually, the panel was refined to improve the coverage of some gene regions.

II. Determination of the Polygenic Risk Score (PRS): the panel can be used to determine the most appropriate interval between two breast screening sessions. Traditionally, the age factor is considered as the main factor in determining the timing of mammography screening. In addition, other pathophysiological factors such as breast density, age of menarche, etc., contribute to an algorithm by which the breast specialist defines the correct interval for each patient's mammograms. The introduction of PRS, with the inclusion of the z-score calculation in the previous algorithm, has demonstrated greater accuracy in identifying the correct individual risk range for these patients. This allows the patient to avoid unnecessary radiation exposure and is also a significant savings to the National Health System, which does not have to bear the burden of unnecessary mammography examinations anyway. It also decreases the incidence of "interval cancers" among those most at risk;

III. Use of the test as a companion diagnostic for precision medicine: the panel can be used, if mutations in relevant genes are present, to target therapy with PARP Inhibitors (Olaparib, Rucaparib, Talazoparib).

The second diagnostic aid, developed by Cogentech and newly introduced, is OncoPed. The latter is a gene panel (31 genes) for identifying genomic risk variants for hereditary cancers in children. However, it also contains some overlap genes with OncoPan®, for evaluation of families with multiple tumors and phenotypic variability.

Pediatric cancers (<15 years of age) account for about 1.2% of all cancers. Environmental factors play a limited role in promoting cancer occurrence in young people. In this context, it was shown that about 8% of children with cancer had a genetic predisposition, most without significant family history.

Correctly diagnosing a genetic predisposition allows for more specific oncologic surveillance to be implemented, both for the patient and for family members at risk, can influence treatment, provide insight into the prognosis of the disease, and allow for the recognition of other signs and symptoms not otherwise correlated with oncologic disease. Although the importance of identifying individuals at genetic risk is recognized, among pediatric cancer patients the ability to offer molecular diagnostic insights is currently limited. OncoPed therefore aims to meet this need, particularly for the analysis of predisposition genes for aggressive neoplasms such as: medulloblastoma, Wilms' tumor, some rare ovarian tumors (Sertoly-Leydig and SCCOTH), retinoblastoma, uveal melanoma/melanoma, renal tumors, some lymphomas, rhabdoid tumors, and tumors developing in Gorlin, DICER1 and Carney syndromes.

Evaluation of Homologous Recombination Deficiency (HRD) in ovarian cancers

It is important to mention that, although not originally developed in our laboratory, we now have available an additional diagnostic tool, the new SOPHiA DDM™ Dx Homologous Recombination Deficiency Solution kit for the evaluation of genomic instability in ovarian cancers and predictivity of response to PARP inhibitors. In fact, after largely passing the quality tests provided by the manufacturer SOPHiA Genetics, which evaluated the performance of the CGT Lab workflow in obtaining data with excellent quality parameters, Cogentech is now an authorized Center to offer the analyses with this diagnostic kit.

As is well known, several studies have shown a benefit of using PARP inhibitors in patients with ovarian cancers with homologous recombination deficiency, even in the absence of mutations in the BRCA1 and BRCA2 genes. Thus, the identification of HRD status appears to be crucial in clinical practice in order to direct therapeutic decisions and improve patient survival.

The analysis measures genomic integrity by assessing the alterations present in the sample, measured over the entire genome at low coverage (low pass WGS). This allows the derivation of a biomarker of genomic instability (Genomic Integrity index), to be added to the evaluation of mutational analysis of BRCA1 and BRCA2 genes and 26 other genes involved in the mechanism of homologous recombination.

Soon the HRD test may also be approved for predicting response to PARP inhibitors in other tumor types, such as prostate and triple-negative breast cancer.

Transcript analysis for evaluation of the effect on RNA splicing of variants of unknown significance (VUS).

The advent of next-generation sequencing (NGS) has greatly enhanced the process of identifying predisposition variants for cancer development, also giving the possibility of identifying a large number of potential new cancer predisposition genes with a significant impact on prevention strategies. However, the analysis of panels consisting of many genes has also increased the finding of variants of uncertain significance (VUS), for which it is difficult to establish a correlation with cancer risk. Some of these VUS, mostly located in the intronic regions of genes, confer pathogenicity through an effect on mRNA splicing and can be classified with high efficiency by in vitro assays.

Cogentech's CGT Lab, in collaboration with the U.O. "Hereditary Tumors of the Digestive System " at the IRCCS Istituto Nazionale dei Tumori (Milan), evaluated the effect on mRNA processing of some variants of uncertain significance in digestive tract cancer predisposition genes, with the aim of classifying them and thus improving the identification of individuals genetically predisposed to cancer, allowing them to be targeted, through precision medicine, to personalized surveillance and risk reduction measures.

The analysis allowed for the reclassification of two variants in intron 3 of the APC gene, responsible for Familial Adenomatous Polyposis, as pathogenic variants, so carriers of these variants and their family members can be placed on a surveillance pathway appropriate to their disease risk. Transcript analysis also made it possible to establish the effect on the splicing mechanism for a variant in intron 4 of the SMAD4 gene, responsible for Juvenile Polyposis, for which, however, more evidence needs to be gathered to reach a definitive classification.

The project continues in 2023 with the analysis of other VUS variants identified in Lynch syndrome susceptibility genes and will be the subject of Dr. Brignola's (INT) doctoral dissertation, followed in the design, implementation and review phase by Dr. De Vecchi (Cogentech).

Evaluation of liquid biopsy for clinical management of hereditary breast and/or ovarian cancer

Cogentech obtained in 2019 an important award from the Ministry of Education, University and Research (MIUR): a PON (National Operational Program "Research and Innovation" 2014-2020) grant for the project "BiLiGeCT - Liquid Biopsies for the Clinical Management of Tumors" successfully concluded at the end of December 2022.

This project, which involved five other Italian entities of excellence (Carebios srl, Consorzio Interuniversitario Nazionale Metodologie e Processi Innovativi di Sintesi-CINMPIS, Istituto Oncologico del Mediterraneo S.p.a., Istituto Superiore di Sanità and Università degli Studi di Torino), aimed to develop new technologies for the analysis of liquid biopsies, an innovative approach for cancer diagnosis and monitoring.

This project was intended to make significant social, political and economic interventions in areas of Southern Italy with historical and geographical difficulties. Cogentech contributed to the project with its new Operating Unit, located in the Science and Technology Park of Sicily, creating opportunities for collaboration and transfer of technical-scientific expertise with local realities.

Cogentech also acted as coordinator, organizing quarterly meetings with all partners to discuss achievements. It also took precise care of the quarterly reporting of the work progress (SAL) and economic situation, which were then validated by the Ministerial control bodies.

The Project was based on 5 lines of research to develop circulating markers, by liquid biopsy, for the prevention, diagnosis and treatment of hereditary and sporadic cancers. The lines of research (called OR) and the main results obtained are summarized below.

OR 1: Early disease diagnosis in healthy BRCA mutated subjects at genetic risk of breast/ovarian cancers for the development of highly sensitive and inexpensive diagnostic assays

The aim of this first objective represents what is the most advanced field of diagnostics in the field of oncology: the extremely early identification of the presence of cancer with a methodology that is sufficiently sensitive and specific and noninvasive and, as such, applicable to a population of healthy individuals. To achieve this ambitious goal, the scope and difficulty of which does not escape us, we planned to focus our attention on a cohort of individuals, those at genetic risk, particularly BRCA1 or 2 mutation carriers, who, compared with an approach concerning the general population, have two experimental advantages: they are at high risk of developing cancer (thus they are included in more intensive follow-up programs than those adopted for the general population) and also, a significant advantage for molecular analysis, we can predict which cancers will arise over time, specifically breast and/or ovarian carcinomas. With this in mind, the main goal of this line of research has been the creation of a biobank of plasma collected from healthy family members of mutated subjects with breast/ovarian cancer who are themselves positive for the same mutation in one of the two BRCA genes. This specimen collection (which currently consists of 20 plasma samples, obtained from 16 individuals in active surveillance programs because they are at high risk, and will be further implemented) is of extraordinary value in that once the disease event has occurred in a subject in follow-up, a retrospective molecular analysis can be conducted to assess how early the liquid biopsy was able to intercept instrumentally or clinically detectable disease. In addition to special attention to the technological developments, which will be produced in the meantime by the research in the field of liquid biopsy, the methodologies that will be employed, since at present no subject in follow-up has developed cancer, will be those derived from the research described in the next line of research, in particular, those derived from

the development of the "holistic protocol" as a useful tool to achieve the present goal. Propaedeutic to and in parallel with the specimen collection activity, described here, all necessary protocols for maximizing the yield of circulating DNA (cfDNA) present in venous blood samples been developed. A data base was developed ad hoc for the management of the collected cases, the recording of their clinical characteristics and, where performed, the relevant molecular analyses. The implementation of these last two aspects of the project, have, in addition, enabled the activation of what is planned in the next line of research.

OR 2: Early detection of disease recurrence in BRCA mutated subjects with prior history of breast/ovarian cancer in surveillance using circulating markers to monitor disease and appropriate use of therapy.

With this in mind, the aim was to test the correspondence between molecular profiling, as determined through whole-exome "next generation sequencing" (NGS/WES) of the analyzed tumor, and what is detectable in the respective ctDNA present in the circulation. The initial step involved NGS/WES sequencing of a total of more than 50 tumors and their respective normal tissue. This analysis, which covered breast and ovarian tumors and with different mutations in BRCA1 or 2, also yielded relevant information on the mutational profile of these tumors, which was used to design a proprietary panel capable of intercepting, by NGS sequencing, the majority of such tumors. This gene panel constitutes one element of a protocol, produced in the project, which we termed "holistic" that combines, for the same sample, genetic, epigenetic and exploiting chemical/physical properties of DNA analyses. Of particular note was the analysis of the feasibility of an epigenetic analysis of the methylome, which required the development of specific bioinformatics tools, validated, preliminarily, with data available in public databases. With the "holistic panel," initial sensitivity data were obtained indicating its feasibility to be used as an analytical tool of ctDNA obtained from liquid biopsy. The results obtained from molecular analysis of this significant series of BRCA mutated tumors are being formalized for scientific publication.

OR 3: Early diagnosis of lung and prostate cancers for the development of new circulating exosomal markers for more effective and less invasive disease diagnosis

As part of the Project, more than 1,000 markers capable of detecting prostate, lung and colon cancer, differentiating the most aggressive forms and suggesting targeted therapies have been defined. analysis of the molecular content (proteins, DNA and RNA fragments) of nano-vesicles (exosomes) released from different tumors, representing the tissue of origin and, consequently, tumor aberrations, has been performed. More than 900 samples of exosomes were processed and analyzed, in patients with prostate, lung and colon cancer. In addition, by means of a novel "reverse phase protein array" (RPPA) technique, which allows the simultaneous analysis of many tumor samples for the expression of multiple protein markers (antigens), about 600 cases of lung cancer were examined for the expression of a total of 160 antigens. Preliminary data from an RPPA analysis thus designed performed between a group of healthy individuals or those with benign inflammatory processes and a group of patients with all types of lung cancer identified 34 as significant antigens, differentially expressed and thus usable for a differentiated diagnosis of these tumors. As for Prostate tumors, in this case the diagnostic approach was focused on the analysis, again through RPPA, of extracellular vesicles (EVs) that are released into biological fluids by tumor cells and that represent a significant source of tumor-associated biomarkers. The study identified a number of protein profiles that correlated with the clinical status of patients as, in particular, their prognostic significance in a retrospective analysis conducted on EV samples isolated at the beginning of follow-up initiated 15 years earlier.

OR 4: Choice of second-line therapies and beyond in colorectal cancer by liquid biopsy

As part of the project the partners responsible for this objective, recruited patients and collected serial blood samples through venous sampling. Next, DNA was extracted from the tumor, then subjected to sequencing, and circulating free DNA (cfDNA) from the blood samples. Biomecular analyses were then performed on both the DNA obtained from the tumor tissue and the cfDNA. The sequencing analyses were performed through a technique known as Next-generation Sequencing (NGS), and the related bioinformatics analysis allowed for the identification of "trunk" mutations (i.e., mutations present in all regions of the tumor) or "driver" mutations (i.e., mutations responsible for the tumor phenotype and possible resistance to molecularly targeted therapies) in specific genes in the patient's tumor tissue. Through ddPCR (droplet digital PCR), a highly sensitive DNA quantification technique, the same trunk/driver mutations were sought in the cfDNA of the same patients. The quantification of cfDNA in blood by liquid biopsy, as a diagnostic, noninvasive, highly sensitive and repeatable test, therefore makes it possible to follow the progress of the disease and the response to therapies. In fact, for some of the patients, included in these analyses, the use of clinical biopsy allowed prediction of clinical disease progression. The data from this project confirm the possibility of clinical application of liquid biopsy to define the prognosis and treatment of colorectal cancer.

OR 5: Development of innovative cell-based assays for screening new drugs or repositioning known drugs for mutations detected by liquid biopsy. Initially, the sensitivity to PARP inhibitors of some BRCA variants of unknown functional significance (VUS) will be tested.

This objective had two aims, on the one hand it wanted to help develop a methodology to functionally assess the significance of variants of unknown significance (VUS) of genes of genetic predisposition to cancer, and on the other hand to provide answers to problems related to therapies, particularly those using so-called PARP inhibitors. The latter base their efficacy on the presence of pathogenic variants in BRCA genes and thus could identify VUS responsive from VUS nonresponsive to this treatment. The problem of VUS is of particular importance in genetic counseling because the finding of such a situation does not allow any definitive diagnosis to be given. The strategy addressed by two partners in the project, involved for one partner the creation of engineered cellular models by genome editing (CRISP-CAS9), and in the course of the study, a new protocol with high transfection efficiency was developed for the functional characterization of VUS of BRCA genes. Using this methodology, 5 isogenic cell lines were constructed, the first termed Parental Line (MCF7 BRCAnull/BRCAwt or HAPLO) was obtained by deleting one of the two wt alleles of BRCA1. Subsequently, 5 mutations were generated from the latter by insertion into the residual BRCA1 locus, 3 with known pathogenicity class, 1 neutral and 1 VUS i.e., unknown significance. With this tool, represented by the coisogenic lines with only variant the different BRCA1 mutations, it will then be possible to test different approaches for the functional definition of a VUS.

In contrast, another line of research has achieved, in several cell lines chronically exposed to the drug, the conversion of the susceptibility phenotype to one of resistance to the treatment. This approach, in addition to highlighting genes and related pathways related to drug resistance phenomena, has enabled the identification of a number of molecules with "dual" activity capable of reversing resistance to Olaparib. Taken together, these results clearly indicate that co-targeting PARP with CDK or mTor inhibitors produce antagonistic effects. Conversely, as suggested by the activity of Gem122, a dual PARP/HDAC antagonist, the combination of PARP inhibitors with HDAC inhibitors might have therapeutic relevance that should be investigated at the clinical level.

Finally, the conclusion of the Project saw a formal moment on December 5, 2022, with a final meeting, which was actively attended by representatives of the Project's Operational Units, who, after a heartfelt appreciation for the coordination activities carried out by Cogentech, represented the desire to continue, even in a different form, the collaborations undertaken judged overall very positively.

Extension of Priam LAG

The innovative Priamo LAG (BCS) software, developed for managing laboratory activities, has been further implemented, with the creation of the Portal for Request Management (Priamo PGR), which allows physicians to fill out requests directly online, avoiding the sending of paper forms. It also allows referrals to be downloaded once available, making the flow of information faster and more secure. With the extension of Priamo LAG, Cogentech increases its flexibility and competitiveness in the public and private diagnostic market. At the same time, with a view to greater environmental sustainability, Priamo PGR enables a significant reduction in paper and ink consumption, indicative of a clear "digital transition" in Cogentech's business.

Development of an Oracle database for laboratory reagent management

The Quality Management system requires that documented information be constantly updated and monitored, which is why it was deemed necessary to develop a database that allows data to be stored, managed, and searched, so that the reagents ordered, those in stock, expiration dates are accurately kept track of, and it is also possible to quickly set up new order requests and track the use of each reagent's lot in protocols for diagnostic analysis.

The Oracle Reagent Database, after undergoing an internal validation process, was introduced into the laboratory routine on March 1, 2022. This database has allowed for greater efficiency in the management, control, and traceability of reagents used by the laboratory, as well as increased cybersecurity of data backup and operator access tracking.

Updating the database for quality data management (NGSource v.2)

The project includes the implementation of the NGSource computer system currently in use. This database makes it possible to bring together the quality parameters that are associated with molecular analyses performed using NGS (Next Generation Sequencing) methodology. It is therefore a fundamental tool for controlling some of the information that is necessary for UNI EN ISO 15189:2013 accredited laboratories, such as CGT Lab. The new version of NGSource is very efficient in handling high numbers of data and includes the possibility of easily entering results from different types of NGS panels currently in use by the laboratory.

Possible association between breast prosthetic implantation and development of anaplastic large cell lymphoma (BI-ALCL)

This Project commissioned by the Ministry of Health, was carried out in collaboration with ISS (Istituto Superiore di Sanità) / La Sapienza University and the European Institute of Oncology (IEO) and involved the Genomic Unit of Milan and the Bioinformatics Unit of the Cogentech laboratory in Catania.

The aim of the project was to investigate possible associations with a genetic risk factor in a case series of 82 subjects, including 41 who developed lymphoma following prosthesis implantation and 41 controls who, despite having prostheses, did not develop any disease. From blood samples, DNA was extracted and used for fragment library generation and very high processivity sequencing (NGS or Next Generation Sequencing) in order to identify germline (carried by 100% of cells) and somatic (carried by only a small fraction of cells) molecular alterations present in affected subjects and absent in healthy subjects that predispose to and participate in the pathogenesis of breast implant-associated anaplastic large cell lymphoma (BI-ALCL). The study ended and added to the analysis 17 saliva samples from subjects in whom the germline WES datum had been determined in blood cells. The results revealed a higher complexity than expected for a simple association and are being discussed between our units and that of Prof. DI Napoli (Uni "Sapienza"). The latter presented a preliminary analysis of our data at the Conference "National breast implant registry: A tool to improve patients' safety," held in Rome on 12/15/2022 at the Ministry of Health.

Identification of germline molecular alterations that may be a possible risk factor for non-small cell lung cancer (NCLC) in non-smoking subjects.

This Project was carried out in collaboration with INT (National Cancer Institute/Dr. Manuela Gariboldi) and involved the Genomic Unit of Milan and the Bioinformatics Unit of the Cogentech laboratory in Catania.

It was a retrospective study carried out on case series of 60 subjects who, despite being non-smokers ("never smokers") developed lung cancer (NSCLC) and was aimed at identifying germline molecular alterations (carried by 100% of the cells) that constitute risk factors and predispose to the onset of the disease. The study involved the search for and identification of germline mutations in the exonic portion of DNA (exome) that predispose to the development of the disease and was carried out by generation of fragment libraries and sequencing of the exonic portions at very high processivity (NGS or Next Generation Sequencing), followed by bioinformatic analysis of the data obtained. The latter indicated, confirming and extending data already in the literature in this type of patient, that pathogenic variants of genes involved directly or indirectly in tumor development can be identified in never-smokers who developed lung cancer. This indicates that germline pathogenic variants may be considered a risk factor for lung cancer suggesting that certain categories of patients with lung cancer should be considered eligible for germline molecular testing.

Molecular characterization of a clinical case of colon carcinoma with a de novo variant of the MLH1 gene

The study, in collaboration with the U.O Hereditary Tumors of the Digestive System " of the Fondazione IRCCS Istituto Nazionale dei Tumori (Milan), describes a young patient with colon cancer and presenting with de novo deletion of exon 6 of the MLH1 gene, identified by NGS and confirmed by Multiplex Ligation-dependent Probe Amplification (MLPA). MLH1 de novo variants are rare in the literature, so it was thought interesting to describe this particular clinical case.

Molecular analyses were conducted in the various available tissues using various methods. First, paternity and maternity were ascertained by STR analysis, and then the variant was analyzed by MLPA and quantified by digital-PCR, both on DNA extracted from peripheral blood, healthy tissue, and tumor tissue. Evaluation of informative SNPs of the MLH1 gene established that the chromosome on which the mutation occurred is paternally derived. Confirmation that the variant is de novo, its precise quantification, and identification of the chromosome of origin may help to better assess risk in the offspring and siblings of the proband.

The description of this case, which is intended to be published as rare, may be useful to the scientific community: it underscores the importance of not neglecting genetic testing for Lynch Syndrome in the absence of familiarity, if immunohistochemistry is found to be defective for one or more Mismatch Repair genes (MMR genes).

Goals for 2023

Iter for CGT Lab reclassification

The CGT Lab is part of the facilities accredited by the Lombardy Region to perform Medical Genetics examinations. In implementation of DGR No. XI/7044 of 09/26/2022 "Determinations regarding the organization of laboratory medicine services and related updating of specific authorization and accreditation requirements" and according to the corresponding implementing decree No. 2197 of 02/16/2023, the laboratory will follow the procedural process for reclassification as a "Specialist Laboratory of Medical Genetics with Molecular Genetics Area" and at the same time will provide for the fulfillment of the minimum requirements, according to the timelines imposed by the same DGR.

However, the laboratory is in a favorable position in that it has already implemented a Quality system according to the standards of UNI EN ISO 15189:2013, which are the basis for the requirements.

Pathway for compliance with EU Regulation 2017/46 on IVDRs for CGTLab Onco gene panels

The entry into force of the first part of the European IVDR Regulation (REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 5, 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Decision 2010/227/EU, has significantly changed the regulatory framework within which it is possible to perform in vitro diagnostic tests with instruments produced "in house" (IVD) as is the case with the OncoPan® and OncoPed panels that represent Cogentech's "core business." Therefore, the company, as a "health institution," has embarked on a path to comply with the General Safety Performance Requirements (GSPR) of Annex1 of this regulation by the end of 2023.

Implement predictive activity for the appropriateness of PARPi prescription

The introduction in our diagnostic offering of the new SOPHiA DDM™ Dx Homologous Recombination Deficiency Solution kit for the evaluation of genomic instability in ovarian cancers and the predictivity of response to PARP inhibitors, an offering made possible, as previously mentioned, by the recognition of CGTLab as a facility qualified to perform the aforementioned test, leads us to assume for 2023 an increase in diagnostic volumes in this area. This goal will be more easily achieved if, as desired by prescribers and patients, the prescription of the drug is expanded to other cancer pathologies such as triple-negative breast cancer and prostate cancers.

Implement diagnostic activity including the Polygenic Risk Score (PRS) for breast carcinomas.

As reported earlier, the development of the OncoPan® panel, which includes 313 SNPs that enable PRS calculation, is a significant example of Cogentech's Mission. Indeed, the latter combines a conventional diagnostic offering with an innovative one. Moreover, given the character of innovativeness that is awaiting full clinical validation, and consistent with the Company's Benefit format, this data is currently provided, upon request, free of charge to the customer. Clinical validation data from the European Union-funded MyPeBS international study of 85,000 women, aged 40 to 70 years, in 6 countries (Belgium, France, Israel, Italy, the United Kingdom, and Spain) which evaluates a new breast cancer screening strategy, including PRS calculation, should be released in 2023. We expect positive results from that study, with the goal of receiving a significant number of applications for PRS.

A small pilot project is also being planned to evaluate the PRS extracted from NGS data obtained with the OncoPan panel, applied, in a research setting, to a limited number of subjects (17/20) carrying a variant of uncertain significance (VUS) of the BRCA1 gene, belonging to different families, and showing significant phenotypic variability, in order to test whether this variability is possibly due to the effect of a different PRS value, suggestive of a different genetic background, in the different subjects analyzed.

The outcome of this pilot study will be the basis for promoting evaluation of the clinical utility of PRS for genetic risk personalization and subsequently proposing to specific entities a more extensive, retrospective or new-case, consortium-type research project, regarding a specific geographic area.

Development of the “holistic” liquid biopsy protocol

In the current year we aim to bring to a significant level of pre-clinical validation the protocol we have termed “holistic' liquid biopsy originally developed by the Catania Unit. This protocol uses cfDNA from a single collection to perform four different types of NGS analysis to intercept both epigenetic and genetic tumor-associated signals. The basic idea behind this approach is that, with integration through appropriate algorithms of the signals obtained and an analysis using AI tools, a limit of detection (LDR) of sufficient sensitivity can be obtained for cancer diagnosis in apparently healthy subjects.

Gene expression profile analysis of co-isogenic variants for BRCA 1 of the MCF-7 cell line

One of the products of the PON project carried out in Catania, Italy, was the construction of co-isogenic variants of the MCF-7 diploid breast cancer line for the normal BRCA1 gene. Through a “genome editing" methodology, variants were derived from the latter that no longer have the BRCA1 gene, have only one copy of it (haploid), or carry different variants with different BRCA1 significance. Originally these cells were used for in vitro sensitivity testing with PARPi. However, the difficulty of obtaining reproducible results did not allow this use. We now propose to use the same cells for an RNAseq analysis through which we hope to obtain useful information to better understand the functional role of this important gene in the genesis of hereditary forms of breast and ovarian cancer.

A quality service

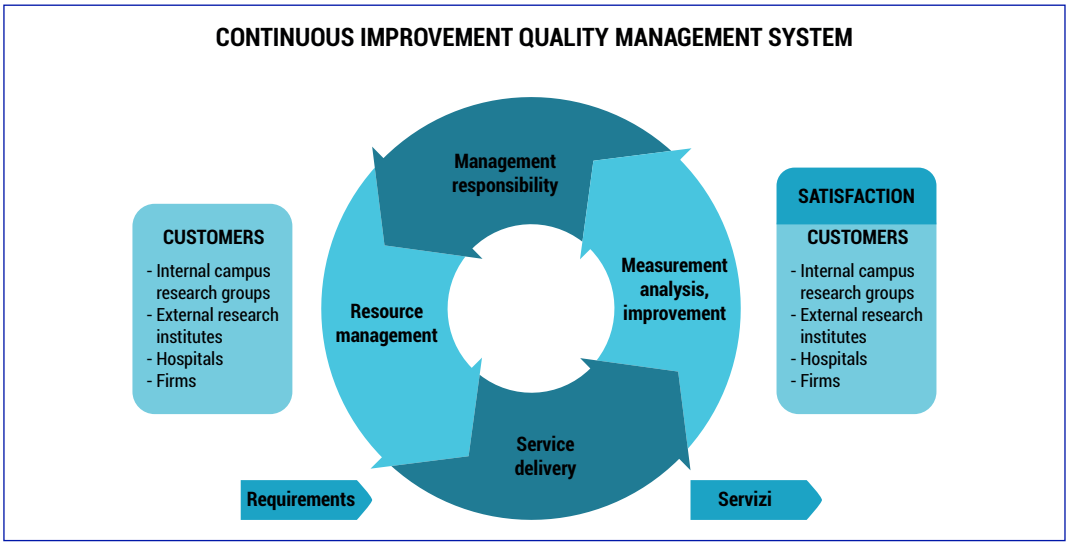
Cogentech has made Quality its strong point, which has the ultimate goal of achieving the satisfaction of its end users. Cogentech's Quality Policy is updated at least annually and is published on its website.

In an ever-changing environment, in order to provide quality service, Cogentech regularly reviews all its business processes and the ability to meet set goals according to customer needs.

Management is aware that the achievement of objectives is subject to a careful analysis of the context, the needs of stakeholders/customers, the risks associated with its activities, and the level of customer satisfaction. For this reason, it periodically analyzes all these elements and identifies improvement actions to be taken.

The quality management system, is experienced by all the operators of Cogentech. Each is aware of the importance of his or her own activity and how each contribution enables the company to achieve the improvement goals it has set for itself.

Cogentech's applied management system (QMS) has been certified and is consistent with the ISO 9001 standard. In addition, CGT Lab has also obtained certification issued by SIGUCERT and is accredited, with Accredia, for ISO 15189. Therefore, the performance of the lab and the entire company is constantly monitored.



Attention to customers' needs is constant: in fact, there is a concrete belief that a new opportunity for collaboration can arise from every interaction, which is of added value to society.

Cogentech stands as a reliable and customer-focused partner: the precise verification and interpretation of results, such as the issuance of reports, is done with the help of rigorous reference standards to which Cogentech itself contributes.

To achieve these high quality standards, Cogentech relies on a team of qualified, constantly updated, motivated, and improvement-oriented people who do not regard Quality as a formal requirement, but experience it as but a distinctive value.

Reliability and timeliness of services offered to clients is certainly one of Cogentech's values. These characteristics are even more relevant in the healthcare field: in this context, delaying the delivery of a report could negatively affect the administration of a therapeutic treatment and, therefore, impact the patient's health.

Therefore, CGT Lab, in accordance with the quality management system, has developed indicators that constantly monitor its performance, with the aim of delivering the correct, complete diagnosis to the client within the contracted timeframe.

On the other hand, even in Scientific Research it is essential to have a reliable, reproducible and correctly interpreted data.

In a context that presents a complex scientific problem, where the sample to be analyzed is valuable and the technique to be applied is highly sophisticated, the most convenient choice for the client is to rely on a highly specialized facility, such as those of Cogentech, equipped with advanced, validated and certified protocols.

The quality of the services offered by Cogentech is guaranteed by several awards obtained over the years. Prominent among them is the UNI EN ISO 9001:2015 certification, issued by Bureau Veritas Italia spa on 08/08/2017 (Certificate No IT256850) and renewed on 24/08/2020, attesting the compliance of the following services: Cancer Genetic Test Lab (CGT Lab), Sequencing Service, QPCR Service, Microarray Service, Mouse Facility, Histopathology Service.

In June 2022, Cogentech, as part of the Maintenance Visit of the UNI EN ISO 9001: 2015 Certification, extended the Scope of Certification to the Training provided for the qualification and technical-scientific updating of researchers, professionals and specialists.

Cogentech, as a Benefit Society, has always been aware that TRAINING, and thus the transfer of COMPETENCES, is a strategic element with positive effects not only on the individual and the group to which he or she belongs, but also on the Community. The goal achieved, therefore, is to provide effective, tracked and, above all, Quality training.

The CGT Lab, since 2011 has been accredited with the National Health Service (Resolution No. 929 ASL Milan) and is registered in the Regional Register of Accredited Facilities (registration No. 1118) in the sub-branch of Cytogenetics and Medical Genetics for Molecular Genetics activities.

Since 2015, CGT Lab has also obtained SIGUCERT No. IT282620 certification from the Italian Society of Human Genetics. Finally, in 2019, CGT Lab achieved another milestone: UNI EN ISO 15189:2013 accreditation by ACCREDIA (number 0015M) for Medical Genetics examinations, with a large number of accredited examinations in Flexible Field.

Cogentech is a laboratory accredited by ACCREDIA, the national body that periodically verifies its technical and management competence according to the criteria of UNI EN ISO 15189:2013 and ACCREDIA's additional specifications. This is what CGT Lab's Service Charter also states, with which Cogentech is committed to meeting its obligations under the agreement.

After the successful conclusion of the Biligect Project (PON), the IFOM Sole Partner decided to fund the Catania branch of Cogentech while maintaining the project focused on the liquid biopsy technique. The Catania laboratory, in addition to representing an opportunity for the area, constitutes the beginning of Cogentech's establishment in new geographical areas, both for scientific services and for possible future developments in diagnostics. In late 2022 and early 2023, steps are being outlined for an extension of ISO9001 certification to the Catania laboratories.

Finally, a project began in 2022 that will lead to the integration within the Cogentech QMS of everything necessary to justify the use of a LTD (Laboratory Test Developed) such as OncoPan and OncoPed, within a Health Institution. In fact, the EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices IVDR, places obligations on Health institutions, such as Cogentech, in verifying the requirements of the regulation.

People at the center

Cogentech is a company that puts people at the center, ensuring their safety, professionalism and well-being. Our goal is to create a cohesive and motivated team, in which everyone feels an integral part of a common project and knows how to contribute with competence and enthusiasm. This allows us to offer quality services in line with the highest industry standards.

In our Code of Ethics, we reaffirm our commitment to fostering a climate of respect and dignity among all employees. We reject any form of discrimination, psychological violence or sexual harassment, and we call for behavior and speech that respects the sensitivities of others. Anyone who feels victimized or witnesses such situations can contact the Supervisory Board, which will assess the situation and take appropriate measures. In 2022, as in 2021, we received no such reports.

As of December 31, 2022, Cogentech has 39 employees, 1 more than in 2021. The workforce is predominantly composed of women (61.5%) and young workers, aged between 30 and 50 (61.5%). Out of 39 employees, 34 have permanent contracts (14 men and 20 women) and 5 have fixed-term contracts (1 man and 4 women). Only one employee (female) is part time. Cogentech also employed 5 non-employee workers during 2022, including 1 professional collaborator, 2 co.co.s and 2 interns . 99% of Cogentech's workers have full-time contracts.

Cogentech employees broken down by sex and gender	2022				
	Total	Men		Women	
		n	%	n	%
Undetermined	34	14	93%	20	83%
Determined	5	1	7%	4	17%
Total	**39**	**15**		**24**	

Cogentech employees broken down by sex and gender	2022				
	Total	Men		Women	
		n	%	n	%
Full-time	38	15	100%	23	96%
Part-time	1	0	0%	1	4%
Total	**39**	**15**		**24**	

Non-employee workers	2022		
	Total	Men	Women
<30	1	0	1
30-50	1	1	0
>50	3	2	1
Totale	**5**	**3**	**2**

Employees by role	UoM	Men			Woamen		
31.12.2022		<30	30-50	>50	<30	30-50	>50
Manager	n.	0	1	2	0	1	2
Employees	n.	1	10	1	5	11	4
Workers	n.	0	0	0	0	1	0
Total	**n.**	**1**	**11**	**3**	**5**	**13**	**6**

31.12.2022	UoM	Men	Women	<30	30-50	>50	
Manager	%	50,0%	50,0%	0,0%	33,3%	66,7%	2
Employees	%	37,5%	62,5%	18,8%	65,6%	15,6%	4
Workers	%	0,0%	100,0%	0,0%	100,0%	0,0%	0
Total	**%**	**38,5%**	**61,5%**	**15,4%**	**61,5%**	**23,1%**	**6**

Reading guide:
- The data shown represent a snapshot of the workforce as of Dec. 31, 2022
- Total number of employees" refers to the number in headcount, not just full-time employees.
- Total number of employees" does not take into account any interns, apprentices, self-employed persons and additional other workers who are not part of the organization (e.g., suppliers).

The development of human capital

Cogentech encourages and supports its Personnel to pursue continuous and qualified professional development, at every stage of their working career and in every area of expertise. Indeed, Cogentech's Management recognizes that the advancement and innovation of its Human Capital is fundamental to the improvement and definition of new strategies, both in research and in diagnostics. This vision translates into management practices aimed at fostering integration among different functions and professions, valuing and rewarding individual contributions, and promoting professional growth.

Cogentech worker training

Employee development consists of a process that enables all workers to harmonize their tasks and aptitudes with the improvement of pre-existing skills and the acquisition of new skills that promote work effectiveness and efficiency. Training sessions are also a valuable opportunity to listen to the contributions and ideas of each individual worker and, above all, to strengthen the relationship between worker and Company.

Cogentech's staff training takes place through different channels: some courses are managed internally by Human Resources, Safety Management, Quality Office or Facilities, while others are outsourced to qualified external entities. Each course follows a formal mode that involves recording attendance and, in some cases, also a final test and the issuance of a certificate. Cogentech employees are required to attend both legally required courses (e.g., CME) and optional courses organized internally, depending on their role in the Organization and the area of expertise they belong to.

Below is a table showing the average hours of training, broken down by job category and gender, provided during 2022 to all internal Cogentech employees, overall slightly up from 2021:

Average hours of training	UoM	2022		
		Men	Women	Total
Manager	h	57,67	60,00	58,83
Employees	h	11,17	23,30	18,75
Workers	h	n.a.	17,00	17,00
Total	**h**	**20,47**	**27,63**	**24,87**

Staff training is a key aspect of Cogentech's operations and is planned annually by each facility and office according to their needs. Facility managers are responsible for organizing in-house courses covering facility access, use of laboratory instruments, and occupational safety. Facilities that have obtained ISO9001 certification must also provide specific courses for quality maintenance. CGT Lab, being a health care facility, must also comply with the training requirements of the CME (Continuing Medical Education) regulations, which ensure that physicians keep up to date professionally. In addition, to foster a collaborative and transparent working environment, training events are offered on topics of general interest such as, for example, waste management and Quality Management System.

Training courses provided to employees

Training courses provided to employees	Uom	Total
Modello di Organizzazione e Gestione 231	h	0
Corsi in ambito Salute e Sicurezza	h	216
Corso Privacy (196/2003)	h	0
Corso per Certificazione Qualità	h	7
Corsi di formazione professionale specifica	h	747
Total hours	**h**	**970**

The IFOM-Cogentech campus offers the opportunity to attend seminars of high scientific and technological quality, given by internationally renowned speakers in the field of research. In 2022 there were 9 such seminars organized by SEMM (European School of Molecular Medicine).

Training delivered by Cogentech personnel

Mouse genetics

Below is the table containing the training courses provided by Mouse Genetics staff (online, in-person or blended modes).

The first three courses cover access to the facility and continuing education within the ISO 9001:2015 system. The other courses are organized by the Guido Bernardini Foundation, a nonprofit, independent organization that aims to disseminate education in laboratory animal science, contributing to the spread of the 3Rs principle, namely Replace, Reduce & Refiniment.

In short, it is the principle taken up by the European legislation that Legislative Decree 04/03/2014, whereby for animal experimentation the need for animal use, the numerosity and the model to be used must always be carefully justified. The head of Mouse Genetics is among the Foundation's historical faculty. In 2020 there were 378 hours of training organized with the Bernardini Foundation, in 2021 there were as many as 822.5 and in 2022 there were 860 going to underscore the staff's commitment to publicizing the proper and ethical use of animals for experimental purposes. Overall, in 2022, Mouse Genetics devoted as many as 1371.5 hours to training delivery.

Training courses provided by Mouse Genetics staff	Uom	Disbursement mode		2022
		Online	In presence	
Animal house access course	h	X	X	145
Course "What should you know about your rodent facility?"	h	X	-	260
Course "Introduction to microbiological monitoring in rodents facilities"	h	X	-	136
Course "Autoclave use and cart handling in the Building 13 animal house"	h	nd	x	4,5
Practical course for the use of gaseous anesthesia	h	-	x	33,75
Update practical course for the use of gaseous anesthesia	h	-	x	2
Course for executing queries entered into the Stilton database	h	x	-	5
Entering requests into the Stilton database	h	x	-	43
Explanatory seminar on training of personnel involved in the use of animals for scientific purposes for project managers (PIs), procedure managers and other senior staff	h	x	-	74
Explanatory seminar on training of personnel involved in the use of animals for scientific purposes for personnel involved in research projects covering the role of experiment performers	h	x	-	94
Training day on functional and organizational aspects of a rodent enclosure	h	-	x	90
Introductory internship training: theoretical foundations	h	x	-	14
Introductory internship training: practical aspects	h	x	-	6,25
Cleansing and decontamination: State of the art, innovative approaches, and challenges in laboratory animal facilities	h	x	-	304
Managing a gnotobiotic rodents facility: tools and challenges	h	x	-	160
Total training hours provided externally	**h**			**1371,5**

The protection of health and safety

Cogentech has made occupational safety one of its core values, committing itself to spreading and strengthening the culture of prevention, raising employees' awareness of the risks existing in the work environment, and encouraging virtuous behavior by all.

Cogentech guarantees all its employees a safe, comfortable, clean and orderly working environment in full compliance with current regulations.

Workplace safety, however, is not just a matter of rules to be observed: it is above all a matter of shared responsibility. Cogentech workers, in fact, are key players in corporate safety. When faced with a potentially dangerous situation ("near miss"), everyone is aware of the importance of promptly reporting what has been observed, in order to be able to take all necessary actions to prevent similar situations from occurring, thus helping to create a safer workplace every day. The Prevention and Protection Service, which assesses and manages the risks present in the company, is composed of easily contactable people, whom all workers can contact at any time, in person or via dedicated e-mail.

Occupational safety is a priority for IFOM and Cogentech, which can count on a qualified and competent team of professionals. The team includes RSPPs, ASPPs, Medical Officer and Safety Managers, as well as RLSs who are experienced and knowledgeable about the conditions and hazards of the various environments. They are joined by Supervisors carefully selected by the LOD, who carry out their role conscientiously and responsibly.

To deal with emergency situations, there is a large Emergency Response Team, consisting of staff distributed equally between IFOM and Cogentech buildings.

During the year 2022, the Campus Emergency Plan was updated, which was followed by the organization of a fire drill aimed at testing the new procedures, on which the Emergency Team was preliminarily trained.

The Evacuation Test was also carried out jointly with IFOM and IEO; thus, communication effectiveness, operational readiness, intervention mode, and coordination among the teams were tested.

The large number of staff and their widespread deployment ensured that the test ran efficiently, quickly and orderly.

During 2022, out of 64730.23 hours worked (both in the Milan office and at the local unit in Catania), there were no accidents at work or commuting accidents.

Only one near miss and one accident were recorded.

In 2022, Cogentech expanded the functionality of the company's intranet, which already housed the Safety Sheets and Procedures (Safety Space). Here one can find all the information, procedures and documents needed to deal with the various scenarios that may arise. Applications have also been developed that allow easy access to documents and quick registration of the use of hazardous substances.

Workplace safety is a priority for Cogentech, and we want it to be a priority for employees and researchers as well. That's why Cogentech offers ongoing, interactive training where everyone is invited to actively participate with questions and comments on the topics covered. The training is based on creative examples, photos, and videos that show you real situations close to your daily experience as a researcher.

The CLP (Classification, Labeling and Packaging of Substances and Mixtures) Regulation has helped ensure effective and responsible chemical risk management. Each internally prepared solution has been labeled with pictograms indicating the hazards of the substance, and equipped with a QR code that allows the operator to easily access the composition information and MSDSs of the solution components using their cell phone.

Welfare: beyond the laboratory

Cogentech cares about the health and safety of its employees not only at work, but also in their daily lives. For this reason, management has launched several initiatives over the years that aim to help improve the quality of life by encouraging healthy and sustainable lifestyles.

The needs of Cogentech's workers are different depending on their situations and experiences: as they are largely young, a number of initiatives have been devised to promote work-life balance.

Social initiatives for employees' families

Cogentech's priority is to continuously improve the quality and competitiveness of its service to meet the challenges of changing markets. At the same time, management is committed to creating a positive work climate that fosters a balance between the social, family and cultural needs of its professionals and their work needs. To this end, several initiatives have been launched to promote the well-being of workers and their families.

Lab G

A safe laboratory for mothers-to-be: this is "Lab G," an innovative initiative by IFOM and Cogentech that offers pregnant and lactating women the opportunity to continue their research activities without risk to their own health or that of their baby. The "Lab G" is in fact a work environment free of any substance, physical or biological agent that could be harmful or incompatible with the condition of motherhood. This is a unique project that demonstrates IFOM and Cogentech's attention and sensitivity to the needs of female workers in a delicate phase of their lives. "Lab G" thus allows "mothers" to reconcile their professional and family roles, providing them with serenity and security throughout the pregnancy and breastfeeding period. During 2022, no one used Lab G.

Corporate nursery

A quality service for toddlers and their parents: this is the bilingual corporate crèche offered by Cogentech to employees with children between 11 and 36 months. In this cozy and safe space, children can learn two languages from an early age and benefit from an innovative educational method that includes music and nutrition education as tools for growth.

The nursery is located near Cogentech's headquarters and is open from September to July with flexible hours (8:30 a.m. to 6:30 p.m.) to meet the diverse needs of workers, facilitating work-life balance.

Cogentech also contributes to the payment of the monthly fee, giving concrete economic help to families. Parents who have taken advantage of this service have been able to carry out their work activities, in attendance or remotely, with the peace of mind of knowing their children are being cared for by qualified and competent staff.

Flexible schedule

Cogentech has always paid attention to the work-family balance and, for this reason, has long introduced a flexible schedule regime. Both scientific and administrative employees can take advantage of flexible hours, both at the beginning and end of the working day and during working hours, so that they can better balance professional needs with personal and family needs.

Solidarity time bank

In compliance with the Jobs Act (Art. 24 Legislative Decree 151/2015) and in line with its Corporate Social Responsibility actions, IFOM and Cogentech have adopted a new Welfare measure that expresses an innovative vision of the Institute's internal relations, fostering dynamics of solidarity and mutual support, for the benefit of workers who find themselves dealing with complex situations of balancing family and work. This is the Solidarity Time Bank initiative: employees can surrender days or hours of unused vacation and leave to colleagues in need, who are forced to stay away from work due to heavy family demands, such as caring for a sick minor child or an elderly and needy parent or other serious problems in the household. In this way, those who offer hours to the solidarity time bank give a colleague a chance to cope with their own difficult family circumstances with greater peace of mind.

Life insurance

Cogentech has decided to offer all its employees an advantageous benefit, paid for entirely by Cogentech, which consists of a life insurance policy. This policy ensures, for as long as the employee works for Cogentech, the payment of an indemnity to his or her legal or testamentary heirs in the event of death for any reason.

Internal CAF service

A free in-house CAF service is one of the initiatives that Cogentech has been offering for a number of years to all those who work in the company, either as direct employees or external contractors. It is a unique opportunity to receive qualified and personalized tax assistance without incurring any cost. The internal CAF service is also extended to family members of employees and contractors, who can take advantage of it by paying a symbolic and advantageous fee. This is a way to demonstrate Cogentech's proximity and attention to the needs and welfare of all its staff and their families.

Employee wellness initiatives

Healthy eating

One way to counter the risk of cancer is to follow a balanced and diverse diet that emphasizes fresh, quality produce, such as fruits and vegetables, grains, and legumes. This principle is well known to Cogentech, which is dedicated to the diagnosis and development of therapeutic solutions for this disease. For this reason, in the company cafeteria areas, Cogentech offers employees, co-workers and guests a menu that is as varied, healthy and suitable for different dietary needs as possible.

Fitness

Regular physical activity, along with proper nutrition, is a key ingredient for good health of the individual. In order to also meet the physical well-being of its workers, IFOM and Cogentech have therefore entered into an agreement with a number of gyms in order to allow each person to identify the most suitable activity, at the most convenient time.

Psychological counseling

The pandemic has strained the mental health of workers, who have faced isolation, distant communication and confusion between personal and professional spheres. For this reason, companies have a duty to offer their employees opportunities to take care of their mental and physical balance. In fact, work is an essential aspect of our existence, and the emotions we experience at work also affect our family life. In order to meet the diverse needs of all staff, IFOM and Cogentech have for the past two years entered into agreements with a psychologist's office and an online psychology start-up.

Smoking free

The health of the cardiovascular system and lung cancer prevention are threatened by smoking, both active and passive. For this reason, Cogentech and IFOM, who care about Social Responsibility in this area, have joined World NO Tobacco Day (June 3, 2019) by making all spaces smoke-free. This initiative, continued in 2022, fits into IFOM and Cogentech's mission of research and care, and is intended to be a signal of awareness and involvement to improve air quality and the well-being of all workers and visitors to our Institute.

Medical Service

A company medical assistance service is available to all employees who request it. This initiative is designed primarily to meet the needs of employees who work outside the main office and have greater difficulty in contacting their own medical doctor. However, the service is open to anyone who wants to take advantage of the expertise and professionalism of the company doctor.

Vaccination campaign

An important health prevention initiative was carried out by IFOM and Cogentech, thanks to the collaboration of the Company Physician, which allowed all employees to be offered free flu vaccination. This Flu Vaccination Campaign was a great success, involving 11 Cogentech workers in 2022. It is a gesture of individual and collective responsibility, helping to protect their own health and the health of others, especially in a time of health emergency such as the current one.

Security Service and NightTime Taxi

Cogentech is concerned about the safety of its employees who end their workday between 7 p.m. and 10 p.m. For this reason, it provides the security service, which is located at the Front Desk, to accompany workers to the parking lot or to remotely monitor their route through the video surveillance cameras. In addition, for the exceptional situations when employees have to leave the Institute after 10 p.m., Cogentech offers the possibility of using a cab voucher.

Our valuable relationships

Cogentech is a Benefit Corporation, which is a type of business that not only pursues profit, but also aims to create value for the community and the environment. Cogentech operates in the field of biomedical research and offers quality services to its clients, with whom it establishes relationships of trust and collaboration.

But Cogentech goes beyond its core business and is committed to supporting initiatives of common benefit in a variety of areas, from science popularization to civic education. Cogentech also cares about protecting the environment and seeks to minimize the impact of its production processes by effectively managing the disposal of special waste and limiting plastic consumption.

Clients

Cogentech attaches paramount importance to its customers and their level of satisfaction. Cogentech staff know that every interaction can be an opportunity for learning and development, which can generate new possibilities. For this reason, Cogentech is dedicated to building a quality relationship with customers, based on attention and dialogue, which is essential to consolidate the continuous improvement process that Cogentech intends to follow.

Cogentech considers it a priority to establish a partnership based on trust with all its clients, given the sensitive nature of the services it offers. For this reason, Cogentech strives every day to put customers and their needs first, in order to understand them and offer the most appropriate solution, in accordance with the highest quality standards, the values that guide it and its Mission.

Cogentech's staff is attentive, helpful and cooperative. When it receives suggestions or comments from customers, Cogentech values them and uses them as an additional stimulus to vigorously pursue a path of constant research and innovation. In the area of scientific research, Cogentech has developed fruitful cooperation with Research Centers and Universities, producing innovations and related publications. In the field of diagnostics, on the other hand, Cogentech has established fruitful relationships with hospitals, large and small, in the public and private sectors.

Cogentech is distinguished by the expertise of its staff and the quality of the services it provides to its clients, with whom it collaborates to create innovative clinical offerings tailored to different diagnostic needs. During 2022 we carried out major projects and collaborations in different areas, even reaching the successful conclusion of the PON project “BiLiGect.”

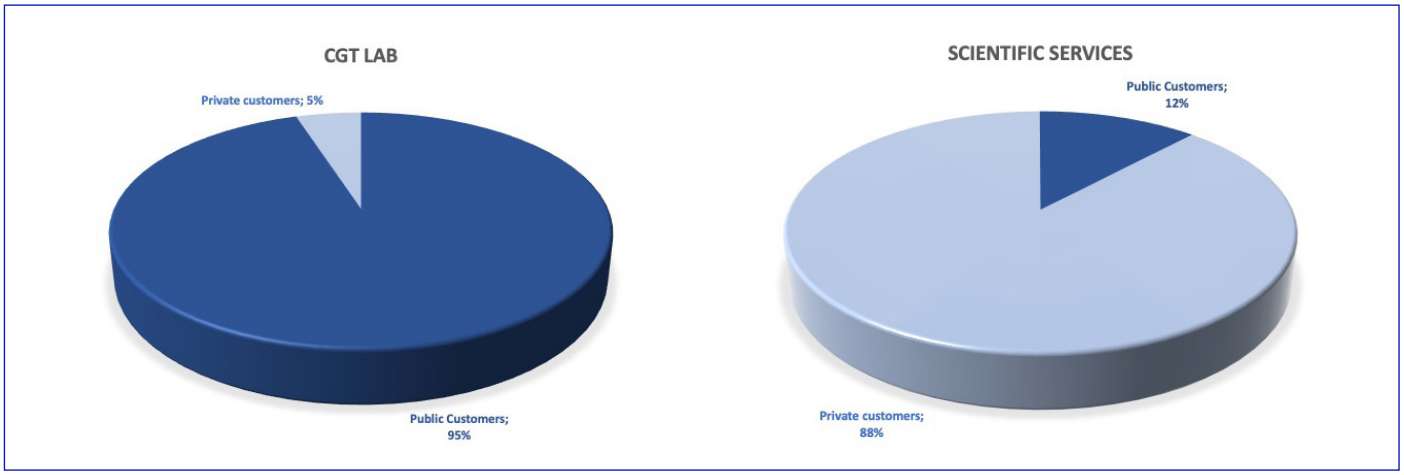
The professional relationships that Cogentech has established with its clients over the years can be analyzed from different perspectives. There are basically four categories of stakeholders to whom Cogentech offers its contribution:

- Clinical Institutes
- Intramural academic clients
- External academic clients

Business customers

Customers can then be divided between public and private and based on the service they require. In 2022, in particular, private customers covered more than 43 percent of Cogentech's revenue, compared to 53.5 percent in 2021.

Looking instead at the breakdown based on the type of service requested, Scientific Services are mainly requested by Private Clients (78 percent) while the demand for CGT Lab Genetic Testing comes mainly from public sector operators (94 percent).



A key element in assessing Cogentech's achievements is the level of satisfaction of customers who use its services. To measure this, Cogentech sends annual "evaluation questionnaires" to clients that collect their opinions and impressions. Analysis of the feedback received allows Cogentech to identify possible areas for improvement and to activate the necessary actions to increase stakeholder satisfaction. In addition, customer feedback is a key component in assessing the effectiveness of updating activities and seeking new opportunities to implement the portfolio of offerings, both for scientific services and for the CGT Lab genetic testing laboratory. Cogentech views customer feedback as a valuable opportunity to proactively define its best offering.

Cogentech is committed to ensuring the quality of its system and processes through a series of indicators that measure their functioning and effectiveness. These indicators are developed by the Quality Management System and are periodically evaluated by Management as part of the Annual Review. On this occasion, the Management critically examines the results obtained and identifies possible actions for improvement in order to offer its customers an increasingly accurate, timely and reliable service based on a relationship of trust and cooperation.

Below is a brief example of the indicators analyzed:

- Response time
- Complaints received
- Outcome of the evaluation questionnaires

Given the peculiarities of Cogentech's different facilities and the different services respectively offered, customer response times vary widely. Despite the different timelines related to the specific testing activities to be performed, it is possible to say that on average, during 2022, about 98 percent of the tests performed and services delivered were completed on time.

The average value of the customer satisfaction index, obtained as a result of the administration of Survey 2022, regarding the services offered by Cogentech, was 9.16 out of a maximum score of 10, continuously improving since 2019. This is an average score, obtained by reworking the scores for facilities that are certified and have a Quality Management System.

	2020	2021	2022
Average annual score	9,03	9,13	9,16

Customers of the scientific services participated in the analysis by accessing an online Survey, via a special link, while CGT Lab customers received the Customer Satisfaction Questionnaire via e-mail. In both cases, customers were asked to express their opinions with absolute impartiality and objectivity since the answers provided were received anonymously and their analysis was done only in aggregate. The results obtained are shared with all operators so that the culture of Quality is spread at all levels and can be constantly nurtured.

In CGT Lab's service charter, it is again emphasized that the complaints received are the starting point for encouraging actions to improve the services offered, involving all operators. Therefore, a complaint procedure has been set up that involves the Service Managers, who are called to report about the event encountered, thus enabling the implementation of effective corrective actions (and to study further preventive actions, to avoid the recurrence of the critical issue encountered) and to then provide a clarifying response to solve the problem, in the shortest possible time. Out of a total of 2670 genetic tests analyzed in 2022, no reports of Non-Compliance or Complaints were received. Similarly, no complaints had been observed in 2021, 2020, and 2019.

The communities in which we operate

Cultural events

From October 6 to 9, 2022, Cogentech participated in partnership with IFOM in the fifth edition of Milan Digital Week 2022, Europe's largest event dedicated to digital education, culture, and innovation promoted by the City of Milan and realized by IAB Italia, Cariplo factory, and Hublab.

The initiative proposed by IFOM and Cogentech and approved by the Digital Week organizing committee, entitled "Genetic predisposition to cancer: the challenges of research," consisted of a lecture on genetic predisposition to breast cancer and the prospects that research opens up conducted by researcher Paolo Peterlongo and an exclusive guided tour of Cogentech's laboratories, genetic testing unit, conducted by researchers Valeria Pensotti, Sara Volorio and Giovanna De Vecchi.

Scientific conferences

From September 21 to 30, Cogentech participated in Expolab 2022, the scientific event showcase that brings together companies, researchers and users in the fields of biotechnology, chemistry and health. The initiative, based in Catania, featured Cogentech with no less than three speakers from the Catania office team: Maria Carmela Di Rosa, Alessandro Gulino and Domenico Scionti. It was a valuable opportunity to share the activities carried out in the Cogentech laboratories in Catania as part of the BiLiGeCT project, the innovative techniques and advanced technologies with which the team faces the scientific reality in the Sicilian territory. Di Rosa showcased new approaches for the study of methylation profiles from liquid biopsy, Scionti spoke about molecular biology techniques for the diagnosis and clinical follow-up of ovarian and breast cancer patients, and Gulino led the audience in the exploration of a new strategy for cancer diagnostics: the laser microdisector.

Communication

In September 2022, Marco Alessandro Pierotti, head of the CGT lab and R&D department at Cogentech, was interviewed by Ian Mundell in Science Business, a European publication aimed at advancing innovation by bringing together universities, companies, research organizations, and policymakers in the light of a solid understanding of European policies to analyze and point the way forward. Pierotti's in-depth interview was on the risks of the US monopoly on genetic testing, offering a concrete analysis and repositioning of risk priorities in this area.

Solidarity events

Also in 2022, Cogentech participated in the traditional IFOM Toys & Clothes Collection solidarity initiative promoted by IFOM in favor of people in need. The initiative, which saw a wide participation of Cogentech employees and collaborators as donors and as volunteers, collected 5 pallets of toys and clothes that were donated to Opera Cardinal Ferrari Onlus and Fata Onlus.

The environment around us

Cogentech regards the environment as a priority: the Company strives to protect it, not only by complying with current legislation, but also by taking into account advances in scientific research and the best experiences in the field. To this end, Cogentech seeks to direct its choices and manage its activities in such a way as to ensure a balance between economic initiatives and environmental needs. Thus, Cogentech cares about the environment and is increasingly manifesting its willingness to adopt environmental sustainability measures, in line with its institutional mission and the goals of the 2030 Agenda for Sustainable Development.

This commitment has always been embodied in virtuous waste management practices: Glass, Plastic and Paper are constantly sorted and disposed of with AMSA.

Special attention is then paid to the management of Special Waste, most of which comes from laboratories.

During 2022, of the approximately 27 tons of special waste produced, almost all of it belongs to the "hazardous" category. Compared to the previous year, there has been a 15.7 percent reduction in waste production: this is mainly due to the proper differentiation between the special waste fraction and municipal waste (in favor of the "urban" fraction).

Destinazione Rifiuti	UoM	2022		
		Non-hazardous waste	Hazardous waste	Total waste produced
Waste not landfilled1	ton	0,65	12,25	12,90
Waste sent to landfill2	ton	-	14,07	14,07
Total waste produced	**ton**	**0,65**	**26,32**	**26,97**

A scientific activity such as Cogentech's involves the generation of waste that requires careful and responsible management and disposal. To ensure safety and respect for the environment, Cogentech relies on a licensed transporter to pick up hazardous waste in accordance with current regulations. In fact, these wastes could cause harm to human health or the ecosystem if not handled with proper precautions. For this reason, Cogentech follows the provisions of the ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road), using approved containers and appropriate labels, to minimize risks throughout the logistics chain. In addition, waste handlers receive periodic specific training in which issues related to waste management are covered in depth.

The waste classification system adopted by Cogentech and IFOM to facilitate the work of laboratory operators is an innovative approach that relies on the use of colored labels with specific indications and symbols to help researchers identify and properly handle each type of waste. The waste is then entrusted to qualified and licensed hazardous waste transport companies. The main contractor handling the collection, transportation, and disposal of special waste has earned several ISO certifications (ISO 9001, ISO 14001, and ISO 45001), which can be viewed on the contractor's website.

Plastic Free Project

With respect to the environment, Cogentech continued to undertake the "Plastic free project" in 2022 geared toward reducing plastic consumption at the site. Cogentech continues to pursue the reduction of purchases of single-use or non-recyclable plastic products, and incentivizes the purchase of products with PSV (plastic second life) certifications.

RiVending project: "glass-to-glass" recycling

In the context of a constant quest for quality, as early as 2021 IFOM decided to participate in the RiVending Project (www.rivending.eu), which is currently implementing an innovative plastic waste management system. The goal is to recover and recycle plastic cups and scoops used by vending machines by separating and collecting them separately. For this reason, next to each vending machine, in the break areas also frequented by Cogentech employees, a special container has been installed that allows the cups to be placed one inside the other. This results in a reduction of the space occupied, compared to traditional collection, by more than 150%. This is an environmentally friendly and responsible initiative that demonstrates IFOM and Cogentech's commitment to environmental protection and sustainability.

Our RiVending program is an innovative and sustainable solution for recycling used cups in vending machines.

Through this program, we are able to transform Styrofoam cups into new, high-quality cups, thus helping to create a circular economy in the industry. RiVending is a "zero-waste" program because the plastic used is 100% washed and recycled, with no need to separate it from other plastics or subject it to polluting industrial washing. In this way, we reduce our environmental impact and save valuable resources.

Cogentech Publications 2022

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Indice dei contenuti GRI

Statement of Use	Cogentech has reported the information mentioned in this GRI content index for the period from January 1, 2022 to December 31, 2022 with reference to the GRI Standards (i.e., "with reference to the GRI Standards").			
Used GRI 1	GRI 1: Fundamental Principles - version 2021			
GRI Standards	**Disclosure**	**Location**		**Notes**
		Section	**Page number**	
General disclosures				
GRI 2: General Disclosures - version 2021	Disclosure 2-1 Organizational Details	Our history and mission statement	5	-
	Disclosure 2-2 Entities included in the organization's sustainability reporting	Our history and mission statement	5	The scope of reporting in this Report coincides with the scope of the Company's financial statements.
	Disclosure 2-3 Reporting period, frequency and point of contact	Methodological note	4	The reporting period of this Report corresponds to the period of the Company's financial statements. Reported points a. b. and d
	Disclosure 2-4 Review of information	n.a.		There are no reported revisions of information from previous periods of reporting
	Disclosure 2-5 External Assurance	-		Rendered point b.
	Disclosure 2-6 Activities, value chain and other business relationships	Our history and mission statement; The services we offer	5, 6	No substantial changes from the previous reporting period are reported.
	Disclosure 2-7 Employees	People at the center	24	All employees work in Italy.
	Disclosure 2-8 Non-employee workers	People at the center	24	
	Disclosure 2-22 Sustainable Development Strategy Statement	Letter from the President	3	
	Disclosure 2-29 Approach to stakeholder engagement.	Methodological note	4	Rendicounted point a.i.
Material themes				
GRI 3: Material Themes - version 2021	Disclosure 3-1 Process for determining material issues	Methodological note	4	-
	Disclosure 3-2 List of material topics	Methodological note	4	-
Material theme: Employee training and professional development				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	The development of human capital; Appendix	26,	-
GRI 404: Training and education - 2016 version	Disclosure 404-1 Average number of training hours per year per employee	The development of human capital	26	

Material theme: staff welfare				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	Welfare: beyond the lab; Employee welfare initiatives; Appendix	28, 30, 42	-
GRI 405: Diversity and equal opportunity - 2016 version	Disclosure 405-1 Diversity in governance bodies and among employees	The composition of corporate governance; People at the center	24, 5	
Material theme: Relationship with the community				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	The communities in which we operate; Appendix	34, 42	-
No GRI	Projects carried out for the benefit of the community	The communities in which we operate	34	-
Material theme: Customer satisfaction and service quality				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	A quality service; Our valuable relationships; Appendix	22, 31, 42	-
No GRI	Customer satisfaction index	Business customers	32	-
No GRI	Response provided to customers on time	Business customers	32	-
No GRI	Complaints received	Business customers	32	-
Material theme: Research and innovation				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	Scientific research and innovation; Appendix	14, 42	-
No GRI	Accomplished publications	Cogentech Publications 2022	37	-
No GRI	Investment in research and development	Scientific research and innovation	14	-

Material Theme: Environmental Sustainability				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	The environment around us; Appendix	35, 42	-
GRI 306: Waste - 2020 version.	Disclosure 306-1 Waste generation and significant waste-related impacts.	The environment around us	35	-
	Disclosure 306-2 Management of significant waste-related impacts.	The environment around us	35	
	Disclosure 306-3 Waste generated.	The environment around us	35	The data provided are for the quantities of special waste handled through the supplier. Municipal waste quantities are not included as they are not available.
	Disclosure 306-4 Waste not landfilled.	The environment around us	35	The data provided are for the quantities of special waste handled through the supplier. Municipal waste quantities are not included as they are not available. The cutaway provided in items i. ii. and iii. is not provided. All operations take place off-site.
	Disclosure 306-5 Waste sent to landfill.	The environment around us	35	The data provided are for the quantities of special waste handled through the supplier. Municipal waste quantities are not included as they are not available. The cutaway provided in items i. ii. iii. and iv. is not provided. All operations take place off-site.
Material theme: occupational health and safety				
GRI 3: Material Themes - version 2021	Disclosure 3-3 Management of Material Issues	The protection of health and safety; Appendix	28, 42	-
GRI 403: Health and safety - 2018 version.	Disclosure 403-2 Hazard identification, risk assessment and accident investigation	The protection of health and safety	28	-
	Disclosure 403-5 Occupational health and safety training for workers	The protection of health and safety	28	-
	Disclosure 403-6 Workers' health promotion	The protection of health and safety	28	
	Disclosure 403-9 Occupational Injuries	The protection of health and safety	28	Rendicounted point a.

APPENDIX

MATERIALITY ANALYSIS

MATERIAL THEME: RESEARCH AND INNOVATION	
Positive impacts generated, actual or potential	**Actions to help generate the positive impacts**
Impacts on the environment, people and the economy • To contribute to scientific and technological progress and its international competitiveness in the field of molecular diagnostics, with a focus on oncological diseases, which represent one of the major health challenges of our time • Support basic and applied research through the provision of innovative, reliable, and customized services and products that meet the needs of researchers and clinicians • Fostering the transfer of knowledge and skills between academia and industry, creating synergies and collaborations with public and private, national and international entities • Promote professional development of internal staff and clients through courses, seminars, workshops and other initiatives. • Generate economic and social value for the area in which it operates by creating skilled employment, supporting local activities and participating in corporate social responsibility projects	• Always ensure high quality of services and products provided, following recognized certification criteria and international standards • Invest in research and development to improve the performance of existing technologies and develop new diagnostic solutions • Enhance human capital by incentivizing continuing education, professional growth, organizational well-being, and the active participation of employees in decision-making processes • Establish transparent and collaborative relationships with internal and external stakeholders based on dialogue, respect, and shared values • Develop innovative, effective, and personalized diagnostic solutions for the prevention, diagnosis, and treatment of various diseases, particularly oncology
Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
Impacts on the environment, people and the economy • Produce special waste from laboratory activities • Causing breaches or losses of sensitive customer and patient data • Expose employees and contractors to possible stressors and occupational health and safety risks	• Continuously monitor the quality of services and products offered, through accredited certification systems and international standards • Comply with national and international regulations on ethics, health and safety, privacy and data protection • Actions to ensure proper and safe disposal of special waste • Devote resources to research and development to optimize existing technologies and create new diagnostic solutions
Impacts on the organization • Meeting the competitive challenges of the global market in terms of innovation and adaptation to customer needs and industry regulations.	

MATERIAL THEME: RELATIONSHIP WITH THE COMMUNITY	
Positive impacts generated, actual or potential	Actions to help generate the positive impacts
Impacts on the environment, people and the economy • Promoting the dissemination of scientific culture and raising awareness of public health and biomedical research issues through outreach initiatives • On the staff involved in the design and management of the initiative, increased awareness of the value produced and the ability to get involved in contexts other than the usual ones, also fostering the professional growth and well-being of employees • Promoting the value of solidarity to local subjects and the value of circular economy	• Enhances the dissemination and media results of corporate social media initiatives • Enhances human capital by encouraging the active participation of employees in project processes • Designs initiatives in order to renew commitment to the common good, in line with the values and goals to benefit the community characteristic of Benefit societies
Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
Impacts on the environment, people and the economy • Exposure of employees and contractors to possible stressors due to putting themselves in different than usual contexts	• Carefully coordinate internally communication processes and content sharing with Governance and staff in charge of communication • Enhances human capital by encouraging the active participation of employees in project processes • Provides hourly flexibility for employees who wish to participate in activities
Impacts on the organization • Exposure of research content to potential message distortion by media and message recipients • Allocation of time by employees on a volunteer basis	

MATERIAL THEME: ENVIRONMENTAL SUSTAINABILITY	
Positive impacts generated, actual or potential	**Actions to help generate the positive impacts**
Impacts on the environment, people and the economy • Reduced ecological footprint through recycling and material recovery • Involvement and awareness of employees and contractors toward a culture of sustainability	• Monitors periodically the quantities and types of waste generated and disposed of • Communicates internally and externally about its best practices and achievements • Participates in projects or initiatives to raise awareness or promote environmental sustainability
Impacts on the organization • Enhancement of Cogentech's image and reputation as a responsible and environmentally sensitive actor	
Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
Impacts on the environment, people and the economy • Environmental contamination by special waste	• Adopts waste prevention and source reduction criteria • Selects qualified and certified suppliers for special waste management • Trains and informs its employees and contractors on the rules and procedures to be followed
Impacts on the organization • Additional costs for separate management and treatment of special waste • Increased organizational and logistical complexity for waste collection and disposal • Possible civil or criminal penalties or liabilities for noncompliance with regulations or procedures	

MATERIAL THEME: A QUALITY SERVICE	
Positive impacts generated, actual or potential	Actions to help generate the positive impacts
Impacts on the environment, people and the economy • Increased customer trust and satisfaction	• Constantly monitors the level of customer satisfaction through periodic surveys and direct feedback • Transparently and timely communicates service quality achievements to clients, partners, and stakeholders (website articles and EMQN or VEQ results) • Participates in quality control programs in order to monitor laboratory performance and compare it with national standards • Periodically validates and verifies the analytical methods used to ensure reliability and reproducibility of results
Impacts on the organization • Increased customer loyalty, resulting in higher demand and greater profitability for the company • Increased credibility in the market, which helps attract new customers and partners • Increased competitiveness through the ability to offer state-of-the-art, standards-compliant services, thus having access to new markets and clients • Performance improvement through implementation of process-based management • Reducing waste through better resource management	
Negative impacts generated, actual or potential	Actions to mitigate negative impacts
Impacts on the environment, people and the economy • Increased pressure and stress for employees to meet high quality standards and meet customer expectations	• Carries out continuing education activities for staff involved in laboratory activities to ensure competence and professional development • Manages complaints and nonconformities in order to identify the causes of any critical issues and take necessary corrective action • Reviews the quality management system periodically in order to assess its operation and its adjustment to the set objectives • Implements continuous improvement processes in order to optimize resources and processes
Impacts on the organization • Need to invest in training and charges related to consulting and certifying bodies	

MATERIAL THEME: THE DEVELOPMENT OF HUMAN CAPITAL	
Positive impacts generated, actual or potential	**Actions to help generate the positive impacts**
Impacts on the environment, people and the economy • Improvement of technical and soft skills of employees • Enhancement of human resources and their potential	• Plans training activities annually based on strategic and operational priorities • Promotes effective and transparent internal communication about training opportunities • Involves employees in the design and implementation of courses • Recognizes and values the merits and skills acquired
Impacts on the organization • Increasing the quality of services offered to clients and patients • Development of corporate culture and sense of belonging • Prevention of risks and non-compliance	
Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
Impacts on the environment, people and the economy • Possible staff dissatisfaction as a result of misalignments between training needs and employee expectationsi	• Search for cost-effective and flexible training solutions (e.g., e-learning, webinars, etc.) • Periodically check the satisfaction and learning of employees • Collects and analyzes feedback and suggestions for continuous improvement • Implements initiatives to enable constant updating of the skills of internal and external trainers • Promotes integration between formal and informal training (e.g., mentoring, coaching, etc.)
Impacts on the organization • Economic and time costs of organizing and participating in courses	

MATERIAL THEME: THE PROTECTION OF HEALTH AND SAFETY	
Positive impacts generated, actual or potential	Actions to help generate the positive impacts
Impacts on the environment, people and the economy • Reduction of occupational injuries and illnesses • Improving the quality of life and well-being of workers	• Promotes a culture of prevention and safety at all company levels • Monitors and periodically evaluates the risks and preventive measures taken • Implements appropriate procedures, protocols, and individual and collective protective equipment • Involves and consults workers in establishing safety policies and practices • Implements information, awareness and training campaigns on health and safety issues • Puts great emphasis on compliance and incorporation, in business activities, of regulatory obligations and stakeholder expectations
Impacts on the organization • Increased productivity and operational efficiency • Strengthening the company's image and reputation	
Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
Impacts on the environment, people and the economy • Possible incidents of occupational injury or illnessi	• Effectively plans and manages economic and human resources dedicated to security • Analyzes and communicates incidents, near misses, and nonconformities in a timely manner to identify causes and necessary corrective actions • Verifies and periodically reviews the safety management system in order to assess its effectiveness and efficiency • Promotes continuous research and innovation to improve health and safety performance • Implements information, awareness and training campaigns on health and safety issues
Impacts on the organization • Economic and organizational costs for risk and emergency management • Possible penalties or litigation for violations or incidents also due to difficulties in complying with changing regulations or standards	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Pregnancy workshop (Lab G)	**Impacts on the environment, people and the economy** • Promote work-life balance by enabling women to continue their research activities without interruption or penalty • To help promote gender equality and the enhancement of women's skills in science, countering stereotypes and discrimination • Provide a safe and comfortable environment for pregnant women and their babies, ensuring compliance with sanitation standards and the presence of qualified staff sensitive to their needs	• Communicate internally and externally the added value of the pregnant researcher lab, highlighting the benefits to female workers, the organization, and society • Recognizing and rewarding female researchers who take advantage of the pregnant researcher workshop, valuing their performance and skills, and facilitating their reintegration into the work team after maternity leave
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • The pregnant researcher lab may elicit resistance or prejudice from some colleagues or superiors, who may perceive pregnant women as less productive or less reliable	• Raising awareness and training of all staff on gender equality and work-life balance, promoting an inclusive and diversity-friendly culture • Careful evaluation of the cost-benefit ratio of the laboratory for pregnant researchers, considering not only the economic but also the social and environmental aspects, and seeking to optimize available resources and reduce waste • Planning research activities and allocation in a fair and transparent manner among various staff members, taking into account the needs and availability of pregnant researchers and other colleagues
	Impacts on the organization • The laboratory entails an additional cost for the company, both in terms of infrastructure investment and operational management and maintenance • The laboratory can generate organizational and logistical difficulties for the company, having to ensure the continuity of research activities and collaboration between different work teams	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Flexible schedule	**Impacts on the environment, people and the economy** • Increased satisfaction of employees, who can choose the schedule that best suits their personal and professional needs • Reducing employees' stress levels	• Enhancement of best practices and successful experiences through internal and external communication • Promotion of corporate culture based on trust, respect and mutual responsibility
	Impacts on the organization • Increased employee retention • Reduced stress and absenteeism, resulting in reduced health care costs and safety risks • Increased efficiency and innovation by working in multidisciplinary and interconnected teams	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Reduced opportunities for social interaction and learning among colleagues	• Organizing periodic meetings (including online) to foster discussion and collaboration among teams • Provision of appropriate technological tools and psychological support to employees working remotely
	Impacts on the organization • Difficulties in coordination and supervision of activities, with possible delays or errors	

Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Solidarity time bank	**Impacts on the environment, people and the economy** • Increased flexibility and work-life balance • Enhancement of skills and human resources	• Establishment of clear and transparent criteria for access to the solidarity time bank • Promoting a culture of solidarity and responsibility among employees • Involvement of human resource managers in the decision-making process • Internal and external communication of the results and benefits of the initiative
	Impatti sull'organizzazione • Improved business climate and cohesion among colleagues • Increased motivation and productivity	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Risks of abuse or exploitation by some employees • Any conflicts or envy between beneficiaries and donors	• Limitation on the number of donable and receivable hours per employee • Periodically verify the operation and equity of the solidarity time bank • Prevention and management of cases of employee discontent or conflict • Training and support of donors and the beneficiaries of the solidarity time bank

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Life insurance	**Impacts on the environment, people and the economy** • Increased motivation of employees, who feel protected and valued by the company	• Clearly and transparently communicates to employees the features and benefits of life insurance, highlighting its added value compared to other forms of corporate welfare • Enhance best practices and testimonials from employees who have taken advantage of life insurance, through newsletters or internal events
	Impacts on the organization • Increased employee productivity • Improved organizational climate and cohesion among colleagues, who share a common benefit • Strengthening the company's image and reputation by demonstrating that it cares about the health and safety of its employees	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible dissatisfaction or discrimination among employees, who may perceive differences in treatment based on type of contract or length of employment	• Ensures equal treatment among employees by extending the benefit to all categories of workers, regardless of the type of contract or length of employment • Try to keep life insurance costs down by negotiating the best possible terms with insurance companies in terms of coverage and premium • Strictly adheres to current life insurance regulations, verifying compliance of contracts entered into and informing employees of the legal and tax implications of the benefit
	Impacts on the organization • Increased costs for the company to bear the cost of insurance and any benefits paid to beneficiaries • Legal or tax risks, which could result from incorrect application of current life insurance regulations or inadequate communication to employees of the terms and limits of the benefit	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
CAF service for employees	**Impacts on the environment, people and the economy** • Increased satisfaction of employees, who appreciate the support they receive from the company to fulfill their tax obligations easily and conveniently • Increased efficiency and time savings for employees, who can use the in-house CAF service without having to go to other agencies or external firms, avoiding queues and waits • Increased transparency and tax fairness, as the in-house CAF service ensures qualified and up-to-date advice on current regulations, avoiding errors or omissions in tax returns	• Internal and external communication of the initiative, highlighting the benefits to employees and the company in terms of well-being, efficiency and social responsibility • Promoting employee participation and involvement in the internal CAF service by providing clear and complete information on how to access and use it, as well as deadlines and required documents
	Impacts on the organization • Increased employee retention	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the organization • Possible conflict of interest between the company and the external tax firm, which could affect the quality and independence of the in-house CAF service, favoring more advantageous solutions for the company at the expense of employees • Possible increase in the complexity and cost of administrative and accounting management for the company, which must enter into and monitor the contract with the external tax firm, in addition to ensuring the operation and security of the internal CAF service	• Selection in a rigorous and transparent manner of the external tax firm, based on criteria of competence, experience, reputation and reliability, as well as compliance with ethical principles and applicable legal standards • Enter into a clear and detailed contract with the external tax firm, which defines how the internal CAF service is to be provided, the rights and duties of the parties involved, guarantees of quality and independence of the service, measures for monitoring and verifying results, and penalties for non-compliance or irregularities

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Food service through company canteen	**Impacts on the environment, people and the economy** • Improving the health and well-being of employees	• In the process of initiating the study of a method for periodic monitoring of employees' levels of satisfaction and adherence to the service, preferably through anonymous questionnaires and/or direct feedback
	Impacts on the organization • Increased employee productivity, motivation and satisfaction, with positive effects on organizational climate and quality of work • Enhancing the company's image as a company that cares about the health of its employees and the environment	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible contamination, intoxication or allergic reactions due to the difficulty in ensuring the quality and safety of food provided by the canteen • Possible conflict or dissatisfaction by some employees who prefer a diet other than that offered by the cafeteria	• Adoption of strict food safety and hygiene protocols in meal preparation and distribution, with regular checks by qualified personnel • Respecting employees' individual needs and preferences by offering menus that are varied and customizable based on nutritional, ethical, or religious criteria
	Impacts on the organization • Increased operating costs associated with service delivery, possibly affecting the company's budget and market competitiveness	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Conventions with fitness centers	**Impacts on the environment, people and the economy** • Increased motivation and satisfaction of employees, who feel valued and supported by the company in improving their physical and mental health • Reduced employee health problems, stress and burnout • Strengthened sense of belonging and cohesion among employees, who can share experiences and interests outside the work environment	• Effective and transparent communication of agreements with gyms and fitness centers, both internally and externally, highlighting the benefits to employees and the company • Promotion of a corporate culture geared toward wellness and health through information campaigns, educational or recreational events, or other initiatives involving employees
	Impacts on the organization • Improved work performance through increased energy, concentration and creativity of employees who engage in regular physical activity • Reduced absenteeism and turnover due to lower health problems, stress and employee burnout • Improved image and reputation of the company, which demonstrates that it cares about the welfare of its employees and is in line with the principles of corporate social responsibility	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible discrimination or exclusion of employees who do not join conventions or who are not interested in or able to engage in physical activity • Possible risk of injuries or accidents of employees attending gyms or fitness centers, which could affect their health	• Ensuring that employees' freedom and diversity are respected, avoiding coercive or discriminatory imposition or incentive conventions • Provide flexibility in work schedules, allowing employees to choose the most appropriate time to take advantage of conventions, as long as it does not affect their duties or the needs of the company • Entering into agreements that provide a discount for the benefit of the employee without generating costs for the Company
	Impacts on the organization • Possible conflict between gym or fitness center schedules and work schedules, which could result in delays, absences, or difficulty reconciling work and personal life • Possible increase in costs to the company due to partial or full coverage of convention fees or lost work hours of employees who go to gyms or fitness centers during working hours • Possible risk of injuries or accidents of employees attending gyms or fitness centers, which could impair their ability to work	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Psychological counseling	**Impacts on the environment, people and the economy** • Increased satisfaction and motivation of employees, who feel supported and valued by the company	• Clearly and transparently communicate to employees the modalities and purposes of psychological counseling services, highlighting the benefits that can be derived from them • Involving employees in the evaluation of psychological counseling service, gathering their feedback and suggestions for improvement • Dissemination of results and best practices related to the psychological counseling service, both internally and externally, through corporate communication channels and the Impact Report • Defines with the outside firm a set of indicators and criteria for evaluating the effectiveness and impact of the psychological counseling service, based on objective data (e.g., number of sessions conducted, employee satisfaction, etc.) and subjective data (e.g., testimonials, success stories, etc.)
	Impacts on the organization • Improving interpersonal relations and organizational climate by fostering collaboration and cohesion among colleagues • Reduced absenteeism and turnover, resulting in increased productivity and quality of work performed • Strengthening the image and reputation of the company, which demonstrates that it cares about the welfare of its employees and acts responsibly and sustainably	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible risk of breach of privacy and confidentiality of employees, who have to provide personal and sensitive information to the external firm	• Negotiating with the outside firm a contract that does not include additional costs to the Company while maintaining guarantees of quality and professionalism of service • Enter into a confidentiality agreement with the outside firm, which protects employees' personal information and prevents its use for purposes other than those stipulated in the contract
	Impacts on the organization • Possible increase in costs for the company, which has to bear the expense of the psychological counseling service and ensure the necessary conditions for its use (e.g., flexible hours, reserved spaces, etc.)	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Membership in the Smoking Free program	**Impacts on the environment, people and the economy** • Reducing health risks for smoking and non-smoking employees • Improving air quality and reducing environmental pollution • Financial savings for smoking employees	• Promotion of the "smoking free" program among employees • Dissemination of achievements among external stakeholders (customers, suppliers, partners, media) through the Impact Report and other communication channels
	Impacts on the organization • Economic savings for the company (lower absenteeism, higher productivity, lower health care costs) • Enhancing corporate image as responsible and caring for the welfare of its employees and the community	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible increase in stress or anxiety on the part of some smoking employees facing the smoking cessation process	• Offer psychological and medical support to smoking employees who want to quit smoking or are having difficulty doing so • Organize alternative or complementary activities to smoking for smoking employees (e.g., sports, hobbies, meditation, etc.) • Raising awareness and involvement of all employees on the issue of personal well-being and the value of the smoke-free program to the company and society • Prevent and manage possible conflicts or tensions among employees through dialogue, respect, cooperation, and mediation
	Impacts on the organization • Possible conflict or tension between smoking and nonsmoking employees or between employees who join the program and those who do not	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**To help generate the positive impacts, the organization...**
Internal corporate medical service	**Impacts on the environment, people and the economy** • Improving the physical and mental health of employees • Increased employee satisfaction and motivation	• Communicate in a transparent and timely manner to employees on how to access and use the in-house corporate medical care service • Monitor employee feedback on in-house corporate medical care service • Disseminate the results and benefits of internal corporate medical service to internal and external stakeholders
	Impacts on the organization ncreased employee productivity • Strengthening the company's image and reputation as a responsible employer that cares about the welfare of its employees	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Possible development of dependence or instances of abuse, by employees, toward the in-house corporate medical care service • Possible violation of privacy or confidentiality of employees' personal and health data	• Establish clear and objective criteria for the provision of in-house corporate medical care, in line with current regulations and industry best practices • Periodically verify compliance with the established criteria and achievement of the targets set by the internal corporate medical care service • Take corrective measures when anomalies or inefficiencies are found in the in-house corporate medical care service
	Impatti sull'organizzazione • Increased costs to the company related to the management of the in-house corporate medical service	

MATERIAL THEME: WELFARE		
Initiative	**Positive impacts generated, actual or potential**	**Actions to help generate the positive impacts**
Influenza vaccination campaign	**Impacts on the environment, people and the economy** • Increased employee health and safety by reducing the risk of contracting influenza and its complications, especially during a pandemic period	• Clearly and transparently communicate the benefits of the flu vaccination campaign to employees and the company, using various information channels and tools • Monitor and evaluate the results of the vaccination campaign by measuring the adherence rate
	Impacts on the organization • Improved productivity and quality of work by avoiding absences and delays due to flu-related illnesses • Strengthening employees' trust and satisfaction with the company, which demonstrates that it cares about their well-being and acts in a socially responsible manner • Enhancing the company's image and reputation as a Benefit Company that cares about the health of its employees and the community	
	Negative impacts generated, actual or potential	**Actions to mitigate negative impacts**
	Impacts on the environment, people and the economy • Discomfort or concern to employees due to possible adverse reactions or side effects to flu vaccine. • Diffusion of resistance or opposition from some employees, who may not join the vaccination campaign for personal, ethical or religious reasons.	nsure the quality and safety of flu vaccine by choosing reliable and certified suppliers, following the directions of health authorities, and informing employees about possible side effects • Carefully plan the logistics and organization of the vaccination campaign, involving human resource managers, the company doctor, and employees, establishing a flexible schedule that is accessible to all • Respecting the freedom and voluntariness of employees, not imposing vaccination as mandatory or discriminating against those who do not adhere to it, but providing correct information and raising awareness of the social value of prevention
	Impacts on the organization • Aggravation of organizational tasks due to the vaccination campaign, which must be carried out efficiently and effectively, taking into account the needs and preferences of employees, current health regulations, and available resources	

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Cogentech S.R.L. Società Benefit a Socio Unico soggetta all'attività di direzione e coordinamento di IFOM – Istituto FIRC di Oncologia Molecolare
Sede Legale: Via Adamello 16, 20139 Milano, Italia - Capitale Sociale 1.100.000 € I.V.
Unità Locale: c/o Parco Scientifico e Tecnologico della Sicilia S.c.p.a. - Z.I. Blocco Palma I - Stradale V.Lancia, 57 - 95121 Catania
P. IVA, C.F. e iscrizione al Registro delle Imprese di Milano, Monza, Brianza e Lodi n. 04641450962 - R.E.A. MI-1763886
Codice Univoco SUBM70N - Tel. +39 02 574303200 - Fax +39 02 574303231 - cogentech@pec.it - www.cogentech.it