

QUALITY POLICY AND QUALITY OBJECTIVES

Starting from 2022, following significant managerial and organizational changes within AIRC and IFOM, Cogentech Srl Società Benefit has further strengthened its commitment to supporting AIRC's mission by providing innovative, high-quality technological services to the researchers funded by AIRC—both those within IFOM and those external to it.

Cogentech Management is committed to defining and implementing, as its Quality Policy, the corporate *Mission*, which can be summarized as follows:

- The distinctive nature of the *Mission of Cogentech* is reaffirmed in its ability to generate, through its activities, social value as well as economic value.
- The conduct—also in collaboration with third parties—of research and development activities in the fields of medicine and molecular diagnostics, aimed at the development and production of new diagnostic, predictive and prognostic tests in human medicine, with particular reference to oncology and age-related diseases, as well as in the veterinary field.

The development and validation of new tools, in particular for NGS analyses, to support the genetics laboratory—both in the germline setting and in performing diagnostic tests requested by hospitals and clinical institutions. In this context, Cogentech maintains close synergy with leading clinical organizations, aimed at developing innovative diagnostic tools built around customer needs and oriented toward more effective and improved protection of an individual's health.

- Cogentech's status as a "Health Institute", recently reaffirmed at institutional level, requires continuous review of the way LDT devices ("in house tests") are managed, in compliance with EU Regulation 746/2017. Such compliance is ensured through the review and updating of the relevant forms and documentation.
- The management of service activities and technical support to Research, through the promotion, management and coordination of proprietary technological platforms in the biomedical and IT sectors. In particular, in order to strengthen the promotion of services for research and clinical activities, the existing staff has recently been supported by a consulting role with marketing expertise.
- The provision to the shareholder and to third parties of services and access to goods, equipment and facilities in relation to the activities described above.
- The management of intellectual property through the registration, acquisition and enhancement of patents, licenses, trademarks and concessions related to the corporate activity.
- In the area of INNOVATION, significant activity is noted for the development of diagnostic tools based on innovative liquid biopsy approaches. In addition, in line with the quality objectives, it is emphasized that several Cogentech functions are strongly committed to implementing the CE-IVDR certification pathway for the OncoPan panel, with the aim of complementing the diagnostic service provided with the production of a commercial kit (ONDA HCS).

The CGT Lab and IGU laboratories—both Specialist Laboratory Medicine Services in Medical Genetics with a Molecular Genetics area within Cogentech—conduct their activities in compliance with the principles of **impartiality** and **non-discrimination**, ensuring the protection of patients' rights and

making sure that these values are not compromised in any way.

The laboratories guarantee their customers the availability and integrity of samples and related records in the event of closure, acquisition or merger of the laboratories.

They also commit to operating in compliance with Regulation (EU) No 2016/679 of the European Parliament and of the Council of 27 April 2016, to ensure communication to the user in the event of mandatory notification obligations, and to guarantee the confidentiality of sources with regard to information received about users.

Cogentech Management is aware that achieving the established objectives is related to an analysis of the context in which it operates, stakeholder needs and the risks associated with its activities. To this end, these elements are periodically analyzed with the support of staff functions reporting to Management, in order to identify and implement the most appropriate improvement actions.

The Quality Management System is continuously applied, updated and improved through appropriate internal communication actions. Personnel are aware of the importance of their activities and of the contribution each person can make to achieving quality objectives and the continuous improvement of the organization.

In this Policy, Cogentech defines its quality objectives. In order to monitor their achievement, the company has identified specific performance indicators, both at a general level and for each facility. All indicators are monitored and updated periodically. The achievement of results is also analyzed during Management Review.

Cogentech also aims to contribute in an increasingly active and concrete way to scientific debate through publications in international journals and active participation in meetings promoted by scientific societies. In addition, it participates in institutional and international programs on quality control of genetic tests and collaborates in the drafting of sector guidelines.

Management commits to ensuring that this Policy is disseminated, understood and implemented at all levels of the Organization.

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Cogentech srl SB Management

