Extract from Multiannual Planning Document

of the ENEA Tech and Biomedical Foundation

EXECUTIVE SUMMARY

Biomedical Sector

The Foundation operates in all areas of the Italian biomedical sector to improve economic development, competitiveness, innovation, skills, completeness of the supply chains, attractiveness towards investments, industrial reconversion and national security in terms of productive autonomy.

It operates through system interventions or projects in collaboration with a single organization, using the two funds entrusted to it.

It intervenes through initiatives identified thanks to interactions with various players in the supply chain, such as Italian and foreign companies, trade associations, research centers, financial operators, consultants, or thanks to comparative studies with other EU and OECD countries, comparing data, policies and best practices.

Sectors of intervention:

- Pharmaceuticals
- Biotechnology
- Medical devices
- Digital Health

Areas of intervention

- Research and Technology Transfer
- Pre-clinical research
- Clinical research
- Actions to support new business initiatives
- Actions to support the competitiveness of the business system
- Attraction of investments

Support for Start-ups in other high-tech sectors

The Foundation's statutory mandate also provides for interventions in favour of start-ups and innovative SMEs in the sectors of green and circular economy, information technology, agri-tech and deep tech sectors.

Biomedical Sector

The genesis of the initiatives

Achieving the statutory purpose requires deep knowledge of the biomedical sector and awareness of the critical factors that hinder its economic development and the opportunities that favor its growth.
The Foundation obtains this awareness through a 'maieutic method': the organization is becoming the reference point of the sector, at the center of a system of relationships that includes all the main stakeholders, to incorporate opportunities and initiatives and intervene accordingly.
The Foundation's system of relationships includes Italian and foreign companies (pharmaceutical, biotechnological, medical devices and IT applied to health), their associations, biomedical research centers, investors, new business ventures, service and consulting companies, professionals.
This modality of attracting projects from stakeholders is complemented by a proactive modality, whereby the Foundation spontaneously promotes its own initiatives aimed at affecting specific critical aspects or opportunities of the system.
For this proactive role, the Foundation leverages its own Study Center which, in close collaboration with the Presidency, generates data, information, market analysis, best practices, project ideas and everything necessary to stimulate initiatives and instruct decision-making processes.
Once the intervention proposals have been identified, the Foundation implements them with its operational structure and its funds, in most cases leveraging resources of third parties.

Punctual initiatives

By specific interventions, we mean initiatives that the Foundation will consider undertaking for the benefit of a single interlocutor who proposes projects characterized by a particular impact.
By way of example:

- Investments in start-ups and innovative SMEs, based on the regulation for the management of the Technology Transfer Fund.
- Initiatives to support investments by companies in the sector, such as industrial conversion plans and manufacturing expansions.
- Initiatives to support investment projects on the national territory by foreign operators.

Specific initiatives will be considered on the basis of their impact:

- On economic development, therefore through indicators such as the creation of direct and indirect jobs (ideally knowledge-intensive, characterized by high remuneration, for activities with a high added value and consistent with the development models of OECD countries without natural resources such as Italy), the size of the invested capital and its impact on national supplier chains, collaborations with research institutions or with Italian industrial partners.

- On the response to health emergencies, national security in terms of productive autonomy, the completeness of the supply chains, or other aspects of a strategic nature.

The types of intervention may be of a financial nature, for example:

- Investments in equity and quasi-equity: in favor of innovative start-ups and SMEs, regulated by the regulation of the Technology Transfer Fund, also carried out in collaboration with external investors.
- Non-repayable loans and loans, regulated by the Biomedical Fund inner rules, favoring research purposes in compliance with state aid European Union legislation, ideally with clawback rules conditional on the effective execution of the investment plans.
- Support in investment execution activities, supply of studies and data, information on regulatory aspects, creation of research and industrial collaborations, and advocacy activities.

System Initiatives

Examples of activities related to enabling infrastructures:

- Initiatives to strengthen Italian technology transfer offices to achieve critical mass and efficiency.
- Creation of enabling infrastructures for pre-clinical research activities.
- Creation of infrastructures for incubation and acceleration of new business initiatives.
- Enabling access to biotech production facilities devoted to the production of batches for clinical trials in cGMP.

Examples of intangible and service system initiatives

- Study Center: activity within the Foundation, in close collaboration with the Presidency, aimed at carrying out sector and market surveys, on intellectual property, best practices, comparative studies of regulations, etc., aimed at supporting the strategic decisions of the Foundation and its investments.
- Initiatives aimed at enhancing clinical data for the benefit of scientific research and clinical experimentation processes.
- Training activities on issues of industrial reconversion, digitalization of clinical research, innovative technologies (eg mRNA), etc.

The system initiatives will be aimed at the creation of enabling infrastructures and the supply of services. As such, they will bring advantages not to a single interlocutor but to a larger environment, to more stakeholders involved in a specific segment. They will be based on the receipt of proposals made by the Foundation's stakeholder or will be proactively devised by the Foundation itself in collaboration with the stakeholders. The Foundation will play a role in planning, financing and coordinating the execution typically through investments, leveraging its biomedical fund.

The Foundation will address economic development in each of the following value chain segments:

Technology transfer

- Creating infrastructures such as innovation poles, aggregations between technology transfer offices, incubators and specialized accelerators.
- Investing in new start-ups in the sector.
- Intervening on tech transfer culture, designing and eventually delivering dedicated training programs and education initiatives.

Compared with OECD countries, Italian research has a good performance in quantity and citations of its publications, but very bad in patents and start-ups (1 order of magnitude less). Among the main causes: inadequate internal policies of research institutes, lack of experience and entrepreneurship of tech transfer teams, lack of competence of researchers about processes, lack of incentive and motivation of the same, factors that consequently imply a lower appetite for investors and limited infrastructures (laboratories for start-ups and incubators).

Pre-clinical trial

As a consequence (but also contributing cause) of the difficulty in progressing from the basic research phase and subsequent ones, the supply of infrastructures for pre-clinical research, in particular, those with adequate standards (SPF) and innovative methodologies (organoids, data processing) are limiting factors.
The Foundation will proceed with adequate initiatives and to create collaborations between organizations involved in these aspects, such as 'IRCCS' research bodies, also involved in the development of innovative platforms for pre-clinical research, such as experimentation with organoids.

Clinical trial

The Foundation:

- Evaluate the possibility of introducing some best practices that have proved highly effective in accelerating the response times of ethics committees, with the effect of attracting investment flows in clinical trials.
- Consider investments for the construction of clinical data platforms.
- Invest in new clinical research service initiatives, and support the establishment of new CROs, laboratories, data processing centres, Phase 1 centres and other enabling infrastructures for clinical research activities.
- Will design and set up training activities dedicated to operators in clinical research, particularly in data management and process digitization.

From the point of view of the impact on economic development, the capital invested in clinical research activities are as important as those dedicated to manufacturing, distribution, or service activities. In addition, they bring significant benefits to patients and hospitals regarding access to innovative drugs, economic benefits, clinical practice, and operator culture.

Actions to support the competitiveness of the sector

The Foundation will:

- Activate investments and initiatives aimed at supporting companies whose leadership position is at risk due to financial, technological, or geopolitical factors.
- Invest in equity and support start-ups specialized in sectors of scientific excellence to enable them to achieve market scale-up objectives.
- Activate international institutional channels when they will be useful for defending competitive advantage.
- Initiate international collaborations to make training programs available in Italy to deal with specific economic development limiting factors, for instance, the conversion of pharmaceutical manufacturing from the chemical synthesis of small molecules to the biotechnological fermentation of large molecular complexes.
- Design specific training for the digitization of clinical trial data management processes.

The Italian system boasts leadership positions or a strong competitive advantage in some areas, such as the pharmaceutical production of small molecules, technologies for the pharmaceutical industry, gene therapy, regenerative medicine, molecular diagnostics, and healthcare software. However, this competitive advantage is subject to erosion due to various geopolitical or regulatory factors, the introduction of technological innovations, and difficulties in accessing skills.
The rapid evolution of knowledge impacts on industrial processes, causing crises or growth opportunities. Rapid industrial conversion processes allow you to take advantage of technological changes, rather than suffer the negative effect.
The dialogue with companies and key players in the leading sectors allows the Foundation to devise and carry out specific interventions to defend leadership positions and accelerate industrial reconversion.

Technology Transfer Area in five high tech sectors

Unlike the biomedical mandate, that of investment in high-tech start-ups is common to many public and private organizations, for example:

- Cassa Depositi e Prestiti (in particular CDP Venture).
- Venture capital operators (either generic or specialized in specific fields).
- Corporate ventures (investing in start-ups on behalf of large industrial groups, including Italians).

- Family office (investing in start-ups on behalf of families of entrepreneurs).

Unlike the Foundation, all these organizations are entirely dedicated to venture capital activities, have substantial financial endowments, and many years of experience, with specialized teams and well-established processes.
The Foundation will leverage its characterizing element (that of a foundation that administers public funds, well connected to the research system), to identify projects otherwise not visible to the private VC, to which then delegate the operations of two technical diligence, to then evaluate co-investment transactions.