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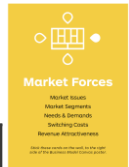# Thematic Areas Agendas

Life Sciences & Healthcare

1) Strategic Domains

Description of the Thematic Area and outline of the Strategic Domains of focus for the Thematic Area are outlined, these represent the area of focus over which the TA will build their Agenda

Description of Thematic Area	• **Life Sciences & Health Care** • Life Sciences encompasses the fields of biotechnology, pharmaceuticals, biomedical technologies, healthcare technologies, botanical science and crop technologies, veterinary fields, environmental sciences, biomedical devices, research products and services that focuses on understanding and providing tangible benefits to living organisms. The healthcare sector, on the other hand, consists of businesses that provide medical services, manufacture medical equipment or drugs, provide medical insurance
Strategic Domains	• **Life Sciences & Health Care** 1. Value Based 2. Digital 3. Sustainability and Circular
Strategic Enablers	1. Collaboration

Thematic Area Agenda

1) Trends and Scenarios – Business Environment – Market Forces

	Outcomes
Market issues	• Empowered, better informed and connected patients • Transition from mass blockbuster solutions to personalised medicine solutions (omics i.e. farmacogenomics, metabolomics etc; gene-therapies, cell therapies, etc.) • Transition from in-patient hospital care only to community/homecare • Collaborative models in R&D commercial and manufacturing operations • Leadership teams in pharma companies able to effectively manage the organization remotely • Resilience of supply chain for pharma companies • Declining productivity and ROI of R&D • Appropriateness and timeliness of clinical intervention (ability to predict clinical and epidemiological patterns; identify subpopulation of patients)
Market segments	• Chronic and non-communicable diseases are growing both in terms of volume and virulence • Hospital patients vs community/homecare patients • Connected healthcare as synonym of e-health, • Prevention and management of health emergencies (e.g. pandemics, major environmental disasters)
Needs and demands	• Scaling up personalized medicine solutions and make them more affordable • Improve the patients' overall quality of life (from patients to citizens) • Omnichannel ecosystem for connected healthcare to enable the movement from patient to citizen • Develop healthier environments within our cities to prevent chronic diseases. *PNRR has set a national reform plan and investments in public health for resilience and sustainable recovery, plus the establishment of the National Prevention System Health-Environment-Climate (SNPS) and related regional articulations. Establishment of new health professionals specifically dedicated to health-environment - climate issues and the definition of the relevant curriculum (PNRR)*
Revenue Attractiveness	• Need to develop value-based healthcare solutions to manage the rising costs of treatments, ushering the tide of value-based services, hospitals, and treatment packages • Co-design of Target Patient Outcomes to measure health outcomes • Leverage a sustainable approach unleashing the power of innovative treatments through both products and services

1) Trends and Scenarios – Business Environment – Industry Forces

	Outcomes
Competitors (Incumbents)	• Pharma companies • Medical devices companies • Diagnostic companies • Public healthcare providers (hospitals, clinics, etc…) • Private healthcare providers • Insurance companies • Banks (e.g. Intesa San Paolo, Mediolanum, ...)
New Entrants	• Tech companies (Big Tech, Software companies, i.e. Amazon, Google, Microsoft etc…) • Start-ups and scale ups • Venture funds focused on tech (Sequoia capital, a16z, ..) • Service pharmacies
Stakeholders	• Patients and Advocacy Groups • Caregivers • Physicians • Nurses • Policy makers • Scientists • Payers • Investors • Pharmacists • Regulators
Substitutes / complementors	• Blockchain-based decentralised healthcare and well-being systems (in the mid to long-term) • Healthy nutrition programs, healthier lifestyle programs (mindfulness, fitness, etc…)
Supplier and other value chain actors	• Universities • Research labs • CROs • Manufacturing companies (CMOs) • Technology companies • Market analysis/research providers/data provider (report or raw)

1) Trends and Scenarios – Business Environment – Key Trends

	Outcomes
Technology trends	• Complete implementation of EHR services throughout the national territory; development of Regional Telemedicine Platforms in an open data prospective. Strengthening the technological and application infrastructure of the Ministry of Health (1 bn) (PNRR) • Emergence of a network of biological and nano-biological data in the form of biobanks, to be connected by search algorithms • AI-based platforms for rapid prototyping of treatments/vaccines • Transition to RWE to improve patient treatment outcomes • 3D printing and robotics to reproduce body parts • Gene/Cell therapies/omics for personalised medicine (cancer prevention, rare disease, …) • Precision diagnostic • Data interoperability to streamline technological and clinical research
Regulatory trends	• Advances in technology are faster than the regulatory advancements • Highly involved regulation, monitoring and potentially restriction of the collection and usage of personal data (data privacy, data protection, data security, AI ethics) • Regulations that define access to the healthcare market (e.g. DiGA or Digital Health Application, which defines what can be classified as a medical device)
Socioeconomic trends	• Increasing per capita demand for healthcare services (aging population, degradation of climate, …) • Shortage of physicians. Set up of a School of Specialization in Health-Environment and Climate at the Departments of Medicine in agreement with the Italian Ministry of University and Research by Q4 2025 (PNRR) • Value-based pricing model • Strong focus on circular and sustainability demands
Societal and cultural trends	• Personal hygiene, exercise and nutrition gaining importance in social and cultural agenda and priorities • Climate issues awareness and the impact on personal choices and lifestyle • Mental health issues have peaked during COVID and isolation (depression, anxiety, ..) • Managing and monitoring disease prevention is a priority • Individuals are more aware and/or conscious of privacy considerations • Increasing pressure on "Big Pharma" pharmaceutical companies on the reputational and economic aspect to deliver their social missions

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1) Trends and Scenarios – Business Environment – Macro Economic Forces

	Outcomes
Global market conditions	• The new PNRR has set important funds for new investments in the national healthcare system (€19.72 bn in Health related missions) • Pharma companies tend to partner with AI-drug discovery start-ups and scale ups to reduce time and costs the development of a new biological principle for new drugs • Availability of EU funds for recognized cutting edge innovation hubs
Capital markets	• Increased share price of vaccine producers • Venture capital funds are investing in gene-therapies due to the possible growth in the next years
Economic infrastructure	• Development of a reliable, secure, energy-efficient and economically viable infrastructure to host the systems and data of the public administration, enabling a new logic of public services provision and data usage based on the cloud paradigm. Use of digital tools and data integration (PNRR) • Make PA databases interoperable and accessible through a catalog of Application Programming Interfaces (APIs) (PNRR) • Ensure the creation of 753 Community hospitals (2bn) (PNRR) • Targeting the national territory that is not reached by the ultra-broadband (€ 3.3 bn) (PNRR)

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2) Strategy – Challenges, Opportunities – *Value Based medicine*

Challenges	Opportunities
• Prevalence of Chronic and non-communicable diseases • Transition from in-patient hospital care only to community/homecare • Increasing per capita demand for healthcare services (aging population, degradation of climate, …) Developing an advocacy model that supports the development of this new healthcare approach	• Improve the patients' overall quality of life (from patients to citizens) • A deep understanding of the patient journey for a specific disease is the starting point of a better treatment as we aim at improving the journey of patients, starting from understanding their disease to diagnosis, treatment and follow up • Develop healthier environments within our cities to prevent chronic diseases (PNRR) • Complete implementation of EHR services throughout the national territory; development of Regional Telemedicine Platforms in an open data prospective. Strengthening the technological and application infrastructure of the Ministry of Health (1 bn) (PNRR)

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3) Strategy –Strategic Implications – *Value Based Medicine*

Strategic implications
How do we: 1. Create an **inclusive** and **affordable** v**alue-based healthcare & community system** that enable transition from patient journey to citizen journey? 2. Develop and share a value-based implementation model to deliver innovation that supports people living longer and healthier lives, creating a continuum between the City of the Future and the Healthcare of the Future. 3. New single/shared model of healthcare based on the collaboration of all stakeholders (specialist doctors, territorial doctors, patients, pharmaceutical and medical device industries, service providers...) ensuring access to healthcare services everywhere and at all times.

4) Strategy – Draft Master Plan – Objectives, Key Results and Initiatives
– Value Based Medicine: new protocol for a better citizen journey & therapeutical efficacy

Objectives	Key Results	Initiatives
Improving the patient journey and maximising the effectiveness of treatments i. Develop and share a value-based implementation model to deliver innovation that supports people living longer and healthier lives with focus on last mile and involvement of multiple stakeholders • Developing new optimised care pathways integrated with new available technologies • Personalised therapies that follow the specific needs of patients • Experiment "Extended treatment coverage" <u>through</u> homecare and territory networks <u>leveraging</u> on societal factors (incl. strengthening active net of caregivers/community people around the patient) • sustainable treatment pathways (go to sustainability working group)	**Improving the patient journey and maximising the effectiveness of treatments** i. Selection of specific pathological conditions where to develop and test a patient-based journey approach (early diagnosis and treatements, precision medicine, chronic disease, home-care services) by July 2021 ii. define the patient parameters of interest and identify the patient cluster to be monitored by October 2021 iii. Monitoring and data collection by _tbd iv. Analysis phase and development of new optimised care pathways/operational protocols by_tbd • Pharmacological therapies • Devices / methods of administration • Devices / monitoring methods / algorithms • Home care protocols i. Performing validation tests of optimised care pathways/operational protocols by_tbd	**Improving the patient journey and maximising the effectiveness of treatments** i. Identify healthcare partner • Check availability IRCS Galeazzi / Lombardy Region / Local medicine • Select medical team to support the project • Define the KPIs to be analysed in the project validation studyIndividuare partner assistenza ii. Define the strategic interest of the project • Stakeholder map • Benefits for the Citizen • Benefits for the SSN / SSR • Benefits for companies iii. Define the roadmap of the implementation ised models

2) Strategy – Challenges, Opportunities - *Digitalisation*

Challenges	Opportunities
• Transition to RWE to improve patient treatment outcomes • Managing and monitoring disease prevention is a priority • Scaling up personalized medicine solutions and make them more affordable • Emergence of a network of biological and nano-biological data in the form of biobanks, to be connected by search algorithms • AI-based platforms for rapid prototyping of treatments/vaccines • Implementing data interoperability to streamline technological and clinical research	• Development of a reliable, secure, energy-efficient and economically viable infrastructure to host the systems and data of the public administration, enabling a new logic of public services provision and data usage based on the cloud paradigm • Use of digital tools and data integration (PNRR) • Make PA databases interoperable and accessible through a catalog of Application Programming Interfaces (APIs) (PNRR)

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3) Strategy –Strategic Implications – *Data and Digital*

Strategic implications
How do we accelerate the digitalisation of the health sector: 1. Creating a real-time big-data ecosystem with AI tools enabling strategic choices of health policy, the creation and offer of services, as well the systematic measurement of the impact of these services/goods on the quality of life and on the improvement of patients' clinical outcomes? 2. Introducing a new clinical and technological research model that leverages shared data and new evidence generated by the data ecosystem?

4) Strategy – Draft Master Plan – Objectives, Key Results and Initiatives – *Data and Digital*

Objectives	Key Results	Initiatives
1. Rising importance of sharing technical-scientific know-how and clinical data among different institutions and strategic partners. 2. Support and contribute to good governance of digital health, adherence to national policies and programmes, and compliance and use of standards required. 3. Build up a holistic patient-centric modular and scalable data platform (regional area) to provide multiple services from clinical research to telemedicine applications 4. Create a network of biological and nano-biological data in the form of biobanks, to be connected by search algorithms 5. Establish criteria for assessing the relevance and impact of digital health solutions on different topics, such as cost-effectiveness, sustainability and affordability, ethical use, privacy and security, and safety	• Modern, timely and efficient measurement of Lombardy's population health status • Diagnose or predict recurrent clinical and epidemiological patterns and identify the subpopulations of patients most responsive to a given therapeutic treatment • Improve clinical outcomes, hospital triage management and resource allocation	DIGITALIZED PLATFORM Creation of a Health **data-trust for the life-sciences and healthcare in Lombardy** ○ Agile Test & Learn and a public-private partnership approach ○ Innovative platform for the creation of a clinical and basic research model ○ Digital Platform for Precision diagnostic and more effective and targeted prevention policies ○ Useful to develop and validate of algorithms based on artificial intelligence

2) Strategy – Challenges, Opportunities and Implications - *Collaboration*

Challenges	Opportunities
• Declining productivity and ROI of R&D • Transition from mass blockbuster solutions to personalised medicine solutions (gene-therapies, etc…)	• Collaborative models in R&D commercial and manufacturing operations

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3) Strategy – Challenges, Opportunities and Strategic Implications – *Collaboration*

Strategic implications
*How can we turn Federated Innovation@ **MIND into a cutting-edge ecosystem** for innovation, TT, technological research activities in the life sciences domain at the national and EU level?* Communicate to the institutions which are the objectives and projects of FEI (processes of innovation and projects undergoing) in order to receive an endorsement towards the other actors external to MIND

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4) Strategy – Draft Master Plan – Objectives, Key Results and Initiatives – Collaboration (Life in MIND)

Objectives	Key Results	Initiatives
Co-innovation. foster, advocate co-innovation @ MIND while creating Joint Labs and improve tech transfer to accelerate opportunities.	**Co-innovation** - Identify other MIND actors' priorities - Build a first projects map inside the MIND ecosystem	**Life in MIND** i. Meeting for sharing of priorities of the LS with other anchors/players in MIND ii. Scientific sharing of projects iii. Way of working
Find friends Interactions with other collaborative ecosystems at national, European and international level. Map of the research and innovation associations active at the European level on the challenges that the area sees ahed (who are the actors already working on these projects?).	- Analysis and focus on a few and most important European ecosystems. - Identify the first ecosystems with which start a relation.	i. Present / introduce MIND to the selected ecosystems ii. Stabilize the priorities between ecosystems and projects in relation with the policies and EU-National budget
Guide Guide the other FEI LS teams/projects on thematic aspects on which there are more chances to develop projects of interest for <u>important institutions and stakeholders</u>.	- Create shared value in relation with the area priorities with the other anchors and the actors of the selected ecosystems	i. Meeting/event inside and outside the contest of MIND the priorities in the LS

4) Strategy – Draft Master Plan – Objectives, Key Results and Initiatives – Joint Labs @ MIND

Objectives	Key Results	Initiatives
Co-innovation. Joint labs to foster, advocate co-innovation @ MIND while creating Joint Labs and improve tech transfer to accelerate opportunities. JLs are conceived to: • create value by stimulating interaction between involved actors (public and private) and "the world outside" • use co-location for co-creation, co-design and co-development as innovative collaborative model • stimulate interdisciplinary approaches to develop innovations • Integrate with both technology transfer activities and pre-startup development activities	JL are part of an innovative system based on open innovation paradigm where relations «many to many» are complemented by more traditional «one to one» and «One to many» interactions • JLs need a suitable environment to be able to demonstrate their potential at systemic level that will include: • Links with R&D centers • Links with TTOS/ incubators/ accelerators/ innovative clusters • Links with counterparts in other sectorial domains (converging technologies)	Activities at the JLs are the results of a "smart mix" of a virtuous cycle of: • Education (implementation and teaching of Master courses), • Research (joint laboratories for selected areas of interest) • Trial & technology/ Industrial Transfer (field testing and transfer in areas of interest to the companies involved, in which the universities excel). Including complementary expertise (e.g regulatory, marketing, etc)

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2) Strategy – Challenges, Opportunities and Implications – *Sustainability and circular economy*

Challenges	Opportunities
• Comply with new environmental regulations • Manage the pressure on «pharma» companies to generate a positive impact	• Leverage on the new Circular Economy paradigm considering the significant focus that at all levels sustainability is getting • Integrate different stakeholders with a systemic approach

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3) Strategy – Challenges, Opportunities and Strategic Implications – *Sustainability and Circular Economy*

Strategic implications
*How to address **climate-change risk, pollution risk, Natural Capital / biodiversity risk** while re-designing how to do business?*

4) Strategy – Draft Master Plan – Objectives, Key Results and Initiatives
– Sustainability / Circular Economy: LifeCycle Assessment on products & services relative to a targeted pathology / therapeutic area at hospital's premises

Objectives	Key Results	Initiatives
Circular Economy: - "Re-design processes and products (e.g. re-use / recycle syringes and relevant packaging)" through integration of Circular Economy principles - preserve both Natural Capital (e.g. preventing pharmaceuticals in the environment)	**Rationale. Places like Hospitals and Households are going to play a significant role in the LifeScience and Healthcare of the future, as pivotal centers of a "Circular Community"** i. Reduce environmental impact of a **targeted pathology / therapeutic area solution (products & services)** provided by LifeScience & Healthcare providers to Hospital ii. In particular, reduce environmental impact related to **End Of Life scenarios** such as of **equip**, **drugs**, **containment / delivery** solutions in regards of **Waste Management** and **residues management in waters** iii. Identify, engage and facilitate funding from private and public sources including but not limited to: **PNRR, Horizon** etc.. iv. Foster **cross-fertilization** and collaboration among Federated Innovation (e.g. **Enel X, sustainable buildings**)	**LifeCycle Assessment Study:** i. **Scope.** Identify and select a short list of Pathologies and Therapeutic Areas of common interest. [by…] ii. **Plan.** Elaborate team, budget, KPIs [by…] iii. **Execute.** iv. Scout and engage potential partners / stakeholders [by…] v. Leverage on synergies and network from Federated Innovation / MIND and relatives vi. Scout and engage a potential advisor [by…] vii. Perform a LifeCycle Assessment of relevant products/services flow within Hospitals (as a first place of focus) [by…] viii. Identify viable circular scenarios, technologies and solutions [by…] ix. Quality & Regulatory compliance verification [by…]

THANK YOU