Piano Nazionale di Ripresa e Resilienza (PNRR) Missione 4 - Istruzione e ricerca Componente 2 (M4C2) – Dalla ricerca all'impresa Investimento 2.3 – Potenziamento ed estensione tematica e territoriale dei centri di trasferimento tecnologico per segmenti di industria

ADDENDUM alla Relazione illustrativa del cronoprogramma previsto dalla M4C2I2.3

(DRAFT V.3 – 20 maggio 2024)

| ANAGRAFICA | | | |
|---|---|--|--|
| Missione | 4 - Istruzione e Ricerca | | |
| Componente | 2 - Dalla ricerca all'impresa | | |
| Investimento | 2.3 "Potenziamento ed estensione tematica e territoriale dei centri di trasferimento tecnologico" | | |
| Titolo del progetto e acronimo | advanCed digitAl TeChnology Hub for the Life Sciences at MIND (CATCH atMIND) | | |
| Importo del progetto indicato dalla Commissione europea (per EDIH importo massimo del Grant Agreement) | | | |
| Centro di trasferimento tecnologico | □ EDIH X Seal of excellence | | |
| Denominazione | CATCH atMIND | | |
| Legale rappresentante (EDIH/Seal of excellence/Capofila) | Ente Capofila: Università degli Studi di Milano Legale Rappresentante dell'Ente Capofila: Prof. Elio Franzini | | |

1) Distribuzione attività da progetto:

Il progetto presentato ha mantenuto la sua struttura di base, sia dal punto di vista realizzativo che organizzativo, rispetto a quanto presentato in fase europea. Si sono registrati alcuni cambiamenti comunicati con opportuna relazione trasmessa in data 18.10.2023 e 06.11.2023 cui si è aggiunto il documento "Addendum alla relazione illustrativa del cronoprogramma previsto dalla M4C2I2.3" inviato al Ministero in data 19.02.2024, in risposta alla richiesta del MIMIT del 04.01.2024.

Le modifiche al progetto intervenute in risposta alle richieste avanzate dal Ministero sono qui di seguito elencate:

- A. Diversa compagnie di progetto
- B. Revisione e integrazione della tabella dei servizi erogati e del loro costo
- C. Variazione della durata temporale del progetto
- D. Revisione del budget di progetto sulla base dei punti di cui sopra finalizzato anche ad una riduzione delle spese ex art. 27 del regolamento (UE) nr. 651/2014 GBER alla linea di finanziamento "Ammodernamento e funzionamento dei Centri di trasferimento tecnologico e funzionali all'erogazione dei servizi".

Sulla base delle interlocuzioni avute con il Ministero, relative alla distribuzione delle attività di progetto tra i partner, ovvero WP e Task, si evidenziano, in particolare, i seguenti cambiamenti:

A. Diversa compagine di progetto

Come meglio illustrato nella relazione trasmessa, i due partner Officine innovazione s.r.l. e The European House- Ambrosetti S.p.A. hanno rinunciato a partecipare alle attività di progetto. In particolare, le attività dei partner rinunciatari erano previste principalmente nel WP 1 ("Project Management and coordination"), nel WP 6 ("Communication and External EDIH collaboration") e, parzialmente, nei WP 4 ("Test-Before-Invest platform, Demo Lab center, D-twins and co-creation environment") e WP5 ("Training, Support to attract investment and Innovation management").

Come da richiesta del Ministero del 23.04.2024, si allegano alla presente relazione gli atti di rinuncia a partecipare al progetto da parte dei due Partner sopracitati.

B. Integrazione alle revisioni della tabella servizi erogati e del loro costo

Rispetto a quanto già trasmesso, si conferma che l'elenco dei servizi erogabili, così come presentato in proposta (cfr. pag. 3 e seguenti della "*Technical Description -Part B*" del project proposal) è stato sottoposto ad una revisione puntuale dal punto di vista dei costi e della fattibilità, anche alla luce del cambiamento di compagine. La tabella aggiornata è stata esposta nella relazione trasmessa.

Alla luce dei cambiamenti citati, si riporta nuovamente qui in calce la suddivisione delle attività secondo i WP di progetto e i relativi Task, con l'indicazione dei partner coinvolti in ciascuna attività.

Si segnala che non sono intervenuti cambiamenti alle attività previste, salvo la riduzione del coinvolgimento del partner Cy4Gate nel Task 2.5. Relativamente a tale task, le cui attività ricadono in quanto coperto da spese ex art. 27, si prevede che ogni partner condurrà i propri servizi in aderenza alle previsioni del GDPR. Il coordinatore e tutti i partecipanti, attraverso gli organi di governo del progetto monitoreranno la corretta implementazione dei servizi.

Cy4Gate verrà inoltre solo coinvolto in servizi relativi al WP4, ed è stato quindi rivisto il suo coinvolgimento su attività relative ad altri WP. Come già indicato si consideri che il WP1 rimane interamente dedicato ad attività di management. Allo stesso modo, gran parte delle attività di WP6 saranno dedicate ad attività di Networking (Task 6.1 e Task 6.2) e Disseminazione/comunicazione (Task 6.4).

Tale indicazione implica che, seppur a supporto dell'erogazione dei servizi, le attività ivi descritte non rientrano in quelle propriamente di servizio ex art. 28-31 GBER.

| Work | Work Package 1. Project management and coordination | | | |
|-------|---|---|-----------------------------------|--|
| T 1.1 | General Administrative coordination | CATCH atMIND Secretariat and Coordinator will ensure the overall EDIH coordination, self-assessment and communication between partners. Activities will include: i) monitoring the achievement of EDIH goals and KPI, ensuring the effective use of human and economic resources; ii) adopting corrective actions if needed, advising SC; iii) developing a risk mitigation plan and implementing it if needed. Administrative staff will also organise and follow-up on: a) the monthly meeting with the Steering Committee, (agenda and minutes); b) the Scientific Board's work and meetings, (scheduled every two months); c) coordinate the activities of the Ethical, compliance and security Committee. Monitor the up-date or amendment to the relevant national, European and international law. | UMIL, all | |
| T 1.2 | Scientific and Technical Coordination | Ensure the implementation of services acting through the partners and the Scientific Board. Evaluate the quality, efficiency and efficacy of the services provided. Refer to the coordinator and the Steering Committee changes to the KPI and services provided. | UMIL | |
| T 1.3 | Contractual and Financial Management | Review and manage the Agreement with the Commission and the Member state. | UMIL | |
| T 1.4 | Relationship with external parties and customers | Liason and Central Contact point, in connection with the local point of the consortium, will manage the relationship and contractual agreements with external Partners and other EDIHs, improve the relationship with third parties according to the Networking and Dissemination strategy set up in WP6. CATCH atMIND Liaison contact point together with all the beneficiaries will provide consulting services on innovation management. The Liaison office team will also interact with all stakeholders (internal and external players) involved in the project. | UMIL, all | |
| T 1.5 | Data Protection, CS and Ethic | Secretariat will also look for solving ethical, data protection and cybersecurity issues that arise during the project lifetime. When such issues have particular relevance or deserve attention, they are proposed to the DPCSEC for their solution or evaluation. Data Protection officer, Chief Information Security Officer (Technical and control management) of EDIH and WP leader will be members of DPCSEC. In particular the compliance assessment with respect to forthcoming UE regulatory framework on the use of AI in Europe, and compliance assessment to EU regulatory initiatives on eHealth and GDPR. Technical and Control personnel is also in charge of carrying out periodic audits of services aimed at providing the security and compliance of European Digital Innovation Hub as well as Coordination of cybersecurity incidents and data breaches. | UMIL CY4GATE TIM, EDI.IT | |

| Work | Package 2: Da | ta preparation, quality, security, governance an | d Al models |
|-------|--|---|---|
| T 2.1 | Data collection, ingestion, and preparation | This task supports the service deployment by the raw data acquisition from diversified sources (imaging, biochemistry, medical sensors and devices) and their harmonization including stewardship of data sets to ensure highest quality and format suitable for the further use in AI/ML model development. In doing that, highest standards of security, integrity and interoperability of the data will be pursued. | UMIL, UNIBS, UNIPV, UNIMIB, OGSA, ADVICE PHARMA |
| T 2.2 | Healthcare data exchange, representation and integration | This task will adopt the specific standards necessary to represent (e.g. OMOP/OHDSI), exchange (e.g. HL7 FHIR) and store healthcare data in an interoperable way. Additionally, specific ethical issues will be addressed according to the national and international rules and managed by the DPCSEC in coordination with the Ethical committees of the Hospital or public administration involved or served as customers. | UMIL, OGSA, TIM, ADVICE PHARMA |
| T 2.3 | Security Assessment & Device Management | This task focuses on both on online and offline methodologies to provide security in an IT healthcare infrastructure. The offline methodology is a security assessment based on static and dynamic techniques. The static assessment guarantees the security-by-design approach and consist of Secure Code Auditing Activities executed on every source code developed for the project by all entities. The dynamic testing test the cyber resilience capability of the project infrastructure against cyber or physical threat and will take advantage of a CY4GATE proprietary software able to provide dynamic verification (PT) of vulnerabilities, system possibly exposed to exploits and error in security configurations. The online methodology is based on a CY4GATE distributed platform for real-time analytics called RTA that will provide coordination and allows for management normalization, | CY4GATE, ADVICE PHARMA |

| | | transformation, analysis and indexing of millions of data. RTA collection uses customizable connectors, which would enable extracting data from many different sources and infrastructures sensors that, together with the platform's real-time analysis and visualization capabilities, allow the security monitoring of the infrastructure. | |
|-------|--|---|-------------------------|
| T 2.4 | ICT Security Monitoring | This task is about CY4GATE providing an i-SOC service to monitor and manage incidents of the hub IT infrastructure. The service will use the RTA platform for cyber security monitoring, identification of anomalies or incidents, investigations of alerts and reporting and continuous improvement to support the analysis and investigations tasks of the team. | CY4GATE |
| T 2.5 | Demo-Lab | This task concerns the SaaS (Software as a Service) platform of GRC (Governance, Risk and Compliance) that provides a way to handle all the obligations defined for documents to be compliant with the GDPR (from data processing impact analysis to record of processing activities, data breach register, draft formal answers to the requests of the data subjects). | UMIL, All |
| T 2.6 | Artificial Intelligence-as-a- Service (Al-aaS) | The task aims to provide an online AI on-demand platform that enables easy-to-use, automation and on-demand design, development, training and optimisation of any AI models to provide services. The tool also exploits external HPC infrastructures by other EDIHs of the NEXTWAVE HCI to boost the training capability and reduce the time to provide optimal models. | UNIPV, COMPLEXDATA |
| T 2.7 | Al Model Federation in virtual Biobanks and in-silico research | The task will support the services based on a federated formation of AI and Machine Learning (AIML) models of interest to the Italian and European LS ecosystem. A virtual multi-source management infrastructure will be provided and access to data for data-driven testing and verification of new products and services in the life and health sciences (such as integration through "digital twin" techniques of digital data and biological samples of biobanks; access via low latency and broadband 5G network, suitable for data consumption by AI applications; access control and protection of clinical data in transit and in the archive; application of innovative AIML models to aggregate, pre-process and expand the clinical data necessary for the experimentation of innovative data-based products and services). | COMPLEXDATA, CY4GATE |

| T 2 4 | Analysis | The took provides a comprehensive analysis and electricated of the | EDLIT |
|-------|---|---|---|
| T 3.1 | Analysis and clarification of the key issues related to the new paradigm of "digital health" | The task provides a comprehensive analysis and clarification of the key issues related to the new paradigm of "digital health", including a review of the best practices and of the related enabling conditions and obstacles. | EDI.IT AREXPO FT I&T HUB, ADVICE PHARMA |
| T 3.2 | CATCH atMIND co-creation methods and tools | The task, aims at defining 1. the methodology to be applied for the integration of the services to be developed in the physical Lab and 2. the selection criteria that will give access to the facilities to SMEs & PA offices. | UMIL TIM LEF, ADVICE PHARMA OGSA EDI.IT |
| Т 3.3 | Design, setup and implementation of the infrastructure and environment of the "active showcase" | In this task new services and products can be prototyped, tested, and fine-tuned in a realistic environment, leveraging on an interactive multidisciplinary environment (co-creation lab) including real endusers (living lab), before incurring in the actual costs for prototyping and pre-production (test-before-invest). EDIH will exhibit its catalogue to interested "customers" in a real, or realistic, virtualized context. A resource center (infopoint) will make available documentation and resources, including presentations of applications, equipment, and procedures. Interaction with selected environments and processes will occur through their virtualized digital representation (digital twin). | EDI.IT LEF AREXPO FT I&T HUB ADVICE PHARMA |
| T 3.4 | Demo-lab and Virtual Facilities | After having collected the services proposed, the Demo-Lab will be set up as a showcase of CATCH atMIND services. The physical Demo-Lab and the related digital facilities will be generated by exploiting the participants' premises and work in the measure of the financing available. | UMIL TIM LEF EDI.IT ADVICE PHARMA |
| T 3.5 | Hospital of the future | The purpose of this task is to consolidate in one experience how the hospital of the future may look like for different type of users: manager, physicians, patients. This fully digital experience, enables | LEF OGSA EDI.IT |

| | | the interaction with potential new services and functions in an ideal hospital where AI, HPC and Cybersecurity are fully exploited. | ADVICE PHARMA |
|-------|---------------------|--|---|
| T 3.6 | Co-creation atelier | This task aim is to complete the Demo Lab, engaging with the user in interactive sessions (also on-line) to know her needs, helping her to navigate through the available resources and support in the cocreation of innovative tools and ways for a given environment and need. | UMIL TIM LEF EDI.IT ADVICE PHARMA |

| 4.1 | Identification of | This task represents the first step in the WP activities. Its outcomes are | LEF |
|-------|--|--|---------------------------------|
| | suitable business candidates (SMEs and PA's segments) and assessment criteria and tools | the rules for engagement for the various business segments addressed, and the assessment tools to evaluate the potential and the current posture of the target organisation (self-assessment of digital maturity, cybersecurity, etc.). | TIM EDI.IT I&T HUB, |
| Γ 4.2 | Establishing a documentation and demonstration service | This task identifies and deliver a portfolio of actions and services that document the potential of the addressed enabling technologies. The output includes the selection of suitable use cases and their documentation through various multimedia tools. The task includes the establishment of a foresight action that scans the scientific and industrial development in the segments of interest. | LEF TIM EDI.IT I&T HUB |
| T 4.3 | Providing services that support the test-before-invest and the prototyping phase (PoC) | The showcase environment is put at work to demonstrate potential customers the technical feasibility of a foreseen development. Potential customers are SMEs interested in establishing new health-related services and/or PA's segments such as regional stakeholders and health services willing to enlarge and strengthen their portfolio of digital health services. | LEF TIM EDI.IT I&T HUB |
| | | Services and tools provided here help the target to design, integrate, develop, and test new digital solutions by exploiting the assets provided by the showcase environment. This includes the access to a simulation environment where new use cases can be developed building upon a hybrid (physical and virtual) infrastructure. | |
| T 4.4 | Services to assist in the development of a minimum viable product (MVC) | This task explores the condition and provides supporting services where a target organisation is matched with a technical partner that assists in further developing a demonstrated PoC or prototype into a solution that is better engineered for implementation in the real business. | LEF TIM EDI.IT I&T HUB |
| | | The output of this task includes matching services with technical and scientific partners (options for sharing knowledge in an open innovation context), contractual services, validation services, support to certification and patenting, etc. | |
| T 4.5 | Services supporting the full implementation of an innovative solution | This task addresses the internal and external conditions that make the innovative solution feasible for a full implementation, and effective and sustainable for the target organisation and its customers. Services provided include tools to assess and improve the internal and external conditions and the compliance by the target organisation, services to access funding options (public funds and private investors), and provisions for a longer-term support by technical and research partners that may be needed to keep operational and maintain the implemented solution. | LEF TIM EDI.IT I&T HUB |

| T 5.1 | Selection, development, and implementation of a set of services | The services are segmented into 3 different streams, according to their content, means of delivery, and target maturity: A. Services targeting startups/spinoffs and research organisations focusing on advanced developments in the healthcare/ life sciences segments. These services mainly focus on innovative data science and AI tools Services addressed to SME's willing to approach the digital healthcare/wellness segment, and to service organisations (public and private) that intend to explore new delivery options for health and social care. They include: assessment services of the current digital posture of the organisation; proactive services accompanying the prospect towards the new market; access to external competencies such as financial, regulatory, insurance, benchmarking, patenting, certification, mutual assurance, etc.;- networking services, that put the prospect in contact with experts/peers and similar/complementary experiences training and skill/competencies assessment and development C. Services addressing the PA and its stakeholders and regulatory bodies to stimulate and support their options for an evidence-based evaluation of innovative technologies (HTA), the "smart" procurement of innovation (PCP, PPI), their compliance to cybersecurity and GDPR provisions, and their shift towards outcome/result-based contracts with the providers (pharma, outsourcers). | EDI.IT AREXPO FT I&T HUB CY4GATE ADVICE PHARMA UMIL |
|-------|---|--|---|
| T 5.2 | Open science: Hackathon Call for solutions, Incubation, Acceleration, Proof of Concept programs | This task will elicit the development of original projects and business ideas. The work will be done at three levels: 1. organization of hackathons to involve communities of developers and data scientists to solve Life Sciences unmet needs; 2. Launching Calls for Ideas that address challenges in health research; 3 connecting corporates with pre-vetted vendors - Research institutions, Start-ups and SMEs members of the EDIH DigitalHub Ecosystem - ready to run PoCs. A more specific and tailor-made program for startups will be designed and developed to support market research, business modelling and planning and go-to-market strategy and incubation and acceleration services will be provided to the highly promising start-ups/projects. | CF Bio4Dreams LEF FT EDI.IT I&T HUB |
| T 5.3 | In-house training | Task 5.3 will be focused on the development of an "in-house training" program in the AI, Cyber, HPC area. The program will be tailored to answer project-specific needs with particular emphasis on the development and application of innovative models of AI and ML to the inference of molecular data analysis for drug target identification and repurposing. It will include workshops and training modules. Each module (3-6 months) will be designed as standalone (frontal lessons and hands-on training on industry-driven real cases), professional. Students completing 3 modules will be awarded with the "CATCH atMIND Academy". | Bio4Dreams TIM |
| T 5.4 | CATCH Experiential learning | A CATCH Executive Master targeting C-levels and managers from the private and the public sector will be created to empower participants with the competences indispensable to stand up to the business competition. Inspirational best practices and casestudies that will be embedded in CATCH Executive Master will be utilized to familiarize and learn to exploit in competitive business strategies Big Data, High Performing Computing, Cybersecurity, Artificial Intelligence, and Machine Learning. | LEF CF LEF ADVICE PHARMA |
| T 5.5 | CATCH Entrepreneurship program | The CATCH atMIND Entrepreneurship program will target STEM young professionals, developers, and researchers and will cover all concepts underlying the conception, design, organisation, and management of new enterprises. The program will be designed to explore the principles of design thinking, entrepreneurship, open innovation, and lean methodologies. | CF EDI.IT I&THUB ADVICE PHARMA |
| T 5.6 | Support to access regional, national and EU funding opportunities | Individual support services to facilitate the access of Enterprises, Corporates and PA to EU, national and regional funding opportunities, mainly Horizon Europe and Structural Funds. The services provided will include: analysis of the clients' needs; search for funding opportunities that meet the clients' needs; prescreening of project ideas, partner search for collaborative projects, consolidation of the business model and exploitation plan, support to improve project proposals. | CF EDI.IT Bio4Dreams AREXPO I&THUB |

| | <u> </u> | ation and External EDIH collaboration | 1.15.411 |
|-------|---|---|--|
| T 6.1 | Mapping of stakeholders and definition of a networking strategy | Identify and map the main stakeholders in the Life Science innovation ecosystem at national and EU level to define the network strategy which will be based on common messages reflecting the composition of the partners. The final aim is to position CATCH atMIND at national/European/international level, networking synergistically also to design effective networking services for beneficiaries. | UMIL EDI.IT AREXPO |
| T 6.2 | European Network of Life Sciences EDIH | This task, based on the analysis of T6.1, will be dedicated to consolidate a well-coordinated network of EU EDIH specialised in the life sciences and healthcare. The activity will start from NEXTWAVE@HCI and other EDIHs already connected with the partners of the MoU: a) Setting-up an EU strategic committee with representatives of all the relevant EDIH and thematic working groups on key areas of work such as health data exchange, regulatory compliance, cybersecurity, access to funding and shared services; b)Creating protocols and contract templates to facilitate collaboration and resources sharing across the EDIH, with a particular focus on access to funding and data sharing; c) Setting-up a shared repository with constantly updated information on infrastructures and services to facilitate transnational collaboration; d)-Building a common knowledge base and a shared communication strategy to accelerate transnational cooperation among EDIH users. The networking strategy of T6.1 will be also implemented with the: 1) creation of a collaborative Joint Working Group with Enterprise Europe Network, Startup Europe and Digital Transformation Accelerator for a shared standardization of information on innovation support services to increase the outreach of the EDIHs network among SMEs and PAs 2) Participation in key events and workshops in Innotech and Lifesciences Communities, 3) Fostering collaboration, networking and best practice sharing with the Italian and International Network of Third Sector. | UMIL AREXPO EDI.IT FT LEF I&T HUB |
| T 6.3 | Networking as a service for Customers | This task aims to create a framework of services, defined on the basis of the results of the previous WPs preparatory and/or preliminary for the activities of WP6 for the beneficiaries (SMEs and PA). In brief we will set up digital tools enabling: 1) collaboration with Enterprise Europe Network for networking at international level to increase funding opportunities; 2) Organization of meetings to promote Open Innovation for startup, SMEs and PA; 3) Design and implementation of B2B meeting, events, round tables to favour beneficiaries relationship at regional, national and international level; 4) implement PPP aimed at promoting sustainable programs of research and innovation in the health field. | UMIL EDI.IT FT LEF AREXPO I&T HUB |
| T6.4 | Communication/Dissemination activities | This task will define, together with the Secretariat and Liason officer of the CATCH atMIND, a communication/ dissemination strategy by realizing a website and social media channels, redacting a Newsletter to present activities and opportunities created by the hub, promoting events to present main results of the hub: Open Innovation Platform Lombardia, specific dissemination events (Meet in Italy for Life Sciences) and developing podcasts, infographics, policy briefs. | UMIL FT LEF EDI.IT AREXPO I&T HUB |

Per i servizi rivisti, di cui il relativo costo è stato indicato nella relazione trasmessa al MIMIT sopra citata, si specifica che essi ricadono principalmente nei WP 2-3-4 e 5 e solo parzialmente nel WP 6, secondo la tabella che segue. Si sottolinea che tale connessione, per i servizi che non sono stati modificati, era già specificata nella proposta presentata.

Le uniche variazioni intervenute nella distribuzione dei servizi rispetto al draft V.2 del 29 febbraio 2024 riguardano i partner Lean Experience Factory S.r.l. ed EDI.IT che hanno accolto l'opportunità di aumentare i servizi offerti e, conseguentemente, il contributo richiesto (per quest'ultimo aspetto si veda nel dettaglio la tabella di budget al paragrafo 2).

Il Partner Lean Experience Factory S.r.l. ha richiesto di aumentare i servizi ex art. 27 ed ex art. 28 in relazione alle attività di "Business analysis and business development", categorie "Prova prima dell'investimento (Proof of Concept (PoC) development based on Customer requirements/needs and Data)" e "Formazione (Training on PoC design and development)". I servizi interessati dall'incremento ricadono rispettivamente nei WP 3-4 e nel WP 5;

Il Partner EDI.IT ha incrementato gli importi classificati come ex art. 27 (voci "Demo center setup & operations" e "Ecosystems & networking"). Al contempo ha richiesto la riclassificazione di alcuni servizi ("Customer journey step 1" e "Healthcare cybersecurity assessment/framework, scoring") dalla voce "Consulenza su accesso ai finanziamenti" alla voce "Prova prima dell'investimento". Parte dell'ammontare destinato alla voce "Prova prima dell'investimento" (Open Innovation initiatives and matchmaking event with other EDIHs) è stato riclassificato sotto la voce "Audit tecnico, valutazione e maturità tecnologica (Assessment)".

Nel caso di EDI.IT i servizi modificati ricadono nei WP 2-3-4 e 6.

| Type of services | Work Package |
|--|-----------------|
| A1. Test Before invest: Biomedical Data Preparation and Management Services | |
| A 1.1 SUPPORT FOR IN SILICO TEST AND EXPERIMENTATION | |
| Collection, digitization, and secure transmission of biodata (including -omics data) on behalf of the customer | WP 2 |
| (Labs or healthcare institution) | |
| Data preparation starting from untargeted lipidomic or metabolomics on biological samples including sample | WP 2 |
| preparation, instrumental and data analysis | |
| Data preparation starting from untargeted proteomics on biological samples including sample preparation, | WP 2 |
| instrumental and data analysis Data preparation starting from targeted lipidomic or metabolomics on biological samples including sample | W/D 2 |
| preparation, instrumental and data analysis (specific standards are not included) | WP 2 |
| Data preparation starting from targeted proteomics on biological samples including sample preparation, | WP 2 |
| instrumental and data analysis (specific standards are not included) | VVF Z |
| Data preparation starting from FRET-FLIM Confocal Microscope with assistance of technical personnel | WP 2 |
| Data preparation starting from SIM Confocal Microscope with assistance from technical personnel | WP 2 |
| Data preparation from slide reader | WP 2 |
| Data preparation from two-photon confocal microscope with assistance from technical personnel | WP 2 |
| Data preparation from MRI Magnetic Resonance Imaging with assistance from technical personnel | WP 2 |
| Data acquisition for automatic analysis | WP 2 |
| Data and with image acquisition from upright bright field and fluorescence microscope | WP 2 |
| Data acquisition from TEM Talos L120C with assistance from technical personnel | WP 2 |
| Data acquisition from automated bright field and fluorescence stereomicroscope with assistance from technical | WP 2 |
| personnel | |
| Data acquisition from FE-SEM SIGMA with assistance from technical personnel | WP 2 |
| Data collection from CRYO-Electron Microscopy - Negative staining EM | WP 2 |
| Data collection from CRYO-Electron Microscopy - Tomography | WP 2 |
| Data collection from CRYO-Electron Microscopy - | WP 2 |
| Data analysis (as a full package) | _ |
| Application of AI-ML models to existing data (biobanks) | WP 2 |
| A 1.2. BIO/CLINICAL DATA MANAGEMENT | |
| Harmonization and standardization of bio-clinical data (cells, animal and Human Data), including custom | WP 2 |
| metadata definition Custom interface for data access guaru and undata | WP 2 |
| Custom interface for data access, query and update | WP 2 |
| Data access control and protection service (in transit and at rest) | |
| Verification and release of quality-controlled data sets Set-up of pathology registries | WP 2 WP 2 |
| Clinical Data Storage platform (electronic case report form) License | WP 2 |
| Clinical Data Management System Platform | WP 2 |
| Clinical study planning | WP 2 |
| Clinical study planning Clinical study start up | WP 2 |
| Clinical study on site monitoring | WP 2 |
| Clinical Data Management on eCRF | WP 2 |
| Software as Medical Device (SaMD) feasibility analysis | WP 2 |
| SaMD development (IT) | WP 2 |
| SaMD clinical validation | WP 2 |

| A2. Test Before invest: Data-driven Product development Services | |
|--|---------------------------------------|
| A2.1. SUPPORT FOR IN SILICO TEST AND EXPERIMENTATION | |
| Evaluation of data relevance for biological analysis and creation of Digital Biobanks | WP 3 |
| Advanced Analytics Packages (Topologic analysis of biological pathways and networks - Clustering coefficients | |
| and hubs analysis - Phylogenetic analysis) | WP 3 |
| Genomic Analytics Packages (Studies of genome sequences and multiple sequences alignment, computation of | WP 2, 3 |
| position-weighted matrices) | |
| A3. Test Before invest: Support Services for in vivo and in vitro studies | |
| Design of digital tissue models | WP3 |
| Creation of custom digital organ Models | WP3 |
| Design Of Digital Animal Models | WP3 |
| A4. Test Before invest/Assessment: Consultancy Services for diagnostics and therapeutics | |
| A 4.1 SUPPORT FOR DIAGNOSTICS AND THERAPEUTICS | |
| Models of AI-based innovative clinical diagnostics | WP 3 |
| Design of experiments targeted to diagnostic and therapeutic targets (e.g. gender-specific medicine) | WP 3, 4 |
| Design of healthcare models for prenatal, chronic and elderly patients | WP 3, 4 |
| Support to design of miniaturized diagnostic devices | WP 3, 4 |
| Support to design and implementation of custom optimized radiotherapy (IMRT – Intensity Modulated Radiation Therapy) | WP 3, 4 |
| Digital Patient Empowerment: Tools and services to develop consumer-centered digital solutions as part of an | |
| ntegrated care plan that coordinates lifestyle, virtuous behaviors with information on clinical decision-making | WP 3, 4 |
| and therapy compliance | 5, 1 |
| Models relying on clinical data for design and custom implementation of orthopedic products | WP 3, 4 |
| Support to Digital clinical trials (therapies, medical devices, SaMD) | WP 3, 4 |
| Support to Design and implementation of advanced therapies and devices- Tools and services to assist pharma | 3, 4 |
| and public bodies in the evaluation and implementation of innovative therapies and devices: bioinformatics, | |
| next-generation biobanking, digital biology, functional human-on-chip systems, HTS computation services for | WP 3, 4 |
| drug repurposing, 3D organ printing, real-world data analytics | |
| Customer journey step 1 (Assessment services): Digital posture assessment (SMEs/PAs) | WP 4 |
| Customer journey step 2: feasibility studies, blueprints for implementation | WP 4 |
| Customer journey step 3: support to PoC, MVP | WP 4 |
| Setting up of dedicated facilities (ageing-friendly) in reception facilities (technologies, regulations, examples of | |
| implementation, economic and social benefits) | WP 4 |
| A 5.1 SUPPORT FOR SERVICE SHOWCASING | |
| Pre-investment simulation for product and services in the fields of healthcare and healthy lifestyle | WP 3 |
| Set up of physical and virtual showcases for healthcare product and services | |
| DTwins for hospitals and other care settings - Al-based tools for a more efficient delivery of services in hospitals | |
| and other care settings: logistics, planning, admittance, reception, scheduling, queuing, etc. | WP 3, 4 |
| Support to Digital tools for the silver economy – health and wellness- Tools and services to help SMEs identify | |
| special needs of elderly and fragile persons and bridge their gap with the living and working environment, by | |
| supporting investments in design and manufacturing of niche products for a "silver" customer segment through | WP 3, 4 |
| open innovation and test-before-invest opportunities: e.g. access to premises, personal mobility, travelling | · · · · · · · · · · · · · · · · · · · |
| options, handling of common objects, hearing and visual aids, communication. | |
| Support to development of Telemedicine Services- Telemedicine/ e-clinics: Tools and services to promote and | |
| support the establishment of remote medical services (telemedicine and teleconsultation, hybrid e-clinics, self- | WP 3, 4 |
| care services) - blueprints, regulations and standards, contracts, reimbursements, investments | -, . |
| EU digital identity eIDAS- Tools and services to implement a secure digital identification of patients and | |
| caregivers: enabling secure access to personal data, implementation of the e-consent, emergency access, chain | WP 3, 4 |
| of custody | 5, 1 |
| · | |
| Evidence-based assessment of digital health. value-based contracts - Tools and services to assess effectiveness | |
| | |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative rechnologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) | |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient tempowerment | |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient tempowerment A6. Test Before invest: Demolab | |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient tempowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient empowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING Virtual and Augmented Reality demos of the EDIH services | |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient empowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING Virtual and Augmented Reality demos of the EDIH services A7. Test Before invest: Security Assessment, Security Device Management Services | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient empowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING Virtual and Augmented Reality demos of the EDIH services A7. Test Before invest: Security Assessment, Security Device Management Services SECURITY/PRIVACY ASSESSMENT AND COMPLIANCE VERIFICATION SERVICES | WP 3, 4 |
| and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient empowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING Virtual and Augmented Reality demos of the EDIH services A7. Test Before invest: Security Assessment, Security Device Management Services SECURITY/PRIVACY ASSESSMENT AND COMPLIANCE VERIFICATION SERVICES Service Vulnerability Assessment | WP 3, 4 WP 3 |
| Evidence-based assessment of digital health, value-based contracts - Tools and services to assess effectiveness and performance of digital services in healthcare, support for the evidence-based evaluation of innovative technologies (HTA), smart procurement of innovation (PCP, PPI) and outcome/value-based contracts with the providers (pharma, outsourcers) GPT generative artificial intelligence tools for doctor-patient communication, self-care, chatbots, patient empowerment A6. Test Before invest: Demolab SUPPORT FOR SERVICE SHOWCASING Virtual and Augmented Reality demos of the EDIH services A7. Test Before invest: Security Assessment, Security Device Management Services SECURITY/PRIVACY ASSESSMENT AND COMPLIANCE VERIFICATION SERVICES Service Vulnerability Assessment Service Penetration test Device Security Assessment | WP 3, 4 |

| Incident management | WP 2 |
|---|---------|
| Privacy Assessment | WP 2 |
| Healthcare cybersecurity - Cybersecurity tools and services dedicated to the healthcare environment: a | |
| standardized reference framework, tools to assess the posture of the healthcare network as a critical | |
| infrastructure, to evaluate and monitor security (endpoint and networks), safety (connected devices) and | WP 2, 4 |
| privacy (patients' data) of a medical organisation, including the supply chain and outsourced facilities for mutual | |
| assurance | |
| Healthcare cybersecurity assessment/framework, scoring | WP 2, 4 |
| Pre-competitive analysis and feasibility studies (IP assessment, market opportunities and development plan) | WP 3, 4 |
| Proof of Concept (PoC) development based on Customer Data and needs | WP 3, 4 |
| Concierge medicine: subscription fee based medical services, insurance coverage, sustainability and cost | WP 3, 4 |
| effectiveness, awareness raising and promotion of healthy lifestyles | |
| Retail medicine: tools and services to help establish and support a retail medical business located at major | |
| retailer sites (store: pharma & devices, provision of vertical diagnostic/ambulatory services, e-clinic, self- | WP 3, 4 |
| medication and self-care): business model, blueprint for implementation, enabling software & technologies, | |
| investments, training and networking Senior living/ personal & environmental monitoring: Tools and services to support physical and behavioral | |
| monitoring and interpretation of patients and other fragile subjects in hospitals and other care settings (e.g. | WP 3, 4 |
| home care, assisted living facilities), early detection and warning of needs and trends | WF 3, 4 |
| B1. Training & skills development: Incubation and acceleration of start-ups and SME in the field of digital | |
| Health and Life Sciences | |
| Incubation (6-9 months), Business strategies definition and business model definition for SME and start-up | WP 5 |
| Acceleration program for SME (7-8 months) | WP 5 |
| B2. Training & skills development: Training for healthcare innovation management | |
| Hackaton- 2 days event on innovation in healthcare based on EDIH and customers data Set | WP 5 |
| Launch and management of calls for Innovative Solutions | WP 5 |
| Training on PoC design and development | WP 5 |
| Training on Digital creativity in healthcare innovation | WP 5 |
| Training on Business modeling and planning in healthcare | WP 5 |
| B3. Training & skills development: Educational Programs in Healthcare Innovation | |
| In-house training program in AI and OR/MS (Operations Research / Management Science) for healthcare | WP 5 |
| Training, information and awareness on EDIH services for SMEs and Public Administration | WP 5, 6 |
| Webinar on vertical topics of digital applications in healthcare and reference markets | WP 5 |
| 1-day short course (10-15 participants) on reference technologies (AI, HPC, cybersecurity, modeling) | WP 5 |
| 1-day certified course on digital innovation management | WP 5 |
| C1. Support to attract investment funding: accessing funding programs, credit and equity funding | |
| BUSINESS ANALYSIS AND BUSINESS DEVELOPMENT SERVICES | |
| Assistance for accessing public funding resources available for healthcare initiatives: program and partner | WP 5 |
| identification, application preparation and submission | |
| Digital or Financial Maturity assessment for healthcare SMEs/Public Administration | WP 5 |
| Awareness/webinar: financial conditions, sustainability | WP 5 |
| Financial assessment of PMI/PA in healthcare | WP 5 |
| Conference/matching event with funds/VC | WP 5, 6 |
| Open Innovation initiatives and matchmaking event with other EDIHs | WP 5, 6 |

2) Contributo Richiesto

1. Revisione del budget di progetto

Sulla base delle revisioni ai servizi e alle attività di cui ai punti precedenti ed in coerenza con quanto concordato nell'Atto di costituzione di associazione temporanea di scopo (ATS) stipulato tra i Partners del progetto, la nuova ripartizione del budget, comprensiva dei costi di spese generali pari al 7% dei costi diretti è riassunta nella tabella seguente:

| | TOTALE PROPOSTA (€) | NUOVO TOTALE COSTI PROGETTO (€) | CONTRIBUTO PNRR (€) | Contributo Spese Ex art. 27 (€) | Contributo Servizi Ex Art.28 (€) |
|---|---------------------------|---------------------------------------|---------------------------|--|---|
| 1 – Università degli Studi di Milano | 659.965,30 | 643.070 | 595.990 | 47.080 | 548.910 |
| 2 - Istituto Ortopedico Galeazzi S.p.A. (Ospedale Galeazzi S.p.A.) | 282.481,07 | 230.000 | 204.700 | - | 204.700 |
| 3 – AREXPO S.p.A. | 192.600,00 | 119.000 | 74.900 | 21.000 | 53.900 |
| 4 – Lean Experience Factory Scarl | 224.700,00 | 457.400 | 389.700 | 55.700 | 334.000 |
| 5 - Cariplo Factory | 256.800,00 | 240.000 | 113.448 | 12.000 | 101.448 |
| 6 - Bio4Dreams S.p.A. | 358.450,00 | 342.013 | 241.203 | 5.500 | 235.703 |
| 7 – The European House Ambrosetti S.p.A. | 203.300,00 | Rinuncia | | | |
| 8 - Deloitte Officine Innovazione | 219.350,00 | Rinuncia | | | |
| 9 – Cy4gate S.p.A. | 358.450,00 | 331.265 | 311.389 | - | 311.389 |
| 10 – Telecom Italia S.p.A. | 337.050,00 | 337.050 | 168.525 | 168.525 | ı |
| 11 - EDI.IT S.r.l. | 829.250,00 | 814.920 | 700.260 | 92.460 | 607.800 |
| 12 - Fondazione Triulza | 149.800,00 | 149.500 | 104.650 | - | 104.650 |
| 13. I&T innovation and Technology Hub Società consortile | 105.930,00 | 105.550 | 95.570 | 3.500 | 92.070 |
| 14. Università degli Studi di Brescia | 125.190,00 | 113.160 | 113.160 | | 113.160 |
| 15. Università degli Studi di Pavia | 321.000,00 | 320.250 | 297.750 | 22.500 | 275.250 |
| 16. Università degli Studi di Milano Bicocca | 125.190,00 | 108.000 | 108.000 | - | 108.000 |
| 17. Complexdata s.r.l. | 73.830,00 | 73.600 | 65.704 | - | 65.704 |
| 18. AdvicePharma Group S.r.l. | 309.016,00 | 308.500 | 216.945 | - | 216.945 |
| TOTALE | 5.132.352,37 | 4.693.278 | 3.801.893 | 428.265 | 3.373.628 |

Rispetto al Draft V. 2 del 29 febbraio 2024, in seguito ad interlocuzioni intercorse tra il Soggetto attuatore (Capofila) ed il MIMIT, due dei partner di progetto hanno accolto l'opportunità di aumentare i servizi offerti e conseguentemente il contributo richiesto. I partner interessati dalla variazione sono Lean Experience Factory Scarl ed EDI.IT S.r.l. i cui nuovi importi richiesti sono evidenziati in tabella in grassetto.

Nel caso di Lean Experience Factory Scarl, il partner ha richiesto di aumentare il numero di servizi offerti alle voci "Prova prima dell'investimento" e "Formazione e sviluppo di competenze".

Il contributo PNRR finale richiesto dal partner ammonta adesso a € 389.700.

Nel caso di EDI.IT, gli incrementi hanno riguardato prevalentemente gli importi classificati come ex art. 27 del GBER. Si è inoltre provveduto ad una riclassificazione di alcuni servizi spostati dalla voce "Consulenza su accesso ai finanziamenti" alla voce "Prova prima dell'investimento" per un importo pari a € 80.000. Una quota pari a € 90.000 è stata inoltre spostata dalla voce "Prova prima dell'investimento" alla voce "Audit tecnico, valutazione e maturità tecnologica (Assessment)" generando un incremento del contributo PNRR richiesto da parte del Partner pari a complessivi € 700.260 a fronte di un costo totale progetto pari a € 814.920.

I costi totali di progetto, inclusivi di spese generali pari al 7% dei costi diretti, sono suddivisi come da cronoprogramma come segue:

- Spese relative a Servizi (Ex art 28-31): € 3.836.748;
- Spese relative a Servizi (Ex art 27): € 856.530.

I contributi PNRR, basati su una stima della tipologia di utenti a cui verranno erogati i servizi, sono quindi così suddivisi, come da tabella che precede:

- Spese relative a Servizi (ex art 28-31): € 3.373.628;
- Spese relative a Servizi (ex art 27): € 428.265.

La quota di cofinanziamento privato da parte delle imprese per l'erogazione dei servizi ex art 28-31, sulla base di una stima della numerosità degli utenti e della loro tipologia, nonché del tipo di servizio erogato, è pari alla differenza tra il totale dei costi e il contributo PNRR, ovvero pari a € 463.120.

Con riferimento al numero di imprese uniche servite o di PA che beneficeranno dei servizi come da cronoprogramma si ritiene di poter confermare in linea generale i KPI di progetto, che, come si evince dalla tabella sottostante, includevano sia PMI che Pubbliche Amministrazioni (PA) e altri fattori, tra cui la capacità del Polo di raggiungere e coinvolgere PMI e PA, capacità di fornire supporto alla richiesta di finanziamenti, ecc.

| Tabella KPI come da Proposta Europea (Totali) | | | | |
|--|-------|--|--|--|
| | Total | | | |
| N. of SMEs contacted as prospects for the EDIH services | 500 | | | |
| N. of PAs and healthcare providers (public and private) contacted as prospects for the EDIH services | | | | |
| Total # of prospects | 560 | | | |
| N. of customers (private) that have used services provided by the EDIH (education and demonstration, up to PoC) | 120 | | | |
| N. of customers (public) that have used services provided by the EDIH (education and demonstration, up to PoC) | 35 | | | |
| Total # of business interactions | | | | |
| N. of businesses participating in facilitating actions to find investment | | | | |
| N. of investment/funding contracts signed under the auspices of the EDIH | | | | |
| N. of digital maturity assessments, with structured reporting of the performed actions and scoring against a common benchmark (whenever possible); | 140 | | | |
| N. Training Events | 20 | | | |
| N. of attendance to training activities | 340 | | | |
| N. of communication/dissemination events | | | | |
| N. of additional cooperation between Hubs, research institutions, Hospitals | 20 | | | |

Con particolare riferimento al nr. di PMI servite si fa riferimento alla seguente tabella numerica rivista, che verrà considerata come target di progetto, tenendo conto di una ipotetica riduzione della durata temporale rispetto a quanto previsto in fase di project proposal, come già evidenziato nelle precedenti relazioni inviate al MIMIT.

| DICITURA PROPOSTA EU | DICITURA CRONOPROGRAMMA | Total |
|--|---|-------|
| N. of digital maturity assessments, with structured reporting of the performed actions and scoring against a common benchmark (whenever possible); | B.1 Audit Tecnico, Valutazione Maturità Tecnologica (Assessment) | 190 |
| N. of customers (private) that have used services provided by the EDIH (education and demonstration, up to PoC) | B.2 Prova prima dell'investimento | 130 |
| N. Training events | B.3. Formazione | 20 |
| N. of businesses participating in facilitating actions to find investment | B.4 Consulenza su accesso ai finanziamenti | 35 |
| N. of communication/dissemination events | B.5 Consulenza su innovazione tecnologica di processo e di prodotto, networking e sensibilizzazione | 30 |

| N. of investment/funding contracts signed under the auspicious of the EDIH | B.5 Consulenza su innovazione tecnologica di processo e di prodotto, | 5 | |
|--|--|---|--|
| | networking e sensibilizzazione | | |

In particolare, fermo restando i numeri di contatti che emergono solamente dalla proposta EU, relativamente ai beneficiari dei servizi EDIH, come indicato nel cronoprogramma allegato, il partenariato si pone come obiettivo il seguente numero di imprese a pubbliche amministrazioni che accederanno al servizio:

- Target numero di aziende uniche servite: 165
- Target numero di pubbliche amministrazioni uniche servite: 25

Rispetto al target definito nella proposta, il numero di imprese uniche servite sale da **120** a **165**, mentre il numero di pubbliche amministrazioni scende da **35** a **25**. Il totale indicato nel cronoprogramma rimane comunque superiore al target indicato in proposta.

Si precisa che le attività dei partner sono state riviste così da poter fornire un numero di servizi pari o superiore alla stima indicata nella proposta originaria riducendo, al contempo, l'onere delle spese ascrivibili all'art. 27 del GBER ("Ammodernamento e funzionamento dei Centri di trasferimento tecnologico e funzionali all'erogazione dei servizi") che verranno in parte sostenute autonomamente dai membri dell'ATS all'interno delle proprie attività istituzionali. L'erogazione del questionario di Digital Maturity Assessment sarà offerta come da proposta originaria a tutte le aziende che richiederanno i servizi, il cui costo è da considerarsi incluso all'interno del costo del servizio stesso.

Legale Rappresentante
Prof. Elio Franzini
(Firma digitale)