INNO4COV-19

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Abbreviation and Acronyms

ICT – Information and Communications Technology

MDR – Medical Device Regulation

MDR – Medical Device Software

PPE – Protective Personal Equipment

SP – Service pack

Contents

Executive Summary

This document provides information about the services offered by INNO4COV19 partners on Sensors, telemonitoring devices and telemedicine systems that are oriented to reach the market and reduce the time to market.

The main objectives of this report are to provide i) more detailed information about the capabilities of partners involved on SP3, ii) identify each kind of service and the appropriate partner iii) Provide a guideline to access at services platform.

This report describes the services offered in the frame of electronic devices, instruments, and wearables for telemonitoring or telemedicine developed in the frame of INNO4COV-19 project.

1. Framework of INNO4COV-19 services platform

The service catalog of Sheet templates consider several categories of emerging and existing technologies for telemonitoring, and telemedicine applications based on connected devices, instruments, or equipment and also wearables that can be used for parameters monitoring in order to increase the health security mechanism on public and private health systems and obtain more specific and relevant data from patients and users of this new and emergent technologies.

It is important to remark that all development needs to identify the potential market to be addressed and consider all regulation and legal requirements that they must achieve before to commercialize. In this context it is important to differentiate the telemonitoring system with and without medical grade.
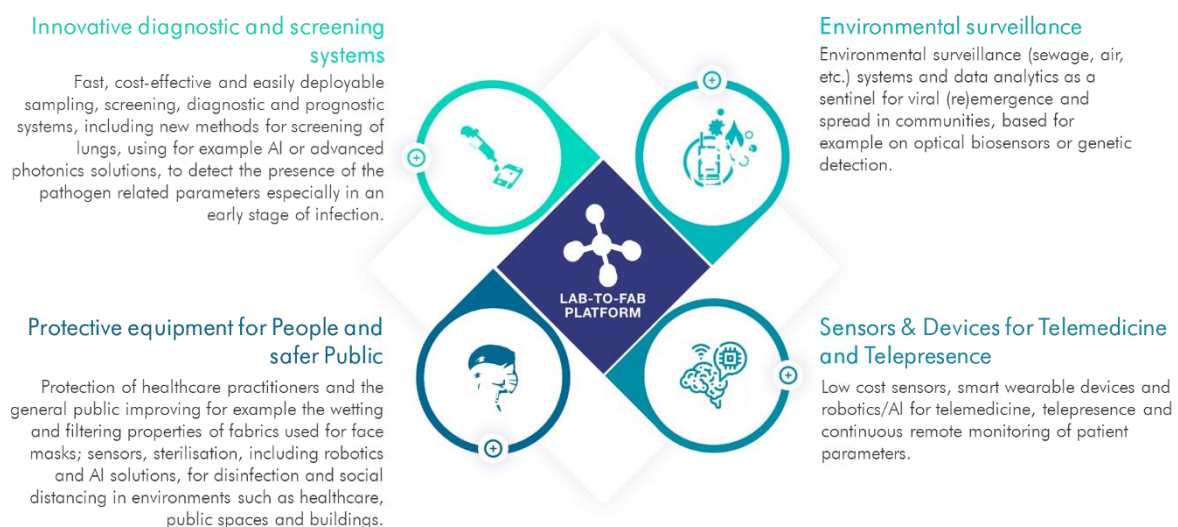

Figure 1 - Technology domains offered for INNO4COV-19 platform

1.1. Description of Partners form INNO4COV-19

Table 1 summarize all partners involved on INNO4COV19 project and their roles and capabilities on this project.

Table 1 – List of INNO4COV-19 platform partners

INNO4COV-19

Partner	Description
INL (logo) International Iberian Nanotechnology Laboratory (INL)	INL will lead the WP1 Open call management being responsible to coordinate and manage this key WPs. INL will be involved in the activities related to the attraction of network members, management and monitoring of the call as well as to ensure an efficient division of roles among the members to guarantee an effective provision of support and services to the third parties. INL will also lead WP3, a technical WP making use of internal expertise in environmental surveillance, in order to facilitate the development of methodologies in collaboration with other partners. Coordination of the execution of use case and call responders.

INL will participate in the technical WPs: WP2, 4 &5 in the development of methodologies in collaboration with other partners. Coordination of the execution of use case and call responders. INL will contribute to WP6 as well as WP8 bringing its capacities and competences to deliver "brokerage services", networking activities, business support as well as to define a sustainable post-project strategy of the platform. INL in WP9, as all the partners, will have an active role in ensuring effective communication and dissemination of the project activities and results.

Finally, INL will provide a test case to INOO4COVID-19, the "Advanced diagnostic system for COVID-19". |
| bioef (logo) The Basque Foundation for Health Innovation and Research (BIOEF) | OSTEBA is a HTA unit with competencies in the area of Health Technology Assessment, Health Needs Assessment and Economic Analysis. This expertise includes economic modelling, micro-costing analysis, outcomes prioritization and elaboration of recommendations. They have been providing early advice and early counselling on health technologies at the regional, national and international levels. |

		The potential of the Innosasun program lies in their capabilities. Innosasun gives ad hoc support to the companies, mainly SMEs, through the know-how and extensive collaborative network of the health system that acts as an open innovation ecosystem as a real testing lab or living lab. In fact, the network, which is coordinated by BIOEF, is formed by highly skilled professionals of the health public system (Osakidetza), Health Research Institutes (HRI), Kronikgune and OSTEBA. BIOEF will be responsible for WP7 - Regulatory Support & Health Technology Assessment.
BioKeralty Research Institute	Biokeralty Research Institute AIE (BK)	Biokeralty (BK) is an industrial Research Unit focused in the development on Research and innovation projects for its shareholders, mainly companies from the Healthcare Sector. Due to this, BK is well positioned in the European Med Tech and Healthcare sector. BK leads one of the Med Tech OITBs (SAFE-N-MEDTECH, which is the bigger one and has wider scope), which are innovation ecosystems that the EC aims to boost and connect to the new COVID 19 expressions of interest. Biokeralty will contribute in the following: Due to our position as OITB leaders, we can contribute to bridge the gap between innovative production and clinical/market uptake, applying the lessons learned in the OITB projects, proposing development roadmaps focused in: ▪ Anticipate regulatory needs-Adequate regulatory pathway-Regulatory preparedness ▪ Health Technology Assessment: Match the production with the real needs from Healthcare Systems ▪ Access to characterization of materials and devices

		▪ Health economics
		Connection with open calls from OITBs, including the one tailored to COVID 19 that will be opened in September under SAFE-N-MEDTECH leadership in order to allow co funding of activities and maximization of EC investments.
		Experience in building innovation networks, application of lessons learned from the OITBs schemes to the new project. Experience as single entry point for innovators in Medtech.
		Stakeholders and eco system building and assessment.
		Capability to attract other companies to the consortium, now or during the project duration (I.e. SME focused in additive manufacturing that has already started this transformation of production to COVID 19 needs).
		Maximization of impact (dissemination, communication, client engagement and exploitation) with connections to the European Commission and Medtech landscape. Experience leading Dissemination, Communication and exploitation in H2020 projects (TAT CF, Nocanther, Smart4Fabry, SAFE-N-MEDTECH).
		As part of Keralty group (www.keralty.com) access to direct Clinical experience and possibilities to open markets beyond Europe (Keralty offers healthcare services to 4.5 million people around the World, mostly in America).
		This will provide insights on American regulatory schemes, clinical practice and business opportunities for Keralty hospitals and clinics.
		As part of Keralty, connection to business intelligence and business development partners, including company incubators, health economics and feasibility analysis.

	Fraunhofer-Institut fúr Organische Elektronik, Elektronenstrahl- und Plasmatechnik FEP (Fraunhofer FEP)	Fraunhofer FEP will provide technical facilities for high-throughput electron-beam sterilisation both of film and fabric materials and medical products (WP5); large-area coating for antiviral- and antimicrobial surfaces (WP1 and WP5; surface modification for plastic and fabric based personal protection equipment (WP5); R&D and pilot facilities for microdisplay and sensor fabrication (backplane IC design, foundry relationship and frontplane post-processing) (WP2 and WP4) and Facilities for Testing and Verification of surface properties of sterilized and antimicrobial surfaces (WP2, WP3); Further Fraunhofer FEP will contribute to the Open Innovation Ecosystem Business Development (WP1, WP7, WP8, WP9) through the expertise gained in the Open Innovation Test Bed Projects FlexFunction2Sustain and NewSkin. Fraunhofer FEP will provide access to the facilities of these Open Innovation Test beds.
	Instituto de Medicina Molecular João Lobo Antunes (iMM)	The main roles of iMM in INNOV4COV-19 are described following: iMM will lead WP8 – Business support and sustainability. We will use our experience on Techologu Transfer R&D business development. iMM will also have an active role in WP8 by using their Business intelligence using proprietary databases (e.g. GlobalData), access to VCs network and other fundraising opportunities, as well as the access to industry network of 300+ companies in different sectors. iMM will provide a test case to INNO4COV-19 - "SARS-CoV-2 ELISA-based antibody test", that will mostly be developed in WP2.
	Joanneum Research Forschungsgesel lschaft mbH (JRO)	In the current pandemic crisis, Sars-CoV-2/Covid-19 test chips are needed in quantities of several millions per month. These quantities demand for new manufacturing approaches, which can be implemented by roll-to-roll (R2R)

		based processes. JR will be responsible for the investigation & development of R2R processes for high throughput manufacturing of polymer-based microfluidic chips for quick tests. Technological tasks will comprise simulation of microfluidic chip components and molecular dynamics in microfluidic sensors, the design of fluidic elements (reaction and mixing chambers, passive valves, capillary pumps) as well as the material design for nanoimprinting, the batch based UV NIL imprinting and the corresponding R2R upscaling process by R2R imprinting, R2R microarray spotting as well as R2R lamination.
		Especially in environments with large numbers of persons with critical underlying health conditions, e.g. in doctor's offices, retirement homes, hospitals, but also in public transport vehicles, often touched surfaces represent significant places for viral (and – in wider perspective – microbial) infection. Laminated foils of anti-viral properties with long durability, i.e. wear and corrosion protection of such functionality may provide additional protection against infection. Roll-to-roll atmospheric pressure plasma coating deposition on polymer foils represents an intensively developed technology with proved quick anti-viral effect, currently at TRL 6. Missing target for placing such novel foils on the market is covered by JOR's project contribution on coating material modifications to enhance the anti-viral durability of the dispersed copper alloy deposits on various polymer foil materials, i.e. the alloying/doping of the multi- and gradient layered architectures and its combination with protection top layers.
LEiTaT managing technologies	Acondicionamiento Tarrasense Association (Leitat)	The main roles of LEITAT in INNOV4COV-19 are described following: ▪ WP4 – Work package leader. Development of methodologies in collaboration with other partners. Coordination of the execution of

		use case and call responders. WP4 are focus on the telemonitoring and telemedicine. In this way LEITAT will offer their support to third parties on electronic devices and sensors design and development with the aim to obtain a product and reduce the time-to-market. ▪ WP5 – Use case "Filtering materials for Protective mask (indoor and outdoor) and filters including antiviral and gas retention properties" ▪ WP8 – Integration of LEITAT's strategic initiatives with INNOV4COV-19's ecosystem.
Obelis GROUP	Obelis	WP 7: Together with all partners, Obelis will ensure regulatory compliance of the project and its results towards relevant target groups. In addition, Obelis will support all partners in their activities and in questions concerning EU Regulations and compliance throughout the project.
Trinity College Dublin Coláiste na Tríonóíde, Baile Átha Cliath The University of Dublin	College of the Holy and Undivided Trinity of Queen Elizabeth near Dublin - Trinity College Dublin (TCD)	WP9 leader dissemination, communication, and training. Participation in the technical WPs with development of methodologies for screening and assessment, as part of the INNO4COV-19 technical team involvement, as well as in the coordination of the execution of use case and call responders.
ALMA MATER STUDIORUM A.D. 1088	Alma Mater Studiorum – Universita Di Bologna (UNIBO	UniBo is the clinical partner in the consortia. The UniBo partners all the expertise and great practical experience of COVID-19 needed to evaluate the upcoming projects (under the open call) as well, to support the design of clinical studies for the novel technologies. Moreover they can assume an important role on providing the needed infrastructures and clinical team for clinical studies. We also will participate in WP7.

		We will be key partners on the WP8 regarding clinical stakeholders (end-users) and WP9 for the dissemination among these stakeholders.
VITO	Flemish institute for technological research (VITO)	VITO will lead technical WP2 related to Innovative Diagnostic and Screening Systems, and will be involved also in WP5.

1.2. Services defined on SP3

SP3 are oriented to telemonitoring and telemedicine solutions against COVID19. These solutions should be improving Healthcare systems capacity and therefore quality of life for patients during a current pandemic emergency and in the future when a "new reality" will be achieved. Commonly, most telemedicine / telemonitoring devices have an electronic base and include sensors. Through the INNO4COV19 partners platforms the services offered will oriented to accelerate and simplify development of new and safe technologically advanced products, including affordable and advanced testing facilities and services, to fulfil the standards and regulations governing the addressed areas, to be compiled in a set of guidelines and practically implemented for the chosen products.

Moreover, INNO4COV-19 services will provide specialized consultants on several fields as Product Life Cycle, access to market and the identification and address current challenges and gaps in the standards and scientific regulatory frameworks. The services offered in SP3 are split in 6 main areas or services:

- **Product and pre series prototyping:** Reduce time to market is a key point on INNO4COV framework. Partners involved on WP4 offer several services related to electronic design, design and sensors development, simulation to accelerate the prototyping of pre series for a new product device.
- **Characterization and Functional testing:** Assessment and support on test plan development for new product/service. Characterization and functional test of pre-series of production or prototypes can be done. Also, will offer to design and implement dedicated testbenches for functional testing and emulates operational conditions and environments.
- **Certification and Marking:** Offered services for certification and CE marking will oriented to obtain and assessment about the strategy and the implementation of some test such as product lifetime, PPE certifications, among other with the aim to obtain the CE marking to enable the product at the European market.
- **Pre-commercial (scanning up)** and manufacturing: INNO4COV19 platform will offer several services for accelerate the product manufacturing such as product engineering and quality assessment to production plan. Assessment on advanced

production methods and technologies for a fast production. Assessment and develop a risk assessment and contingency plan for a manufacturing process.

- **Market evaluation and recommendation:** to provide and assessment about the European market and the impact of the target product and, also, to find the better strategy for improve the penetration at global market. INNO4COVID19 partners will advise and recommend on the business plan development.

- **Regulatory assessment:** As a previous step before the market access, the regulatory applied to each product shall be identified. INNO4COV19 platform will advise to granted projects to identify the applied regulation and to design the better strategy to accelerate and fulfil the regulation process. Moreover, once a certification process for specific product will be identified, some tests for this certification could be carried on by INO4COV19 partnership (verify with each certification facility).

2. Catalogue of Services

Catalogue of services of SP3 are summarized on Table 2. Services have been obtained from the identification of the capabilities of INNO4COV19 partners related to the potential requirements on projects with sensors, wearables, electronics devices or systems where are involved.

Table 2 - Specifications Sheet template for telemonitoring telemedicine systems – description of key performance features

Type of service	Services required	Partner	Services offered	Define service charactristics	Facilities (quality level) certifications (ISO, CE Marker, …)	Time expected to results (days/weeks/months,…)	Experience in giving the service to externals	Costs
Product/pre-Serie prototyping	Electronics/ Sensors developing	LEITAT	Electronics developement	Schematics and Layout designs. Sensors screening and front end design. Interoperability electronics systems. IoT Devices.	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017	Depends of design complexity	more than 15 years	
		INL	Full-value chain and pre-series manufacturing	Simulation, Design, fabrication, testing, characterization.				
	Data management & analysis	LEITAT	Data analysis	Data management, starage and analysis. Edge computig solutions	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017		More than 7 years	
		INL		AI, Data analysis				
	Product design and design engineering	LEITAT	Product design	Design product and apply product engineering.	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017		more than 15 years	
	Additive manufacturing prototyping	LEITAT	Pre series Manufacturing	Additive manaufacturing as a fast manufacturing for preseries using several materials: metal, resin, ABS, poliamide, …	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017		More that 10 years	
	Antibodies	LEITAT	In house developed mouse mAbs, VHH and human scFv against several variants of Sars-cov-2 Spike protein. Mouse mAbs against human IgG, IgM, IgA	Mouse monoclonal antibodies were raised againts sars-cov-2 Spike protein and some of them are able to recognize several Spike variants and neutralize the interaction with ACE2. Phage display libraries of VHH contains a wide range on single domain antibodies with recognition agaiats all the variants described up to date. Phage display library of human scFv contructed from the immune repertoire of asimptomatic patients that tested positive in a PCR test and that showed a strong IgG response. This library contains a wide range of scFv that can be selected based on their recognition pattern and the neutralizing potential. The mouse monoclonal antibodies agains human IgG, IgM and IgA are useful tools for the inclusion in serologic tests.	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017	depending on the molecule (between ready to use to 6 months)	We have over 15 years of experience developing monoclonal antibodies and over over 5 years working with phague display libraries	depending on the molecule
		INL	Sensors	Simulation, Design, fabrication, testing, characterization., electronics integration				
		FEP	Sensors	Vision sensors				
		FEP	Wearables	electronics and sensor integration				
Product/pre-Serie characterization and functional testing	Validation functiona Electronic design	LEITAT	Electronic functional test	Preparation of testbech specific for multimple parameter measuring in operation an non operational range.	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017		More than 15 years	
	Product lifetime	LEITAT	Aging electronics and plastic meterials	Thermal and humidity cycling of electronics. Precertificacition of lifetime test. Also can be perform the test with Xenon Light in order to provide a solar aging over plastic material	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2018		More than 15 years	
	Validation functional Electronic design	INL	Electrical/electronic and mechanical characterization and functional testing					
Product/pre-Serie Certification and marking	Product lifetime	LEITAT	Consultancy and Lifetime test for devices	lifetime accelerated test with temperature, humity and solar irradiance	ISO 105-B06, ISO 4892-2-2006, ISO 11341:2004, ISO 4892-2:2006	It is necessary to evaluate the specific product requirements	More that 30 years	Cost depends of specific assay
		INL	Consultancy and Lifetime test for devices	lifetime accelerated test with temperature, humity				
	Textile Certificaction test EPIS	LEITAT	Consultancy and Certification Textile for PPI and other purposes	Certification PPI	EN 1486:2008,	It is necessary to evaluate the specific product requirements	More that 30 years	Cost depends of specific assay
	Textile Certificaction wearables	LEITAT	Consultancy and Certification Textile for waerable	No specific Certification for wearable but it can be selected depending of utility	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017	It is necessary to evaluate the specific product requirements	More that 30 years	
Precommercial (Scaling Up) and Manufacturing	Product engineering	LEITAT	Product design and product engineering	Design and egineering of final product considering also the manufacturing process and certification requirements	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017			
		INL	Product design and product engineering	Design and egineering of final product considering also the manufacturing process and certification requirements				
	Risck assessment and contingency plan		Consultancy	Support and assesment in manufactury plan risk analysis				
	Manufacturing and/or Fast prototyping short product series	LEITAT	Pre series Manufacturing	Additive manaufacturing as a fast manufacturing for preseries using several materials: metal, resin, ABS, poliamide, …	EFQM+500, UNE EN ISO 9001:2015, UNE EN ISO/IEC 17025:2017		More than 15 years	Cost depends of material, samples and size
	Quality assesment and control		consultancy	Supporton quality analysis of final production				
	Test plan		Consultancy	Supporton test plan development for manufacturing				
Market Evaluation and Recommendation	Market analysis	IMM	consultancy	Scan market evolution and changes and evaluate brand position and opportunities				
	Patent landscape analysis	INL	consultancy	search for competitors and protection barriers				
	Increase Market positioning		To be confirm	Strategies to increase brand positioning on target market. Specially on SME				
	Business model		consultancy	Support on Business plan improvements adaptted to market modulation				
	IPR support		consultancy	Support on protection strategies applied to devices, sensors & products				
	Access to venture capital and other funding		consultancy	Financial acces				
Regulatory Assessment and recommendations	Certification PPI textiles.	LEITAT	Textile Certification		EFQM+500, UNE EN ISO 9001:2015,		More that 30 years	
	Regulatory roadmap	Obelis	Regulatory strategy					
	Adaptation to ISO 13485:2016	Obelis	Gap analysis report					
	Conformity assessment	Obelis	Regulatory strategy					
	Risk management	TBC						
	Data management	Obelis	Gap analysis report					
	CEMarking	Obelis	Consultancy					

3. Services offered on SP3

On this section a short brief about the offered services will be explained:

3.1. Product/pre-Serie prototyping

Service is oriented to provide a technological assessment during the prototype or product pre-series development in several areas:

- Electronics, design schematics and layouts and also validation of design
- Product design and manufacturing prototypes or short pre series using additive manufacturing
- Sensors and (Bio) sensors design and development. In this case depends strongly of the sensor transduction to identify the specific partner for the development.

3.2. Product/pre-Serie characterization and functional testing

During this section, a test development for a functional testing of prototypes or pre-series will be offered. The tests are oriented to verify the electronics functionality and also the lifetime. Several facilities are identified on the INNO4COV19 project that can be covered these services.

3.3. Product/pre-Serie Certification and marking

The objectives is to provide assessment to requestors to achieve CE marking and the identification and achievement of certification test involved on the technology validation before the market access. This service will be focus on the identification, assessment and advice in the certification process. Moreover could be studied to perform a precertification in some test in the INO4COV19 partner facilities if it is required.

3.4. Precommercial (Scaling Up) and Manufacturing

Service are oriented to identify the requirements for a precommercial lunch of a product developed. Several subservices are offered in this framework:

- Product engineering for refine the final product
- Risk assessment and contingency plan for production
- Manufacturing and/or Fast prototyping short product series
- Quality assessment and control of production
- Test plan for production

3.5.   Market Evaluation and Recommendation

The market evaluation has the objective to scanning and evaluate the market restrictions and opportunities in order to design a strategy for market access.

3.6.   Regulatory Assessment and recommendations

Regulatory assessment and recommendation services are oriented to facilitate the fulfil of regulation requirements thought the identification and advisor from the first steps of project (beyond TRL6) with the scope to accelerate this steps, especially in medical devices.

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4. Summary

In this report, a catalogue of services offered on SP3 are presented. These services are oriented to the help the requestors in next fields:

- Product/pre-Serie prototyping
- Product/pre-Serie characterization and functional testing
- Product/pre-Serie Certification and marking
- Precommercial (Scaling Up) and Manufacturing
- Market Evaluation and Recommendation
- Regulatory Assessment and recommendations

The main objective is to accelerate the new products and/or solutions against SARS-COV2. INNO4COV19 partners have been consulted in order to identify their capabilities in terms of pre-series accelerating and scale up, market analysis and regulatory and certification assessment. As a result of this identification the reports present in a table format the summarized of SP3 services provided from the inno4cov19 project.