

INNO4COV-19

Grant Agreement No. 101016203



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## **Document History**

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2	29/11/2022	First complete version	CM, MV, All partners
3	30/11/2022	Final version	CM, MV, Ángel del Pozo

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## 1. Abbreviation and Acronyms

BK - Biokeralty Research AIE

HTA - Health Technology Assessment

MDR – Medical Device Regulation

Q&A – Questions and Answers

WP - Work Package

### 2. Executive Summary

The circulation of knowledge between research, industry, education and training has been identified as one of the cross-cutting issues in Horizon Europe. This shows the importance that intra- and inter-project training is gaining in science at the European level.

The present document complies information on all the formal training activities implemented during the project lifespan. Constant informal inter exchange of knowledge has also constantly happened during the project duration.

BK, thanks to the collaboration of all the partners of the consortium, was in charge of co-organizing and collecting all the training activities to elaborate the present deliverable.

## 3. Training activities

Inno4cov-19 has offered training, firstly, to apply for the project's own funds, through two Open Calls that focused on 4 technological domains eligible for funding: i. Innovative diagnostic and screening systems; ii. Protective equipment for People and safer Public; iii. Environmental surveillance; iv. Sensors & Devices for Telemedicine and Telepresence.

Specific and specialised training was also given on aspects related to the core of Inno4cov-19, such as MDR, Regulatory for start-ups or regulatory aspects on sterilization. Regulatory knowledge as a whole was identified as a key topic for the different stakeholders involved in the project, leading to a strong focus of the training activities towards the fulfilment of such needs. The Community Workshop was intended both as an approach to other stakeholders and as a training on technological exploitation. The final event included 5 talks aimed at providing open innovation focused tools that can help sub-grantees to succeed after the end of their Inno4cov-19 funding.

Training activity	Partner	Hours	Number attendees	Date
Applying to INNO4COV-19 Project Open Call – First Info Session Second Info Session	INL	1 hour each	>150 from >10 EU countries.	1st: 12/11/2020 2nd: 30/03/2021
INNO4COV-19 Community Workshop	INL	5h30	61	09/03/2021
MDR training	Obelis	2h	~5	20/01/2022
INNO4COV-19 Workshop on sterilization – regulatory aspects	Obelis	2h	~15	29-30/03/2022

Back to a Healthy Future Final event	All partners	2 day event	~130	21-22/09/2022
Regulatory challenges for start-ups	Obelis			29/11/2022

## Applying to INNO4COV-19 Project Open Call - First Info Session & Second Info Session

Each webinar lasted two hours. The agenda of comprised a 10min presentation of the INNO4COV-19 project, followed by the description of the eligibility and conditions, the overview of the technical proposal structure, the evaluation process and a Q&A session.

### **INNO4COV-19 Community Workshop**

The objectives of the workshop were: i. Promote interaction between Inno4cov-19 third parties; ii. Promote the proximity between Inno4cov-19 consortia and third parties; iii. Discuss the technological exploitation. The agenda included:

Table 1: INNO4COV-19 Community Workshop agenda

Time (CET)		Speakers
10h	Welcoming & Who are we? Inno4cov-19 project.	INL
10h10	How can we help you? Inno4cov-19 services pitch.  Technical SP  Business support Regulatory framework HTA Network	VITO, INL, LEITAT, Fraunhofer, iMM, Obelis, Bioef and BK
11h10	Open Forum on Inno4cov-19 services	
12h	Lunch	
13h	Who are we? Inno4cov-19 third parties	Pitch from 3 <sup>rd</sup> parties
14h	Coffee Break	
14h15	<ul> <li>SP gatherings – 4 Breakout romos</li> <li>Sub-platform 1: Innovative diagnostic and screening systems</li> <li>Sub-platform 2: Environmental Surveillance</li> </ul>	Moderators: SP leaders

	<ul> <li>Sub-platform 3: Protective Equipment for People and Safer Public</li> <li>Sub-platform 4: Sensors and Devices for Telemedicine and Telepresence</li> </ul>	
15h	Closure	INL

### European MDR 2017/745 training

Roland Gerard, form Obelis, was in charge of this training on the regulation on medical devices. The content of this event can be consulted in table 4.

Table 2: European MDR 2017/745 training

European MDR 2017	/745 training agenda
1. Background	11. Post Marketing Surveillance
2. Timelines for enforcement	12. Vigilance Requirements
3. Manufacturer's obligations	13. EUDAMED
4. Scope of the Regulation	14. UDI System
5. Changes to Classification Rules	15. Person Responsible for Regulatory Compliance
6. Common Technical Specifications (CTS)	16. Technical documentation
7. Notified Bodies	17. Declaration of conformity
8. Conformity Assessment	18. Quality Management System
Procedures	· ·
9. Clinical Investigation	19. Final recommendations
10. Clinical Evaluation	

### Back to a Healthy Future

Final event co-organized with Covid-X (another European Funded Project).

The event included 5 inspirational talks designed to deliver tools that may help the sub-grantees to be successful in their endeavours.

 Table 3: Back to a Healthy Future's inspirational talks

Speakers	Title/Topic	Time
Jose Pedro Almeida, Chief Wellness Officer at Healthy Moment	Healthy and Happy Workplaces	
Marina Dias, EU funding coordinator at INL	Cross-cutting Initiatives & Funding Opportunities for the Industry	30 min
Andreas Lymberis, EISMEA, EC	EIC Accelerator Opportunities	
Walter Eevers, Director R&D at VITO	The Sustainability in Healthcare	
Henrik Ibsen, OTH.IO	Power of Networking	



The event also included two round tables. The first dealt with regulatory barriers during the Covid19 health crisis. During this roundtable, the participants discussed what went right and what went wrong during the health crisis in relation to the current regulatory framework, as well as what could be improved in the future to avoid future pitfalls should such a crisis occur again. The views of the different stakeholders were received: industry, policy makers/regulators and notified bodies. Sandra Ferretti, from OBELIS participated in this round table. The second one dealt with the views of the different stakeholders were received.

A website with all the information about the event was generated: <a href="https://covidx-inno4cov.eu/">https://covidx-inno4cov.eu/</a> It included companies, speakers, participants, agenda, exhibitors and organizers



Figure 1: event announcement

# INNO4COV-19 Seminar on sterilization: Fighting pathogens – sterilization, disinfection and biocide approaches

The seminar focused on three distinct aspects: i. regulatory insights (talks 1 and 2); ii. Different sterilization and disinfection technologies (talks 3 and 4), iii. commercial products that figh pathogens (talks 5 to 9).

The deliverable D5.5 contains more details of the seminar. The content of the talks can be consulted in table 3.

Table 4: Sterilisation seminar agenda

Title	Speaker	Country	Starting time
Welcome message from Director of Institute FEP	Elizabeth von Hauff	Germany	09:00
Introduction on IVDR and MDR	Sandra Ferretti	Belgium	9:15
Presentation on sterilization requirements - a regulatory view	Jan Havel	Germany	9:35
	Break		10:50
Hygenization with UV radiation	Linda Steinhäußer	Germany	11:05
Lu	nchbreak		12:15
Sterilization and disinfection by electron beam irradiation	Steffen Günther	Germany	13:00
Natural antimicrobial additives for paints and inks	Gonçalo Costa	Potugal	13:50
ALD coated bactericide/virucide stickers	Jacques Kools	France	14:10
Novel Materials on the battle against Nosocomial infections	George Kiriakidis	Greece	14:30
Natural, safe, and cost- effective virucidal technology for single use facemasks	Marcelo Milani	Luxemburg	14:50
tbd.	Carlo D'Alesio	Italy	15:10
Farewell and Lab tour (optional)	Steffen Günther	Germany	15:30

Sandra Ferreti, from Obelis, was in charge of the introductory talk on MDR and IVDR.



Figure 2: Agenda of the Introduction on IVDR and MDR, by Sandra Ferrtti (Obelis)

### Training on regulatory challenges for start-ups

A 30'min presentation from Sandra Ferretti (from Obelis Group) and a 30'min open forum for Q&A. The presentation included, among others, the main legal reference, other legal references, new classification system for IVD, conformity assessment route and identify regulatory requirements



Figure 3: INNO4COVID-19 Workshop: "Regulatory challenges for start-ups".



### 4. Main conclusions

The INNO4COV-19 project aims to facilitate the establishment of a fully functional innovation platform by pan-European supporting developers in the last steps of the value chain.

With all the activities described in this deliverable, not only the consortium members but also the funded projects and other third parties and stakeholders that form the Inno4cov-19 ecosystem have been trained. The activities have been tailored towards the identified needs, including applying for funding, business development into Open Innovation schemes and Regulatory science and compliance

In total more than 160 people have received some kind of training thanks to this project.