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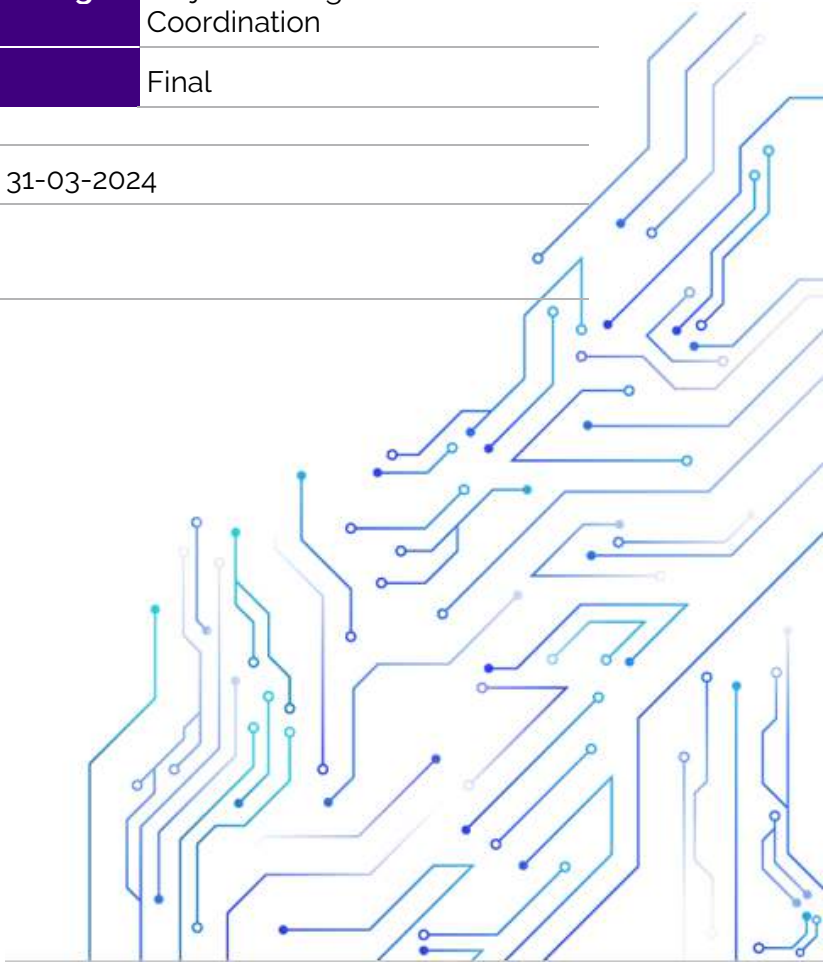
SusFE

D6.2 First progress and financial report

Deliverable No.	D6.2	**Due Date**	31/03/2024
Description	Report summarizing all the activities done during the first year of the project, as well as risk management with mitigation measures (including ethical risks)		
Type	Report	**Dissemination Level**	PU
Work Package No.	WP6	**Work Package Title**	Project Management and Coordination
Version	1.0	**Status**	Final

Period covered	From 01-10-2022 to 31-03-2024
Periodic report version	1st ☒ 2nd ☐



Abstract

This report summarizes all the activities done during the first period of the project (M01-M18). The complete version can be found in the Technical Report for the 1st Periodic reporting process.

This document is organized in four main sections:

Section 1: "About this deliverable"

Section 2: "Explanation of the work carried out by the beneficiaries and overview of the progress". We present here:

a) the objectives of the project along with the measurable results that are expected to achieve along the project execution (Subsection 2.1).

b) the explanation of the work carried per WP.

Section 3: Use Cases

a) Wound Monitoring

b) Blood Sampling Card

c) Point of Care (PoC)

d) Cardiometabolic Sensing

Section 4: Gender Distribution

Statement of originality

This deliverable is a public summary based on the Technical Report which contains unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

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1. About this deliverable

This document describes the activities carried out during the first 18 months of the SusFE project. Each section of this deliverable corresponds to the first period progress report of each Work Package and follows earlier deliverables submitted during the first 18 months of the SusFE project.

Table 1 Deliverable List for First Period

Deliverable Number	Deliverable Name	Description	Month
D1.1	State-of-the-art study report	Report on existing technical solutions, promising innovations, and academic research for roll-to-roll manufacture of higher functional medical devices including wearables.	M03
D1.2	Market Analysis report	Document describing the current European market of flexible electronics, including various points such as market segmentation, competitors' analysis, current differentiation strategies, drivers, barriers, trends, and opportunities.	M03
D1.8	Ethics Report by External Advisor	Ethics report by an external advisor to the project demonstrating compliance with all ethical and regulatory frameworks regarding the subcontracting of animal models for the use case of wound care	M03
D6.1	Quality Assurance Plan	Document describing QA procedures and reporting and the relevant checkpoints, guidance and responsibilities for risk management related to each project activity.	M03
D1.3	User technical requirements for three use case	User & technical requirements report which will detail specifications of the three use cases: 1) Wound monitoring bandage 2) blood self-sampling and 3) POC diagnostics. Report will be the result of interviews with external stakeholders and communication with all consortium partners to ensure agreement on the specifications for the three use case devices.	M06
D1.5	SusFE Standardization	SusFE standardization, and policies document detailing implemented standards and policies, risk analysis and guidance based on SusFE learnings,	M06

		including a summary of the evolving landscape and identification of the key stakeholders related to the project.	
D6.1	Dissemination and Communication Plan	This document will describe how SusFE will establish and follow highly effective dissemination and communication activities to promote the project.	M06
D1.6	Market Analysis report	Document describing the current European market of flexible electronics, including various points such as market segmentation, competitors' analysis, current differentiation strategies, drivers, barriers, trends, and opportunities.	M12
D2.3	Novel sensor with biomolecule immobilised using an atmospheric plasma	Report with protocols for immobilisation of biomolecules on transducer and performance evaluation of the diagnostic device compared with conventional wet immobilisation processes of the bioreceptor.	M12
D4.1	Report on measured power and energy profiles for each subassembly and the summated global profile	Report on measured power and energy profiles for each subassembly and the summated global profile, resulting in a digital model that can estimate such profiles based on suitable inputs (measurement frequency, external interrupts, etc.)	M12
D6.6	Report on Dissemination and Communication Activities	This document will describe how SusFE will establish and follow highly effective dissemination and communication activities to promote the project.	M12
D4.2	Batch(es) of suitable printed biofuel cells	Batch(es) of suitable printed biofuel cells that meet the required target specification agreed by the consortium partners, packaged, and delivered to ensure simple integration.	M15
D8.1	Functional "Cardiometabolic Monitoring" device with technical report	A functional prototype with a technical validation report of the device based on a novel multielectrode array for sensing connected to the data acquisition testbed	M18

Find below a SusFE timeline (Figure 1) encapsulating the main project meetings and each deliverable achieved during this first period:

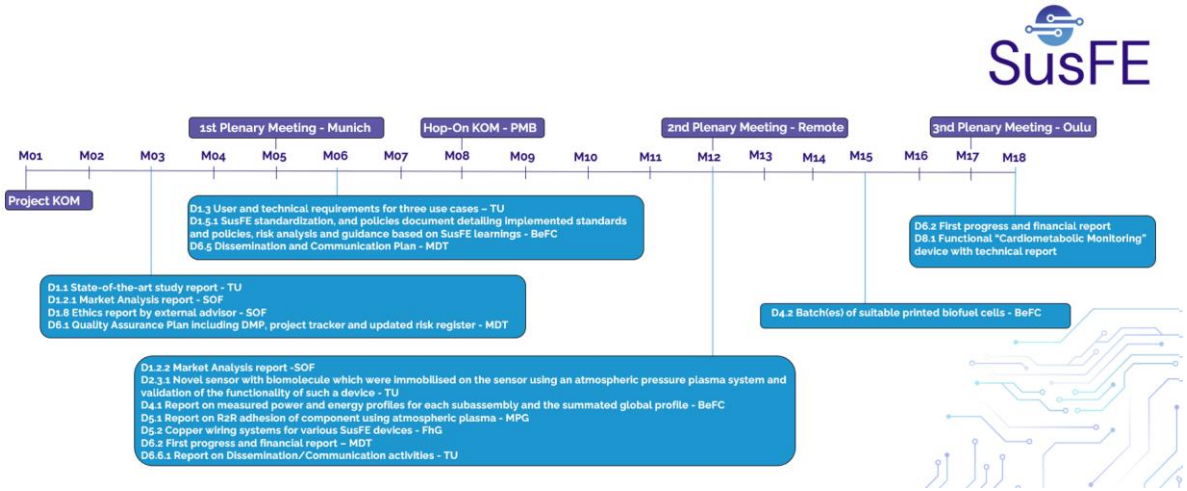

Figure 1. SusFE timetable for 1st period

1.1 Deliverable context

Table 2. Deliverable context

PROJECT ITEM IN THE DOA	RELATIONSHIP
Project Objectives	This deliverable does not directly contribute to the objectives of the project, but it serves as a description on how the project is developing to meet with the expected objectives.
Exploitable results	There is no specific contribution to any exploitable result. Instead, this document shows the status and development of the projects results.
Workplan	D6.2 is attributed to the tasks of WP6, Project Management and Coordination. Nevertheless, as this deliverable reports the status of all the project activities, the involvement of all WPs and their respective tasks has been necessary to complete this report.
Milestones	This deliverable does not directly contribute to any milestone of the project
Deliverables	D6.2 summarizes the work done in all the deliverables released during the first month of the project. See complete list of deliverables in section 1.
Risks	This deliverable has a risk management section that addresses the risk status of the project, including the ethical risks.

2 Explanation of the work carried out by the beneficiaries and overview of the progress

For the detailed explanation on the work carried out, refer to the Technical Report.

2.1 Objectives

The main objective of SusFE is to develop a design and production platform for roll-to-roll manufacturing of the next generation of wearable and diagnostic devices that combine a **SusFE toolbox of components** comprising novel **flexible integrated circuit (FlexIC) on polymer substrate** and textile substrates with **ultra-low power printed sensors/biosensors**, **wireless communication driven** by an **organic and recyclable bioenzymatic fuel cell**. This will lead to highly integrated and autonomously operating systems that are lightweight, environmentally sustainable, and low-cost through the use of a combination of materials and processes to deliver climate-neutral digital solutions. SusFE innovative processes and products will lead to a breakthrough for wearable and diagnostic devices driven by European companies for a broad range of application that will be demonstrated for the health sector but applicable to a diverse range of sectors including agriculture and the environment. This will enhance the EU's competitiveness in important and fast-growing global medical wearables, IVD, and wider functional electronics market.

The achievement of the overall objective is supported by the following specific objectives:

- Deliver innovative (beyond state-of-the-art) R2R functional electronics manufacturing approach and specifications for next generation functional electronics components and systems:
- Deliver circuitry on flexible polymer substrate linear conditioning for sensing and analogue to digital interfacing - using low cost and non-silicon manufacturing processes.
- Deliver circuitry that will allow simple integration of novel sensors into textile-based wearables.
- Deliver eco-friendly power using recyclable bioenzymatic fuel cell in an R2R process.
- Deliver innovative method of integration of biological receptor deposition with R2R functional electronics manufacturing:
- Deliver Eco-friendly power using recyclable bioenzymatic fuel cell in an R2R process.
- Deliver climate neutral sensor components.
- Deliver beyond state-of-the-art R2R processing for next generation functional electronics (e.g., medical wearables, IVD, POC Diagnostics).
- Deliver Smart wound monitoring bandage with sensors.
- Deliver a recyclable polymer and paper hybrid intelligent blood self-sampling device.
- Deliver novel POC diagnostics device: produce biomaterial-based diagnostics device for electrochemical detection of different biomarkers.

- Deliver novel textile-based environmentally friendly sensors resulting in easy to wear smart garments for monitoring cardiometabolic parameters.
- Achieve TRL4/5 for innovative functional electronics manufacturing processes and products.
- Maximize SusFE Impact via dissemination/exploitation measures including engagement of relevant value/supply chain stakeholders including end-users/consumers, policy makers, regulators, investors, and early industrial adopters.

2.2 Work Package 1 - Eco-design and specification of R2R processes and novel functional electronics components and systems

Task 1.1 – Market Analysis

A first deliverable D1.1 was a state-of-the-art study report that summarized how functional electronics will enable the creation of more functional, less expensive, and higher volume diagnostic devices, with reduced environmental impact.

Task 1.2 – User & Technical Requirements

User and technical requirements have been defined for three of the use cases and these were incorporated in the deliverable D1.3. This document serves as a review and guideline for the user and technical requirements of three distinct devices tailored for three unique use cases within the SusFE project.

Task 1.3 – Business Models

The market analysis performed in D1.6 is being refined into a more exhaustive analysis on the targeted medical use cases including the needs assessment, current clinical guidelines and practises, and identification of competitors.

Task 1.4 – Standardization and policies

A review of standards and regulations was provided by deliverable D1.3. It covered both the functional testing and electro-magnetic compatibility aspects of electronic medical devices (e.g. Low Voltage Directive, Electromagnetic Compatibility, Radio equipment directive), necessary for CE marking as well as compliance with European texts regulating chemical products (e.g. ROHS, REACH) and the management of waste from electrical and electronic equipment (WEEE). Eco-design and circular economy issues were also discussed.

2.3 Work Package 2 - Sensor fabrication and characterisation

Task 2.1 - Development of a flexible polymer-based pH-sensor for integration into wound dressings

FHG have carried out several experiments using hybrid integration of CMOS pH sensor to the flexible plaster and operating reliably for at least one day.

Task 2.2 - Sensors for wound monitoring

The focus for a first prototype of the wound monitoring system has been on the evaluation of the individual sensing elements, specifically on pH sensing which is being developed within T2.1 as well as temperature sensing.

Within this task, we have also explored immobilisation strategies of bioreceptor onto the electrochemical transducer.

Task 2.3 - Point-of-care device

During the reporting period the focus has been on the development of electrochemical (EC) sensing, mainly investigating suitable substrate materials, printing inks, insulators and strategies for immobilizing antibodies on the electrodes. In addition, options for the fabrication of fluidic structures by using sustainable materials have been studied.

The user and technical requirements, that are used as the basis for the POC device development work, have been reported in deliverable D1.3.

2.4 Work Package 3 - Analog and Digital Circuitry on Polymer

User requirements have been collected and design specifications agreed and passed through Pragmatic's internal quality control system. Three design – manufacturing – testing cycles have been planned of increasing complexity, each with regular internal design reviews to ensure the quality of the delivered system. Design activities have commenced on both the wound monitoring and blood sample timestamp systems.

2.5 Work Package 4 - Power management

Task 4.1 - Measurement of power and energy needs of platform subassemblies and prototyping of printed biofuel cells, power conditioning circuitry and/or firmware optimisation

Paper-based bioenzymatic fuel cells are a novel technology meaning that there are no premade solutions unlike in the conventional battery. With conventional batteries it is possible to choose a battery that fits the application out of standard modules. Therefore, the fuel cells need to be customised to each specific use case ensuring they provide adequate power to fulfil the needs of the electronics to be powered.

Task 4.2 - Characterisation of printed biofuel cells, power conditioning circuitry and/or firmware optimisation

As with Task 4.1, conventional electronics were used to demonstrate the operation of the customised fuel cells. At this stage in the project some simulated values of the power requirements of the polymer electronics were available. These were used in customising the fuel cells.

2.6 Work Package 5 - Integration of components in R2R for production, testing, validation and LCA/LCCA

Task 5.1 - Manufacture of copper wiring systems on film substrates

For this task, the first step was to check the compatibility of a biodegradable substrate in the lithography process.

Two different biodegradable substrates were tested.

Task 5.2 - Adhesion improvement

One of the main challenges that arises from Task 5.1 is the need to promote adhesion between the deposited metallic layers and the base substrates. Some issues were observed during the initial trials.

Note: Tasks 5.4, 5.5 and 5.6 are fully described in the Technical Report.

2.7 Work Package 6 - Project management, dissemination, communication, and exploitation

The goal of WP6 is to:

- assure proper interaction between partners;
- establish effective communication with European Commission (EC);
- identify conflicts and risks;
- protect background/foreground IP;
- promote the SusFE results and solution; and
- develop a plan for the exploitation and sustainability of SusFE.

Task 6.1 - Operational management

Grant Agreement – 1st Amendment

During the first year of the project SusFE consortium prepared an amendment to:

1. Request the inclusion of a new partner in the consortium: Tecnalia Serbia (TECSR).
2. Changes to Dissemination and Communication KPIs

3. Changes to progress and financial report deliverables
4. Changes to due month of D5.1 and D5.2

Plenary Meetings

During the first year of the project, 5 plenary meetings were convened. From which, three of them were in-person meetings (UK, Germany and Finland) and two remotes. Even in-person meetings had appropriate online connection to facilitate the participation of people not able to be present in the agreed venues. The plenary meeting was scheduled every 6 months approximately (see Figure 2).

These meetings have been ordinarily hosted in the countries and venues of the Consortium members where industrial facilities can be found, giving the opportunity to other SusFE members to learn about the activities carried out in other locations across Europe, exchanging knowledge and know-how. Moreover, this allows to distribute the responsibility of organising these meetings and limiting the need for extensive partner travel.

Figure 2 Main General Meetings Dashboard

1. KOM Meeting – Darlington (UK)

   SusFE kick-off meeting took place on October 26th and 27th, 2022 in Darlington (UK) at National Horizons Centre (Teesside University facilities).

Figure 3 SusFE Consortium at the KOM in Darlington (UK)

2. 1st Plenary Meeting – Munich (Germany)

   This meeting was carried out on March 8th and 9th, 2023 in Munich (Germany) at Fraunhofer Research Institution for Microsystems and Solid State Technologies EMFT.

Figure 4 SusFE Consortium at 1st Plenary Meeting in Munich (Germany)

3. Hop-on kick-off meeting – Remote

   Once TECSR was officially part of SusFE, the consortium organised a dedicated remote meeting (June 28th) to present TECSR's additional activities to the SusFE partners. SusFE partners also presented the status of their respective tasks and activities to TECSR.

4. 2nd Plenary Meeting – Remote

   The 2nd Plenary Meeting held remotely was carried out on October 24th and 25th.

5. 3rd Plenary Meeting – Oulu (Finland)

   The 3rd Plenary Meeting took place just before the end of the first period on March 12th and 13th in VTT facilities located in Oulu (Finland).

Figure 5 SusFE Consortium at 2nd Plenary Meeting in Oulu (Finland)

Remote Meetings

For the day-to-day project organization, it is necessary to set up regular meetings of the different WPs and key governance bodies within the project. With that aim, remote meetings using the online Zoom tool have been set up. The organization of these meetings have been centralized from the coordinator in order to assure that the meetings do not overlap, and all the requested partners can participate.

Task 6.2 - Financial management

During the first period of the project, the first payment instalment was disbursed to all partners in accordance with the final amounts approved by the European Commission.

Task 6.3 - Quality assurance and risk management

Risks within the project have been regularly considered and these are summarised in the SusFE critical risks in the PMR.

Task 6.4 - Dissemination and Communication plan

During the first 6 months of SusFE project, this task was devoted to analysing the ecosystem of SusFE project in order to provide a report where the Dissemination and Communication plan for SusFE would be outlined. Firstly, an environmental analysis was undertaken. Considering this information and the alignment with the objectives of the project, the D&C objectives, target audiences, messages and tools were described.

MDT team, in charge of this task, created a visual identity for the project, as well as set up the different channels: website, Twitter (X) and LinkedIn accounts.

Moreover, publications, conferences and clustering events were analysed and described by the work carried out in this task.

The detailed plan for D&C activities was thoroughly described in D6.5 Dissemination and Communication Plan at M06.

This report outlined a comprehensive D&C strategy for the SusFE project. The aim was to create a plan that will be adapted to the project growth, remaining always aligned with the exploitation and business activities of the project.

In this report, the external context was analysed to understand the environmental factor impacting SusFE project. Based on this, the objectives for D&C activities were stated together with the timeline of activities in a yearly basis.

Then, the target audiences were described, including the key messages and preferred channels to reach each of them. It is also important to highlight the visual identity of the project was shared (logo, colours, ppt template…).

The project website was built as one of the key channels so share relevant information about the project: objectives, use cases, consortium, news, public deliverables, etc. Moreover, the social media accounts were set up and their usage described: Twitter (X). LinkedIn and YouTube.

Besides all of that, the Deliverable also described the plan related to the use of media channels such as public press, TV or radio programs to spread the word about SusFE. Publications in this research context are also a key asset, identifying 17 example journals in which SusFE consortium can publish their research articles. Also, several conferences were identified to promote the advances of the project,

Task 6.5 - Dissemination and Communication activities

The SusFE project has generated two peer reviewed publications with several other publications that are planned. A number of conference presentation have been made including at the: Zulf Ali from TU chaired at special session on “Emerging Circuits and Systems for Diagnostics” which included presentation from Pragmatic at the IEEE Biomedical Circuits and Systems Conference (BioCAS) 2022 in Taipei in Taiwan; a poster presentation at LOPEC 2024 in Munich, Germany; and PRINSE’24 in Oulu, Finland. Zulf Ali from TU will give a keynote presentation along with a further presentation from VTT at the IEEE Medical Measurement and Applications (MeMeA) 2024 Conference in Eindhoven, Netherlands. There have been a number of engagement and networking meetings including workshops that have been organised with related projects funded under EU Call HORIZON-CL4-2021-DIGITALEMERGING-01-31 which have been supported by the OE-A and EPoSS. Two webinars have been held on (i) 'Safe & Sustainable by Design' framework & EU legislative context for sustainable electronics and (ii) Wearable sensors for healthcare monitoring that highlighted expertise of the SusFE partners. Further webinars are planned that will include key thought leaders in flexible and sustainable electronics.

Wider promotion of the SusFE project has been through press releases as well as through the SusFE website and social media channels (LinkedIn, X and YouTube).

Table 3 Journal Publications

Title	Authors	Journal details	DOI
Flexible SAR ADC with resistive DAC for Conformable On-Body Sensing Applications	Alkhalil, F., et.al.,	IEEE Biomedical Circuits and Systems Conference: Intelligent Biomedical Systems for a Better Future, Proceedings, 2022, 110-114	10.1109/BioCAS54905.2022.9948629
An autonomous wheelchair with health monitoring system based on Internet of Thing	Hou, L., et.al.,	Scientific Reports, 2024, 14,1, 5878	10.1038/s41598-024-56357-y

The Dissemination & Communication activities from M1 to M12 were reported in D6.6.1 Report on Dissemination and Communication Activities at M12.

Note: Tasks 6.6 (Exploitation strategy) and 6.7 (IP management) are fully described in the Technical Report.

2.8 Work Package 8 - Cardiometabolic wearable

Task 8.1 - Multielectrode arrays for sensing

The first multi electrode array design was developed and prototyped. This design was created with the aim to allow testing the initial hypothesis of multimodal sensory recording with the data acquisition testbed.

This electrode is used in series of experiments with human volunteers, to examine the system characteristics, as well as determine the influence of sensor placement on the quality of recorded signals and feasibility of extracting the targeted biomarkers in a repeatable and reliable manner.

Task 8.2 - Iontophoretic patch

This task started in M13. The prototype is implemented in the testbed hardware which was delivered at the end of M18 within D8.1.

Task 8.3 - Data acquisition testbed

This task started in M7 and ended in M18. The first functional prototype of the data acquisition testbed was delivered at the end of M18 and is described in detail in D8.1..

Task 8.4 - Processes for implementation with biodegradable substrates and inks

This task has started at M18, just before the end of this reporting period. So far, we have initiated identification and analysis of biodegradable inks that can be used for prototyping of the next iterations of the multielectrode arrays for sensing.

Task 8.5 - Data fusion and management

This task started in M13. Over the first six months of the execution the activities have focused on the review of the available literature on the state of the art, establishing the testing protocols, and performing parallel test with the commercial devices and the testbed prototype throughout its development.

Task 8.6 - Widening activities

This is an ongoing activity for TECSR, that started in M7 and will last throughout the project. Over the 12 months of the current reporting period, we have made significant progress in disseminating information about the SusFE action and concepts in the widening countries, most notably in Serbia, as well as Croatia, Slovenia and Bosna and Herzegovina. In addition to this we have won a Pathways to Synergy grant (HEU CSA) for valorisation of RIA assets where SusFE developments for cardiometabolic monitoring are defined as one use case. Three types of dissemination activities have been actively pursued: dissemination to stakeholders through presentation in bilateral meetings, dissemination to students and academia stakeholders in invited lectures and dissemination through reginal conferences.

Dissemination to regional stakeholders in bilateral meetings

SusFE concept and project aims have been presented to a large number of regional stakeholders as part of TECSR business development activities. In the list below we present some of the notable stakeholders to which SusFE was introduced:

Dissemination to students and academia stakeholders in invited lectures

A lecture including dissemination of SusFE concept, and results achieved within WP8 was presented to students in 2 occasions:

Dissemination through reginal conferences

The SusFE project concept and the initial WP8 results were presented in November 2023 at the TELFOR conference in Belgrade, Serbia.

IEEE conference TELFOR is an international annual gathering organized by the Telecommunications Society and the School of Electrical Engineering at the University of Belgrade, in collaboration with IEEE Serbia & Montenegro ComSoc Chapter, IEEE Serbia & Montenegro Section, and IEEE Region 8. This long-standing conference, held at the Crowne Plaza in Belgrade, Serbia on November 21st and 22nd, 2023, attracts participants from across the globe, with a special emphasis on the southeast European region. Most notably, in the section where the SusFE paper was presented the audience and other presenters were from Serbia, Romania and Czech Republic.

More information can be found on this link: https://www.telfor.rs/sr/program/#aem1

As part of Applied Electronics (AEL) Section, team of Tecnalia Serbia presented a paper called „Advancing cardiometabolic monitoring: A hybrid study on smart garments and wearables". This paper provides an overview of the latest advancements and research in wearable devices for continuous cardiometabolic monitoring.

The conference paper presentation went well, with an engaging discussion that followed. Attendees showed interest in the topic, and there were a few insightful questions, particularly regarding the further design and testing protocols, as well as the planned solutions. The interactive session allowed for a fruitful exchange of ideas, enhancing the overall quality of the presentation.

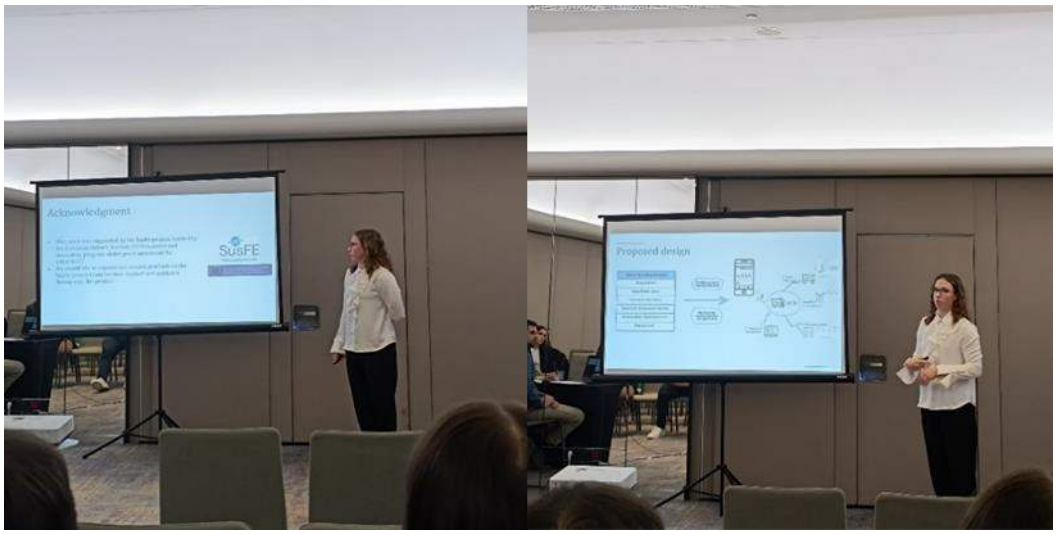

Figure 6 Presentation of the paper

3 Use Cases

3.1 Wound Monitoring

Globally, it is estimated that the annual incidence of laparotomies is about 1:1,000 population. Skin closure is usually achieved with sutures or staples. Surgical site infection (SSI) is a common complication which can occur in more than 20% of patients having emergency laparotomies. To some extent, wound dehiscence is also observed. These clinical outcomes strongly suggest a clinical need for smart dressings that can monitor the healing process and potential complications, for emergency laparotomies and, in all laparotomy cases, for patients with known comorbidities (e.g. diabetes, morbid obesity) impairing wound healing.

3.2 Blood Sampling Card

A thorough analysis of the two main user profiles 1) pharmaceutical company and 2) health care provider was made (WP1). The necessary functionalities were identified, and it was concluded that for the blood sampling card to be as attractive and competitive a product as possible.

3.3 Point of Care (PoC)

Conventional diagnosis of sepsis by blood culture takes several days which may cause delays in accurate treatment of the conditions whereas PoC testing can provide a diagnosis result within one hour and the testing can be performed near the patient. In the case of monitoring of chronic diseases, the testing can be performed in the home healthcare setting without the need for travelling to central laboratories or hospitals which saves time and effort.

3.4 Cardiometabolic sensing

The first functional prototype of the data acquisition testbed was delivered at the end of M18 and is described in detail in D8.1.

4 Gender distribution

This graph illustrates the gender distribution within the first period of the SusFE project across partners institutions.

In TECSR, there are 4 female and 3 male researchers, with female researchers contributing 64% and male researchers contributing 36% of the total TECSR effort. At VTT, out of 26 employees contributing, 15 are female and 11 are male. SOF has one male employee contributing. FhG's involvement includes 9 females (41%) and 13 males (59%). MDT's participation comprises 5 females (71%) and 2 males (29%). The Pragmatic core team for SusFE WP3 has 1 female and 5 male team members. MPG features 2 female researchers, 1 female non-researcher, and 3 male researchers, maintaining a balanced workforce (50/50). BeFC reports 1 female and 4 male researchers, with 2 females and 8 males in non-researcher roles. At CAP, 1 female and 3 male researchers/engineers are involved, while TU has three male participants (100%) contributing to the project.

In conclusion, for this first period, the gender distribution of SusFE is 41 females (46%) and 56 males (54%).

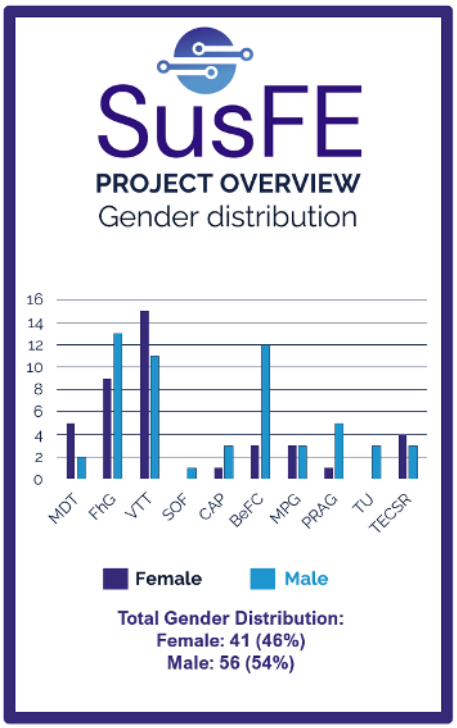

Figure 7 SusFE gender distribution