DECISION

Subject: Memorandum of Understanding for the implementation of the COST Action "European Network to Advance the Development and Implementation of Vocal Biomarkers" (eVoiceNet) CA24128

The COST Member Countries will find attached the Memorandum of Understanding for the COST Action European Network to Advance the Development and Implementation of Vocal Biomarkers approved by the Committee of Senior Officials through written procedure on 19 May 2025.

———————————

MEMORANDUM OF UNDERSTANDING

For the implementation of a COST Action designated as

COST Action CA24128
EUROPEAN NETWORK TO ADVANCE THE DEVELOPMENT AND IMPLEMENTATION OF VOCAL BIOMARKERS (eVoiceNet)

The COST Members through the present Memorandum of Understanding (MoU) wish to undertake joint activities of mutual interest and declare their common intention to participate in the COST Action, referred to above and described in the Technical Annex of this MoU.

The Action will be carried out in accordance with the set of COST Implementation Rules approved by the Committee of Senior Officials (CSO), or any document amending or replacing them.

The main aim and objective of the Action is to create a network of clinicians, AI experts, speech/voice processing specialists, speech-language pathologists, privacy/data protection experts, go-to-market specialists, patients organisations, policy makers, industrial partners and other stakeholders (end users, regulators, and other decision makers), to tackle the major challenges associated with the integration of voice technologies into clinical practice. This will be achieved through the specific objectives detailed in the Technical Annex.

The present MoU enters into force on the date of the approval of the COST Action by the CSO.

———————

OVERVIEW

Summary

The recent emergence of Artificial Intelligence (AI) methods and audio signal processing techniques open new perspectives on the use of voice to detect or monitor diseases. The vocal biomarker research field is booming but is facing, like other AI-driven fields, a reproducibility and generalisability crisis. To move this promising field of research forward, there is an urgent need to develop a common research framework in Europe, with standardization principles and definitions of good practices and guidelines to help it reach its full potential. A multidisciplinary approach is necessary to tackle this complex task impacting all stakeholders in healthcare virtually.

eVoiceNet aims to establish Europe as a leader in vocal biomarkers, create a collaborative and multidisciplinary network, and facilitate knowledge sharing, standardisation, and the development of privacy-aware solutions, by creating an international network of clinicians, AI experts, speech/voice processing specialists, voice pathologists, privacy/data protection experts, go-to-market specialists, venture capitalists and other providers of financial resources, patients organisations, policymakers as well as industrial partners and other stakeholders (end users, regulators, and other decision-makers), to overcome the major challenges and boost the integration of voice technologies into clinical practice.

Areas of Expertise Relevant for the Action	Keywords
● Health Sciences: Health services, health care research ● Electrical engineering, electronic engineering, Information engineering: Statistical data processing and applications using signal processing (eg. speech, image, video) ● Computer and Information Sciences: Artificial intelligence, intelligent systems, multi agent systems ● Clinical medicine: Integrative and complementary medicine (alternative practice systems) ● Clinical medicine: Databases, data mining, data curation, computational modelling	● Digital Health ● Audio Signal Processing ● Telehealth and remote patient monitoring ● Personalised Healthcare ● Vocal biomarkers

Specific Objectives

To achieve the main objective described in this MoU, the following specific objectives shall be accomplished:

Research Coordination

● To foster collaborative and interdisciplinary efforts in vocal biomarkers research, in order to bring together experts and expertise across different disciplines involved in vocal biomarker research

● To enhance standardisation and validation of vocal biomarkers by comparing and harmonising methods and approaches to design and validate vocal biomarkers, to go beyond the existing proofs of concept and increase the impact on the healthcare sector

● To ensure ethical, legal, and secure handling of personal data by identifying, addressing and mitigating ethical, data protection, and privacy issues that may arise in the collection, storage, use, and sharing of personal or sensitive data

● To disseminate vocal biomarkers research to stakeholders, to increase vocal biomarkers research impact

● To integrate vocal biomarkers with other digital therapeutics and explore the multimodal fusion with other technologies (e.g. video, wearable sensors, IoT, etc.) and relevant clinical parameters

Capacity Building

● To create and maintain a comprehensive repository of open source data and software resources for vocal biomarkers, accessible to all

● To foster establishment of large-scale, multilingual, longitudinal and privacy- preserving audio databases by defining the foundations and guidelines for building and secure sharing of audio databases accompanied with clinical data, to support vocal biomarkers research

● To establish an European framework to develop safe and trustworthy vocal biomarkers by creating guidelines for regulators, including those involved in AI, medical devices and the European Medicines Agency (EMA)

● To support knowledge transfer, inclusiveness, leadership development and interdisciplinary research

TECHNICAL ANNEX

1. S&T EXCELLENCE

1.1. SOUNDNESS OF THE CHALLENGE

1.1.1. DESCRIPTION OF THE STATE OF THE ART

The human voice is a powerful tool for communication, connection and self-expression, enabling us to effectively transmit thoughts, emotions and knowledge. With its unique acoustic characteristics, the voice also serves as a promising indicator of various health conditions and offers insights into an individual's health and well-being [1]. Since it is easy to use, cheap to collect, and non-invasive, the voice is a valuable source of data that has the potential to revolutionise healthcare. Besides voice and speech, other respiratory sounds that require involvement of vocal tract and/or vocal cords, such as cough or breathing, can provide additional layers of information that could be used to characterise or monitor a disease.

In both research and industry, the field of voice technology is booming as it is driven by continuous advancements in artificial intelligence, audio signal analysis and natural language processing. The global voice market was estimated at USD 1.8 billion in 2022 with an anticipated value of USD 6.2 billion by 2030 [2]. It is one of the most rapidly growing technologies, with healthcare expected to be among the dominant application sectors [1]. Recent advancements have paved the way for numerous applications, some of which are already in use, such as voice-assisted medical documentation. Voice technology improves the efficiency of clinical documentation in the electronic health records, thus reducing the physicians' workload and enabling them to spend more time with patients [3,4]. The benefits in healthcare are reaching far beyond voice-assisted medical documentation, with voice being used for identification of vocal biomarkers for screening and diagnosing diseases, monitoring symptoms and disease progress, and enhancing clinical research and practice.

A *vocal biomarker* is a **signature, feature, or a combination of features extracted from the audio signal of the voice that is associated with a clinical outcome**. Vocal biomarkers can capture and employ these special features of human voice in a way that translates across many application domains. Diseases or injuries affecting the organs responsible for producing sound (such as lungs, vocal folds, or articulators) [5], as well as respiratory diseases (e.g. asthma, chronic obstructive pulmonary disease, etc.) [6], speech and language disorders (dysarthria, stuttering, aphasia, etc.), neuromotor disorders (e.g. Parkinson's disease) [7] and neurocognitive disorders (e.g. Alzheimer's disease) [8] that affect phonation or respiration, can result in measurable changes in human voice, or even in the breathing and cough patterns. These changes could be used to identify relevant biomarkers. Voice alterations can also be caused by systemic diseases impacting the cardiovascular [9], endocrine (e.g. diabetes) [10], or immune systems (e.g. multiple sclerosis) [11], due to substance abuse and medication side effects, or simply due to a patient's psychological and mental state (e.g. depression, anxiety, post-traumatic stress disorder, etc.) [12]. Vocal biomarkers can be a valuable adjunct tool to screen symptoms, monitor patients, diagnose a condition, grade disease severity/stages or to assess drug efficacy for treating a condition. Vocal biomarkers are non-invasive, economical, scalable, and hold great potential for early detection, personalised treatment, and monitoring of various health conditions, but also face several challenges that can affect their reliability and effectiveness, such as background noise, variability of input signals, inter-speaker variability or variation across acquisition devices.

However, despite the immense potential of vocal biomarkers, we do not see them being widely adopted yet in clinical practice or used in clinical research. There are multiple reasons that can explain this discrepancy, which the Action will help to mitigate. First, there is a lack of collaboration and transdisciplinary engagement within the research community. Most of the existing voice-based initiatives have had a limited scope, as they were primarily conducted within individual disciplines or isolated research teams. This prevents the full exploration and understanding of vocal biomarkers, and the generation of robust and conclusive clinical evidence. Second, the pharmaceutical industry and healthcare providers worldwide have been hesitant to switch to large-scale development and implementation of digital biomarkers - including vocal biomarkers - in clinical trials and practice. This is caused by multiple factors: the relatively small body of clinical evidence to date, the perceived risk around the return on investment, the still-evolving regulatory landscape for digital biomarkers, medical devices and artificial intelligence, the lack of comprehensive guidelines and standardisation principles (both for data collection and implementation) for vocal biomarkers, and ultimately the inherent difficulty of sharing voice data due to privacy concerns, which increases the risk of low user acceptability of such technology.

oc-2024-1

To circumvent these issues, interdisciplinary researchers, healthcare stakeholders, patients' organisations, and regulatory bodies must work together to ensure user-driven, evidence-based and transdisciplinary research and design of vocal biomarkers. As of now, there are no existing comprehensive efforts to bring these stakeholders together around the issues. Therefore, developing a framework that addresses technical, ethical, and privacy considerations is crucial.

Looking ahead, vocal biomarkers hold immense promise for the future of healthcare. Continued research, collaboration, and integration of vocal biomarkers into routine healthcare practices will be instrumental in unlocking their full potential. With standardised guidelines in place, healthcare providers will confidently embrace vocal biomarkers, transforming the way we diagnose, monitor, and treat a wide range of health conditions.

1.1.2. DESCRIPTION OF THE CHALLENGE (MAIN AIM)

Vocal biomarkers are promising digital health technologies that have the potential to transform care provision for various serious health outcomes. However, they are under-used because of discipline siloing leading to a lack of standardised guidelines, best practices, clinical validation studies, and access to high-quality and large-scale data. This creates, for the entire healthcare ecosystem (pharma industries, contract research organisations, clinical researchers, clinicians and patients), a lack of opportunity to improve research or care and facilitate the daily management of complex diseases.

Given that research of vocal biomarkers requires engaging a highly interdisciplinary community, eVoiceNet aims at creating an international network of clinicians, AI experts, speech/voice processing specialists, speech-language pathologists, privacy/data protection experts, go-to-market specialists, patients organisations, policy makers as well as industrial partners and other stakeholders (end users, regulators, and other decision makers), to tackle the major challenges associated with the integration of voice technologies into clinical practice. The end-users of technology based on vocal biomarkers may include patients, healthcare practitioners, and even IT experts in charge of protecting sensitive databases of speech data.

The Action will primarily focus on the most active areas of research in vocal biomarkers, including neurological disorders, mental health and respiratory conditions, while ensuring that the progress made is transferable and beneficial to less explored outcomes, such as cardiovascular, cardiometabolic and autoimmune diseases, or certain cancer types. Additionally, the Action aims to promote a symptom-based approach, encompassing a diverse range of symptoms, rather than focusing on a single disease.

By being non-invasive, scalable and efficient, vocal biomarkers offer a new way to measure health, and improve health monitoring and preventive healthcare. They complement other clinical measurements by providing information which may not be available with existing health assessment methods. Addressing the barriers and challenges throughout standardised guidelines, improved data accessibility, and enhanced integration into healthcare systems will be crucial to promote the wider adoption and use of vocal biomarkers in clinical practice. This research framework may empower the healthcare ecosystem to deliver more personalised and more effective care. It will enable advancements in the management of complex diseases such as Parkinson's disease, Alzheimer's disease, respiratory or cardiovascular disorders, and facilitate better outcomes for patients. Moreover, by promoting collaboration among stakeholders in Europe, the Action aligns with the growing need for multidisciplinary approaches and sets the stage for innovation, growth, and improved healthcare practices in the field of vocal biomarkers. Ultimately, vocal biomarkers can be used to complement classical biomarkers and add a new level of important information to a deep phenotype in complex pathophysiological conditions.

1.2. PROGRESS BEYOND THE STATE OF THE ART

1.2.1. APPROACH TO THE CHALLENGE AND PROGRESS BEYOND THE STATE OF THE ART

The Action presents an innovative solution to address the challenges related to under-utilisation and lack of standardisation of vocal biomarkers. The primary objective of eVoiceNet is to establish a comprehensive and transdisciplinary research framework in Europe to foster advancements in the field and to facilitate the integration of vocal biomarkers into routine healthcare practice.

There is a lack of harmonisation across studies on vocal biomarkers, with inconsistency in methods, protocols and standards used for data acquisition, annotation, preprocessing, quality control, as well as preserving privacy and security of voice data. This limits the integration of vocal biomarkers into healthcare solutions. Therefore, the Action will propose **comprehensive standardised guidelines and**

principles for data acquisition, development, validation, and implementation of vocal biomarkers. This collaborative effort will be the first of its kind to bring together experts from diverse disciplines such as medicine, engineering, linguistics, data science and law, to establish a consensus on best practices. By providing clear guidelines, eVoiceNet aims to enhance the quality, reproducibility, robustness and reliability of vocal biomarkers, making them more widely accepted for clinical trials and everyday medical practice.

Different sensors are used to capture voice data, ranging from dynamic/condenser microphones and microphone arrays that convert sound waves into electrical signals, to sensors positioned on the person's neck that capture contact patterns of the vocal fold vibration, such as electroglottographs or contact microphones (laryngophones) [13]. Smartphones have been extensively used in recent studies as acquisition devices due to their widespread availability and integrated microphones, as well as different wearable devices, such as smart watches or neck-bands. eVoiceNet will propose guidelines for standardisation of data acquisition across different use cases to ensure consistency, reliability, and comparability across studies and clinical applications [14,15].

There is also a lack of large-scale datasets with both audio databanks and comprehensive clinical annotations, longitudinal datasets for tracking voice and disease changes over longer periods of time, and multilingual datasets that would take into account diversity in languages and dialects within Europe. The consequence of this data gap has adverse impacts on research in terms of diversity, generalizability, equity and inclusion, resulting in limited clinical utility and interpretability of obtained results [16]. Recognizing the critical role of **large-scale and high-quality data** in the development and validation of robust vocal biomarkers, eVoiceNet will encourage collaborative research and data sharing among researchers and institutions across Europe. The Action will create a **repository** consisting **of the most relevant datasets and software solutions**, following FAIR (Findable, Accessible, Interoperable, and Reusable) principles, which will serve as a one-stop shop for vocal biomarkers research. The Action will provide recommendations and good practices for data collection (e.g. standardised protocols of vocal tasks and meta-data, consistent recording environments), data sharing, data analysis and quality control, as well as for rigorous model validation, to ensure reproducibility and replication of research findings. These efforts will facilitate integration across studies, allowing healthcare professionals and policy makers to accurately assess the value of the technology.

Existing solutions for vocal biomarkers fail to adequately address the privacy and security risks associated with the technology (e.g. risk of person identification or leakage of private information) [17]. The Action will develop and propose **best practices for privacy-preserving voice data acquisition and storage**, ensuring that an individual's privacy rights and data security are safeguarded to the highest standards. In the cases where data sharing is not possible due to privacy constraints, **privacy-preserving aggregation protocols for federated learning** will be established that: 1) do not require any data exchange between the client nodes, only the model parameters are shared; 2) have additional measures implemented to prevent privacy leakage and reconstruction of sensitive information even from the model parameters; 3) establish technical, legal, and ethical measures to ensure compliance with General Data Protection Regulation (GDPR) and local privacy laws. Furthermore, best practices for **synthetic clinical voice data generation** will be proposed, that allow data sharing without disclosing personally identifiable information or sensitive details about individuals; thus, enabling them to adhere to regulations for data protection and privacy imposed by the GDPR [18]. Finally, there are emerging efforts recently for **voice/speech anonymization**, which aim at obfuscating the speaker identity, at the same time preserving the linguistic content and paralinguistic attributes [19]. However, the impact of these approaches on the performance of vocal biomarkers is not well investigated yet. The Action will initiate discussion that should promote a **responsible AI framework** for vocal biomarkers that addresses the **ethical, legal, and social challenges** associated with voice data analysis.

Vocal biomarkers are currently not integrated into routine healthcare practice. Through active engagement with healthcare providers and regulatory bodies, eVoiceNet will establish a **transparent regulatory landscape** and address privacy considerations. This concerted effort will advance the acceptance and **integration of vocal biomarkers into healthcare systems** and **set the stage for other international communities to follow the European approach.**

There is a pressing need for highly trained individuals in the field of vocal biomarkers due to the rapid evolution and advancements in AI and voice technology. The Action will organise comprehensive **training programs and educational initiatives**. These initiatives will foster the development of expertise in this emerging field, catering to the needs of researchers, clinicians, and industry professionals.

1.2.2. OBJECTIVES

1.2.2.1. Research Coordination Objectives

The research coordination objectives (RCO) are adjusted to the main aim of eVoiceNet and also transversally related to the different Working Groups (WG) detailed in section 4.1.1. These objectives are following the SMART (**S:** Specific, **M:** Measurable, **A:** Achievable, **R:** Relevant, **T:** Time-bound) principle.

RCO 1: S: To foster collaborative and interdisciplinary efforts in vocal biomarkers research, in order to bring together experts and expertise across different disciplines involved in vocal biomarker research, including clinicians, researchers, voice processing and AI experts, regulatory and ethics experts, go-to-market specialists, SMEs and startups, as well as end-users, policy and decision makers and patients organisations. M: This objective will be measured by the number of stakeholders within eVoiceNet. **A:** The Action proposers already consist of a wide range of recognized experts from academia, industry and healthcare, ensuring a well-functioning collaborative environment. **R:** Annual MC meetings, biannual face-to-face/hybrid/online WG meetings, workshops and training schools, biannual roundtables, as well as short-term scientific missions (STSM) and conferences will facilitate the exchange of relevant knowledge and foster interdisciplinary collaboration among the participants, enabling advancements in the field of vocal biomarkers research. **T:** It will remain an active objective during the lifespan of the Action (0 - 4 years).

RCO 2: S: To enhance standardisation and validation of vocal biomarkers by comparing and harmonising methods and approaches to design and validate vocal biomarkers, to go beyond the existing proofs of concept and increase the impact on the healthcare sector. M: This objective will be measured by the published guidelines, technical reports, protocols and papers. **A:** Through networking activities, eVoiceNet will encourage the exchange of best practices, facilitators/barriers, experiences and expertise of different stakeholders (researchers, healthcare providers, pharmaceutical companies, startups, regulatory agencies, governmental bodies and patients' organisations, all of whom are already represented in the Action) on the implementation of vocal biomarkers. **R:** The Action will analyse the current stage of development to identify the major challenges related to implementation, deployment and adoption of vocal biomarkers, and publish position papers on state-of-the-art technologies for vocal biomarkers. To further address these challenges, guidelines for voice data acquisition, annotation, data quality control, audio processing, and evaluation will be proposed and promoted. This will facilitate the design and execution of rigorous validation studies, which will contribute to the development of a robust body of clinical evidence supporting the use of vocal biomarkers in healthcare. **T:** The objective will be achieved during the 4-year Action period.

RCO 3: S: To ensure ethical, legal, and secure handling of personal data by identifying, addressing and mitigating ethical, data protection, and privacy issues that may arise in the collection, storage, use, and sharing of personal or sensitive data. M: This objective will be measured by the published guidelines, technical reports, white papers. **A:** The Action involves leading ethical, legal and voice privacy experts who will propose guidelines for design of privacy-aware vocal biomarkers that comply with the GDPR, and propose best practices for privacy-preserving federated learning, synthetic clinical voice data generation and voice anonymisation. **R:** Conducting an assessment to determine how the use of vocal biomarkers impacts users' fundamental rights, identifying potential risks, and proposing methods to mitigate them, will ensure compliance with relevant regulations and standards and maintain the trust and confidence of stakeholders. **T:** The objective will be achieved during the 4-year Action period.

RCO 4: S: To disseminate vocal biomarkers research to stakeholders, to increase vocal biomarkers research impact. M: This objective will be measured by the number of networking activities organised. **A:** The Action already involves dissemination experts, including researchers and recognized experts in the field with a proven track record of publications in leading journals, and experience in organising challenges/competitions and conferences/workshops, as well as patients' organisations and professionals from governmental organisations. **R:** Organising forums, training programs, workshops, challenges/competitions, publishing open access papers, and preparing educational tools, software, and seminars will ensure that all stakeholders are up-to-date and aware of the latest improvements in vocal biomarkers. A strong focus will be on the clinical interpretability and explainability of vocal biomarkers, which will facilitate their use and understanding by clinicians, healthcare providers, and end-users. **T:** It will remain an active objective during the lifespan of the Action (0 - 4 years).

RCO 5: S: To create a roadmap for design, clinical validation, regulatory compliance and deployment of vocal biomarkers by gathering expert input for future market applications and implementation of state of the art digital vocal biomarker technology. M: This objective will be measured by the improvement in Technology Readiness Level (TLR) of vocal biomarkers. **A:** The Action

includes clinicians, industry experts, policy makers, regulators and government organisations that will promote and advocate for vocal biomarkers, to facilitate their buy-in by all European stakeholders. The Action will also help in identifying the most pressing clinical needs, as well as gaps and requirements that may be less obvious, but where vocal biomarkers could play a crucial role. While the progress of audio/speech-based technologies has been rapid in recent years, the availability of vocal biomarkers in the market remains limited. The majority of these developments have not surpassed the Technology Readiness Level (TRL) 5 [20]. To address this, eVoiceNet will establish mechanisms to foster collaboration with key industries and services, aiming to enhance the adoption, sustainability, and scalability of reliable voice technologies. This will be achieved through active participation in various European and local events organised by industry, service providers, end users, policy makers and government representatives, such as All About Voice (Germany), Connected Consumer Summit (United Kingdom), CogX (United Kingdom), VivaTech (France), etc. The Action will organise STSMs, conferences, roundtables and training schools to promote collaborative research and innovation projects between academia, industry and other stakeholders. **R:** The overall goal of these initiatives will be to advance the technology readiness level to TRL 6 to 9. This will ensure enhanced adoption and scalability of vocal biomarkers. **T:** This objective will be achieved during the 4-year Action period.

RCO 6: S: To integrate vocal biomarkers with other digital therapeutics and explore the multimodal fusion with other technologies (e.g. video, wearable sensors, IoT, etc.) and relevant clinical parameters. M: This objective will be measured by the integration of vocal biomarkers into clinical practice and digital therapeutics, with success defined through pilot studies, clinical validation, and feedback from healthcare professionals on its utility and impact on patient outcomes. **A:** The Action will liaise with related COST Actions focused on digital health solutions, collaborate with clinicians, healthcare professionals and technology experts. **R:** Vocal biomarkers as a stand-alone diagnostic tool won't be a panacea. Instead, they must fit into the existing healthcare ecosystem and work as an adjunct support tool for early detection, monitoring and management of various health conditions. Successful integration of vocal biomarkers into clinical practice and digital therapeutics will lead to a more comprehensive and efficient healthcare approach, enhancing early detection and management of health conditions. **T:** This objective will be achieved during the 4-year Action period.

1.2.2.2. Capacity-building Objectives

The following capacity-building objectives (CBO) will be pursued:

CBO 1: S: To create and maintain a comprehensive repository of open source data and software resources for vocal biomarkers, accessible to all. M: This objective will be measured by the number of technical reports and the release of the repository of software and data. **A:** The Action has means to achieve this objective, in terms of tools, expertise and know-how. The objective includes mapping existing resources and creating an up-to-date and crowdsourced dictionary of the most relevant datasets and software solutions used to develop vocal biomarkers. **R:** The repository will foster collaboration and innovation across various fields. The aim is to facilitate the exchange of resources between all stakeholders involved, and furthermore help researchers from Inclusiveness Target Countries (ITCs), Young Researchers and Innovators (YRI) and start-ups with restricted resources for data acquisition to get access to high-quality data and software tools that will facilitate development or validation of vocal biomarkers. **T:** This objective will be achieved during the 4-year Action period, with the release of the final repository of software and data.

CBO 2: S: To foster establishment of large-scale, multilingual, longitudinal and privacy-preserving audio databases by defining the foundations and guidelines for building and secure sharing of audio databases accompanied with clinical data, to support vocal biomarkers research. M: This objective will be measured by the published white papers, technical reports and ethics guidelines. **A:** The Action has researchers with experience in mid-to-large-scale voice data collection, as well as voice privacy experts, who will provide guidelines and best practices for longitudinal, multilingual and privacy-preserving voice data acquisition and storage, standardised voice tasks, and robust language-independent feature extraction. **R:** Establishing longitudinal databases would enable tracking voice changes over time, and provide continuous measurement of disease risk, assessment of disease progression, and better detection of response to treatment. Moreover, multilinguality across datasets may have a non-negligible effect on performance of vocal biomarkers, influencing their functionality and robustness. Finally, providing best practices for privacy-preserving data storage can ensure the security of the data and sensitive information, promoting trust and compliance with privacy regulations, and in turn, enhancing the integrity and credibility of the research. **T:** This objective will be achieved during the 4-year Action period.

CBO 3: S: To establish an European framework to develop safe and trustworthy vocal

biomarkers by creating guidelines for regulators, including those involved in AI, medical devices and the European Medicines Agency (EMA). M: This objective will be measured by the published guidelines, and organised training schools. **A:** The Action will target European and local events on voice technologies organised by industry, service providers, end-users, policy makers and government representatives. The Action will also organise training schools on European procedures. **R:** The aim is to ensure regulatory compliance, foster innovation, and enhance the adoption of vocal biomarkers, while emphasising safety and trustworthiness. **T:** This objective will be achieved during the 4-year Action period, with the publication of guidelines for regulators.

CBO 4: S: To support knowledge transfer, inclusiveness, leadership development and interdisciplinary research. M: This objective will be measured by the number of participants from newly established research teams, YRI, innovators, under-represented genders, and teams from ITCs (with limited capacity to independently develop vocal biomarkers) who are engaged in eVoiceNet and taking on leadership positions. **A:** The targeted groups will benefit from targeted networking activities (training schools, workshops, conferences, etc), mentorship programs (pairing YRI with experienced researchers, STSMs), and will be encouraged to take on leadership roles. **R**: The objective is to foster a collaborative environment where established and emerging researchers can grow, and share knowledge and expertise. **T**: It will remain an active objective during the lifespan of the Action (0 - 4 years).

2. NETWORKING EXCELLENCE

2.1. ADDED VALUE OF NETWORKING IN S&T EXCELLENCE

2.1.1. ADDED VALUE IN RELATION TO EXISTING EFFORTS AT EUROPEAN AND/OR INTERNATIONAL LEVEL

The Action on vocal biomarkers brings significant added value in addressing the lack of concerted efforts and collaboration in the European Union (EU) so far. To date, different research groups have independently conducted their research on vocal biomarkers with very limited communication and mutual knowledge sharing. This fragmented approach hampers full progress and potential impact of vocal biomarkers in Europe.

There are only few EU-funded projects dealing with the voice-based technology for health applications:

- TRUSTING: running until December 2028, the project aims to develop a speech-based AI monitoring system for prediction of relapse in individuals with schizophrenia.
- EAR: running until September 2024, the project aims to understand how sounds from the human body can be used to improve the automated (or semi-automated) diagnosis of diseases. The project focuses on data acquisition with wearable devices that people commonly use.

While these projects have limited coverage in terms of vocal biomarker applications and diversity of end users, and fail to address the broader challenges associated with vocal biomarkers (e.g. guidelines, best practices), they remain highly relevant to eVoiceNet.

Speech Consortium Initiative established by the Alzheimers' Drug Discovery Foundation (ADDF) conducts a large-scale, longitudinal, multi-site data collection study for the discovery and development of speech and language biomarkers for the Alzheimers' disease.

The only existing network with a subproject focusing exclusively on vocal biomarkers - Bridge2AI - exists in the United States. Bridge2AI aims to advance the use of artificial intelligence (AI) in biomedical research. The consortium consists of multiple cores and data generation projects, focused on developing ethical and standardised practices for AI research, optimising AI tools and generating high-quality data. Within Bridge2AI, the Voice Data Generation Project (DGP) aims to use voice as a biomarker for health assessment in clinical care. The project's key approach involves creating a comprehensive voice database sourced from multiple institutions and linked to annotated clinical data. The goal is to develop predictive models that can be used for screening, diagnosis, and treatment of a broad range of diseases.

The Action on vocal biomarkers addresses the lack of concerted efforts within the EU and bridges the gap with existing initiatives like the NIH-funded Bridge2AI in the United States. By bringing together researchers, experts, and stakeholders from across Europe, eVoiceNet will establish a collaborative platform for vocal biomarker research. Through collaboration, knowledge exchange, and multidisciplinary approaches, eVoiceNet will empower European researchers to collectively advance their understanding, methodologies, and applications of vocal biomarkers.

The Action will establish connections with Bridge2AI, enabling more synergies at the international level

beyond the EU. Additionally, eVoiceNet will promote interaction with the existing European initiatives for trustworthy AI, such as TAILOR, or AI HLEG, and adhere to EU regulations for building trustworthy AI, data access, sharing and usage, such as AI Act or Data Act. The Action will connect with international organisations targeting voice security and privacy (e.g. ISCA Special Interest Group on Security and Privacy in Speech Communication - SIG SPSC). The Action will also analyse the outcomes of the ongoing or previously funded COST Actions that partly address similar aspects, such as 2103 (Advanced Voice Function Assessment), IC1206 (De-identification for privacy protection in multimedia content), CA19121 (Network on Privacy-Aware Audio- and Video-Based Applications for Active and Assisted Living), CA19132 (European Network to Advance Best practices & technoLogy on medication adherencE) and CA19136 (International Interdisciplinary Network on Smart Healthy Age-friendly Environments), build on top of the lessons learned there and promote an inter-action dialog.

This concerted effort will strengthen Europe's position and significantly contribute to the advancement and widespread adoption of vocal biomarkers in healthcare.

2.2. ADDED VALUE OF NETWORKING IN IMPACT

2.2.1. SECURING THE CRITICAL MASS, EXPERTISE AND GEOGRAPHICAL BALANCE WITHIN THE COST MEMBERS AND BEYOND

The rationale for this initial consortium is to propose an open, translational and multidisciplinary network to address and overcome the challenges related to vocal biomarkers.

Critical mass: This initial set of Action proposers includes clinicians, researchers, leading experts in voice processing and AI, regulatory and ethics experts, go-to-market specialists, venture capitalists and other providers of financial resources as stakeholders, as well as prominent SMEs and start-up companies. By involving stakeholders from various sectors, public and private, **eVoiceNet aims to build a strong, sustainable network that bridges gaps between academia, industry, and healthcare**. Ultimately, the Action aims to break the silos between disciplines, facilitate exchange of ideas, methodologies and technologies, and develop further interdisciplinary research to speed up the development and implementation of vocal biomarkers into clinical practice.

Expertise: The Action already includes **technical specialists** in audio processing, speech signal processing, machine learning, **healthcare experts** covering a wide range of conditions including neurodegenerative diseases (Parkinson's disease, Alzheimer's disease), mental health, voice disorders, respiratory diseases (chronic obstructive pulmonary disease, asthma, COVID-19), cardiovascular diseases and risk factors (heart failure, coronary artery disease, valvular disease, diabetes mellitus, hypertension), dysphagia, oncology, psychology, **clinicians** including general practitioners, cardiologists, neurologists, and laryngologists / phoniatricians / phonosurgeons, **experts in law and privacy / biometrics / ethics** and **business experts** involved in SMEs and startups developing health and well-being voice-based solutions, and additional experts in **regulatory matters**, **market strategies**, **financial resources management**, **policy**, **and scientific and patients organisations**.

For the standardisation and validation of vocal biomarkers, the technical and healthcare experts will collaborate to harmonise methods, develop guidelines, and publish technical reports. Legal and privacy experts will contribute by designing guidelines for ethical data handling, ensuring compliance with GDPR, and addressing privacy concerns. To support market adoption, business, regulatory, financial and market experts will help define the roadmap for clinical validation and the deployment of vocal biomarkers, engaging key European stakeholders to facilitate their progression to higher TRL. Finally, the integration of vocal biomarkers into clinical practice will be driven by healthcare experts, clinicians, policy makers, relevant scientific associations and patient organisations, ensuring that the voice technology reaches the hands of those who ultimately need it: healthcare professionals and patients.

Plan for securing the critical mass, expertise and geographical balance: The Action will deploy a Core Group composed of the Action Chair, Vice Chair, WG leaders and their deputies, Grant Awarding Coordinator, Science Communication Coordinator, as well as appointed ITC representative, YRI representative, and Gender Equality representative. Together, they will secure a geographical, gender and career status balance across operations and activities. Particularly, eVoiceNet will specifically prioritise collaborative opportunities, decision-making access, and leadership roles for stakeholders from COST Full Member countries, ITCs, YRI, and will maintain gender balance within the network and decision-making positions. For example, should the Action Chair be non-ITC/male/non-YRI, the Vice Chair would be ITC/female/YRI, where possible. The Action will offer equal access to knowledge and resources to the different research communities, including those with restricted access to funding and/or infrastructure. Recruitment of additional stakeholder representatives from COST Full country, ITC and NNC that are not yet covered within the Action will be actively pursued through personal contacts,

engagement with professional organisations, as well as by participation of eVoiceNet in meetings and scientific conferences of the related fields, at the national and international level. Detailed plans to attract YRI, participants from ITCs, and to ensure a gender-balanced network are presented in section 3.2.1 and in the COST Mission and Policy.

2.2.2. INVOLVEMENT OF STAKEHOLDERS

Relevant stakeholders representing a broad spectrum of research disciplines will be fully integrated in the Action, both from the public and the private sector. **Patients' organisations** will have an active role in eVoiceNet. Establishing patient advisory groups and panels will allow their voices to be heard in decision-making processes. Surveys, interviews, focus groups and workshops will be conducted to gather their valuable input and understand their needs. Educational events and awareness campaigns will be organised to inform patients about vocal biomarkers and their potential benefits. Collaboration with patient organisations will provide insights into patient experiences and facilitate advocacy efforts. Collaboration with **healthcare providers (hospitals, clinicians, caregivers)** is vital for achieving the Action goals. Training programs, workshops, and conferences will be organised to enhance their understanding and utilisation of vocal biomarkers in clinical practice. Efforts will be made to foster collaboration between researchers and healthcare providers, ensuring that the research findings can be easily understood and interpreted by clinicians. It is crucial that clinicians take an active role in defining the strategies of vocal biomarkers research, ensuring that clinical research goals and improved patient care are the main focus. Collaboration with **medical device** and **AI regulators** is crucial to address regulatory and ethical considerations. Regular communication channels and consultation sessions will be established to seek their input on validation, compliance, and ethical aspects of vocal biomarkers. These collaborations will ensure adherence to regulatory requirements and ethical standards. Engaging **industry** stakeholders, including SMEs, vocal biomarker providers, pharma companies and technology companies, will drive research and development efforts forward, ultimately expanding market reach. Partnerships will be formed to support new research projects (e.g. EU Horizon Europe Consortia), data sharing, and technology transfer. Industry experts will be invited to contribute actively as MC and/or WG members, or as participants in activities organised by eVoiceNet, ensuring the alignment of research outcomes with practical applications. Engaging **venture capitalists** and **other providers of financial resources** will also facilitate the continued funding for network activities and will make it easier to further build on the network's achievements to develop sustainable innovation through the development of spin-off and startup companies. Engaging **policy makers** is essential to create a favourable environment for the implementation of vocal biomarkers in healthcare. Briefings, policy dialogues, and consultations will be conducted to provide evidence-based research findings, policy recommendations, and impact assessments.

The stakeholder's involvement plan will include:

- **Internal communication channel for eVoiceNet members.** To ensure seamless exchange of information among all eVoiceNet participants, the Action will establish dedicated communication channels such as a Slack workspace. This platform will serve as a central hub for circulating key updates, sharing working documents, and coordinating tasks across the network. This approach will facilitate efficient collaboration, allowing members to stay informed, contribute to discussions, and access necessary resources in real time. By using these tools, the Action will ensure transparency and active participation from all stakeholders throughout the Action's duration.

- **Introducing a dedicated website for vocal biomarkers.** The website will provide a place where all stakeholders, including patients, healthcare professionals, patients' organisations and researchers, can easily access relevant information, news, and documents. The website will contain all the Action information (general summary of the objectives and the WGs, central contact point for vocal biomarker experts), eVoiceNet outputs (controlled access to the repository of data and software resources, links to open access scientific papers, guidelines, best practices, presentations, etc.), eVoiceNet activities (meetings, training schools, workshops, STSMs, conferences, etc.), and educational materials (brochures, fact sheets).

- **Organising conferences and workshops for the research community.** Each year eVoiceNet will target a top-tier conference related to a specific area in the Action and organise a satellite workshop, or a challenge: INTERSPEECH conference, IEEE International Conference on Acoustics, Speech, and Signal Processing (ICASSP) and Voice & AI conference. In the last year, eVoiceNet will organise a final conference. Books of abstracts and proceedings of these events will be edited and published, including organising Special Issues in prominent journals.

- **Organising conferences and workshops for other stakeholders.** The Action will target European and local events on voice and digital technologies that are organised by industry, service

providers, end users, policy makers, and government representatives, such as All About Voice (Germany), Connected Consumer Summit (United Kingdom), CogX (United Kingdom), VivaTech (France), etc. Workshops and roundtables will also be organised between stakeholders, to exchange and collaborate. Short policy and/or professional briefings will provide concise and accessible summaries of the potential impact of vocal biomarkers.

- **Publishing position papers, white papers and guidelines.** The Action will publish a position paper on state-of-the-art technologies for vocal biomarkers; guidelines for voice acquisition, annotation, and audio processing; a technical report with a review of currently available datasets; ethics guidelines for vocal biomarker development and use; ethics guidelines on the use and processing of human voice samples; a white paper on ethical, data protection and privacy issues of vocal biomarkers; a technical report for on-device analysis and privacy-preserving federated learning; and guidelines for go-to-market strategy, vocal biomarkers validation, EMA procedures. These publications will consolidate the current state of knowledge, best practices, and recommendations for researchers, healthcare professionals, and policy makers regarding vocal biomarkers.

- **Publishing research papers and special issues in relevant journals.** The multidisciplinarity of eVoiceNet will result in high quality work, published in relevant journals (such as Digital Biomarkers, npj Digital Medicine, PLOS Digital Health, DIGITAL HEALTH, Frontiers in Digital Health, IEEE/ACM TASLP, Speech communication, etc.) and conferences (INTERSPEECH, ICASSP, EUSIPCO, etc.). The Action will encourage cooperation between the members, which will result in multiple collaborative papers. Publishing in open access journals and conferences will be highly encouraged to enable a maximal accessibility and dissemination of the work.

Tools	Target audiences	Performance indicator	Target*
Website	Peers, general public	Number of visitors	1000-5000
Social media	Peers, general public	Number of followers	500-1000
Awareness campaign	Peers, general public	Number of participants	200-1000
Broadcasting media	General public	Number of viewers/listeners	1000-10000
National / International conferences	Peers	Number of papers	10
Scientific journals	Peers	Number of papers	10 journal papers, 2 special issues, 2 edited books

*Predictions are based on previous COST Actions, existing follower base, target audience and engagement trends, industry benchmarks, geographical and demographic considerations, popularity of broadcasting media, number of students in academic institutions, average number of people attending national/international conferences.

3. IMPACT

3.1. IMPACT TO SCIENCE, SOCIETY AND COMPETITIVENESS, AND POTENTIAL FOR INNOVATION/BREAKTHROUGHS

3.1.1. SCIENTIFIC, TECHNOLOGICAL, AND/OR SOCIOECONOMIC IMPACTS (INCLUDING POTENTIAL INNOVATIONS AND/OR BREAKTHROUGHS)

The Action will have significant **scientific, technological** and **socio-economic impacts** in both the short and long term.

Scientific impact: The Action will bring together fragmented and isolated teams into a **cohesive** and **cooperative pan-European community,** by establishing a collaborative and multidisciplinary network on vocal biomarkers. This network will facilitate interactions between clinicians, researchers, voice processing and AI experts, regulatory and ethics experts, go-to-market specialists, industry and other stakeholders. The Action network will apply to **further research and innovation funding opportunities** such as Horizon Europe, facilitating joint research projects that could lead to groundbreaking discoveries in vocal biomarker research and associated technologies. By establishing standardisation principles and guidelines for voice acquisition, annotation, audio processing, and vocal biomarkers validation, eVoiceNet will facilitate the design and execution of rigorous **validation studies**. This will contribute to the development of a robust body of clinical evidence supporting the use of vocal biomarkers in healthcare. Special focus will be on the development and validation of novel privacy- aware solutions by providing **ethical guidelines** for human voice sample collection and processing, as well as the best practices for privacy-preserving data storage, synthetic clinical voice data generation and voice

anonymisation, integrating privacy by default and by design. These principles will help ensure that privacy is not an afterthought, but a foundational element of any product, service, or system based on vocal biomarkers. To establish a lasting and significant impact within the scientific community, the major scientific accomplishments will be disseminated via collaborative **open-access publication** in

high impact journals, and showcasing in prestigious scientific forums. Thus, eVoiceNet intends to establish **Europe as a leader and central hub** in vocal biomarkers.

Technological impact: The Action will facilitate the development and validation of vocal biomarkers by creating a **curated repository** of the most relevant datasets and software in voice technology. It will especially focus on studies oriented towards acquiring data identified as missing in the current research, such as multilingual, longitudinal, and/or privacy preserving data collections. This will enable relevant stakeholders to access and use high-quality data and tools for the development and validation of vocal biomarkers. The Action will organise challenges and competitions and release datasets and evaluation criteria for these competitions. The Action expects them to be widely accepted by the community and become reference benchmark datasets for vocal biomarker research. The Action will serve as a **catalyst for innovation and progress** in vocal biomarker research, with the ultimate goal to enhance medical diagnosis and treatment of various medical conditions, but also to foster ethical and equitable healthcare practices, on the benefit of patients and healthcare systems. Building on the funding opportunities available through initiatives like Horizon Europe, the Action will **drive the development of new large-scale datasets and technologies**, including innovative hardware and software solutions and algorithms for vocal biomarkers. This will not only enhance the technological landscape of vocal biomarker research but also provide essential tools for practical applications in clinical settings.

Socio-economic impact: By developing ethical, data protection and privacy guidelines, eVoiceNet will increase **inclusiveness, explainability, security** and **trust** in vocal biomarkers. This will improve users' acceptance of vocal biomarkers. The Action will facilitate the **adoption of vocal biomarkers in clinical practice**, by providing valuable tools for healthcare professionals and researchers for diagnosing diseases, monitoring symptoms and enhancing clinical practice. This may lead to better patient outcomes, reduced hospitalisations, and improved quality of life, patient care and well-being. The Action will increase vocal biomarkers awareness by **disseminating eVoiceNet outcomes and involving patient organisations**. The Action will foster innovation among new and existing **spin-offs, start-ups** and **SMEs** focused on developing or implementing vocal biomarkers into healthcare or clinical research, through meetings with venture capital funds and angel investors to support fundraising. This approach will attract investments and foster innovation in the European market. The Action will overcome the barriers to market entry through translational research, **go-to-market strategies**, and health technology assessments, making sure that Europe is at the forefront of the new market opportunities.

3.2. MEASURES TO MAXIMISE IMPACT

3.2.1. KNOWLEDGE CREATION, TRANSFER OF KNOWLEDGE AND CAREER DEVELOPMENT

Knowledge creation: The Action aims to **combine the knowledge of a wide range of experts**, starting from voice experts and healthcare professionals, all the way to industry and go-to-market experts. By bringing together experts from different disciplines, the networking facilitates the exchange and integration of knowledge, leading to the creation of new insights and understanding in the field. The production of comprehensive guidelines and state-of-the-art good practices will help **harmonise the production and validation of vocal biomarkers**. The creation of a comprehensive repository of open source data and software resources, accessible to all, will **facilitate the development and validation of new vocal biomarkers**. This is particularly relevant for SMEs, small research institutions, and researchers in ITCs, as they may not have enough technical resources to address the challenge of developing and implementing vocal biomarkers.

Transfer of knowledge: The Action will organise awareness campaigns through workshops, webinars, public lectures and round tables. These initiatives aim to **enhance knowledge exchange** and **promote dialogue** with all involved stakeholders. The Action will facilitate the **development of entrepreneurial skills**, by transferring knowledge from participating companies to researchers. The Action will organise 4 Training Schools, to bring together PhD students, postdoctoral researchers, YRI as well as established researchers from a wide range of disciplines (AI, machine learning, voice processing, clinics, policy making, go-to-market, leadership, presentation, scientific writing, innovation…). Through the organisation of STSMs, eVoiceNet will provide opportunities for researchers to **share techniques and gain new insights and skills** that may not be available at their home institution. STSMs will be organised with both academic and industrial partners, to foster bidirectional knowledge transfer and interactions between two sectors.

oc-2024-1

Career development: The Action will support and promote the research of vocal biomarkers in **ITCs**, by organising and supporting events to increase their visibility among institutions, funding bodies and industry; and providing ITC conference grants for attending relevant international events. The Action will also encourage ITC members to take on leadership roles in the management body of eVoiceNet. The Action will support **YRI** by facilitating their mobility via STSMs and their multidisciplinary training. Moreover, eVoiceNet will also establish a mentorship programme, so that experienced researchers can advise and guide YRI in their research and career path. All these activities support YRI to participate in research excellence funding programmes, such as Marie Skłodowska-Curie Actions (MSCA) postdoctoral fellowships or European Research Council (ERC) grants. The Action will also involve YRI in decision-making processes and allocate positions within the managing body of eVoiceNet. The Action will implement a Gender Equality Plan (GEP), and annually monitor **gender balance** within eVoiceNet. The GEP's objectives include achieving gender balance across all levels, particularly in leadership and decision-making positions, to foster a culture of gender equality, providing targeted training programs and communication towards young female academics or stakeholders, identifying female ambassadors, and ensuring gender-neutral and equitable access to the Action network, leadership roles, activities and grants.

3.2.2. PLAN FOR DISSEMINATION AND/OR EXPLOITATION AND DIALOGUE WITH THE GENERAL PUBLIC OR POLICY

Dissemination strategy and dialogue with the general public: The focus of the dissemination plan will be to make all stakeholders aware of the potential of vocal biomarkers, the challenges, the advancements, and the benefits for end-users. The dissemination strategies will include:

1) *Online presence*
   - **Website section for the general public.** The website will contain targeted and accessible information and resources created through the Action: news, public outreach materials, brochures, fact sheets, etc.
   - **Using social media to engage with the general public.** A variety of social media networks will be used to regularly engage with the general public and stakeholders to increase awareness and understanding of vocal biomarkers, to foster public interest and participation in related research initiatives, and to promote the benefits of vocal biomarkers in healthcare. This may include creating videos, podcasts, infographics and interactive web content. The Action will use specific hashtags to create a sense of community and facilitate conversations around vocal biomarkers.
2) *Face-to-face events*
   - **Establishing patient advisory groups and panels.** Establishing patient advisory groups and panels is crucial for integrating the end users into co-design of vocal biomarkers from the early research phases to dissemination of the results. To ensure meaningful patient engagement, eVoiceNet will conduct surveys, interviews, focus groups, and workshops. These activities aim to capture detailed and actionable insights on patients' needs, concerns, and expectations. Active involvement of patients in the research process improves the chances of vocal biomarker adoption in daily practice, and increases the impact on patient care.
   - **Launching a public awareness campaign on vocal biomarkers.** The campaign will be launched in the first month of April after the start of the Action, as the 16th of April is the World Voice Day. The Action will organise workshops, webinars and public lectures in collaboration with relevant stakeholders (AI regulators, clinicians, healthcare professionals, patients' organisations, researchers).
3) *Communications*
   - **Collaborating with media outlets.** The Action will engage with media outlets, science journalists and influencers to increase the visibility of vocal biomarkers. The Action will offer interviews, press releases, and experts' views.

Exploitation strategy: To further strengthen industrial engagement, the Action will develop a clear exploitation and Intellectual Property Rights (IPR) strategy. This strategy will include mechanisms for protecting the results of eVoiceNet's work, especially those with potential commercial value. Partners will be provided with guidelines on IP management, licensing agreements, and potential routes for commercialization, ensuring their innovations are safeguarded.

4. IMPLEMENTATION

4.1. COHERENCE AND EFFECTIVENESS OF THE WORK PLAN

4.1.1. DESCRIPTION OF WORKING GROUPS, TASKS AND ACTIVITIES

The Action will be organised in 5 WGs. While WG1-WG4 are focused on fulfilling the research coordination and capacity-building objectives, WG5 will coordinate dissemination activities.
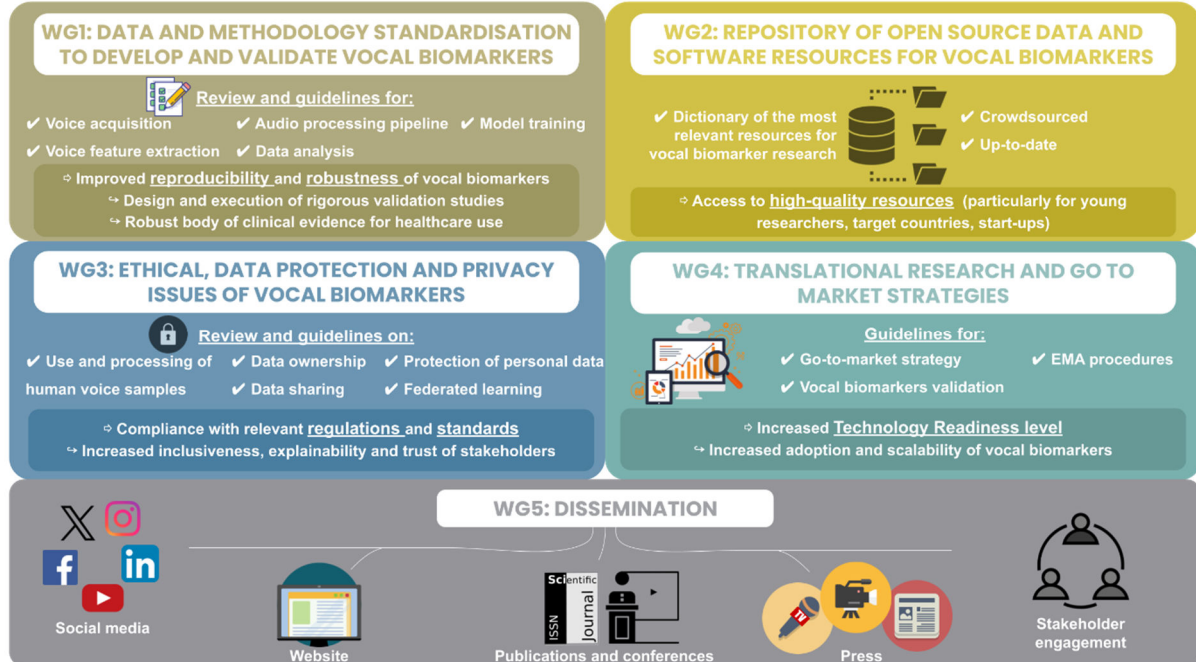

Figure 1. eVoiceNet implementation plan

WG1: Data and Methodology Standardisation to Develop and Validate Vocal Biomarkers	
This WG will bring together clinicians (laryngologists, phoniatricians, voice quality experts, neurologists, cardiologists, pulmonologists, oncologists, psychiatrists…), academics (audio signal processing experts, AI experts), industry (including SMEs and start-ups focusing on a voice technology) and policy makers and regulators.	
Objectives	Improve reproducibility, robustness of vocal biomarkers Develop and validate standardised protocols for voice acquisition, voice feature extraction, audio processing pipeline, data analysis and model training
Tasks	Identify and review the state-of-the-art technologies and algorithms for voice feature extraction, audio signal processing, data analysis and model training Create a taxonomy of methodologies and algorithms for vocal biomarkers Promote training and educational resources for vocal biomarkers
Activities	**A1.1** Workshop held in conjunction with a main conference on voice technology or digital biomarkers (year 1) **A1.2** Training school on AI, machine learning, voice/audio signal processing, vocal biomarkers (year 3) **A1.3** Roundtables (biannually) **A1.4** WG meetings (in-person and/or remote, biannually) **A1.5** STSMs (annually)

WG2: Repository of Open Source Data and Software Resources for Vocal Biomarkers	
This WG will be of particular interest for researchers and industry representatives involved in the design and development of vocal biomarkers.	
Objectives	Create and maintain a comprehensive repository of open source data and software resources

Tasks	Release the challenge dataset and evaluation criteria Review the currently available data and software resources for voice analysis in the context of vocal biomarkers Create an up-to-date and crowdsourced dictionary of the most relevant datasets and softwares used to develop vocal biomarkers Foster an acquisition of new datasets for longitudinal studies, validation studies Promote open data, open access publications and open source within the research community Encourage the use and growth of the repository
Activities	**A2.1** Challenge held in conjunction with a main conference on voice technology or digital biomarkers (year 2)

	A2.2 Roundtables (biannually) **A2.3** WG meetings (in-person and/or remote, biannually) **A2.4** STSMs (annually)

WG3: Ethical, Data Protection and Privacy Issues of Vocal Biomarkers	
This WG will bring together data privacy and security, ethics and legal experts to ensure the design and development of privacy-preserving vocal biomarkers.	
Objectives	Increase inclusiveness, explainability and trust of vocal biomarkers Promote ethical and responsible practices in vocal biomarker research Ensure data ownership and privacy protection in voice-based data collection efforts and studies Facilitate collaboration and advancement in vocal biomarker research through data sharing and federated learning

Tasks	Review the current methodology for:
	    ● Use and processing of human voice samples
	    ● Data ownership
	    ● Data sharing
	    ● Privacy preservation and protection of personal data
	    ● Federated learning

Activities	**A3.1** Training school on best practices and data handling (year 2) **A3.2** Workshop held in conjunction with a main conference on voice technology or digital biomarkers (year 3) **A3.3** Roundtables (biannually) **A3.4** WG meetings lead by a dedicated ethical board (in-person and/or remote, biannually) **A3.5** STSMs (annually)

WG4: Translational Research and Go To Market Strategies	
This WG will bring together researchers and industry working in different aspects of voice-based solutions: applications (e.g. for diagnosing diseases, monitoring symptoms), integration with other technologies (e.g. video, wearable sensors, IoT…), health economics and business models.	
Objectives	Overcome go-to-market barriers Enhance understanding and compliance with EMA procedures, Act AI and 2017/745 (EU MDR) for the development of vocal biomarkers
Tasks	Review the state-of-the-art of voice-based diagnosing and monitoring technologies and potential applications of vocal biomarkers Integrate knowledge of WG1, WG2 and WG3 in the design and development of vocal biomarkers Review the EMA procedures for the development of vocal biomarkers
Activities	**A4.1** European and local events on voice technologies that are organised by industry, service providers, end users, policy makers and government representatives (annually) **A4.2** Training school on go-to-market barriers and European procedures (year 3) **A4.3** Roundtables (biannually) **A4.4** WG meetings (in-person and/or remote, biannually) **A4.5** STSMs (annually)

	WG5: Dissemination		
	This WG will involve all stakeholders, and will be a crucial point to increase the impact of eVoiceNet.		
Objectives	Gain end users' trust Reach policy makers, service providers, the public, and ultimately the market		
Tasks	Disseminate the outcomes of eVoiceNet (brochures, fact sheets, educational materials, interviews, press releases, videos, digital content) Promote innovation and collaboration with the industry Organise events to engage with stakeholders		
Activities	**A5.1** Public engagement activities (throughout the year) **A5.2** Awareness campaign (workshops, webinars, public lectures) (annually) **A5.3** Roundtable (biannually) **A5.4** WG meetings (in-person and/or remote, biannually)		
	A5.5 Monitoring of dissemination activities and general knowledge about vocal biomarkers (through the number of citations of published research or stakeholder engagement in workshops) (annually)		

4.1.2. DESCRIPTION OF DELIVERABLES AND TIMEFRAME

Deliverables	Deliverable Title	WG	Due Date
D1.1	Position paper on state-of-the-art technologies and algorithms for voice data collection, voice feature extraction, audio signal processing, data analysis and model training	1	24
D1.2	Guidelines for voice acquisition, annotation, and audio processing	1	36
D2.1	Technical report with a review of currently available datasets	2	12
D2.2	Paper describing the challenge	2	18
D2.3	Initial repository of software and data	2	24
D2.4	Final repository of software and data	2	48
D3.1	White paper on ethical, data protection and privacy issues of vocal biomarkers	3	12
D3.2	Technical report for on-the-device analysis and privacy-preserving federated learning	3	24
D3.3	Position paper on enhancing inclusiveness, explainability and acceptability in vocal biomarker research, building trust through transparent practices and data ownership	3	36
D3.4	Ethics guidelines for vocal biomarkers development and use, including human voice sample collection and processing	3	48
D4.1	Guidelines for go-to-market strategy, vocal biomarkers validation, EMA procedures	4	48
D5.1	Initial version of the website as a central source of information	5	6
D5.2	Social media implementation and engagement	5	0-48
D5.3	Launch of the awareness campaign	5	9
D5.4	Establish patient advisory groups and panels	5	12
D5.5	Proceedings of the final conference	5	48

4.1.3. RISK ANALYSIS AND CONTINGENCY PLANS

The risk analysis and contingency plans related to the Action are described below:

Risk	Level	Contingency Plan
Lack of collaboration, communication and understanding between different stakeholders (clinicians, academics, industry experts) leading to misalignment and delays	Medium	Establish clear communication channels (regular meetings, dedicated communication tools on the website). Organise cross-disciplinary workshops, problem-solving sessions, knowledge transfer programs. Conduct regular monitoring of the collaboration process
Low engagement from industry, policy makers and end users / insufficient number of YRI participating to STSMs	Low	Implement a targeted outreach strategy (identify key stakeholders, conduct personalised outreach, offer incentives for participation, and leverage strategic partnerships to enhance engagement)
Difficulty in obtaining relevant and high-quality datasets for inclusion in the repository and audio datasets	Medium	Actively engage with researchers and industry professionals to encourage them to contribute datasets to the repository and audio datasets. Provide incentives or recognition for contributors to motivate their participation (e.g. access to exclusive training materials).
Insufficient collaboration and data sharing due to privacy-related apprehensions	High	Promote federated learning approaches and on-the-device analysis to address privacy concerns while still enabling collaboration and advancement in vocal biomarker research. Implement a clear IPR strategy to protect the ownership and usage rights of data and innovations.
Recommendations by WG3 on ethico-legal issues limit the developments to be carried out in WG4	Medium	Establish close collaborations and communication channels between WG3 and WG4 to ensure early alignment of ethical and legal considerations
The technology is not widely adopted by the end users	Medium	Increase clinical interpretability and explainability of vocal biomarkers; increase AI transparency and trustworthiness (fact sheets, documentations) Develop tailored educational tools, software solutions, and seminars for clinicians to improve their skills in using vocal biomarkers
Workshop cannot be held in conjunction with a main conference on voice technology	Medium	Target different high-quality events related to voice technology

	Year 1				Year 2				Year 3				Year 4			
	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48
WG1																
Deliverables								D1.1				D1.2				
Activities				A1.1						A1.2						
WG2																
Deliverables				D2.1		D2.2		D2.3								D2.4
Activities								A2.1								
WG3																
Deliverables				D3.1				D3.2				D3.3				D3.4
Activities						A3.1				A3.2						
WG4																
Deliverables																D4.1
Activities				A4.1				A4.1		A4.2		A4.1				A4.1
WG5 Deliverables																
Deliverables		D5.1 D5.2	D5.3	D5.4												D5.5
Activities	A5.1	A5.1	A5.1 A5.5	A5.1 A5.2	A5.1	A5.1	A5.1 A5.5	A5.1 A5.2	A5.1	A5.1	A5.1 A5.5	A5.1 A5.2	A5.1	A5.1	A5.1 A5.5	A5.1 A5.2
Networking activities																
Kick-off meeting																
MC meetings																
Roundtables (A1.3, A2.2, A3.3, A4.3, A5.3)																
WG meetings (A1.4, A2.3, A3.4, A4.4, A5.4)																
STSMs calls																
STSMs (A1.5, A2.4, A3.5, A4.5)																

A: Activities; D: Deliverables