Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità **PNRR: M6/C2_CALL 2022 Full Proposal**	Finanziato dall'Unione europea NextGenerationEU
Project Code: PNRR-POC-2022-12375925	**Call section:** Proof of concept
Applicant Institution: Sardegna	**Applicant/PI Coordinator:** Bussu Francesco

1 - General information

Project code: PNRR-POC-2022-12375925	**Project topic:** A) Proof of concept
	Applicant Institution: Sardegna
PI / Coordinator: Bussu Francesco	**Istitution that perform as UO for UO1:** Azienda Ospedaliera Universitaria di Sassari

Call section: Proof of concept

Proposal title: PRECISION - Proof of concept of remote management of chronic inflammatory airway diseases for patient empowerment

Duration in months: 24

MDC primary: Otorinolaringoiatria e Odontoiatria

MDC secondary: Cardiologia-Pneumologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Healthcare Delivery and Methodologies Small Business - - SBHD

Project Keyword 1: applications seek to understand and elaborate the broader socioenvironmental contexts in which health and health-related behavior are embedded and to examine the interaction of these socioenvironmental factors with the health and health-related behavior of individuals and populations are reviewed within dedicated special emphasis panels within the HOP IRG. The socioenvironmental factors studied may include social class, socioeconomic conditions, cultural factors and processes, institutions, social organization, social networks, neighborhood and regional characteristics, media, policies, social and family group membership, and racial and ethnic identity

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☒

Patent number: IT202000001492A1 **Patent owner:** MARROCCO GAETANO; OCCHIUZZI CECILIA; AMENDOLA SARA; MIOZZI CAROLINA; CAMERA FRANCESCA

Project total financing request to the MOH: € 810.000

Free keywords: Chatbot, patient empowerment, chronic rhinosinusitis, airway diseases, asthma, PROM

Declarations

In case of a Synergy grant application 'Principal Investigator'(PI) means 'corresponding Principal Investigator on behalf of all Principal Investigators', and 'Host Institution' means 'corresponding Host Institution'.

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1) The Principal Investigator declares to have the written consent of all participants on their participation and on the content of this proposal, as well as of any researcher mentioned in the proposal as participating in the project (either as other PI, team member or collaborator).	X
2) The Principal Investigator declares that the information contained in this proposal is correct and complete.	X
3) The Principal Investigator declares that all parts of this proposal comply with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	X
4) The Principal Investigator is only responsible for the correctness of the information relating to his/her own organisation. Each applicant remains responsible for the correctness of the information related to him and declared above.	X

Personal data protection

The assessment of your grant application will involve the collection and processing of personal data (such as your name, address and CV), which will be performed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions in this form and any personal data requested are required to assess your grant application in accordance with the specifications of the call for proposals and will be processed solely for that purpose. Details concerning the purposes and means of the processing of your personal data as well as information on how to exercise your rights are available in the privacy statement. Applicants may lodge a complaint about the processing of their personal data with the European Data Protection Supervisor at any time.

Abstract

Chronic rhinosinusitis (CRS) is an adult-onset, not life-threatening multifactorial syndrome affecting 5-12% of the general population in Western countries; there are two main forms, one with nasal polyps (CRSwNP) and one without polyps (CRSsNP). It is frequently associated (in particular CRSwNP) with other inflammatory diseases and in particular asthma, with whom it shares molecular patterns at the level of the airway mucosa and in particular type II inflammation. Asthma, in turn, is a common condition affecting about 4% of the Western population, with a prevalence increasing by 50% every decade, determining a high number of death, hospitalizations and severe long term morbidity worldwide. On the whole both conditions have a strong impact on quality of life and extremely high direct and indirect costs.
The management of chronic inflammatory airway diseases such as CRS and asthma has improved significantly over the last decades thanks to better knowledge and classification and novel therapeutic agents, in particular "biologic" molecular targeted drugs, mostly antibodies against key molecules of typical inflammatory pathways involved in the pathogenesis of both diseases.
Yet, the new standard of care, both for classification and treatment, is very expensive, both in terms of time required for healthcare workers and patients and in terms of drugs. This is critical, now that COVID pandemic dramatically unveiled an insufficiency of personnel and resources of Western National Health Systems. In fact it means that in a real-world setting a standard of care management of the diseases along time may be no longer sustainable.
Standard of care and in particular novel classification approaches for both diseases require periodic, complex evaluations with subjective assessments provided by patients and objective assessments provided by doctors.
In the subjective assessment, a key role is played by patient-reported outcome measures (PROMs), which have been increasingly used. They improve shared decision making, symptom management, patient satisfaction and quality of life. On the other hand, questionnaires present problems of accuracy and response rate and, most of all, the administration of PROMs is definitely time-consuming. This project aims to test effective ways to enable patients to provide PROMs in time at home. As an alternative to traditional office visits, we will test 3 different remote approaches to acquire subjective data from

patients: AI-enabled chatbots using Social Network, phonebot for automatic phone calls, and mobile apps. Through specifically designed clinical trials, we will evaluate the best channel according to patients' profile (e.g. age, level of education), the obtained compliance in terms of retention, patient's satisfaction and quality of the answers.
As for the objective assessment the present project aims at testing tools for remote monitoring of upper and lower airways patency, which are the main issues respectively in chronic rhinosinusitis and asthma using points of care and exploiting the RFID technology and the connectivity of common mobile devices.
Available platforms (e.g. those provided by ABLE srl and by Radio6ense srl) for multichannel PROM collection and unobtrusive remote monitoring will be used, tested and validated in the described clinical settings.
Patient empowerment will be assessed in relation with both the assessments (subjective and objective).

In order to best review your application, do you agree that the above non-confidential proposal title and abstract can be used, without disclosing your identity, when contacting potential reviewers? Yes

2 - Participants & contacts

Operative Units

Institution that perform as UO	CF Institution	Department / Division / Laboratory	Role in the project	Southern Italy	SSN
1 - Azienda Ospedaliera Universitaria di Sassari	02268260904	Azienda Ospedaliera Universitaria Sassari	Clinical Partner	X	X
2 - Università di Roma Tor Vergata	80213750583	Dipartimento di Ingegneria Elettronica	Technological partner		

Principal Research Collaborators

Key Personnel Name	Operative Unit	Role in the project
1 - Bracciale Lorenzo	Università di Roma Tor Vergata	Ricercatore principale
2 - Pirina Pietro	Azienda Ospedaliera Universitaria di Sassari	Ricercatore principale co PI
3 - LORETI PIERPAOLO	Università di Roma Tor Vergata	Ricercatore principale
4 - Canu Sara	Azienda Ospedaliera Universitaria di Sassari	Ricercatore principale
5 - Marrocco Gaetano	Università di Roma Tor Vergata	Ricercatore principale
6 Under 40 - occhiuzzi cecilia	Università di Roma Tor Vergata	Ricercatore principale
7 Under 40 - PIRAS ANTONIO	Azienda Ospedaliera Universitaria di Sassari	Ricercatore principale

Key Personnel Name	Co-PI	Resp. CE	Resp. Animal	Birth Date	Gender
1 - Bracciale Lorenzo				22/02/1982	M
2 - Pirina Pietro	X			12/07/1956	M
3 - LORETI PIERPAOLO				28/02/1973	M
4 - Canu Sara				27/06/1986	F
5 - Marrocco Gaetano				29/08/1969	M
6 Under 40 - occhiuzzi cecilia				13/10/1983	F
7 Under 40 - PIRAS ANTONIO				01/12/1983	M

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Responsible who requests CE authorization: Bussu Francesco

Additional research collaborators under 40 to hire

Key Personnel Name	Operative Unit	Birth Date	Gender	Role in the project	Degree	Actual Pos. and Inst.
0 - CRESCIO CLAUDIA	Azienda Ospedaliera Universitaria di Sassari	20/11/1982	F	Data manager	Degree in Molecular Biotechnologies	Data manager at AOU Sassari
1 - Benvegna Chiara	Azienda Ospedaliera Universitaria di Sassari	04/11/1988	F	Pneumologist	Degree in Medicine and Surgery	Pneumologist at AOU Sassari
2 - Bianco Giulio Maria	Università di Roma Tor Vergata	07/04/1994	M	Engineer	Degree in Medical Engineering	Post-doc at Università Roma Tor Vergata

2.1 Administrative data of participating

Operative Unit Number 1:

Address: viale San Pietro 43, Sassari, 07100, Italy
PEC: protocollo@pec.aou.ss.it

Operative Unit Number 2:

Address: via del Politecnico 1, 00133, Roma, Italy
PEC: ing-elettronica@pec.torvergata.it

Operative Unit Number 3:

Address: -
PEC: -

Operative Unit Number 4:

Address: -
PEC: -

Operative Unit Number 5 (self financing):

Address: -
PEC: -

2.2 Principal Investigator (PI) Profile

Last Name: Bussu
First Name: Francesco

Last name at birth:
Gender: M

Title: Principal investigator
Nationality: Italiana
Date of birth: 04/04/1974

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Cagliari

Official H index (Scopus or Web of Science): 27.0

Scopus Author Id:57215521657 **ORCID ID:**0000-0001-6261-2772 **RESEARCH ID:**AAA-7610-2019

Contact address

Current organisation name: Azienda Ospedaliera Universitaria di Sassari
Current Department / Faculty / Institute / Laboratory name: Azienda Ospedaliera Universitaria Sassari
Street: via san Pietro 10
Postcode / Cedex: 07100
Town: Sassari
Phone:+393296024900
Phone 2: 079/228509

Education / training

Educational institution and location	Degree	Field of study	From year	To year
Università Cattolica del Sacro Cuore, Facoltà di Medicina e Chirurgia, Roma	Master's Degree / Laurea Magistrale	Medicine and Surgery	1993	1999
Università Cattolica del Sacro Cuore, Facoltà di Medicina e Chirurgia, Roma	PhD	Phisiopathology of the rhino-pharyngo-tubaric district	2002	2006
Università di Roma Tor Vergata	Specialization / Specializzazione	Otorhinolaryngology	2006	2010

Personal Statement:

Francesco Bussu, the principal investigator, is the project coordinator.
He is also in charge for the clinical aspects of the project, and for the clinical validation of technological tools developed, in particular in the field of chronic rhinosinusitis.
He will also be the PI of all the validation studies to be submitted to the ethical committee(s).

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
Università degli Studi di Sassari	Dipartimento di Medicina, Chirurgia e Farmacia	Sassari	Professore Ordinario (full Professor)	2019	2022
Azienda Ospedaliera Universitaria di Sassari	Azienda Ospedaliera Universitaria di Sassari	Sassari	Head of Department	2018	2019
Azienda Ospedaliera Universitaria di Sassari	Otolaryngology	Sassari	Head of Division (Primario)	2017	2022
Policlinico Agostino Gemelli	Otorhinolaryngology	Rome	Dirigente Medico di Primo Livello	2004	2017
Università Cattolica del Sacro Cuore	Facoltà di Medicina e Chirurgia	Rome	Assistant Professor	2004	2019

Other awards and honors

1999 - Cash prize for the best oncologic degree theses of the year;
1999 - `Award Agostino Gemelli 1999', to the best Medical graduated of the year in Università Cattolica del Sacro Cuore;
2013 - `Award Italo Serafini 2013', by the Italian Society of Head and Neck Oncology (AIOCC) for the best free paper in the national congress;
2018 Cash prize for 'High quality publication' from Catholic University of the Sacred Heart

Other CV informations

About 6000 surgical procedures as first operator in all the subspecialties of Otolaryngology.

AFFILIATION TO PROFESSIONAL SOCIETIES.
Società Italiana di Otorinolaringoiatria (SIO) (member of the board of directors), Associazione Italiana di Oncologia Cervico-Cefalica (AIOCC), Società Italiana di Rinologia (SIR), Società Italiana di Otorinolaringoiatria Pediatrica (SIOP) (member of the board of directors); European SocieTy for Radiotherapy and Oncology (ESTRO)

REVIEWER ACTIVITY for many impacted journals.

REVIEWER ACTIVITY for RESEARCH PROJECTS funded by:
EUROPEAN COMMISSION (since 2014 Horizon 2020 programme and 3rd Health Programme; since 2021 Horizon Europe programme; since 2022 EU4Health Work Programme); MIUR (PRIN e Futuro in Ricerca); several Italian universities.

Selected peer-reviewed publications of the PI valid for minimum expertise level

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
IFN-? and other serum cytokines in head and neck squamous cell carcinomas	Article	94-102	38	2018	10.14639/0392-100X-1530	29967556	11	F
Nasopharyngeal swab collection in the suspicion of Covid-19	Article	NOT_FOUND	41	2020	10.1016/j.amjoto.2020.102551	32487335	12	L
Immunohistochemical expression patterns of the HER4 receptors in normal mucosa and in laryngeal squamous cell carcinomas: Antioncogenic significance of the HER4 protein in laryngeal squamous cell carcinoma	Article	1724-1733	122	2012	10.1002/lary.23311	22549618	13	F

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Clinical history, prognostic factors, and management of facial nerve in malignant tumors of the parotid gland	Article	126-132	7	2014	10.3342/ceo.2014.7.2.126	NOT_FOUND	13	F
HDR interventional radiotherapy (brachytherapy) in the treatment of primary and recurrent head and neck malignancies	Article	1667-1675	41	2019	10.1002/hed.25646	30701614	14	F
Vocal fold nodules in school age children: Attention deficit hyperactivity disorder as a potential risk factor	Article	287-291	29	2015	10.1016/j.jvoice.2014.07.019	25444156	16	L
Perioperative HDR brachytherapy for reirradiation in head and neck recurrences: Single-institution experience and systematic review	Article	516-524	103	2017	10.5301/tj.5000614	28291904	18	C
Endoscopy-guided brachytherapy for sinonasal and nasopharyngeal recurrences	Article	419-425	14	2015	10.1016/j.brachy.2014.11.012	25620162	19	C
HPV and EBV Infections in Neck Metastases from Occult Primary Squamous Cell Carcinoma: Another Virus-Related Neoplastic Disease in the Head and Neck Region	Article	979-984	22	2015	10.1245/s10434-015-4808-5	26286196	19	F
Contemporary role of pectoralis major regional flaps in head and neck surgery	Article	327-341	34	2014	NOT_FOUND	25709148	21	F
Oncologic outcomes in advanced laryngeal squamous cell carcinomas treated with different modalities in a single institution: A retrospective analysis of 65 cases	Article	573-579	34	2012	10.1002/hed.21785	21692130	26	F
HPV as a marker for molecular characterization in head and neck oncology: Looking for a standardization of clinical use and of detection method(s) in clinical practice	Article	1104-1111	41	2019	10.1002/hed.25591	30747478	27	F
Comparison of interstitial brachytherapy and surgery as primary treatments for nasal vestibule carcinomas	Article	367-371	126	2016	10.1002/lary.25498	26372494	28	F
Inappropriate Nasopharyngeal Sampling for SARS-CoV-2 Detection Is a Relevant Cause of False-Negative Reports	Article	459-461	163	2020	10.1177/0194599820931793	32450754	30	L
Human papillomavirus (HPV) infection in squamous cell carcinomas arising from the oropharynx: Detection of HPV DNA and p16 immunohistochemistry as diagnostic and prognostic indicators - A pilot study	Article	1115-1120	89	2014	10.1016/j.ijrobp.2014.04.044	25035216	32	F
Comparison of total laryngectomy with surgical (cricohyoidopexy) and nonsurgical organ-preservation modalities in advanced laryngeal squamous cell carcinomas: A multicenter retrospective analysis	Article	554-561	35	2013	10.1002/hed.22994	22495830	34	F
Oncologic results of the surgical salvage of recurrent laryngeal squamous cell carcinoma in a multicentric retrospective series: Emerging role of supracricoid partial laryngectomy	Article	84-91	37	2015	10.1002/hed.23563	24327466	35	C
A comprehensive approach to long-standing facial paralysis based on lengthening temporalis myoplasty	Article	145-153	32	2012	NOT_FOUND	22767978	39	C

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
HPV infection in squamous cell carcinomas arising from different mucosal sites of the head and neck region. Is p16 immunohistochemistry a reliable surrogate marker?	Article	1157-1162	108	2013	10.1038/bjc.2013.55	23403821	75	F
New insights into human papillomavirus-associated head and neck squamous cell carcinoma	Article	77-87	33	2013	NOT_FOUND	23853396	79	C

* Position: F=First L=Last C=Correspondent O=Other N=Not applicable

** Autocertificated

Selected peer-reviewed publications of the PI for the evaluation CV

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**
A prospective pilot study on the effects of endoscopic sinus surgery on upper and lower airway performance	Article	544-549	41	2021	10.14639/0392-100X-N1361	34928265	0
Endoscopy-guided brachytherapy for sinonasal and nasopharyngeal recurrences	Article	419-425	14	2015	10.1016/j.brachy.2014.11.012	25620162	19
Nasal lavage levels of granulocyte-macrophage colony-stimulating factor and chronic nasal hypereosinophilia	Article	557-562	5	2015	10.1002/alr.21519	25821067	21
Nasal fluid release of eotaxin-3 and eotaxin-2 in persistent sinonasal eosinophilic inflammation	Article	617-624	4	2014	10.1002/alr.21348	24989688	23
Comparison of interstitial brachytherapy and surgery as primary treatments for nasal vestibule carcinomas	Article	367-371	126	2016	10.1002/lary.25498	26372494	28
Inappropriate Nasopharyngeal Sampling for SARS-CoV-2 Detection Is a Relevant Cause of False-Negative Reports	Article	459-461	163	2020	10.1177/0194599820931793	32450754	30
Ent cobra ontology: the covariates classification system proposed by the Head & Neck and Skin GEC-ESTRO Working Group for interdisciplinary standardized data collection in head and neck patient cohorts treated with interventional radiotherapy (brachytherapy)	Article	260-266	10	2018	10.5114/jcb.2018.76982	NOT_FOUND	36
HPV infection in squamous cell carcinomas arising from different mucosal sites of the head and neck region. Is p16 immunohistochemistry a reliable surrogate marker?	Article	1157-1162	108	2013	10.1038/bjc.2013.55	23403821	75
Olfactory and gustatory function impairment in COVID-19 patients: Italian objective multicenter-study	Article	1560-1569	42	2020	10.1002/hed.26269	32437022	150
Objective evaluation of anosmia and ageusia in COVID-19 patients: Single-center experience on 72 cases	Article	1252-1258	42	2020	10.1002/hed.26204	32342566	251

** Autocertificated

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Sardegna Ricerche	AOU Sassari	2020	Revealing - Studio osservazionale per la valutazione della storia clinica (pattern di presa in carico e di trattamento) e trattamento delle neoplasie del distretto cervico-facciale nel centro di riferimento per il Nord Sardegna	Coordinator	50.000,00	https://www.sardegnaricerche.it/
Fondazione Banco di Sardegna	AOU Sassari	2018	Screening neonatale e sorveglianza audiologica infantile¿ funded by Fondazione Banco di Sardegna	Coordinator	20.000,00	https://www.fondazionedisardegna.it/
Università Cattolica del Sacro Cuore	Università Cattolica del Sacro Cuore	2017	Ruolo epidemiologico e prognostico dei Papillomavlrus tunani nella carcinogenesi della testa e del collo. Approcci diagnostici ed implicazioni per la pratica clinica	Coordinator	7.200,00	www.unicatt.it
Università Cattolica del Sacro Cuore	Università Cattolica del Sacro Cuore	2016	Definizione del ruolo complessivo dei virus oncogeni nel distretto testa e collo	Coordinator	7.200,00	www.unicatt.it

2.3 CO-PI Profile

Last Name: Pirina
First Name: Pietro

Last name at birth:
Gender: M

Title: Ricercatore principale co PI
Nationality: Italiana
Date of birth: 12/07/1956

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Luogosanto

Official H index (Scopus or Web of Science): 31.0

Scopus Author Id:57189226636 **ORCID ID:**0000-0003-1457-8025 **RESEARCH ID:**0

Contact address

Current organisation name: Azienda Ospedaliera Universitaria di Sassari
Current Department / Faculty / Institute / Laboratory name: Azienda Ospedaliera Universitaria Sassari
Street: viale Sa Pietro 43
Postcode / Cedex: 07100
Town: Sassari
Phone:+393371001313
Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Sassari - School of Medicine	Single-cycle master's degree / Laurea magistrale a ciclo unico	As a medical student he did an internship at the Unit of Respiratory Diseases and he worked on data collection of patients affected by asthma, rhinitis, COPD and lung cancer.	1978	1984
University of Sassari - School of Medicine	Specialization / Specializzazione	His main interests focused on respiratory diseases, in particular asthma, COPD, rhinitis, tuberculosis and lung cancer. He collaborated in several national and international clinical trials and research projects.	1987	1991

Personal Statement:
Pietro Pirina is the head of the Department of Respiratory Diseases of the Azienda Ospedaliero Universitaria of Sassari since 2004 and he is full professor at the University of Sassari (SS MED/10) since December 2021.
His main research interests cover several topics: asthma, rhinitis and chronic bronchitis and also the epidemiology of lung cancer and of tuberculosis in Sardinia.
He covered the role of Principal Investigator in several international Clinical Trials principally about asthma and COPD. He collaborates with Verona University in the studies on ¿Asthma in Young Adults (ISAYA)¿ and ¿Gene Environment Interactions in Respiratory Diseases (GEIRD)¿ that investigate the interactions between genes, climate and air pollution in asthma, rhinitis and chronic bronchitis.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Sassari	Department of Medicine, Surgery and Pharmacy	Sassari	Researcher (SSD (MED-10))	1994	2001
University of Sassari	Department of Medicine, Surgery and Pharmacy	Sassari	Associate professor (SSD (MED-10))	2001	2021
University of Sassari	Department of Medicine, Surgery and Pharmacy	Sassari	Full professor (SSD (MED-10))	2021	2022
Azienda Ospedaliero Universitaria (AOU Sassari)	Clinical and Interventional Pneumology	Sassari	Head of the Department	2004	2022

Other awards and honors

None

Other CV informations

None

Selected peer-reviewed publications of the Co-PI valid for minimum expertise level

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Circulating malondialdehyde concentrations in obstructive sleep apnea (Osa): A systematic review and meta-analysis with meta-regression	Article	NOT_FOUND	10	2021	10.3390/antiox10071053	NOT_FOUND	1	L
Serum albumin concentrations in stable chronic obstructive pulmonary disease: A systematic review and meta-analysis	Article	1-12	10	2021	10.3390/jcm10020269	NOT_FOUND	3	L
Increased kynurenine plasma concentrations and kynurenine-tryptophan ratio in mild-to-moderate chronic obstructive pulmonary disease patients	Article	229-237	12	2018	10.2217/bmm-2017-0280	29506391	8	L
Blood global DNA methylation is decreased in non-severe chronic obstructive pulmonary disease (COPD) patients	Article	11-15	46	2017	10.1016/j.pupt.2017.08.006	28818709	10	L
Systemic transsulfuration pathway thiol concentrations in chronic obstructive pulmonary disease patients	Article	NOT_FOUND	50	2020	10.1111/eci.13267	32378181	8	L
Reliability and Usefulness of Different Biomarkers of Oxidative Stress in Chronic Obstructive Pulmonary Disease	Article	NOT_FOUND	2020	2020	10.1155/2020/4982324	32509143	14	L
Oxidative stress biomarkers in chronic obstructive pulmonary disease exacerbations: A systematic review	Article	NOT_FOUND	10	2021	10.3390/antiox10050710	NOT_FOUND	2	L
Chest tuberculosis with mediastinal asymptomatic lymphadenitis without lung involvement in an immunocompetent patient	Article	280-285	7	2013	10.3855/jidc.2973	23493008	6	F
Circulating serotonin levels in COPD patients: A pilot study 11 Medical and Health Sciences 1102 Cardiorespiratory Medicine and Haematology	Article	NOT_FOUND	18	2018	10.1186/s12890-018-0730-5	30409142	4	F

Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Circulating serotonin levels in COPD patients: A pilot study 11 Medical and Health Sciences 1102 Cardiorespiratory Medicine and Haematology	Article	NOT_FOUND	18	2018	10.1186/s12890-018-0730-5	30409142	4	F
Small airway inflammation and extrafine inhaled corticosteroids plus long-acting beta<inf>2</inf>-agonists formulations in chronic obstructive pulmonary disease	Article	74-81	143	2018	10.1016/j.rmed.2018.08.013	30261996	6	F
Prevalence and management of COPD and heart failure comorbidity in the general practitioner setting	Article	1-5	131	2017	10.1016/j.rmed.2017.07.059	28947013	18	F
Amyotrophic lateral sclerosis in Sardinia, insular Italy, 1995-2009	Article	572-579	260	2013	10.1007/s00415-012-6681-5	23052600	34	L
Circulating biomarkers of oxidative stress in chronic obstructive pulmonary disease: A systematic review	Article	NOT_FOUND	17	2016	10.1186/s12931-016-0471-z	27842552	64	C
Biomarkers of oxidative stress and inflammation in chronic airway diseases	Article	1-13	21	2020	10.3390/ijms21124339	32570774	10	C
Recent advances in inflamation and treatment of small airways in asthma	Article	NOT_FOUND	20	2019	10.3390/ijms20112617	31141956	14	C
Plasma protein thiols: An early marker of oxidative stress in asthma and chronic obstructive pulmonary disease	Article	181-188	46	2016	10.1111/eci.12582	26681451	33	C

* Position: F=First L=Last C=Correspondent O=Other N=Not applicable

** Autocertificated

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Banco di Sardegna Foundation	University of Sassari	2010	Study of the Prevalence of Obstructive Sleep Apnea in the geographical area of Northern Sardinia - Phase II	Coordinator	13.000,00	None
the Italian Medicines Agency (AIFA)	AOU Sassari	2010	Severe asthma: follow up of epidemiological and clinical cohorts, through register and questionnaires; therapeutic appropriateness and evaluation of outcomes, in relation to the GINA Guidelines - (AGAVE Project)	Coordinator	10.000,00	None
Banco di Sardegna Foundation	University of Sassari	2007	Study of patients with Sleep Respiratory Disorders in the Provinces of Sassari and Olbia	Coordinator	30.000,00	None
Italian Ministry of Health	Italian multicenter study (Verona, Sassari, Pavia, Torino)	2009	Oxidative stress, aging, and respiratory diseases. A multi-centre epidemiological and genetic study on the general adult and elderly population in Italy	Coordinator	31.000,00	None

2.3 Research Collaborators n. 1

Last Name: Bracciale
First Name: Lorenzo

Last name at birth:
Gender: M

Title: Ricercatore principale
Nationality: Italiana
Date of birth: 22/02/1982

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Marino

Official H index (Scopus or Web of Science): 13.0

Scopus Author Id:24722537100 **ORCID ID:**0000-0002-6673-3157 **RESEARCH ID:**AAG-6136-2019

Contact address

Current organisation name: Università di Roma Tor Vergata
Current Department / Faculty / Institute / Laboratory name: Dipartimento di Ingegneria Elettronica
Street: via del policlinico 1
Postcode / Cedex: 00133
Town: Roma
Phone:+393478081098
Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Rome "Tor Vergata"	Bachelor Degree / Laurea Triennale	Telecommunication Engineering	2000	2003
University of Rome "Tor Vergata"	Master's Degree / Laurea Magistrale	Telecommunication Engineering	2003	2005
University of Rome "Tor Vergata"	PhD	Telecommunication Engineering	2006	2010

Personal Statement:

Lorenzo Bracciale is an Assistant Professor (RTD-B) in the University of Rome Tor Vergata where he received his Ph.D. degree in Telecommunication and Microelectronics in 2010 and teaches Computer Science, Digital Health and Web Programming.
He had several collaborations with Massachusetts Institute of Technology (MIT), Trinity College Dublin, Galápagos National Park and Sheffield Information School.
He authored more than 40 international publications and served as reviewer in many international journals.
He has been in the technical program/organizational committee of many prestigious conferences such as SECON 2021, WCNC 2018 CoNEXT 2015, Topic Editor for MDPI Sensors and General Chair for BHCC2022.
His current research topics include machine learning, digital health and data privacy.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Rome "Tor Vergata"	Department of Electronic Engineering	Rome	Junior Assistant Professor (RTD-A)	2013	2017
University of Rome "Tor Vergata"	Department of Electronic Engineering	Rome	Research Fellow	2021	2018
University of Rome "Tor Vergata"	Department of Electronic Engineering	Rome	Assistant Professor (RTD-B)	2022	2022

Other awards and honors

Best Paper Award in the International Symposium on Networks, Computers and Communications with a crowd-sourcing problem optimisation using machine learning and bayesian inference.

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
POR FESR 2014 ¿ 2020 Regione Lazio	CNIT - University of Rome "Tor Vergata"	2016-2019	SESAMO	Collaborator	400.000,00	https://www.cnit.it/progetti/progetti-regionali/progetto-sesamo/
European Union	University of Rome "Tor Vergata"	2016-2019	ICN2020	Collaborator	1.300.000,00	http://www.icn2020.org/
European Union	University of Rome "Tor Vergata"	2018-2021	BPR4GDPR	Collaborator	2.900.000,00	https://www.bpr4gdpr.eu/

2.4 Research Collaborators n. 3

Last Name: LORETI
First Name: PIERPAOLO

Last name at birth:
Gender: M

Title: Ricercatore principale
Nationality: Italiana
Date of birth: 28/02/1973

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Roma

Official H index (Scopus or Web of Science): 15.0

Scopus Author Id:7003459349 **ORCID ID:**0000-0002-2348-5077 **RESEARCH ID:**AHE-3304-2022

Contact address

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Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Rome Tor Vergata, Rome, Italy	Single-cycle master's degree / Laurea magistrale a ciclo unico	Electronic Engineering Dissertation title: Analysis and simulation of co-channel interference of non GEO satellite constellations for the S-UMTS system", tutor: Prof. F. Vatalaro.	1992	1998
University of Rome Tor Vergata, Rome, Italy	PhD	Telecommunication and Microelectronic Engineering Dissertation title: ¿Mobile Satellite Channel Shadowing Characterization and Impact on Internet Applications", tutor: Prof. F. Vatalaro.	1999	2002

Personal Statement:

Pierpaolo Loreti is a Professor in Telecommunications at the University of Roma Tor Vergata. Since 1998 he has collaborated with several public and private research consortiums (CNIT, Co.Ri.Tel, RadioLabs, NITEL) and companies (Selex Communications, Thetis, Telecom Italia). Since 1998 he has worked on several European and national projects performing research and coordination activities. He has authored more than 80 peer reviewed articles in journals and international conferences and he served as reviewers of numerous journals and conferences. His research activity spans different topics in the areas of wireless and mobile networks, IoT systems and platforms, framework design, analytic modeling, performance evaluation through simulation and test-bedding.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Los Angeles California	CS Department	California, USA	Visiting Researcher Co-Investigator, Project Management, Scientific and Technical Committee in the VICOM satellite access networks, satellite mobile internet access	2000	2001
CNIT ¿ Consorzio Nazionale Interuniversitario per le Telecomunicazioni, Tor Vergata - Rome	UdR Roma Tor Vergata	Rome, Italy	Researcher Co-Investigator, Project Management, Scientific and Technical Committee in the VICOM Project (FIRB-MIUR ¿ National Project)	2003	2005
University of Rome Tor Vergata, Rome, Italy	Department of Electronic Engineering	Rome, Italy	Researcher	2006	2021
University of Rome Tor Vergata, Rome, Italy	Department of Electronic Engineering	Rome, Italy	Associate Professor	2021	2022

Other awards and honors

Innovation Award 2008 Selex Communications
Mobile communication wireless network with detection and affiliation of extraneous nodes and related exploration and affiliation request methods. Awarded for the results achieved and design of the SelfNet Mesh Network.
2015 Prize in memory of Engineer Franco Arzano"WIGUANA - Wireless non-invasive infrastructure-less wild animal monitoring system" awarded as the most innovative project in the ICT area in the Uncovering Excellence call for proposals.

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
European Commission	University of Rome Tor Vergata	2019-2021	BPR4GDPR: Business Process Re-engineering and functional toolkit for GDPR compliance" (BPR4GDPR)	Collaborator	2.900.000,00	https://www.bpr4gdpr.eu/
European Commission	CNIT	2010-2012	FLexible Architecture for Virtualizable wireless future Internet Access" (FLAVIA)	Collaborator	3.600.000,00	None
European Commission	University of Rome Tor Vergata	2000	Multi-Segment System for Broadband Ubiquitous Access to Internet Services and Demonstrator¿ (IST-1999-10469 SUITED)	Collaborator	3.900.000,00	None
European commission	CNIT	2015-2016	"Superfluidity A Super-Fluid, Cloud-Native, Converged Edge System" (SUPERFLUIDITY)	Collaborator	7.800.000,00	http://superfluidity.eu/
Sicilia Region	University of Rome Tor Vergata	2021-2022	"Blockchain per la gestione decentrata delle Rinnovabili" (BLORIN)	Collaborator	80.000,00	https://www.blorin.energy/
Lazio Region	NITEL	2011-2012	"Multimedia Gate Control" (MGC)	Coordinator	260.000,00	None

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Tor Vergata University "Uncovering Excellence" co-founded by Atlantic Production and San Diego RCD Zoo	University of Rome Tor vergata	2014-2016	Wireless non-invasive infrastructure-less wild animal monitoring system" (WIGUANA)	Coordinator	90.000,00	None
Lazio Region	NITEL	2014-2015	Logistics Innovative Coordination Suite/System (LOGICOS)	Coordinator	260.000,00	None
European Commission	University of Rome Tor Vergata	2008-2011	Proximity and Emergency Networks for Common European Communication" (PenForCec)	Coordinator	980.000,00	None
Lazio Region	NITEL	2013-2015	Dsa Dysgraphia Screening Assessment - Platform" (DSA-PLAT)	Coordinator	100.000,00	None

2.5 Research Collaborators n. 4

Last Name: Canu
First Name: Sara

Last name at birth: Canu
Gender: F

Title: Ricercatore principale
Nationality: Italiana
Date of birth: 27/06/1986

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Sassari

Official H index (Scopus or Web of Science): 6.0

Scopus Author Id:8712142000 **ORCID ID:**0 **RESEARCH ID:**0

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Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Sassari	Specialization / Specializzazione	Pulmonary Disease	2012	2017
University of Sassari	Single-cycle master's degree / Laurea magistrale a ciclo unico	Respiratory Disease	2005	2011

Personal Statement:

Sara Canu (MD) is a pulmonary physician at the Department of Respiratory Diseases of the Azienda Ospedaliero Universitaria of Sassari since 2021. She has developed a research interest in Interstitial lung diseases (ILD) whit special focus on Idiopathic Pulmonary Fibrosis. She is the co-authors of publications and sub investigators in several clinical Trials in ILD and GEIRD (Genes Environment Interaction in Respiratory Diseases) .The aim of this study was the role of genetic and environmental factors in the natural history of asthma, allergic rhinitis and chronic obstructive pulmonary disease (COPD).
Furthermore, in clinical practice she has expertise in chronic lung disease such as asthma and chronic obstructive pulmonary disease.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
Azienda Ospedaliero Universitaria (AOU Sassari)	Pulmonary Unit	Sassari	Physician	2021	2022
Azienda Ospedaliero Universitaria	Internal Medicine	Sassari	Physician	2020	2021
San Martino Hospital	Internal Medicine	Oristano	Physician	2018	2019
GB Morgagni Hospital	Pulmonary Unit	Forlì	Physician	2018	2018

Other awards and honors

None

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
None	None	0	None	Coordinator	0,00	None

2.6 Research Collaborators n. 5

Last Name: Marrocco
First Name: Gaetano

Last name at birth:
Gender: M

Title: Ricercatore principale
Nationality: Italiana
Date of birth: 29/08/1969

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Teramo

Official H index (Scopus or Web of Science): 33.0

Scopus Author Id:7006055951 **ORCID ID:**0000-0003-3151-3071 **RESEARCH ID:**0

Contact address

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Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of L¿Aquila, Italy	Single-cycle master's degree / Laurea magistrale a ciclo unico	Electronic Engineering Modeling of Electromagnetic propagation in the human head	1988	1994
University of L¿Aquila, Italy	PhD	Electronic Engineering: ¿Finite Difference Method for the modeling of highly in-homogeneous systems¿	1995	1998

Personal Statement:

Full Professor at the University of Roma Tor Vergata as chair of the Medical Engineering School.
His research is now focused to wireless-activated sensors in particular to Wearable and Epidermal Electronics and structural antennas for smart prosthesis and finger augmentation devices for Tactile Internet.
He serves as Associate Editor of the IEEE Journal of Radiofrequency Identification and of the IEEE Journal of Flexible Electronics. He is chair of the Italian Section of URSI Commission D Electronics and Photonics and of co-founder and president of the University spin-off RADIO6ENSE that is active in the short-range electromagnetic sensing for Industrial Internet of Things, Smart Manufacturing, Automotive and Digital Health.He is listed in the PLOS ranking of Top 1.5% Scientists Worldwide.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Rome Tor Vergata	Department of Informatics, Systems and Production (DISP)	Rome, Italy	Researcher	1997	2013
RADIO6ENSE srl	Spin-off University of Roma Tor Vergata	Rome, Italy	President	2013	2022
University of Rome Tor Vergata	Department of Civil and Informatics Engineering	Rome	Associate Professor of Electromagnetics	2013	2018
University of Rome Tor Vergata	Department of Civil and Informatics Engineering	Rome	Full Professor of Electromagmetics	2018	2022

Other awards and honors

2021Best Paper Award IEEE RFID-TA-N. Panunzio, G, Ligresti, M. Losardo, D. Masi, A. Mostaccio, F. Nanni,G. Tartaglia and G.Marrocco, ¿Cyber-Tooth: Antennified Dental Implant for RFID Wireless Temperature Monitoring¿
2017Best Paper Award IEEE RFID-TA 2017-M. C. Caccami,M.Y.S. Mulla,C. Di Natale and G. Marrocco ¿An Epidermal Graphene Oxide-based RFID Sensor for the wireless analysis of human breath¿
2017Best Paper Award IEEE 14th International Conf. on Wearable and Implantable Body Sensor Networks

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
MIUR	University of Rome Tor Vergata	2012-2013	PRIN-2008: Electromagnetic Technology for Multiple-Interrogation Active and Passive RFID Systems	Coordinator	150.000,00	http://www.pervasive.ing.uniroma2.it
Selex Communcations, Finmeccanica	University of Rome Tor Vergata	2003-2005	Novel wideband antennas for Naval Communications	Coordinator	158.000,00	http://www.pervasive.ing.uniroma2.it/Alab_people_marrocco_PROJECTS.htm
Selex Communcations, Finmeccanica	University of Rome Tor Vergata	2005-2007	Multi-function structural antenna systems for naval Software-Defined Radio	Coordinator	185.000,00	http://www.pervasive.ing.uniroma2.it/Alab_people_marrocco_PROJECTS.htm
Regione Lazio	University of Roma Tor Vergata	2018-2020	SECOND-SKIN: Bio-integrated Wireless Sensors for the monitoring of the epidermis and for the recovery of tactile senses	Coordinator	150.000,00	http://www.pervasive.ing.uniroma2.it/secondskin.htm
European Space Agency	University of Rome Tor Vergata	2009-2010	Miniaturized Multi-Function Antenna System for Micro/Nano-Satellites	Coordinator	60.000,00	http://www.pervasive.ing.uniroma2.it/Alab_people_marrocco_PROJECTS.htm
University of Roma Tor Vergata	University of Roma Tor Vergata	2019	Beyond Borders 2019 ¿Epidermal Sensor Networks for Emerging 5G systems¿	Coordinator	13.000,00	None

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
European Space Agency	University of Rome Tor Vergata	2012-2013	ESA-ESTEC "Modular and customisable accomodation friendly antenna system for satellite avionics¿	Coordinator	100.000,00	http://www.pervasive.ing.uniroma2.it/Alab_people_marrocco_PROJECTS.htm
MIUR- FISR COVID	University of Rome Tor Vergata	2021-2022	DUAL SKIN: Dual-sensor wireless and flexible skin thermometer for fast and reliable detection of feverish states	Coordinator	57.000,00	http://www.pervasive.ing.uniroma2.it

2.7 Research Collaborators n. 6 - Under 40

Last Name: occhiuzzi
First Name: cecilia

Last name at birth:
Gender: F

Title: Ricercatore principale
Nationality: italiana
Date of birth: 13/10/1983

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Paola

Official H index (Scopus or Web of Science): 18.0

Scopus Author Id:35090485700 **ORCID ID:**0000-0002-7761-8293 **RESEARCH ID:**0

Contact address

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Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Rome Tor Vergata, Rome, Italy	Single-cycle master's degree / Laurea magistrale a ciclo unico	Medical Engineering Dissertation title: ¿The RFID Technology for Neurosciences: Limbs¿ Monitoring in Sleep Diseases ", tutor: Prof. F. Marrocco	2002	2008
University of Rome Tor Vergata, Rome, Italy	PhD	GeoInformation and Electromagnetic fields Dissertation title: ¿PERVASIVE HEALTHCARE: Wearable and Implantable RFID Technologies for Human Identification and Sensing ", tutor: Prof. F. Marrocco.	2008	2011

Personal Statement:

Cecilia Occhiuzzi has a MSc degree in medical engineering and a PhD from University of Rome2, where is Associate Professor,teaching electromagnetic fields and biomedical interaction.She is Co-Founder and CEO of RADIO6ENSE,a spin-off of Tor Vergata active in RFID solutions for the industrial sector.Her research interests are wireless health monitoring through wearable and implantable radiofrequency/mmwave identification techniques and pervasive sensing paradigms for the food sector and Industry 4.0.She co-authored several international papers,conferences and ten patents on RFID sensing systems.She is scientific advisor of the Italian Ministry of Health-Sperimentazione clinica dei dispositivi medici, Member of Commission on the Third Mission. DICII-Tor Vergata and Innovation Manager of MISE.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Warwick	School of Engineering	Warwick (UK)	Visiting Researcher Supervisor Prof. Julian Gardner	2008	2008
Georgia Institute of Technology	ECE Department	Georgia, USA	Visiting Researcher Supervisor. Prof. Manos Tentzeris	2010	2010
University of Rome Tor Vergata	Department of Informatics, Sistems and Production (DISP)	Rome	Researcher Co-Investigator, ESA-ESTEC "Modular and customisable accomodation friendly antenna system for satellite avionics¿	2011	2013
University of Palermo	Department of Chemistry and Physics (DIFC)	Rome	Researcher	2014	2015
RADIO6ENSE srl	Spin-off University of Roma Tor Vergata	Rome	CEO	2013	2022
University of Rome Tor Vergata	Department of Civil and Informatic Engineering	Rome	Researcher	2019	2022
University of Rome Tor Vergata	Department of Civil and Informatic Engineering	Rome, Italy	Associate Professor	2022	2022

Other awards and honors

- IEEE APS Doctoral Award 2012. ¿RFID Implantable Technology for Monitoring the Human Body and the Medical Devices: the StenTag
- First Prize at the Student Competition at EUCAP-2012 Prague,
C. Occhiuzzi and G. Marrocco, "Experimental Characterization of the RFID STENTag for passive Vascular Monitoring"
- Best Thesis Award at RFID Journal Live 2012, Orlando C. Occhiuzzi, "Wearable and Implantable RFID Technology for Pervasive Healthcare: Human Identification and Sensing"

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
University of Rome Tor Vergata	University of Rome Tor Vergata	2022	¿W-E-L-F-A-R-E: Wireless Electronics Labels for Food Assesment and waste REduction¿	Coordinator	7.000,00	None
Regione Lazio	University of Roma Tor Vergata	2021-2023	¿E-crome: biosensori su carta wireless per la telemedicina in oncologia e la misura di emocromo ed elettroliti¿.	Collaborator	150.000,00	None
University of Roma Tor Vergata	University of Roma Tor Vergata	2019	Beyond Borders 2019 ¿Epidermal Sensor Networks for Emerging 5G systems¿	Collaborator	13.000,00	None
Ministero della Difesa PNRM	RADIO6ENSE	2019	Patch Stress Wireless skin PATCH per diagnosi precoce di disturbi post-traumatici da STRESS	Collaborator	150.000,00	None

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
European Commission	RADIO6ENSE	2015-2018	H2020. SCISSOR. "Security in Trusted SCADA e Smart grids¿.	Collaborator	210.000,00	None
ESA	University of Rome Tor Vergata	2012-2013	ESA-ESTEC "Modular and customisable accomodation friendly antenna system for satellite avionics¿	Collaborator	0,00	None
MIUR	University of Rome Tor Vergata	2011-2012	PRIN-2008 Multi-tag	Collaborator	0,00	None

2.8 Research Collaborators n. 7 - Under 40

Last Name: PIRAS
First Name: ANTONIO
Last name at birth:
Gender: M

Title: Ricercatore principale
Country of residence: ITALY
Nationality: italiana
Country of Birth: ITALY
Date of birth: 01/12/1983
Place of Birth: Nuoro

Official H index (Scopus or Web of Science): 9.0

Scopus Author Id:57216932425 **ORCID ID:**0000-0002-5724-9355 **RESEARCH ID:**0

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Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Sassari	Single-cycle master's degree / Laurea magistrale a ciclo unico	School of Medicine	2003	2014
University of Sassari	Specialization / Specializzazione	Otorinolaringoiatria	2016	2020

Personal Statement:

Dr. Antonio Piras is an otorhinolaryngologist with an expertise in medical and surgical treatment of Chronic Rhinosinusitis with (CRSwNP) and without nasal polyps (CRSsNP). He is involved in several clinical trials, in particular on biological drugs for CRSwNP treatment. From 2021 he is responsible for the rhinologic outpatient division where CRSwNP patients are evaluated and treated with traditional and new biological drug in a multidisciplinary team together with Expertise in Audiology and Vestibology.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
Azienda Ospedaliero Universitaria di Sassari	Otorhinolaryngology	Sassari	Otorhinolaryngologist (dirigente medico)	2021	2022
University of Sassari	Dipartimento di scienze mediche, chirurgiche e sperimentali	Sassari	Researcher	2022	2022

Other awards and honors

None

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
None	None	0	None	Collaborator	0,00	None

2.9 Additional Research Collaborators n. 2 - Under 40 to hire

Last Name: CRESCIO
First Name: CLAUDIA
Last name at birth:
Gender: F

Title: Data manager
Country of residence: ITALY
Nationality: Italiana
Country of Birth: ITALY
Date of birth: 20/11/1982
Place of Birth: Sassari

Official H index (Scopus or Web of Science): 3.0

Scopus Author Id:55672853000 **ORCID ID:**0000-0003-1515-1867 **RESEARCH ID:**0

Contact address

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Phone 2:

Education / training

Educational institution and location	Degree	Field of study	From year	To year
Dept. of Biomedical Sciences - University of Sassari	Bachelor Degree / Laurea Triennale	Biotechnologies: Use of PCR and Real-time PCR to identify genes codifying pore-forming proteins (Saposin-like proteins) of Trichomonas Vaginalis, an anaerobic protozoan causative agent of trichomoniasis, a sexually transmitted infection.	2001	2005
Dept. of Biomedical Sciences - University of Sassari	Master's Degree / Laurea Magistrale	Molecular Biotechnologies: During the internship, my work focused on the analysis of tissue samples from healthy donors and patients affected by different type of cancer using a proteomic approach (SDS-PAGE, Western Blotting and mass spectrometry) to identify possible biomarkers of interest.	2005	2007
Dept. of Biomedical Sciences - University of Sassari	PhD	Biomolecular and Biotechnological Sciences: the aim of this research was to study the protein expression and post-translational modifications of human T cells undergone to microgravity and oxidative stress. Microgravity effects were studied in the suborbital space flight mission MASER-12 and applying microgravity on Earth through a three dimensional clinostat hardware. Components of the IL2/IL-2R signalling system and cytoskeletal components - known to be negatively affected - were analysed.	2009	2012

Personal Statement:

Claudia Crescio is an experienced clinical study coordinator, working on profit and non-profit phase II, II and IV clinical trials.She spent 7 years at European Institute of Oncology of Milan,where she learnt how to ensure compliance with Good Clinical Practices, protocol guidelines and requirements of regulatory agencies, scientific integrity of data and protection of the rights and safety of patients enrolled in clinical trials.She currently works at Otolaryngology Unit of AOU in Sassari where assisting Principal Investigators in timely submission of accurate documents and set up and reviews databases and case report forms (CRFs).She also meets Clinical Research Associates on site visits.Finally, she trains to junior staff on conducting trials and contributes to departmental initiatives.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
IRCSS Istituto Europeo di Oncologia (IEO)	Data Management	Milan	Clinical data manager	2014	2020
Azienda Ospedaliera Universitaria (AOU)	Otorhinolaryngology Unit	Sassari	Clinical data manager	2021	2022

Other awards and honors

BD and BSc obtained with Magna cum laude.

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
None	None	0	None	Collaborator	0,00	None

2.10 Additional Research Collaborators n. 3 - Under 40 to hire

Last Name: Benvegna
First Name: Chiara
Last name at birth:
Gender: F

Title: Pneumologist
Nationality: Italiana
Date of birth: 04/11/1988
Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Sassari

Official H index (Scopus or Web of Science): 0.0

Scopus Author Id:0 **ORCID ID:**0 **RESEARCH ID:**0

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Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Sassari	Specialization / Specializzazione	Respiratory Disease	2018	2022
University of Sassari	Single-cycle master's degree / Laurea magistrale a ciclo unico	Respiratory Disease	2009	2015

Personal Statement:

Chiara Benvegna is a final year resident doctor at the Dept. of Respiratory Diseases of the AOU in Sassari. She started working at the pulmonology dept. in 2018, where she learned the clinical management of interstitial lung disease and chronic lung disease, interacting daily with patients and their biological balances, often requiring frequent monitoring and therapeutic adjustments. She participated as a sub-Inv in several clinical trials related to idiopathic pulmonary fibrosis and asthma. Recently she was involved as study investigator in a multi-center multi-country prospective observational study on patterns of care of mild asthmatic patients. The aim was to depict the real pattern of care of mild asthmatic patients, collecting data through electronic diary filled by patients weekly.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
None	None	None	None	0	0

Other awards and honors

None

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
None	None	0	None	Collaborator	0,00	None

2.11 Additional Research Collaborators n. 4 - Under 40 to hire

Last Name: Bianco
First Name: Giulio Maria

Last name at birth:
Gender: M

Title: Engineer
Nationality: Italiana
Date of birth: 07/04/1994

Country of residence: ITALY
Country of Birth: ITALY
Place of Birth: Roma

Official H index (Scopus or Web of Science): 5.0

Scopus Author Id:57209684894 **ORCID ID:**0000-0002-3216-5884 **RESEARCH ID:**ABC-2884-2020

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Education / training

Educational institution and location	Degree	Field of study	From year	To year
University of Rome Tor Vergata	Bachelor Degree / Laurea Triennale	Medical Engineering: Topics related to the fundamentals of medical engineering: mathematical analysis, general physics, anatomy, neurophysiology, electrotechnical, mechanics of biological systems, construction science, science and technology of biomaterials. I did an internship long three months at the clinical engineering service of the Tor Vergata Polyclinic.	2013	2016
University of Rome Tor Vergata	Master's Degree / Laurea Magistrale	Medical Engineering: Topics related to the industrial applications of medical engineering: pathophysiology, electronics, technical physics, pattern recognition, signals, bio-prostheses, automatic controls, electromagnetic fields and wireless electromagnetic technologies, and medical radio systems.	2016	2018
University of Rome Tor Vergata	PhD	Design, manufacturing, and testing of wearable and epidermal antennas for sensing of measurands on the body or in the environment. Radiofrequency identification (RFID) systems and devices. Design and evaluation of telecommunication systems, procedures, and performance evaluation. Characterization of radiowave propagation of links involving body-worn radios and unmanned aerial vehicles. Localization of a radiofrequency beacon through algorithms based on the strength of the transmitted signal.	2018	2022

Personal Statement:

My interest in the body-area internet of things has its roots in medical engineering, which drastically improved countless people's quality of life in recent years. During my PhD, I soon discovered that the electromagnetic links in the body-area network are still little known as well as the internet of things (IoT) systems in the body area network. To contribute to life improvement, I focused my research on such topics to pursue achievements in safety, assistance to impaired and ill people, health monitoring and IoT.

I am also a member of the Youth Council of the Pontifical Council for Culture since 2019, where I was head of the Science thematic area for a year. The Council analyzes contemporary culture to address the issues of younger generations.

Positions and honors

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Rome Tor Vergata	Pervasive Electromagnetics Laboratory	Department of Civil Engineering and Computer Science Engineering, Macro area of Engineering of the second University of Rome Tor Vergata, via del Politecnico 1, Rome, Italy	Grant researcher	2022	2022

Other awards and honors

1. PhD and MSc obtained with honors.
2. "Young Scientist Award" by the Union Radio-Scentifique Internationale, in the URSI AT-AP-RASC 2022 conference for the publication Indirect Propagation of Body-UAV LoRa Links over Wood and Suburb, Commission B (Fields and waves).
3. "Young Scientist Award" by the Union Radio-Scentifique Internationale, in the URSI GASS 2020 conference for the publication Near-field modeling of Self-tuning Antennas for the Tactile Internet, Commission B (Fields and waves).

Grant

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
European Regional Development Fund under the Cooperation Programme Interreg V-A Italia Austria 2014-2020, ITAT3023, Smart Test for Alpine Rescue Technology START	Center for Sensing Solution of the European Academy of Bolzano and Pervasive Electromagnetics Laboratory of the University of Rome Tor Vergata	January 2018 - October 2021	START ¿ Smart Test for Alpine Rescue Technology	Collaborator	827.268,18	https://www.eurac.edu/en/institutes-centers/institute-of-mountain-emergency-medicine/projects/start
POR FESR Lazio 2014-2020	Pervasive Electromagnetics Laboratory and NanoBioSensing Lab of the Tor Vergata University of Rome	January 2022 ¿ present	E-CROME: biosEnsori su Carta wiReless per la telemedicina in Oncologia e la misura di eMocromo ed Elettroliti	Collaborator	149.921,85	https://www.ism.cnr.it/en/research/projects/item/270-e-crome-project-is-starting-now.html

2.17 Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators

Collaborato	Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
PIRAS ANTONIO	Utility of ultrasound-guided fine needle aspiration cytology in assessing malignancy in head and neck pathology	Article	407-415	32	2021	10.1111/cyt.12955	33501764	1	O
PIRAS ANTONIO	Medical-surgical management and clinical outcome in cervical abscesses	Article	527-531	14	2020	10.3855/jidc.12191	32525840	2	C
PIRAS ANTONIO	Tracheotomy in COVID-19 patients: preliminary experience and technical refinements	Article	e304	107	2020	10.1002/bjs.11757	32542655	2	O
PIRAS ANTONIO	Audiovestibular symptoms and sequelae in COVID-19 patients	Article	381-387	31	2021	10.3233/VES-201505	NOT_FOUND	10	O
PIRAS ANTONIO	Nasopharyngeal swab collection in the suspicion of Covid-19	Article	NOT_FOUND	41	2020	10.1016/j.amjoto.2020.102551	32487335	16	F
CRESCIO CLAUDIA	T cell tyrosine phosphorylation response to transient redox stress	Article	777-788	27	2015	10.1016/j.cellsig.2014.12.014	25572700	7	O
CRESCIO CLAUDIA	Immunomodulatory properties of carbon nanotubes are able to compensate immune function dysregulation caused by microgravity conditions	Article	9599-9603	6	2014	10.1039/c4nr02711f	25029354	15	F
CRESCIO CLAUDIA	Signal transduction in primary human T lymphocytes in altered gravity - Results of the MASER-12 suborbital space flight mission	Article	NOT_FOUND	11	2013	10.1186/1478-811X-11-32	NOT_FOUND	23	O
Canu Sara	Tracheobronchopathia Osteochondroplastica: A rare case report of a non-smoker and non-atopic patient, with a long history of wheezing since childhood	Article	NOT_FOUND	11	2016	10.1186/s40248-016-0050-7	NOT_FOUND	8	O
Canu Sara	Desmoplastic small round cell tumors of the pleura: A review of the clinical literature	Article	NOT_FOUND	12	2017	10.1186/s40248-017-0103-6	NOT_FOUND	8	O
Canu Sara	Observational, multicentre study on the epidemiology of haemoptysis	Article	NOT_FOUND	51	2018	10.1183/13993003.01813-2017	29301924	38	O

Collaborato	Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Canu Sara	Effect of ambulatory oxygen on quality of life for patients with fibrotic lung disease (AmbOx): a prospective, open-label, mixed-method, crossover randomised controlled trial	Article	759-770	6	2018	10.1016/S2213-2600(18)30289-3	30170904	86	O
Canu Sara	Patient-reported outcome measures in idiopathic pulmonary fibrosis: Where do we stand?	Article	628-629	22	2017	10.1111/resp.13030	28328170	4	F
Bianco Giulio Maria	Performance evaluation of LoRa LPWAN technology for mountain Search and Rescue	Article	NOT_FOUND	NOT_FOUND	2020	10.23919/SpliTech49282.2020.9243817	NOT_FOUND	4	F
Bracciale Lorenzo	Towards fully ip-enabled ieee 802.15.4 LR-WPANs	Article	NOT_FOUND	NOT_FOUND	2009	10.1109/SAHCNW.2009.5172967	NOT_FOUND	13	C
Bracciale Lorenzo	Delay tolerant wireless sensor network for animal monitoring: The Pink Iguana case	Article	18-26	429	2017	10.1007/978-3-319-55071-8_3	NOT_FOUND	13	F
LORETI PIERPAOLO	Optimized Neighbor Discovery for Opportunistic Networks of Energy Constrained IoT Devices	Article	1387-1400	19	2020	10.1109/TMC.2019.2908402	NOT_FOUND	14	C
LORETI PIERPAOLO	Let me grab your App: Preliminary proof-of-concept design of opportunistic content augmentation	Article	7034-7039	NOT_FOUND	2012	10.1109/ICC.2012.6364952	NOT_FOUND	14	C
LORETI PIERPAOLO	Better than nothing privacy with bloom filters: To what extent?	Article	348-363	7556 LNCS	2012	10.1007/978-3-642-33627-0_27	NOT_FOUND	28	L
Bracciale Lorenzo	Performance assessment of an epidemic protocol in VANET using real traces	Article	92-99	40	2014	10.1016/j.procs.2014.10.035	NOT_FOUND	51	C
LORETI PIERPAOLO	Opportunistic communication in smart city: Experimental insight with small-scale taxi fleets as data carriers	Article	43-55	43	2016	10.1016/j.adhoc.2016.02.002	NOT_FOUND	61	C
Bracciale Lorenzo	The Sleepy Bird Catches More Worms: Revisiting Energy Efficient Neighbor Discovery	Article	1812-1825	15	2016	10.1109/TMC.2015.2471299	NOT_FOUND	19	F
Bracciale Lorenzo	Lightweight named object: An ICN-based abstraction for IoT device programming and management	Article	5029-5039	6	2019	10.1109/JIOT.2019.2894969	NOT_FOUND	19	F
LORETI PIERPAOLO	The design of an energy harvesting wireless sensor node for tracking pink iguanas	Article	NOT_FOUND	19	2019	10.3390/s19050985	30813516	28	F
Bianco Giulio Maria	Experimentation and calibration of Near-Field UHF Epidermal Communication for emerging Tactile Internet	Article	NOT_FOUND	NOT_FOUND	2020	10.23919/SpliTech49282.2020.9243753	NOT_FOUND	4	F

Collaborato	Title	Type	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Bianco Giulio Maria	Near-Field Constrained Design for Self-Tuning UHF-RFID Antennas	Article	6906-6911	68	2020	10.1109/TAP.2020.2995315	NOT_FOUND	6	F
Bianco Giulio Maria	Sensorized Facemask with Moisture-Sensitive RFID Antenna	Article	NOT_FOUND	5	2021	10.1109/LSENS.2021.3059348	NOT_FOUND	7	F
Bianco Giulio Maria	LoRa System for Search and Rescue: Path-Loss Models and Procedures in Mountain Scenarios	Article	1985-1999	8	2021	10.1109/JIOT.2020.3017044	NOT_FOUND	19	F
occhiuzzi cecilia	Constrained-design of passive UHF RFID sensor antennas	Article	2972-2980	61	2013	10.1109/TAP.2013.2250473	NOT_FOUND	39	F
occhiuzzi cecilia	RFID passive gas sensor integrating carbon nanotubes	Article	2674-2684	59	2011	10.1109/TMTT.2011.2163416	NOT_FOUND	78	F
Marrocco Gaetano	Multi-Chip RFID antenna integrating shape-memory alloys for detection of thermal thresholds	Article	2488-2494	59	2011	10.1109/TAP.2011.2152341	NOT_FOUND	50	L
occhiuzzi cecilia	NIGHT-care: A passive RFID system for remote monitoring and control of overnight living environment	Article	190-197	32	2014	10.1016/j.procs.2014.05.414	NOT_FOUND	50	F
occhiuzzi cecilia	Design of implanted RFID tags for passive sensing of human body: The STENTag	Article	3146-3154	60	2012	10.1109/TAP.2012.2198189	NOT_FOUND	55	F
Marrocco Gaetano	Humidity sensing by polymer-loaded UHF RFID antennas	Article	2851-2858	12	2012	10.1109/JSEN.2012.2202897	NOT_FOUND	82	L
Marrocco Gaetano	Feasibility of body-centric systems using passive textile RFID tags	Article	49-62	54	2012	10.1109/MAP.2012.6309156	NOT_FOUND	64	L
Marrocco Gaetano	Design, Calibration and Experimentation of an Epidermal RFID Sensor for Remote Temperature Monitoring	Article	7250-7257	16	2016	10.1109/JSEN.2016.2594582	NOT_FOUND	65	L
occhiuzzi cecilia	Passive UHF RFID antennas for sensing applications: Principles, methods, and classifcations	Article	14-34	55	2013	10.1109/MAP.2013.6781700	NOT_FOUND	111	L
Marrocco Gaetano	RFID technology for IoT-based personal healthcare in smart spaces	Article	144-152	1	2014	10.1109/JIOT.2014.2313981	NOT_FOUND	421	L

* Position: F=First L=Last C=Correspondent O=Other N=Not applicable

** Autocertificated

3 - Ethics

1. HUMAN EMBRYOS/FOETUSES	
Does your research involve Human Embryonic Stem Cells (hESCs)?	No
Does your research involve the use of human embryos?	No
Does your research involve the use of human foetal tissues / cells?	No
2. HUMANS	
Does your research involve human participants?	Yes
Does your research involve physical interventions on the study participants?	No
3. HUMAN CELLS / TISSUES	
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses?	No
4. PERSONAL DATA	
Does your research involve personal data collection and/or processing?	Yes
Does your research involve further processing of previously collected personal data (secondary use)?	No
5. ANIMALS	
Does your research involve animals?	No
6. ENVIRONMENT & HEALTH and SAFETY	
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	No
Does your research deal with endangered fauna and/or flora and/or protected areas?	No
Does your research involve the use of elements that may cause harm to humans, including research staff?	No
7. DUAL USE	
Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an	No
8. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	
Could your research raise concerns regarding the exclusive focus on civil applications?	No
9. MISUSE	
Does your research have the potential for misuse of research results?	No
10. OTHER ETHICS ISSUES	
Are there any other ethics issues that should be taken into consideration? Please specify	No

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents. [X]

4 - Call-specific questions

Eligibility	
I acknowledge that I am aware of the eligibility requirements for applying as specified in the Call-PNRRXXXX_M6/C2, and certify that, to the best of my knowledge my application is in compliance with all these requirements. I understand that my proposal may be declared ineligible at any point during the evaluation or granting process if it is found not to be compliant with these eligibility criteria.	[X]
I confirm that the proposal that I am about to submit draws substantially don't repeat on an existing or recently finished GRANT funded.	[X]
Data-Related Questions and Data Protection (Consent to any question below is entirely voluntary. A positive or negative answer will not affect the evaluation of your project proposal in any form and will not be communicated to the evaluators of your project.)	
For communication purposes only, the MoH asks for your permission to publish,in whatever form and medium, your name, the proposal title, the proposal acronym, the panel, and host institution, should your proposal be retained for funding.	[X]
Some national and regional public research funding authorities run schemes to fund MoH applicants that score highly in the MoH's evaluation but which can not be funded by the MoH due to its limited budget. In case your proposal could not be selected for funding by the MoH do you consent to allow the MoH to disclose the results of your evaluation (score and ranking range) together with your name, non- confidential proposal title and abstract, proposal acronym, host institution and your contact details to such authorities?	[X]
The MoH is sometimes contacted for lists of MoH funded researchers by institutions that are awarding prizes to excellent researchers. Do you consent to allow the MoH to disclose your name, non-confidential proposal title and abstract, proposal acronym, host institution and your contact details to such institutions?	[X]
The Ministry of Health occasionally could contacts Principal Investigators of funded proposals for various purposes such as communication campaigns, pitching events, presentation of their project's evolution or outcomes to the public, invitations to represent the Ministry of Health in national and international forums, studies etc. Should your proposal be funded, do you consent to the Ministry of Health staff contacting you for such purposes?	[X]
For purposes related to monitoring, study and evaluating implementation of MoH actions, the MoH may need that submitted proposals and their respective evaluation data be processed by external parties. Any processing will be conducted in compliance with the requirements of Regulation 45/2001.	

5 – Description Project

Summary description

Sustainability of chronic disease management in the public National Health Systems worldwide has become a critical issue. The project will evaluate systems for monitoring chronic rhinosinusitis (CRS) and Asthma, two highly prevalent chronic diseases, at home. The frequent association between the two pathological conditions is a further argument supporting the

rationality of a common approach.
Current standard of care requires periodic patient-reported outcome measures (PROMs) and objective assessments provided by physicians.
As for PROMs collection, three acquisition channels will be compared: i) AI Chatbots; ii) PhoneBot ; iii) Mobile App. The data will be analyzed in relation to patient profiles to devise quality and quality of response.
As for objective assessment, the project will investigate the efficiency of remote objective airflow measurements both for the upper (CRS) and the lower (asthma) airways exploiting dedicated non-invasive points of care based on RFID technology.

Background / State of the art

Chronic rhinosinusitis (CRS) is a multifactorial disorder characterized by persistent symptomatic inflammation of the nose and paranasal sinus mucosa, with (CRSwNP) or without (CRSsNP) presence of nasal polyps. It affects from 5 to 12% of the general population.
CRS is often associated with asthma, which has a 4% prevalence in the general population, reaching 30%¿70% among CRS patients.
The current standard clinical evaluation of patients for both diseases have two main components: a subjective (by patient), mainly based on PROMs questionnaire, and an objective (by physician) one.
Questionnaires present problems of accuracy and response rate which have been investigated in literature, finding out that short questionnaires, incentives, personalization of questionnaires as well as repeat mailing strategies or telephone reminders have a beneficial impact on the quantity and quality of the responses.
Today there are many new channels provided by technology. Among them, AI chatbots have been utilized in a variety of health care domains such as medical consultations, disease diagnoses, mental health support, and more recently, risk communications for the COVID-19 pandemic and may offer a better way to collect questionnaires.
At the same time, recent technical solution of new non-invasive techniques for airflow measures based on RFID allows the subjective reports to be accompanied with objective reports.

Description and distribution of activities of each operating unit

OU 1: AOU Sassari:
Screening and enrollment of patients affected by CRSwNP and asthma and their management according to GCP and current international guidelines
Definition of of questionnaires to be collected remotely
Definition of content of explanation chatbots
Assessment of patients¿ satisfaction about the proposed approaches
Handle clinical trials, from patients enrollment to treatment, clinical evaluation and follow up visits (subjective and objective component)
Collection, management and data analysis from the clinical trials

OU 2: University of Tor Vergata:
Architecture of dialogue management for chatbot-based PROMs acquisition
Data acquisition and processing (for both the trials)
Analysis and profiling of patients for the PROMs acquisition trial
Management and setup for the objective data acquisition experiment
Evaluation of the results of RFID-based airflow monitoring

5.4 Specific Aims and Experimental Design

Specific aim 1

Set up of a PoC for subjective/objective remote data acquisition for patients with Asthma and CRS

In the current standard clinical evaluation of patients with chronic diseases such as asthma and CRS there are two main components, a subjective (provided by the patient) and an objective (provided by the physician) one.
Specifically, subjective data are acquired through standardized PROMs (as SNOT-22 for CRS and ACT for asthma).
Objective data collection is obtained through clinical evaluations, such as endoscopic assessment, smell tests as Olfactometry, Radiological evaluation (with the definition of Lund-Mackey score), measurement of nasal flow (usually through PNIF or rhinomanometry), cytology, bloodwork (in particular eosinophilic count and IgE), FeNO (Fractional exhaled Nitric Oxide).
Both kinds of data are needed at the same time for the correct treatment and follow up of the disease and, importantly, the quality of the measurements is fundamental.
The first specific aim is to design an approach allowing to collect many of the above subjective and objective data remotely, exploiting two existing platforms. As for subjective data, we will define the PROMs to be collected, exploiting a multi-channel approach to collect them using and customizing the platform(s) described in specific aim 2. Likewise, as for objective data we will define parameters, related to airflow, included in the clinical assessment of asthma and CRS, which is possible to collect remotely, along with the technique(s) and the available platform as described in specific aim 3.
The expected results of this specific aim include:
Definition of the PROMs to be acquired, of the means and of the platform(s)
Definition of the objective airflow data (e.g. PNIF, FEV1), of the means of acquisition and of the available platform (s)
Design of the clinical trials for the proofs of concept for the two different assessments (subjective and objective).

Specific aim 2

Evaluation of the best channels for administering PROMs according to age group and cultural level

We will specifically evaluate different channels and strategies for administering Patient-Reported Outcome Measures (PROMs) to patients.
PROMs capture a person's perception of their own health through questionnaires, have a definitely preponderant role in clinical evaluation of CRS and Asthma patients according to the new classification systems, and are the core of the subjective part (e.g., SinoNasalOutcomeTest(SNOT), AsthmaControlTest(ACT),Chemosensory Complaint Score(CCS)).
Given the time-consuming nature of compiling PROMs and the ease with which they can be carried out remotely, more and more PROMs are provided online (e.g., with website forms).
The problem of such modality in the real-world setting, is the compliance of the patient over time, as the low morbidity of the controlled disease may be associated with a decreased motivation. Moreover, on several occasions, patients may need clarifications about specific questions by healthcare professionals, which concur to the causes for which PROMs are still administered inside many hospital facilities today.

Which is the best way to provide PROMs remotely? Literature does not provide a unique solution also because of keeping pace with technology which makes available different channels to reach patients remotely.
In this project we will evaluate three different channels:
Social Network Chatbot: Chatbots are ¿online human-computer dialog system[s] with natural language¿. The underlying technology behind chatbot today is rather complex and spans the fields of Natural Language Processing, Response Generation and Dialogue Management. Our goal is to evaluate the use of chatbots to boost engagement and implement explanations of PROMs. Chatbot will be used also for medical remainders which contributes to improve follow up adherence. Using existing Social Networks (e.g., Whatsapp, Telegram), patients do not need specific training since they are already accustomed to using instant messaging applications.
Phonebot is a phone system that manages incoming and outgoing phone calls as well as an organization's internal communications. We will evaluate the effectiveness of using phone calls to complete the survey required for PROMs. The evaluated system uses synthetic voice to enunciate questions to the patients, and speech/tone recognition to acquire answers.

Mobile Apps: The availability of dedicated apps on smartphones and the possibility offered by such technology (push notifications, customized graphics and usability) is another possible channel to administrate PROMs. We will evaluate the effectiveness of such a channel to acquire PROMs responses.
The channels will be provided to different patients with the goal of:
Understand which channel provides a better compliance i.e. persistence of data acquisition over the time
Understand whether channel shows difference in the quality of acquired data thanks to baseline data acquisition and clinical monitoring
Understand which channel is more suited to a specific patient profile, analyzing the correlation of the activity with the age and education of the individual
Evaluation of patient empowerments provided by the channel

Specific aim 3

Evaluation of objective airflow data acquisition techniques using non-invasive techniques
Breath monitoring is an essential tool in the early diagnosis of respiratory and cardiovascular diseases. In particular, the breath rate is crucial to monitor the evolution of respiratory up- sets, like the Chronic Obstructive Pulmonary Disease (COPD), Chronic rhinosinusitis (CRS), Asthma or the recent COVID-19 illness.
Breathing is typically monitored within a spirometry examination that measures the respiratory flows and, accordingly, estimates respiratory volumes and rates. However, it can be performed only in hospitals with the supervision of an operator, and requires that the patient breathes in a controlled manner while wearing nasal or mouth probes. Wearable and epidermal technologies may offer attractive alternatives to mitigate such discomfort. In particular, battery-less Ultra High Frequency (UHF) Radio Frequency IDentification (RFID) devices could provide low-invasive, easy-to-use and low-cost diagnostic procedures, as opposed to cumbersome devices that exploit Bluetooth Low Energy (BLE) that instead require batteries for power supply.
The capability of RFID devices to monitor breathing patterns by means of temperature measurements of the respiratory air flow has been already demonstrated. The rationale is that the temperature gradient of the air flow in and out of the airways can be correlated to the flow-based respiratory patterns.. Accordingly, a temperature-based breath monitoring can be achieved by means of on-skin RFID sensors attached below the nose or within a facemask. Finally, a bilateral measurement of nostrils¿ respiratory flow can provide more information since nasal cavities do not behave in the same way during a respiratory cycle, even in the absence of pathologies, for example in case of temporary obstruction, or deviation of the nasal septum due to trauma.
In this project we will evaluate the possibility to perform domestic breath flow analysis by exploiting thin, lightweight and battery-less sensing plasters directly attached under the nose. The system includes a proper external reader interrogating the face sensors that is capable to directly communicate with smartphone/pc/tablet/cloud environment. Thanks to the user-friendly interfaces, Patients can autonomously perform the analysis, with minimal involvement and cooperation.

Expected results of this specific aim are:
Definition of the patient's breath pattern using the available tools and reliability for the early detection of anomalous events;
Analysis of the nostrils performance independently, and assessment of the reliability in obtaining an analogue of PNIF;
Evaluation of the reliability of the tools in the definition of equivalent spirometry parameters.

Experimental design aim 1

Task 1.1 (M1-6): Definition of the PROMs to be collected
1. PROMs to assess the profile of the patient (biographical data, education, computer literacy, etc.) in order to evaluate the effectiveness of the proposed methodology according to different profiles
2. Standardized PROMs for CRS and asthma such as Asthma Control Test (ACT); The SinoNasal Outcome Test (SNOT)

-22 and the Visual Analogue Scale (VAS)
3. PROMs to assess patient empowerment to be administered at the beginning and along treatment
4. PROMs to assess patient satisfaction concerning the remote management of its chronic disease(s)

Task 1.2 (M1-6) Design of remote airflow data acquisition and integration with subjective measurements
The methodology for remote acquisition of objective data and integration with PROMs will be defined.
As for CRS and asthma objective parameters, the project will consider techniques for airflow assessment, and in particular
-in asthma are the Forced Expiratory Volume in one second (FEV1), and the Peak Expiratory Flow (PEF) [Bri2015]
-in CRS the peak nasal inspiratory flowmetry (PNIF) which appears more reliable than (active anterior) rhinomanometry (AAR), and acoustic rhinometry (AR) [OTT 14][FOK20].
i) a commercially available portable Spirometer will be used to measure PEF, FEV1 at home, with an intuitive APP assisting the patients in providing data, receiving them and forwarding to the hospital ii) the same hardware can be used for measurement of PNIF, through an adaptation of the software and of commercially available connectable nasal masks. As a result, a dual-function portable device suitable for remote evaluation of both upper and lower airway function will become available, re-using and adapting available technology. The interoperability of the same will represent a clear strength point in the common case of patients affected by co-morbidity.

Task 1.3 TRIAL 1 (M6-21)- Clinical trial for remote patient monitoring
40 patients will be enrolled:
20, the control group (10 asthma and CRSwNP, 5 CRSwNP without asthma, 5 asthma without CRSwNP) will continue their standard follow up each 3 months with access to the hospital facilities.
20 subjects matched by pathology with the control group, will have their standard on site follow up every 6 months, and will be asked by the app to provide PROMs, and to perform FEV1 and PNIF by connecting the spirometer to the app immediately before the standard on site visit and every month at home, with remote data acquisition.
Withdrawal of the patients from the ¿remote monitoring¿ group and their readmission to the standard follow up will be always possible upon patients¿ request.
Engineers from UO2 will be available within 24 hours through email/whatsapp in case issues with the remote monitoring should occur. The issues during the trial will be recorded, to improve performance of the system accordingly after but also during the trial itself (¿real time¿platform updates along the trial).
Patient satisfaction,evaluated through specific PROMs, concerning the management of its chronic disease(s) (remote vs. standard), including the acquisition of subjective and objective (FEV1, PNIF, etc.) data [BAR15] will be the primary endpoint of the trial.
Other endpoints will be the rate of correctly acquired forms and airflow measurements (reliability of the remote management, target 80%), the rate of remotely monitored patients completing the 1-year trial (target 80%), number of patients requiring respectively physicians¿ (UO1) and engineers¿ (UO2) interventions, and absolute number of health-related and technology-related issues occurred during remote monitoring.

Task 1.4 (M18-24) Analysis of results of clinical trial 1
See methodology/statistical analysis below.

Ethics:
Once the trial details are defined in Task 1.1 and 1.2, the protocol is submitted to the local ethical committee in order to get approval before the start of the Trial 1 (Task 1.3).

Experimental design aim 2

Task 2.1 (M1-6): Setup of pipelines for remote questionnaire administration
We will implement three different channels to administer PROMs: Social Network Chatbot, Phonebot and Mobile App. The

channels are provided by the MySurvey service of the Able SRL.
Each channel has its own benefits. The messages of the chatbot implemented on social networks (e.g. Whatsapp) are often seen within 5 minutes and the opening rate is 99%.
Phonebot, using phone calls, may result in more easy use for elderly people.
Mobile applications, on their side, allow the design of very customized user experience and the access to native sensors of the mobile phones (e.g., to interact with the spirometer with Bluetooth), so offer the potential great advantage to have a single platform both for the collection of subjective (PROMS) and objective (airflow) data concerning the diseases.

Task 2.2 (M1-6): Definition of quantitative methods to evaluate the quality of PROMs collection
The project will apply techniques to monitor the quality of responses, borrowing from established solutions in crowdsourcing, i.e the process of using many people to perform services or to generate ideas or content. The PROM effectiveness will be assessed considering Compliance measurement and the Quality of answers introducing Gold Questions, evaluating the Auto-Similarity or using the expert assistance
The activity will be carried out in collaboration with CNIT personnels which are experts in crowdsourcing, UX and NLP. A systematic analysis of the interaction between behavioural data (e.g. response time, language style, etc), demographics, and responses will be carried out to assess data quality and to ultimately fine-tune the chatbot behaviour.

Task 2.3 (M6-18): TRIAL 2 - Multichannel PROM management trial
A four-arm randomized trial will be set up; in each arm the enrolled patients will receive the PROMS via a single different channel (standard in presence visit, Social Network Chatbot, Phonebot and Mobile App). 80 patients that will access rhinology and/or Asthma ambulatories at AOU Sassari will be enrolled, 40 with concomitant diagnosis of asthma and CRSwNP, 20 with CRSwNP without asthma, 20 with asthma without CRSwNP. Each person will undergo a questionnaire in order to obtain a definition of his technological level, then the patients from the three groups will be randomized in one of the four arms of the experiment.
Considering the number of patients, enrollment will last from month 6 to 12 and each patient will remain in the trial for 6 months.
Patients will answer the PROM remotely weekly, while monthly, on the occasion of the routinary follow-ups, they will fill questionnaires first by themselves through one of the three channels and then under direct supervision of the clinicians on paper forms. Patients in the ¿standard¿ channel will just fill the forms every month.
At month 6th patients will answer PE questionnaires.
At the end of the trial we will evaluate for the four channels:
Adherence to follow-ups for each administration channel through the compliance measurement (primary endpoint: assess differences in the four arms in completion rate of the planned questionnaires)
Quality of answers through Gold Questions, Auto-Similarity and answers with expert assistance as described before
The technological profile for witch the channel seems to be more suitable through the evaluation of adherence and quality of answer in different population subgroups divided on the base of the technological level emerged from initial questionnaire
Patients empowerment through designed questionnaires

Task 2.4 (M18-24). Analysis of results of the clinical trial 2
See methodology/statistical analysis below

Ethics:
Once the trial details are defined in Task 2.1 and 2.2, the protocol is submitted to the local ethical committee in order to get approval before the start of the Trial 2 (Task 2.3).

Experimental design aim 3

We will refine non-invasive strategies for the remote assessment of airflow. In particular, novel battery-less sensors will be tested. They appear like a medical plaster suitable to adhere to the prolabium, and comprise two coupled antennas whose Ultra High Frequency (UHF) Radio Frequency IDentification (RFID) ICs are placed at the entrance of the nostrils. The two nostrils can be independently monitored due to a negligible cross-sensitivity of the two ICs¿ temperature data. The RFID device is made of soft and adhesive biocompatible elastomeric compounds that permit a comfortable adhesion on the skin and the possibility of reusing the sensor by the same patient.

Taks 3.1 (M1-12): Technology calibration and measurements campaign

Calibration measurement campaign will be performed in the laboratory under medical supervision. Starting from a temperature trace, the following breathing features can be extracted to perform the comparison between the instruments:

Inspiratory Time (IT) and Expiratory Time (ET): The inspiratory time (IT) and expiratory time (ET) are the time intervals during which the respiratory flow trace gets negative and positive, respectively
Respiratory Rate (RR) corresponds to the number of breaths a person takes per minute. For each breathing pattern it is evaluated as: RR = 60/ (IT + ET)
Peak ratio rT = PIT/PET where Peak Inspiratory Temperature (PIT) and Peak Expiratory Temperatur (PET) correspond to the minimum and the maximum of the temperature respiratory trace, respectively. rT is expected to be independent of absolute temperature and hence it can be correlated with the corresponding ratio PIF/PEF derived from flow-based measurements
Left/Right Peaks Ratio between the peaks of left and right nostrils give an indication about congenital or permanent asymmetry of breathing (i.e., nasal septum deviation) or about the presence of possible temporary occlusion

The goal of this task is to two-fold:
confirming the capability of the RFID sensor to monitor the two nostrils independently on pathological subjects an to reproduce the typical clinical parameters of breath, and hence to quantify the level of agreement with conventional equipment
Estimating true absolute value of the PIF and PEF, as well as the respiration volume. To this purpose, a temperature flow calibration will be derived.

Once the details are defined, the protocol is submitted to the local ethical committee in order to get approval before the start of the Trial 3

Taks 3.2 (M12-18): TRIAL 3: assessment of RFID Technology assessed in laboratory and at home.
A small trial (trial 3) will be performed. Sixteen patients will be selected to test the Usability of RFID- breath sensors in comparison with the commercially available spirometers.
All the patients will be affected both by asthma and CRSwNP, and will be randomized for airflow monitoring with Spirometer (as in TRIAL 1) or with RFID.
The enrolment will last from month 12 to month 15, each patients will be in the study for 3 months, the measurement of the flow will be recorded every 2 weeks with the spirometer, and daily with the RFID, and for both groups every 2 months in the ambulatory setting (rhinology and asthma ambulatories).
The primary endpoint will be the reliability outside the laboratory settings of different modalities of remote acquisition of airflow measures (innovative wearables sensors, RFID, versus commercially available devices, Spirometer), in comparison with the present stard.
Seccondarily we will evaluate the usability of systems in daily life conditions, short term changes of airflow and its clinical significance, patients¿ acceptability and feedback.

Task 3.3 (month 18-24). Analysis of results of clinical trial 3
see methodology/statistical analysis below

Ethics:
Once the trial details are defined in Task 3.1, the protocol is submitted to the local ethical committee in order to get approval before the start of the Trial 3.

Picture to support preliminary data

PNRR_img.png

Hypothesis and significance

As chronic conditions, with a relatively early clinical onset and a not decisive impact on life-expectancy, the patients are followed for a long time(decades), requiring, according to the current standard of care, periodic evaluations. COVID pandemic unveiled a chronic insufficiency of personnel and resources in the Western National Health Systems(NHS). It means that in a real-world setting it can become not sustainable to provide to all patients affected an adequate management of the diseases along time.
An important, and the most time consuming, part of the evaluation is the collection of PROMs. In the long term, the compliance of the patients to the standard of care, including providing PROMs, is also compromised by low morbidity of CRS in no-exacerbation periods, by difficult and time consuming access to NHS facilities, and by economic costs(which are not usually fully covered by NHSs).
The above considerations configure clear and urgent unmet needs, which we believe our proposal can adequately address. Some preliminary experience in English and Dutch, confirms that CRS and Asthma can be a very fit setting for patient empowerment through a remote approach.
The problem of such modality in the real-world setting, is the compliance of the patient over time, as the low morbidity of the controlled disease may be associated with a decreased motivation. Patient empowerment should be pursued deploying proper tools with the function of explaining, reminding, and obtaining further feedbacks. Very promising approaches are represented by mobile apps and AI-powered chatbots which have been successfully adopted to improve monitoring and treatment adherence. However, patients with a poor alphabetization, with a low income and/or elderly patients, may have issues in accessing mobile devices. An alternative approach could be the use of phonebots.
From a research perspective, the remote approach will generate real life data improving the effectiveness of management and at the same time providing data to improve our knowledge of asthma and CRS in general, validate clinical studies, patient stratification and improve understanding of the socio-economic impact, thereby paving the way for better treatment strategies.
Specific perspectives are:
Rethinking endpoints and classification parameters itself based on the huge amount of data which would become available;
Develop predictive algorithms on the course of the diseases basing upon the information progressively acquired about patterns of changes along time in PROMs and most of all in data recorded by sensors;
Better assess and early predict response to therapies and recommendations and adapt them faster basing on real time information from the remote health technology;
Acquire information for better patient stratification and push further our current ability to define phenotype and endotype.

In detail we aim at obtaining the following S.M.A.R.T.(Specific, Measurable, Assignable, Realistic, Time-related) objectives:

Contribute to the sustainability of adequate care for asthma and CRS patients by optimizing the PROMs administration
Measurements: difference in number of patients evaluated in the same interval with the traditional and the remote approach; quality assessment of the responses through comparison with the traditional approach; evaluation of the

increased incomes from the spared HCPs time and the highest number of patients evaluated.

To improve patient compliance and quality of care through patient empowerment
Measurements: Evaluation of Patient Empowerment Scale Questionnaires; evaluation of patient satisfaction and time saved; measurement of the drop-out rate.

Objective and continuous remote assessment of airflow in asthma and CRS
Measurements: Agreement of nasal and bronchial obstruction as evaluated through our tools with those established though PROMs and exams performed by physicians.

5.5 Methodologies and statistical analyses

Methods of data collection

Data types and data Management
Data management will be done according to the rules defined by the Health Information Portability and Accountability Act (HIPAA) and in Europe by the General Data Protection Regulation (GDPR).
The remote approaches tested in this project will generate a huge amount of real life data to be analyzed. To reach the goals proposed a specific data management plan will be elaborated to predefine how clinical research data will be collected, managed, and protected. The plan will define the specific goals of data collection, data type and location, access to the data, roles and responsibilities, allowing the research team a thorough understanding of the requirements.
A key role will be played by the REDCap (Research Electronic Data Capture) platform, which will be used by OU1 to collect and manage data properly. It is a secure web-based application, compliant with many standards as FISMA and HIPAA, developed to manage data for clinical research [PAT18] . Specific modules are already in use at AOU Sassari with an already populated database: demographics, inflammatory airway disease history and related factors, comorbidities, questionnaires administration, treatments and follow up visits will be collected for each patient. Anonymization procedures will be carried out.
Data Acquisition modalities
Along the trials data will be collected in 2 modalities: one will be standard with acquisition of subjective (PROMs) and of objective information(airflows, but also clinical and endoscopic findings) and subsequent manual insertion of data. The other modality will benefit from the specifically built pipelines (task1.2) and will allow to acquire data directly through MHT and, in case of the phonebots, directly through the cloud, and will be hence totally automatized. This will drastically increase the amount of potentially acquirable data through this second modality, with no logistical limitations and increased possibilities, working with big data, to build reliable predictive models for the diseases under evaluation.
Collection Pipelines
The project will devise dedicated data pipelines to automatically fill with PROMs and airflow data acquired through MHT into the Redcap database.
Data acquisition and management tools
The phonebot and chatbot will make use of cloud solutions such as Twilio (¿Communication APIs for SMS,Voice,Video & Authentication n.d.) or Amazon Connect (which, in turn, is based on Twilio).
Such systems were born as Private Branch Exchanges (i.e. enterprise phone systems that handle inbound and outbound calls) and evolved towards multi-channel communication systems. Now they integrate telephony, SMSs, chatbots with different Instant Messaging channels, real time video streaming and e-mail systems. Moreover they also integrate several related technologies such as AI systems to handle conversation, text-to-speech systems, data flow and dialog composing tools.
We will make use of such systems as convenient under several perspectives.
First, because of their company policy, Whatsapp forces their customers to use resellers (such as Twilio) to access Whatsapp Business APIs which otherwise can not be reached directly by us. Second, such cloud systems have the ability to scale to millions of users in a few minutes because of the use of cloud computing, which is very convenient since the

project has the ambition to be replicated in an easy way. Finally, solutions such as Amazon Connect make use of state of the art solutions for Artificial Intelligence (natural language processing) which are shared and thus tested their effectiveness with the popular ¿Amazon Alexa¿ product.
Custom mobile applications will be developed to provide questionnaires to patients. Such applications will be released on Android and iOS platforms. All these applications will be designed together with project partners, to derive Finite State Machine specifications and clarify use flows.

Statistic plan

Planning of the three clinical trials has been done considering the desired statistical power, the short time for completing the project (just 2 years) and the fact that the three clinical trials are ¿de facto¿ also Proofs of concept for a very innovative approach with ambition to change the daily management of 2 very common chronic diseases and to obtain a breakthrough towards a real Patient Empowerment.

For clinical trial 1, to obtain a confidence level 95% and a confidence interval 15 the required sample size was estimated at 40.

As for the clinical trial 2, we wanted to set up a study able to detect a 20% difference among the arms, for which, being a four-arm trial, 12 patients would be sufficient for each arm. But also, being a four-arm study, some correction (even a Bonferroni correction) should be applied, and if applied on the alpha value, with six possible comparison (not only of the treatment groups with the control group, but also among the treatment groups) the alpha value would go from 0.05 to about 0.009, so that we deemed useful to increase each arm to 20 subjects (total number of subjects 80).

Finally, for the clinical trial 3, we desired to be able to detect differences of 25% in airflow measures between the standard ambulatory testing and the 2 at home systems, for which a sample of 15 patients is required.

Statistical analysis

To assess statistically significant differences for the primary endpoints in the 3 trials we will use:

For trial 1, where the primary endpoint is patient satisfaction R-Squared, Chi-Squared, Pearson test and Fisher's exact test to assess the satisfaction of patients in the treatment group versus control group. Alpha value will be set up at 0.05.

For trial 2, to assess the primary endpoint, which is the completion rate of the questionnaires in the four arms, we will use ANOVA followed by t-test to perform the 6 possible comparisons among the 6 groups. For ANOVA alpha value of 0.05 will be used, while for single comparisons a Bonferroni adjustment will be applied, bringing the alpha down to 0.009.

For trial 3, the hypothesis of non-inferiority will be tested, comparing remote measurements with standard ambulatory testing through paired t-tests. Alpha will be set up at 0.05.

The secondary endpoints will be evaluated with the same software (JMP of the SAS institute) with proper statistical instruments.

Timing of analysis data

Duration: 15 months
Enrollment: months 6 to 9
Follow up: 1 year
40 patients:
20 (control group): standard follow up each 3 months
20: standard on site follow-up visit every 6 months + electronic questionnaires to report PROMs + FEV1 and/or PNIF to be

performed by turning on the spirometer and connecting it to the app.

TRIAL 2
Duration: 1 year
Enrollment: months 6 to 12
Follow up: 6 months
80 patients:
40 + asthma + CRSwNP
20 + CRSwNP - asthma
20 + asthma - CRSwNP
PROM answered remotely weekly + monthly at hospital first by themselves with the aid of one of the three channels on the electronic forms and then under direct supervision of the clinicians.
Patients in the ¿standard¿ channel will just fill the forms every month.
At month 6th patients will answer PE questionnaires.

Trial 3
Duration: 6 months
Enrollment: months 12 to 15
Follow up: 3 months
Performed at home and periodic visits in the hospital
16 patients + asthma + CRSwNP
Randomized trial (two arms, 8 patients per arm): airflow monitoring recorded remotely with Spirometer (every 2 weeks) vs. RFID (daily) + every 2 months at hospital (baseline, month 2) for both arms.

5.6 Expected outcomes

The PRECISION project is expected to deliver four main outputs:
1. New models for remote PROMs collection
The project will produce new models for collecting periodic PROMS, necessary for the long-term treatment of several chronic inflammatory airway pathologies.
2. Novel MHT tools for patient empowerment
The project will validate systems to engage patients in treating their pathologies.
3. New methodologies for large-scale and sustainable monitoring of upper and lower airway obstruction
The project will exploit existing technology and develop new tools to monitor common chronic respiratory diseases
4. Designing of new data pipelines for dedicated medical datasets
This project will develop specific pipelines for importing data acquired from patients' mobile tools directly into scientific datasets enabling real-time and smooth data visualization and analysis by clinicians and removing error prone and time consuming manual operations.
Economic impact
One of the main goals of the PRECISION project is to reduce the cost on the NHS and thus have a tangible economic impact. In Italy the cost of public healthcare accounts for 6,4% of the Gross Domestic Product (GDP), far less than the 11,7% in Germany and of 9,4% in France, which call for better cost-effective solutions. This is a lesson learnt also during the COVID pandemic, which unveiled a chronic insufficiency of personnel and resources in the Western NHSs.
For their characteristics (chronicity, wide distribution), CRS and asthma are the perfect candidate.
The PRECISION project will impact the NHS by offloading clinicians from time-consuming PROMs administration. By the introduction of usable technology, the project will experiment with how chronic monitoring can be optimized on one hand, reducing the access to healthcare facilities, and on the other hand keeping a larger amount of patients monitored.
Also, the project has the clear potential to reduce indirect costs through a better compliance of the patients to therapy and

follow up. This will generate an economic advantage through reduction of productivity losses attributable to employee work absence and disability, and, most of all, to the reduced efficiency at work of uncontrolled CRS and asthma patients. Uncontrolled CRS and asthma patients resort to more expensive (including hospitalization, novel biological drugs, antibiotics and surgery) and more invasive (surgical) treatments, with further direct and indirect costs. Our approach with empowerment and better compliance of the patients will also reduce such costs.
Impact on data collection and analysis
The MHT supporting the experimented strategy of continuous remote collection and import of data through dedicated pipelines to existing datasets, is going to change general strategies and modalities of analyzing data concerning chronic disease. Traditional analysis based on limited time points and requiring limited statistical tools and skill is going to be replaced by a BigData approach based on markedly larger amount of data and a higher number of timepoints to get almost continuous, which will require much more powerful statistical tools(including AI) with a higher potential to obtain insights into the diseases with respect to both clinical and scientific knowledge.
Measures to maximize impact
Dissemination plan
The project will define a dissemination plan with the aim of maximizing the potential impact of the project through the implementation of dissemination activities that will exploit multiple vehicles. The plan will identify the targets among specialized groups, for example the scientific community, the policy makers, Medical Stakeholders, etc. For each target the most suitable venue and the best way to communicate the results will be selected. Communication methods will range from scientific articles to posters, from press releases to websites. The plan will define the timing of communication in accordance with the milestones of the project.

5.7 Risk analysis, possible problems and solutions

Risk 1
Description: Delayed development of the software and of the app for unified management of remote subjective and objective measurements
Probability: Medium
Impact: Medium
Mitigation strategy: Close monitoring, and communication with the company producing the spirometer, in case of inadequate TRL use of different solutions for the collection of PROM and airflow measurement (resort to native application for airflow measurement)

Risk 2
Description: Technology integration more involved than expected
Probability: Medium
Impact: High
Mitigation strategy: Simplified versions of some of the components may be adopted.

Risk 3
Description: COVID-19/other type of crisis
Probability: Medium
Impact: Medium
Mitigation strategy: Meetings held online, remote workshops and evaluation sessions, supporting all UCs/Pilots.

Risk 4
Description: Insufficient acceptance of the remote tools based on user experience
Probability: Low

Impact: High
Mitigation strategy: Strengthen patient participation procedure.

Risk 5
Description: Insufficient acceptance of the remote tools based on user experience
Probability: Low
Impact: High
Mitigation strategy: Strengthen patient participation procedure.

Risk 6
Description: Non-availability of key personnel
Probability: Low
Impact: Medium
Mitigation strategy: The partners view this project as essential for their operations and, thus, have committed the required personnel, also basing upon the call they also identified in advance the new personnel to hire with the project funding. In cases where this option might be not possible the work can be shifted to other personnel of the units which have sufficient resources to mitigate this risk.

Risk 7
Description: Lack of reliability of remote airflow measurement (both of the spirometer, in particular for PNIF, and of RFID)
Probability: Medium
Impact: Low
Mitigation strategy: The assessment of reliability of remote monitoring is one of the main objectives of the present project, so also a failure would be a valuable result, besides as for spirometer there is already a high TRL and a native validated application for the remote airflow measurement in asthma, the consortium could use the native application in case of poor performance of the specifically developed application

Risk 8
Description: Delays of the development of the pipelines for automatic data import
Probability: Low
Impact: Medium
Mitigation strategy: Both subjective and objective data can anyway be acquired on the cloud and until delays are solved they can be inserted manually. A data manager is specifically foresee to be hired with the requested funding

Risk 9
Description: Low technological acceptance of the device by patients
Probability: Medium
Impact: High
Mitigation strategy: The PRECISION tools will be designed according to a full user centered design. Patients will be involved since the early phase of the protocol design and during its implementation. PRECISION system and its technological Acceptance will be evaluated through the use of Patient Reported Outcomes and electronic Performance Measure, ensuring an assessment from the patient perspective.

Risk 10
Description: Requirements of patients and clinicians change during the course of the project
Probability: Medium

Impact: Medium
Mitigation strategy: User-centred, incremental and iterative design and development will reduce risk to miss changing needs.

5.8 Significance and Innovation

CRS and asthma are highly prevalent conditions with a relatively early onset (usually within the third decade), without a decisive impact on life-expectancy, so that patients are expected to be followed for years. Also, recent changes in standard of care requireperiodic complex evaluations made of subjective (provided by patients) and objective (provided by doctors)assessments and scoring. In the long term, the compliance of the patients is compromised by low morbidity during remissions, by difficult and time consuming access to NHS facilities, and by costs. Moreover, COVID pandemic unveiled an insufficiency of personnel and resources of Western NHS. It means that in a real-world setting it can become not sustainable to provide to all patients adequate management of the disease over time.To meet these urgent needs, PRECISION aims to study methodologies and tools for remote management to drastically change and make sustainable the standard of care for all patients with asthma and CRS.

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5.10 Timeline / Deliverables / Payable Milestones

The project foresees 4 payable milestones (one each 6 months, see below).

The following deliverables will be produced:
Data management plan (month 3)

Dissemination plan (month 6)
Description of the developed technological infrastructures (month 12)
Mid-term report on clinical trials' enrolment (month 13)
Mid-term project report (month 13)
Final report on clinical trials' enrolment (month 21)
Analysis of trials' results (month24)
Final project report (month 24)

Milestones 12 month

M1: Experiments Design (Y1Q2)
The first phase of the project is dedicated to the preparation of the three trials, preparing the technological infrastructure and defining in detail the methodologies to be tested

M2: End of the recruitment and the first part of the trials (Y1Q4)
At month 6 the trials and the patient recruitment phase begin; the first six months are important to verify the actual effectiveness of the technological infrastructure and the progress of the first phase of the trial

Milestones 24 month

M3: End of the trials (Y2Q2)
month 18 will finish the three trials and the data management part will begin to prepare the next analysis phase

M4: Results Validation and Final Report (Y2Q4)
the final phase of the project is dedicated to the evaluation of trial results and the publicizing of the final results

Gantt chart

GANTT.png

5.11 Equipment and resources available

Facilities Available

AOU ENT division (OU1) is a referral center for head and neck oncology in Sardinia and a 3rd-level center for diagnosis and treatment of nasosinusal, audiovestibular and laryngeal diseases. Day hospital, ward and surgical activities are carried out.
Physical exam and fibroendoscopy are carried out in a first level ambulatory with preliminary diagnosis of CRS. Successively in the rhinology second level ambulatory, patients with CRS undergo rigid endoscopy, olfactometry, PNIF measurement, PROM administration and post-operative medications. Patients with severe uncontrolled CRSwNP are referred to OU1 from the north-Sardinia for medical/surgical treatment.
AOU Respiratory Diseases Unit is a 2nd level academic center dedicated to the diagnosis and treatment of lung diseases and includes 38-bed inpatient, outpatient clinics and a day-hospital service.
Asthma unit is composed by 2 physician with extensive experience in the management of asthma and related comorbidities, a long-trained nurse specialist, an accredited pulmonary function laboratory with 2 body-plethysmography machine and 2 technician with skills in lung volumes measurements, gas diffusion studies, assessment of airways hyperresponsiveness(methacholine challenge test),FeNO measurement and allergy skin test interpretation.

Subcontract

It is necessary to make use of the expertise of CNIT, because of the specific issues arising from the use of chatbots and crowdsourced data, requiring expertise in UX/UI design, NLP and Crowdsourcing bias analysis. In particular, it has been shown that the use of chatbots may introduce several biases. First, the inherent difficulty in replicating medical expert moderation during the administration of the questions potentially taints the collected data with scale bias and complicates

the estimation of the answers' confidence.
Secondly, designers' and UX/UI bias (e.g. graphics and natural language models choices), together with algorithmic biases introduced by the training data can negatively affect the chatbot effectiveness, and consequently, the patients trust in such solutions.
Best practices in design of crowdsourcing solutions, including real-time feedback and interaction with patients will be employed to remedy the lack of medical expert moderation, and more in general to address the aforementioned biases.
The team members lack expertise in such domains. Such a lack is filled by Prof. Alessandro Checco of CNIT who is an expert of crowdsourced data, UX and NLP.

5.12 Desc. of the complementarity and sinergy of secondary collab. researchers

Secondary collaborator researchers will work in synergy with OU1 and OU2.
In the presence of digital health solutions such as the ones proposed in the present project, a key aspect is the patient data management. It must be done according to the rules defined by the Health Information Portability and Accountability Act (HIPAA) and by the European General Data Protection Regulation (GDPR).
For this purpose, Dr. Claudia Crescio will exploit her experience as Clinical Data Manager to supervise patients¿ enrollment and set up specific case report forms in a designated online database. It will be created on REDCap (Research Electronic Data Capture), a web-based application developed by Vanderbilt University to capture data for clinical research and create projects. She will ensure accuracy of data collection and their FAIRification. Moreover, she will support clinicians in the collection of questionnaires and definition of content of explanation chatbots. Finally, she will handle statistics at the end of the studies.

Pneumology
Dr. Chiara Benvegna, who is currently concluding her Specialization period, will be a relevant member of the pneumologist unit and will work along with the Co-PI prof. Pirina and Dr. Canu in the enrollment and general clinical management, including assessment of patients¿ satisfaction, of patients affected by asthma.

Dr. Bianco obtained his PhD studying the effects of electromagnetic links on body-area networks and internet of things (IoT) systems. His research interests cover how body-area internet of things can help people's quality of life, and how to exploit electromagnetic technology to this aim.
His role in the project is related to the objective measurement of airflow. In particular, he will give his contribution to the evaluation of the results and in the experiment design (data acquisition control, calibration and evaluation, technology deployment).

5.13 Translational relevance and impact for the national health system (SSN)

What is already know about this topic?

CRS affects 5.5% to 28% out of the general population. It is associated with asthma, which has a prevalence around 25% in patients with CRS compared to 5% in the general population(1,2). Direct costs in Europe are estimated at 2500 euro per pat/year in CRSwNP(3) with large indirect costs based on the patient's CRS-specific QoL impairment(4).
Asthma costs in Europe are very variable, however it is estimated a mean cost per patient per year, including all asthmatics, is about 1.800 euro(5).
Notably, both diseases have a relatively early onset, without a decisive impact on life-expectancy (in particular CRS), so that patients are expected to be followed for decades.
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Details on what is already know about this topic

CRS is a complex syndrome consisting of several variants, characterized by persistent symptomatic inflammation of the nose and paranasal sinus mucosa for more than 12 weeks. Nasal obstruction and olfactory impairment are its cardinal symptoms. Diagnostic protocols used in accordance with the recent European guidelines consist of: history and symptoms, Nasal Endoscopy assessment, VAS and SNOT22 questionnaires, PNIF, Allergy tests, IgE and eosinophils levels, Imaging evaluation CT scan. Asthma is an airway inflammatory disease with an heterogeneous clinical presentation. It is promoted by 2 different cellular pathways, the TH2 and not TH2 phenotypes, leading to mucus hyper-production, obstruction and airway wall remodeling. Symptoms such as wheeze, shortness of breath, chest tightness, cough, in association with a not fixed expiratory airflow limitation are its main features. Diagnosis is based on history of respiratory symptoms, pulmonary function testing and other laboratory tests.

What this reasearch adds?

It is a proof of concept, involving small clinical trials, finalized to evaluate feasibility of a remote management of these highly prevalent diseases.
There are two orders of improvements that will be tested, one concerns the acquisition of PROMs, which have become fundamental in the current guidelines but are time consuming for patients and physicians and require motivation and attention of patients along time.
The second one concerns objective information and in particular the monitoring of airflow and airway patency at the level of the nose (for CRS) and of bronchi (for asthma).
If the present proofs of concept demonstrate feasibility and reliability of such remote approaches, with adequate compliance and satisfaction by patients, the standard of care defined by current guidelines could be obtained at a markedly lower cost and would become accessible to a larger number of patients.
In general , remote management could become standard for asthma and CRS.

Details on what this reasearch adds

MHTs are being developed for various diseases and several RCT have investigated MHT efficacy in remote patient monitoring. CRS and asthma, with their peculiarities of early onset and low life-threat, are optimal to test integrated approaches. So, the aim of this project is to evaluate whether and how this technology can increase patient self-management.
This project will compare different mobile-health-based care approaches in a real-world setting, to test tools and their applicability. As the low morbidity of a controlled disease may be associated with a decreased motivation, patient empowerment will be pursued deploying tools with the function of explaining, reminding, and obtaining further feedback. Very promising approaches are represented by mobile apps and AI-powered chatbots which have been successfully adopted to improve monitoring and treatment adherence. For patients with a poor alphabetization and/or elderly patients, an approach with phonebots will be tested.

What are the implications for public health, clinical practice, patient care?

The large amount of data coming from the approach described in the project is going to improve the clinical understanding impacting the clinical practice.
The present proofs of concept are also finalized to promote an improvement in the quality of life of patients. Other prevalent comorbidities, associated with CRS and asthma, as obstructive Sleep Apnea, cardiovascular diseases and COPD will have an improvement.
Also the present approach could clearly be scalable to many other chronic diseases.

A very relevant consequence will be the reduction of public national health system costs, with a tangible economic impact. One of the lessons learnt during the COVID pandemic is a chronic insufficiency of personnel and resources in the Western

NHSs. Better cost-effective solutions, as the ones we are going to test, have become mandatory.
The project has also the clear potential to reduce indirect costs through reduction of productivity losses.

Details on what are the implications for public health, clinical practice, patient care

We want to demonstrate the feasibility and the acceptability of remote monitoring for asthma and CRSwNP (trial 1) and refine the tools for the remote collection of subjective (trial 2) and objective (trial 3) information.
This would definitely increase sustainability, for the national health system, of an optimal management, usually very costly and time consuming, in patients with chronic and usually non lethal diseases which will be in lifelong follow up.
This is particularly valuable in a NHS that COVID pandemic poses under permanent stress, with clear scalability potential.
Also, the large amount of data coming from the approach described in the project is going to improve the clinical understanding and approach to chronic respiratory inflammatory diseases by:
Rethinking endpoints and classification parameters, developing predictive algorithms on the course of the disease, adapt therapies and recommendations faster basing on real time information from the MHT.

6 - Budget

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1 Staff Salary	121.000,00	121.000,00	not permitted	0,00
2 Researchers' Contracts	228.000,00	0,00	228.000,00	28,15
3a.1 Equipment (Leasing -	0,00	0,00	0,00	0,00
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	0,00	0,00	0,00	0,00
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts *	62.220,00	0,00	62.220,00	7,68
5 Patient Costs	130.000,00	0,00	130.000,00	16,05
6 IT Services and Data Bases	239.974,00	0,00	239.974,00	29,63
7 Travels	24.000,00	0,00	24.000,00	2,96
8 Publication Costs	32.000,00	0,00	32.000,00	3,95
9 Dissemination	23.000,00	0,00	23.000,00	2,84
10 Overheads *	55.806,00	0,00	55.806,00	6,89
11 Coordination Costs	15.000,00	0,00	15.000,00	1,85
Total	931.000,00	121.000,00	810.000,00	100,00

* percentage calculated as average value between all the Operating Units.

Report the Co-Funding Contributor:

The co-funding consists of man-months of staff members composed by 3 full professors, 2 associate professors, 2 researchers, 1 hospital doctor for a total of 19 MM

Budget Justification

1 Staff Salary	The structured staff consists of 8 people for a total of 19 man-months
2 Researchers' Contracts	The project involves the hiring of 3 junior researchers for two years each
3a.1 Equipment (Leasing - Rent)	NO
3a.2 Equipment (buying)	NO
3b Supplies	NO
3c Model Costs	NO

4 Subcontracts	Subcontract to the Inter-university Consortium CNIT
5 Patient Costs	cost for the patients involved in the trials
6 IT Services and Data Bases	costs for the acquisition of IT services from Able Srl and Radio6ens Srl as per offers received by PEC on 7/7/22
7 Travels	costs for participating to project meetings and for attending the trial activities
8 Publication Costs	costs to pay for at least 7 publications in international journals with open access gold
9 Dissemination	participation and organisation of national and international conferences
10 Overheads	evaluated against other costs to support project management
11 Coordination Costs	expenses for organising meetings, legal and administrative support for the project

Proposed total budget UO1 Institution: Azienda Ospedaliera Universitaria di Sassari (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1 Staff Salary	72.000,00	72.000,00	not permitted	0,00
2 Researchers' Contracts	152.000,00	0,00	152.000,00	22,32
3a.1 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	0,00	0,00	0,00	0,00
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts	62.220,00	0,00	62.220,00	9,14
5 Patient Costs	130.000,00	0,00	130.000,00	19,09
6 IT Services and Data Bases	239.974,00	0,00	239.974,00	35,24
7 Travels	6.000,00	0,00	6.000,00	0,88
8 Publication Costs	19.000,00	0,00	19.000,00	2,79
9 Dissemination	14.000,00	0,00	14.000,00	2,06
10 Overheads	42.806,00	0,00	42.806,00	6,29
11 Coordination Costs	15.000,00	0,00	15.000,00	2,20
Total	753.000,00	72.000,00	681.000,00	100,00

Project Code: PNRR-POC-2022-12375925	**Call section:** Proof of concept
Applicant Institution: Sardegna	**Applicant/PI Coordinator:** Bussu Francesco

Budget Justification	
1 Staff Salary	Prof Bussu, Prof Pirina, Dott. Piras, Dott. Canu
2 Researchers' Contracts	2 research contacts for two years
3a.1 Equipment (Leasing - Rent)	NO
3a.2 Equipment (buying)	NO
3b Supplies	NO
3c Model Costs	NO
4 Subcontracts	Subcontract to the Inter-university Consortium CNIT
5 Patient Costs	cost for the patients involved in the trials
6 IT Services and Data Bases	costs for the acquisition of IT services from Able Srl and Radio6ens Srl as per offers received by PEC on 7/7/22
7 Travels	costs for participating to meetings and trial activities
8 Publication Costs	costs to pay for at least 4 publications in international journals with open access gold
9 Dissemination	participation and organisation of national and international conferences
10 Overheads	evaluated against other costs to support project management
11 Coordination Costs	expenses for organising meetings, legal and administrative support for the project

Proposed total budget UO2 Institution: Università di Roma Tor Vergata (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1 Staff Salary	49.000,00	49.000,00	not permitted	0,00
2 Researchers' Contracts	76.000,00	0,00	76.000,00	58,91
3a.1 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	0,00	0,00	0,00	0,00
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts	0,00	0,00	0,00	0,00
5 Patient Costs	0,00	0,00	0,00	0,00
6 IT Services and Data Bases	0,00	0,00	0,00	0,00
7 Travels	18.000,00	0,00	18.000,00	13,95
8 Publication Costs	13.000,00	0,00	13.000,00	10,08
9 Dissemination	9.000,00	0,00	9.000,00	6,98
10 Overheads	13.000,00	0,00	13.000,00	10,08
11 Coordination Costs	not permitted	not permitted	not permitted	0,00
Total	178.000,00	49.000,00	129.000,00	100,00

Budget Justification	
1 Staff Salary	Prof Marrocco, Prof Loreti, Prof Bracciale, Prof Occhiuzzi
2 Researchers' Contracts	1research contacts for two years
3a.1 Equipment (Leasing - Rent)	NO
3a.2 Equipment (buying)	NO
3b Supplies	NO
3c Model Costs	NO
4 Subcontracts	NO
5 Patient Costs	NO
6 IT Services and Data Bases	NO
7 Travels	costs for participating to meetings and trial activities
8 Publication Costs	costs to pay for at least 4 publications in international journals with open access gold
9 Dissemination	participation and organisation of national and international conferences
10 Overheads	evaluated against other costs to support project management
11 Coordination Costs	NO

Principal Investigator Data

Cognome: Bussu
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Istituzione: Azienda Ospedaliera Universitaria Sassari
Datore/ente di lavoro? Yes
Datore/ente di lavoro SSN? Yes
Nome datore/ente di lavoro non SSN:
Nome istituzione SSN: Azienda Ospedaliera Universitaria di Sassari
Tipo contratto: Professore Ordinario distaccato presso IRCCS/IZS/ISS/Ente SSN (convenzione di clinicizzazione e/o ricerca)

Con l'invio della presente proposta si dichiara che la stessa o parti significative di essa non sono oggetto di altri finanziamenti pubblici o privati e che di conseguenza vi è assenza del c.d. doppio finanziamento ai sensi dell'art. 9 del Regolamento (UE) 2021/241, ossia che non ci sia una duplicazione del finanziamento degli stessi costi da parte di altri programmi dell'Unione, nonché con risorse ordinarie da Bilancio statale.

By submitting this proposal, I declare that no significant part or parts of it are recipient of any other public or private funding and that consequently there isn't any so-called double financing pursuant to art. 9 of Regulation (EU) 2021/241, i.e. that there is no duplication in the financing of the same costs by other Euopean Union programs or any other ordinary resources from the State budget.

Project validation result