Ministero della Salute       Finanziato         Direzione generale della ricerca e dell'innovazione in sanità       Finanziato         PNRR: M6/C2_CALL 2022 Full Proposal       NextGenerationEU         Project Code:       PNRR-MAD-2022-12376692         Call section:       Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi s         Applicant Institution:       Lazio
Project Code:       PNRR-MAD-2022-12376692       Call section:       Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi s         Applicant Institution:       Lazio       Applicant/PI Coordinator:       VADALÀ GIANLUCA
Applicant Institution: Lazio Applicant/PI Coordinator: VADALÀ GIANLUCA
1 - General information
Project code:       PNRR-MAD-2022-12376692       Project topic:       C1) Malattie croniche non trasmissibili, ad a impatto sui sistemi sanitari e socio-assistemi fattori di rischio e prevenzione
Applicant Institution: Lazio
PI / Coordinator:       VADALÀ GIANLUCA       Istitution that perform as UO for UO1:       Fondazione Policlinico Universit
<ul> <li>Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e socio-assistenziali</li> <li>Proposal title: An artificial intelligence approach for risk assessment and prevention of low back pain: towards precisespine care</li> <li>Duration in months: 24</li> <li>MDC primary: Ortopedia</li> <li>MDC secondary: Riabilitazione</li> <li>Project Classification IRG: Musculoskeletal, Oral and Skin Sciences</li> </ul>
Project Classification SS: Musculoskeletal, Oral and Skin Sciences Small Business - SEMO
<b>Project Keyword 1:</b> Connective tissue, skin, and inflammatory conditions of the joints including: products and device used in the diagnosis and treatment of diseases, disorders or injuries; the validation of imaging methods or device development related specifically to evaluation of function or the assessment treatment of diseases; gene or drug delivery, when the purpose is treatment of inherited or acquire disorders; wound healing and skin substitutes; photobiology and the skin; alopecia; treatment of
connective tissue and skin function in diabetic complications.
Project Request:       Animals:       Humans:       X       Clinical trial:       X
connective tissue and skin function in diabetic complications.         Project Request:       Animals:       Humans:       X       Clinical trial:       X         Project total financing request to the MOH: €       1.000.000       1.000.000         Free keywords:       I ow Back Pain Artificial Intelligence Precision Medicine Spine       Spine

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

1 Direzione a

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

LBP is a major global problem that affects more than 500 million people, approximately 7.5% of the world population. Since the first Global Burden of Disability study in 1990, LBP has been considered the leading global cause of disability. Nowadays, diagnosing and treating LBP requires and is based on several data, such as radiological images, patient-reported outcome evaluation questionnaires, biomarkers, etc. Therefore, the ultimate therapeutic decision is often guided by elaborating a vast body of information using an algorithmic approach. However, given the contribution of multiple factors in the definition of LBP, a personalized, multidimensional, and precision medicine approach is urgently needed to improve the care and outcomes of patients with LBP.

In the last decade, the use of Artificial Intelligence (AI) is being increasingly investigated in medical research. To date, AIbased methods have been proposed in the LBP prevention and management framework on different types of data. Although the recent advances in the application of AI in LBP are noteworthy, some concerns still exist.

This project aims to develop and demonstrate the clinical use of a novel interactive, AI-based platform for the personalized care of low back pain (LBP), a societal challenge affecting millions of people in Europe and worldwide.

The specific aims are to: 1) Validate a platform for the physician to estimate the risk of LBP onset, predict outcomes and foster personalized LBP care based on the patients; phenotypes; 2) Develop a platform for patients for the evaluation of the progression of LBP and the effect of treatments; 3) Test the platforms in the real-world clinical setting and compare with the standard cares.

The consortium will: 1) enroll patients affected by LBP and gather data regarding lifestyle, occupational, environmental, socio-economic, behavioral, and clinical features of LBP, as well as from imaging, biomarkers, and biosensors; 2) combine different AI technologies to analyze the data and recognize specific LBP phenotypes; 3) establish two virtual platforms ¿ one for the physician and one for the patient ¿ to deliver personalized, longitudinal and continuous LBP care; 4) validate and test the AI platforms in the real-world setting compared to standard of care.

The project aims to establish a significant contribution to the development of an evidence-based, multidimensional, patient-

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centered care of LBPI. This approach may potentially revolutionize the treatment of patients affected by this condition and reduce the socio-economic burden for public health.

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?

# 2 - Participants & contacts

Operative Units					
Institution that perform as UO	CF Institution	Department / Division / Laboratory	Role in the project	Southern Italy	SSN
1 - Fondazione Policlinico Universitario Campus Bio-Medico	96493500589	UOC di Ortopedia e Traumatologia	Coordination, clinical data collection and clinical study coordinator		х
2 - Università degli Studi di Sassari	00196350904	UOC di Ortopaedia e Traumatologia	Clinical data collection	х	Х
3 - Consiglio Nazionale delle Ricerche	80054330586	Istituto di Linguistica Computazionale "A. Zampolli" (ILC)	Feature extraction, develop the IT infrastructure, development the AI algorithms		
4 - Università degli studi di Messina	80004070837	Dipartimento di Ingegneria	Development AI algorithms	Х	

Principal Research Collaborators	8	
Key Personnel Name	Operative Unit	Role in the project
1 - PEDONE CLAUDIO	Fondazione Policlinico Universitario Campus Bio- Medico	Clinical data collection and data analysis
2 - DORIA CARLO	Università degli Studi di Sassari	Clinical data collection
3 - Venturi Giulia	Consiglio Nazionale delle Ricerche	Development of AI platforms
4 - D'AGUI' GIUSEPPINA	Università degli studi di Messina	Development of AI algorithms
5 - Fogolari Marta	Fondazione Policlinico Universitario Campus Bio- Medico	Biomarkers analysis
6 Under 40 - RUSSO FABRIZIO	Fondazione Policlinico Universitario Campus Bio- Medico	Clinical data collection
7 Under 40 - BRUNATO DOMINIQUE PIERINA	Consiglio Nazionale delle Ricerche	Development of AI platforms

Yes

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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Key Personnel Name	Co-PI	Resp. CE	Resp. Animal	Birth Date	Gender
1 - PEDONE CLAUDIO	Х			09/11/1969	М
2 - DORIA CARLO				06/02/1966	М
3 - Venturi Giulia				31/01/1982	F
4 - D'AGUI' GIUSEPPINA				18/11/1979	F
5 - Fogolari Marta				31/07/1988	F
6 Under 40 - RUSSO FABRIZIO				25/06/1988	М
7 Under 40 - BRUNATO DOMINIQUE PIERINA				29/08/1982	F

#### Responsible who requests CE authorization: VADALÀ GIANLUCA

Additional research co	ollaborators under 40	to hire				
Key Personnel Name	Operative Unit	Birth Date	Gender	Role in the project	Degree	Actual Pos. and Inst.
0 - MURESU FRANCESCO	Università degli Studi di Sassari	10/06/1982	М	Clinical data collection	Medicine and Surgery	Azienda Ospedaliero Universitaria di Sassari
1 - GUARNOTTA UMBERTO	Università degli studi di Messina	31/12/1994	М	Development AI algorithms	PhD in Matematics	University of Palermo

# 2.1 Administrative data of participating

## **Operative Unit Number 1:**

- Address: Via Alvaro del Portillo, 200, 00128, Roma
- PEC: ricerca@pec.policlinicocampus.it

# **Operative Unit Number 2:**

- Address: Piazza Università 21, 07100, Sassari
- PEC: protocollo@pec.uniss.it

# **Operative Unit Number 3:**

Address: Piazzale Aldo Moro 7, 00185, Roma,

PEC: protocollo-ammcen@pec.cnr.it

# Operative Unit Number 4:

Address: Contrada Di Dio (S. Agata), 98166, Messina

PEC: dipartimento.ingegneria@pec.unime.it

# Operative Unit Number 5 (self financing):

## Address:

PEC:

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** ****	Finanziato dall'Unione euro NextGenerationEU	opea	
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Applicant Institution: Lazio	Applicant/PI C	oordinator: VAD	ALÀ GIANLUCA		
2.2 Principal Investigator (PI) P	Profile				
Last Name: VADALÀ		Last name at	birth:		
First Name: GIANLUCA		Gender: M			
Title: Principal investigator	Country of residence: ITALY				
Nationality: Italiana		Country of Bi	irth: ITALY		
Date of birth: 14/03/1979		Place of Birth	: Soveria Mannelli		
Official H index (Scopus or Web of Science)	: 29.0				
Scopus Author Id: 16426262100	RCID ID:000	0-0001-7142-166	60 RESEARCH ID:B-15	538-2014	
Contact address					
Current organisation name: Fondazione Policii	nico Universitar	io Campus Bio-Me	edico		
Current Department / Faculty / Institute / Lak	poratory nam	e: UOC di Orto	opedia e Traumatologia		
Street: Via Alvaro del Portillo 200					
Postcode / Cedex: 00128		Town: Roma			
Phone:+393389831497 Phone 2:					
Education / training					
Educational institution and location		Degree	Field of study	From year	To year
Campus Bio-Medico University of Rome, Italy	Phi	D	Tissue Regeneration for Functional Restoration	2009	2012

Personal Statement:	

Campus Bio-Medico University of Rome, Italy

Campus Bio-Medico University of Rome, Italy

Dr Vadalà will be in charge of project management and coordination ensuring the respect of the scheduled timing and estimated costs. He will give specification for the physicians and patients platform and the clinical study including patient recruitment.

Specialization /

Specializzazione

Master's Degree /

Laurea Magistrale

# **Positions and honors**

2003

1997

Orthopaedic and Trauma

Medicine and Surgery

Surgery

2008

2003



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Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

#### Positions

Applicant Institution:

Institution	Division / Research group	Location	Position	From year	To year
Fondazione Policlinico Universitario Campus Bio- Medico	Complex Operative Unit of Orthopaedic and Trauma Surgery	Rome	Orthopaedic and Spine Surgery	2022	0
Campus Bio-Medico University of Rome	Dept. of Medicine and Surgery	Rome, Italy	Assistant Professor (RTD-A)	2017	0
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico	Cell Factory, Center of Cellular Therapy and Cryobiology	Milan, Italy	Project Coordinator	2012	2015
Campus Bio-Medico University Hospital	Dept. of Orthopaec and Trauma Surgery	Rome, Italy	Orthopaedic Surgeon	2009	2021
University of Pittsburgh	Dept. of Orthopaec Surgery, Ferguson Laboratory for Spine and Orthopaedic Risearch	Pittsburgh, PA, USA	Research Associate	2005	2006

## Other awards and honors

ON Literature Grant Corona for the COVID-19 impact in Orthopaedics
2018 AOSpine Europe Young Researcher Award
2017 ISSLS Clinical Traveling Fellowship Award
2016 Best Paper Award, ISSLS annual meeting, Singapore
2015 Best Poster Award, 100th SIOT annual Meeting, Rome
2013 AOSpine Europe Young Researcher Award
2011 Best Presentation Award, Spine Research Symposium, Philadelphia, USA
2008 SIOT 2nd Level Scholarship
2004 Michael J. Jerva MD Award

2004 NASS Research traveling Fellowship Award

## Other CV informations

Scientific Society Appointments 2021-Present: Vice-President, Italian Orthopaedic Research Society (IORS) 2020-Present: President, European Orthopaedic Research Society (EORS) 2019-Present: Associate Member AOSpine Knowledge Forum (KF) Degenerative, AOSpine International 2016-2019: European Representative, International Society for the Study of the Lumbar Spine (ISSLS) 2015-2021: General Secretary and Treasurer, IORS 2018-2020: 1st Vice-President, EORS 2014-2018: Treasurer, EORS 2009-2011: Stem Cells Committee, Italian Society of Spine Surgery (SICV&GIS)

Organization of scientific meetings 2021 President, 29th EORS Meeting, Rome, IT 2019 President, 7th BioSpine 7, Rome, IT 2017 Co-President, BioSpine 6, Berlin, DE 2016 President, 17th IORS Congress, Rome, IT



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Applicant/PI Coordinator:

VADALÀ GIANLUCA

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

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

Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Mesenchymal stem cell-derived exosomes: The new frontier for the treatment of intervertebral disc degeneration	Article	1122	11	2021	10.3390/app112311222		0	С
Stem cells and intervertebral disc regeneration overview-what they can and can't do	Review	S40-S53	15	2021	10.14444/8054	34376495	5	F
Bevacizumab arrests osteoarthritis progression in a rabbit model: A dose-escalation study	Article	NOT_FO UND	10	2021	10.3390/jcm10132825	34206900	0	F
Physical activity for the treatment of chronic low back pain in elderly patients: A systematic review	Review	1023	9	2020	10.3390/jcm9041023	33559626	11	F
Robotic spine surgery and augmented reality systems: A state of the art	Review	88-100	17	2020	10.14245/ns.2040060.03 0	32252158	21	F
Intervertebral disc degeneration: A focus on obesity and type 2 diabetes	Review	e3224	36	2020	10.1002/dmrr.3224	31646738	26	F
Interaction between Mesenchymal Stem Cells and Intervertebral Disc Microenvironment: From Cell Therapy to Tissue Engineering	Review	-	2019	2019	10.1155/2019/2376172	30973512	36	F
The Role of Type i Diabetes in Intervertebral Disc Degeneration	Article	1177- 1185	44	2019	10.1097/BRS.00000000 00003054	30973512	18	С
Novel stepwise model of intervertebral disc degeneration with intact annulus fibrosus to test regeneration strategies	Review	2460- 2468	36	2018	10.1002/jor.23905	29603340	11	F
Clinically relevant hydrogel-based on hyaluronic acid and platelet rich plasma as a carrier for mesenchymal stem cells: Rheological and biological characterization	Article	2109- 2116	35	2017	10.1002/jor.23509	28019703	24	F
Autologous bone marrow concentrate combined with platelet-rich plasma enhance bone allograft potential to induce spinal fusion	Article	165-172	30	2016	NOT_FOUND	28002915	8	F
Stem cells sources for intervertebral disc regeneration	Review	185-201	8	2016	10.4252/wjsc.v8.i5.185	27247704	67	F
A Nucleotomy Model with Intact Annulus Fibrosus to Test Intervertebral Disc Regeneration Strategies	Article	1117- 1124	21	2015	10.1089/ten.tec.2015.00 86	26035644	24	F
Intervertebral disc regeneration: From the degenerative cascade to molecular therapy and tissue engineering	Article	679-690	9	2015	10.1002/term.1719	23512973	68	F
Early intervertebral disc degeneration changes in asymptomatic weightlifters assessed by T1?' -magnetic resonance imaging	Article	1881- 1886	39	2014	10.1097/BRS.00000000 00000554	25099319	15	F
The transpedicular approach as an alternative route for intervertebral disc regeneration	Article	E319- E324	38	2013	10.1097/BRS.0b013e31 8285bc4a	23324932	45	F
The transpedicular approach for the study of intervertebral disc regeneration strategies: In vivo characterization	Article	S972- S978	22	2013	10.1007/s00586-013- 3007-y	24105019	39	F
T1rho Magnetic resonance imaging quantification of early lumbar intervertebral disc degeneration in healthy young adults	Article	1224- 1230	37	2012	10.1097/BRS.0b013e31 824b2450	22281486	66	С



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Applicant/PI Coordinator: VADALÀ GIANLUCA

Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Mesenchymal stem cells injection in degenerated intervertebral disc: Cell leakage may induce osteophyte formation	Article	348-355	6	2012	10.1002/term.433	21671407	208	F
Bioactive electrospun scaffold for annulus fibrosus repair and regeneration	Article	S20-6	21	2012	10.1007/s00586-012- 2235-x	22411039	67	F

\* 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	Туре	Pag	Vol	Year	DOI	PMID	Cit.**			
Restoring tactile sensations via neural interfaces for real-time force-and-slippage closed-loop control of bionic hands	Article	-	4	2019	10.1126/scirobotics.aau 924	31620665	57			
Controversies in regenerative medicine: Should intervertebral disc degeneration be treated with mesenchymal stem cells?	Review	e1043	2	2019	10.1002/jsp2.1043	31463457	44			
Stem cells sources for intervertebral disc regeneration	Review	185-201	8	2016	10.4252/wjsc.v8.i5.185	27247704	67			
Platelet rich plasma and hyaluronic acid blend for the treatment of osteoarthritis: Rheological and biological evaluation	Article	-	11	2016	10.1371/journal.pone.01 57048	27310019	49			
Intervertebral disc regeneration: From the degenerative cascade to molecular therapy and tissue engineering	Review	679-690	9	2015	10.1002/term.1719	23512973	68			
The transpedicular approach as an alternative route for intervertebral disc regeneration	Article	E319- E324	38	2013	10.1097/BRS.0b013e31 8285bc4a	23324932	45			
Use of an antifibrotic agent improves the effect of platelet-rich plasma on muscle healing after injury	Article	980-988	95	2013	10.2106/JBJS.L.00266	23780535	83			
Mesenchymal stem cells injection in degenerated intervertebral disc: Cell leakage may induce osteophyte formation	Article	348-355	6	2012	10.1002/term.433	21671407	208			
Bioactive electrospun scaffold for annulus fibrosus repair and regeneration	Article	S20-26	21	2012	10.1007/s00586-012- 2235-x	22411039	67			
T1rho Magnetic resonance imaging quantification of early lumbar intervertebral disc degeneration in healthy young adults	Article	1224- 1230	37	2012	10.1097/BRS.0b013e31 824b2450	22281486	66			

\*\* Autocertificated

Grant		_				
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed



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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Italian Workers Compensation Authority (INAIL)	Campus Bio-Medico University of Rome	2021	Development of an innovative, multidisciplinary and integrated approach for workers suffering from degenerative pathologies of the lumbar spine based on advanced technologies, capacity building, and feasibility analysis for the creation of a reference center for prevention, diagnosis, treatment, and professional reintegration (SPINE 4.0)	Collaborator	1.196.000,00	https://www.inail.it/cs /internet/attivita/ricerc a-e- tecnologia/finanziam enti-per-la- ricerca/bando-bric- 2021.html
Italian Minister of Education, University and Research	Campus Bio-Medico University of Rome	2019	Advanced injectable nano- composite biomaterials with dual therapeutic/regenerative behaviors for bone cancer (ACTION).	Coordinator	142.556,00	https://prin.mur.gov.it /Iniziative
Italian Minister of Health	Campus Bio-Medico University of Rome	2019	Intervertebral disc regeneration mediated by autologous mesenchymal stem/stromal cells intradiscal injection: a phase IIB randomized clinical trial.	Coordinator	450.000,00	https://www.salute.go v.it/portale/ricercaSa nitaria/archivioNotizie RicercaSanitaria.jsp
Italian Workers Compensation Authority (INAIL)	Campus Bio-Medico University of Rome	2018	Development of a Multidisciplinary and Integrated Approach, for the management of the worker affected by degenerative spine pathBRIC2018ologies: study of the occupational aspects and an innovative regenerative treatment of the intervertebral disc to favor return to work (ACTIVE).	Collaborator	630.000,00	https://www.inail.it/cs /internet/attivita/ricerc a-e- tecnologia/finanziam enti-per-la- ricerca/bando-bric- 2018.html
European Commission (Horizon 2020)	Campus Bio-Medico University of Rome	2018	Induced pluripotent stem cell-based therapy for spinal regeneration (iPSpine)	Coordinator	557.975,00	https://cordis.europa. eu/project/id/825925
European Commission (Horizon 2020)	Campus Bio-Medico University of Rome	2017	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lumbar SPINE unresponsive to conventional therapy (RESPINE)	Coordinator	331.362,00	https://cordis.europa. eu/project/id/732163/ it



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Applicant/PI Coordinator: VADALÀ GIANLUCA

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Italian Minister of Health	Campus Bio-Medico University of Rome	2012	Towards intervertebral disc regeneration: mesenchymal stem/stromal cells with a novel bioactive hydrogel based approach.	Coordinator	291.000,00	https://www.salute.go v.it/portale/ricercaSa nitaria/archivioNotizie RicercaSanitaria.jsp
Italian Minister of Education, University and Research (MIUR)	Campus Bio-Medico University of Rome	2011	Mesenchymal Stem Cells Therapy for the treatment of intervertebral disc degeneration: from bench to animal model for future translational research	Collaborator	270.000,00	https://prin.mur.gov.it /Iniziative/Detail?key =E8WOkB6aKsjECur Ep2gC7A%3D%3D
North American Spine Society (NASS) 2005 Research Grant	University of Pittsburgh	2005	Mesenchymal Stem Cell Injections for Treatment of Intervertebral Disc Degeneration	Collaborator	85.000,00	https://www.spine.or g/Who-We- Are/Grants- Awards/NASS- Funded-Research
Albert B. Ferguson Jr., M.D. Orthopaedic Fund of The Pittsburgh Foundation	University of Pittsburgh	2005	Role of Notochordal cells in intervertebral disc degeneration	Coordinator	5.000,00	https://pittsburghfoun dation.org/

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Applicant Institution: Lazio	Applicant/P	Applicant/PI Coordinator: VADALÀ GIANLUCA				
2.3 CO-PI Profile						
Last Name: PEDONE		Last name at b	pirth:			
First Name: CLAUDIO	Gender: M					
Title: Clinical data collection and data analysis	Country of residence: ITALY					
Nationality: Italiana		Country of Bir	th: ITALY			
Date of birth: 09/11/1969		Place of Birth:	FOGGIA			
Official H index (Scopus or Web of Science	<b>):</b> 44.0					
Scopus Author Id:7005510028	ORCID ID:00	000-0003-1847-9032	2 RESEARCH ID:F-948	8-2010		
Contact address						
Current organisation name: Fondazione Polici	inico Universi	itario Campus Bio-Meo	dico			
Current Department / Faculty / Institute / La	boratory na	ame: UOC di Ortop	edia e Traumatologia			
Street: VIA ALVARO DEL PORTILLO 200						
Postcode / Cedex: 00128		Town: ROMA				
Phone:+393398352032	Phone 2:					
Education / training						
Educational institution and location	Degree	From year	To year			

Educational institution and location	Degree	Field of study	From year	To year
Università Cattolica del Sacro Cuore, Roma, Italy	Specialization / Specializzazione	Geriatrics	1994	2001
Brown University, Providence RI, USA	Master's Degree / Laurea Magistrale	Master in Public Health - Epidemiology	1999	2001
Università Cattolica del Sacro Cuore, Roma, Italy	PhD	Medicine	1996	2000
Università Cattolica del Sacro Cuore, Roma, Italy	Single-cycle master's degree / Laurea magistrale a ciclo unico	Medicine	1988	1994

## Personal Statement:

The overall goal of the project is to develop an AI system for LBP care. The researcher will support data collection from multiple sources and help in data analysis

# **Positions and honors**



PNRR: M6/C2\_CALL 2022 Full Proposal



# Finanziato dall'Unione europea NextGenerationEU

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Project Code: PNRR-MAD-2022-12376692

Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

#### Positions

Applicant Institution:

Institution	Division / Research group	Location	Position	From year	To year
Università Campus Bio- Medico di Roma	MD Degree Program (English track)	Rome	Head	2022	2022
Fondazione Policlinico Campus Bio-Medico	Unit of Geriatrics	Rome	Head	2020	2022
Università Campus Bio- Medico di Roma	Residency Program in Geriatrics	Rome	Director	2017	2022
Università Campus Bio- Medico di Roma	School of Medicine and Surgery	Rome	Full Professor	2020	2022
Università Campus Bio- Medico di Roma	School of Medicine and Surgery	Rome	Associate Professor	2015	2020
Policlinico Universitario Campus Bio-Medico di Roma	Unit of Geriatrics	Rome	Attending Physician	2012	2020
Università Campus Bio- Medico di Roma	School of Medicine and Surgery	Rome	Researcher	2007	2015
Policlinico Universitario Campus Bio-Medico di Roma	Unit of Geriatrics	Rome	Geriatrician	2005	2012
Policlinico Universitario ¿Agostino Gemelli	Unit of Geriatrics	Rome	Geriatrician	2001	2005

#### Other awards and honors

Charles Ragus Award for the best scientific paper. American College of Nutrition, 2011.

## Other CV informations

Selected peer-reviewed publications of the Co-PI valid for minimum expertise level											
Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*			
Curcumin use in pulmonary diseases: State of the art and future perspectives	Review	133-148	115	2017	10.1016/j.phrs.2016.11.0 17	27888157	171	L			
Efficacy of multiparametric telemonitoring on respiratory outcomes in elderly people with COPD: A randomized controlled trial	Article	82	13	2013	10.1186/1472-6963-13- 82	23497109	83	F			
Systematic review of telemonitoring in copd: An update	Review	476-484	83	2015	10.5603/PiAP.2015.0077	26559801	46	F			
Chronic obstructive pulmonary disease in the elderly	Review	320-328	25	2014	10.1016/j.ejim.2013.10.0 01	24183233	33	L			
Efficacy of a physician-led multiparametric telemonitoring system in very old adults with heart failure	Article	1175- 1180	63	2015	10.1111/jgs.13432	26031737	25	F			
Longitudinal association between serum leptin concentration and glomerular filtration rate in humans	Article	e0117828	10	2015	10.1371/journal.pone.01 17828	25710704	22	F			
Are Performance Measures Necessary to Predict Loss of Independence in Elderly People?	Article	84-89	71	2015	10.1093/gerona/glv096	26273019	21	F			



#### PNRR: M6/C2\_CALL 2022 Full Proposal

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Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
Relationship between renal function and functional decline: Role of the estimating equation	Article	84.e11- 84.e14	13	2012	10.1016/j.jamda.2011.01 .009	NOT_FOUND	17	F
Impact of low muscle mass and low muscle strength according to EWGSOP2 and EWGSOP1 in community-Dwelling older people	Article	1324- 1330	75	2020	10.1093/gerona/glaa063	32157272	16	L
Association Between Sodium Excretion and Cardiovascular Disease and Mortality in the Elderly: A Cohort Study	Article	229-234	19	2018	10.1016/j.jamda.2017.09 .004	29042264	15	L
Alternative ways of expressing FEV1 and mortality in elderly people with and without COPD	Article	800-805	41	2013	10.1183/09031936.0000 8812	22790922	14	F
Association of reduced total lung capacity with mortality and use of health services	Article	1025- 1030	141	2012	10.1378/chest.11-0899	NOT_FOUND	14	F
BODE index or geriatric multidimensional assessment for the prediction of very-long-term mortality in elderly patients with chronic obstructive pulmonary disease? A prospective cohort study	Article	553-558	43	2014	10.1093/ageing/aft197	24333803	13	F
Binding ability of a thymine-functionalized oligolysine towards nucleic acids	Article	997-1002	22	2014	10.1016/j.bmc.2013.12.0 53	24411200	11	L
Association between non-invasive liver fibrosis scores and occurrence of health adverse outcomes in older people	Article	1330- 1336	51	2019	10.1016/j.dld.2019.01.01 7	30808572	10	L
Impact of statin therapy on plasma leptin concentrations: a systematic review and meta- analysis of randomized placebo-controlled trials	Review	1674- 1684	82	2016	10.1111/bcp.13086	27509867	10	L
Age-Related Changes in Clinical Presentation of Covid-19: the EPICOVID19 Web-Based Survey	Article	41-47	86	2021	10.1016/j.ejim.2021.01.0 28	33579579	8	L
Predictive Capacity of Frailty Phenotype Toward Patterns of Disability Identified Using Latent Class Analysis	Article	1026- 1031	20	2019	10.1016/j.jamda.2018.12 .018	30772170	5	L
Relationship between bone cross-sectional area and indices of peripheral artery disease	Article	508-516	93	2013	10.1007/s00223-013- 9782-y	23995829	4	F
Telemonitoring in older adults: Does one size fit all?	Article	1611	172	2012	10.1001/archinternmed.2 012.4415	23147457	3	F

\* 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					
Fondazione ANIA	Università Campus Bio-Medico di Roma	2018	Telemonitoraggio Multiparametrico Remoto per la Gestione delle Patologie Croniche nell'Anziano	Coordinator	225,00						





# Finanziato dall'Unione europea NextGenerationEU

PNRR: M6/C2\_CALL 2022 Full Proposal

Project Code: PNRR-MAD-2022-12376692 Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Fondazione Roma	Università Campus Bio-Medico di Roma	2015	A novel approach to identify COPD phenotypes, forecast clinical course and plan the therapeutic strategy Multidimensional phenotyping of patients with COPD	Coordinator	280,80	

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** **** ****	Finanziato dall'Unione europ NextGenerationEU	oea	
Project Code: PNRR-MAD-2022-12376692	Call section: M	Ialattie Croniche no	n Trasmissibili (MCnT) ad alto impat	to sui sistem	ii sanitari e
Applicant Institution: Lazio	Applicant/PI C	oordinator: VAD	ALÀ GIANLUCA		
2.3 Research Collaborators n.	2				
Last Name: DORIA First Name: CARLO		Last name at Gender: M	birth:		
Title: Clinical data collectionNationality:italianaDate of birth:06/02/1966	Country of residence: ITALY Country of Birth: ITALY Place of Birth: Sassari				
Official H index (Scopus or Web of Science) Scopus Author Id:7004914620	): 13.0 DRCID ID:000	0-0002-3822-26	08 <b>RESEARCH ID:</b> 70049	14620	
Current organisation name: Università degli St Current Department / Faculty / Institute / Lal Street: viale San Pietro	udi di Sassari boratory nam	e: UOC di Orto	opaedia e Traumatologia		
Postcode / Cedex: 07100		Town: Sassar	i		
Phone:+393384412346		Phone 2:			
Education / training					
Educational institution and location		Degree	Field of study	From year	To yea
University of Verona Mas		ster's Degree / urea Magistrale	Spine Surgery	2009	200
Catholic University of the Sacred Heart Rome	PhI	D	Experimental methodologies in surgery, angiology and orthopedics	2002	200
University of Sassari	Ma	ster's Degree / urea Magistrale	Postgraduate Course in Spinal Surgery	1998	199
University of Sassari	Spe	ecialization /	Orthopedics and Traumatology	1992	199

# Personal Statement:

University of Sassari

Prof Doria will contribute to the development of the AI platform by enrolling patients and collect data from multiple sources.

Specializzazione

degree / Laurea magistrale a ciclo unico

Single-cycle master's

Medicine and Surgery

## **Positions and honors**

1984

1991



\*\*\*\*

# Finanziato dall'Unione europea NextGenerationEU

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

PNRR: M6/C2\_CALL 2022 Full Proposal

Project Code: PNRR-MAD-2022-12376692

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Positions									
Institution	Division / Research group	Location	Position	From year	To year				
University Hospital of Sassari	Orthopedic Clinic of the University Hospital of Sassari	Sassari	Director	2016	2022				
University Hospital of Sassari	U.O.C. of the Orthopedic Clinic of the University Hospital of Sassari	Sassari	Head of the inpatient department	2013	2016				
San Martino Hospital	Orthopedics and Traumatology Department	Oristano - ASL 5	Director	2011	2012				
University Hospital of Sassari	Orthopedics and Traumatology	Sassari	Medical director	1999	2007				

## Other awards and honors

1999 Postgraduate Course in Spinal Surgery-University of Sassari.

2009 Second Level University Master in Spinal Surgery-University of Verona.

Obtained the National Scientific Qualification for eligibility as a First Level Professor in the competitive scientific sector 06/F4 Locomotor System Diseases and Physical Rehabilitation Medicine in the 5th quarter ASN 2016-18.

Grant						
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
				Collaborator	0,00	

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** * * ***	Finanziato dall'Unione europ NextGenerationEU	oea			
Project Code: PNRR-MAD-2022-12376692	Project Code: PNRR-MAD-2022-12376692 Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari						
Applicant Institution: Lazio	Applicant/PI C	coordinator: VADA	ALÀ GIANLUCA				
2.4 Research Collaborators n.	3						
Last Name:     Venturi     Last name at birth:     Venturi       First Name:     Giulia     Gender:     F							
Title: Development of AI platforms		Country of rea	sidence: ITALY				
Nationality: italiana		Country of Bi	rth: ITALY				
Date of birth: 31/01/1982		Place of Birth	Moncalieri				
Official H index (Scopus or Web of Science)	: 12.0						
Scopus Author Id:27568199800	DRCID ID:000	0-0001-5849-097	9 RESEARCH ID:AAY-3	932-2020			
Contact address							
Current organisation name: Consiglio Naziona	le delle Ricerch	e					
Current Department / Faculty / Institute / La	boratory nam	e: Istituto di Lin	guistica Computazionale "A. Za	ampolli" (IL	C)		
Street: via G. Moruzzi 1							
Postcode / Cedex: 56124		Town: Pisa					
Phone:+393339212763		Phone 2:					
Education / training							
Educational institution and location		Degree	Field of study	From year	To year		
University of Torino, Torino, Italy	Ph	D	Linguistics, Applied Linguistics, Linguistic Engineering	2008	2011		
University of Pisa, Pisa, Italy	Ma	ster's Degree /	Language and Italian Culture	2004	2006		

#### **Personal Statement:**

University of Pisa, Pisa, Italy

Giulia Venturi as a member of the Italian Natural Language Processing Laboratory (ItaliaNLP Lab) of CNR will contribute to the project with her expertise in the design of NLP-based technologies. Her activities will be focused on the development and customization of solutions able to automatically extract and organize relevant information from text, provide the most appropriate answer to questions typed in natural language (Frequently Asked Questions systems), and to check the stylistic form of medical reports and their compliance to the standard way of writing. Such solutions will enable more straightforward processing of the semantic content and linguistic peculiarities of medical textual sources.

Laurea Magistrale

Bachelor Degree /

Laurea Triennale

Modern Literature

## **Positions and honors**

2001

2004



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Project Code: PNRR-MAD-2022-12376692

Applicant Institution: Lazio Applicant/PI Coordinator: VADALÀ GIANLUCA

#### Positions

Institution	Division / Research group	Location	Position	From year	To year
National Research Council (CNR)	Institute of Computational Linguistics (ILC)	Pisa (Italy)	Permanent Researcher	2019	0
National Research Council (CNR)	Institute of Computational Linguistics (ILC)	Pisa (Italy)	Temporary Researcher	2018	2019
National Research Council (CNR)	Institute of Computational Linguistics (ILC)	Pisa (Italy)	Research Fellow	2012	2018
Sant'Anna School of Advanced Studies	Institute of Law, Politics and Development	Pisa (Italy)	Research Fellow	2011	2012
National Research Council (CNR)	Institute for Research on Innovation and Services for Development	Napoli (Italy)	Research Fellow	2010	2011
National Research Council (CNR)	Institute of Computational Linguistics (ILC)	Pisa (Italy)	Scholarship	2007	2010

## Other awards and honors

2020 Outstanding Paper (International Conference on Computational Linguistics)

2014 Distinguished Young Paper mention (First Italian Conference on Computational Linguistics)

2013 Best Verifiability, Reproducibility, and Working Description award (International Conference on Intelligent Text Processing and Computational Linguistics)

Grant						
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Tuscany Region	National Research Council (CNR)	2020- 2023	New strategies for promoting attendance in colorectal cancer screening programmes of Tuscany	Coordinator	355.900,00	
SOLCO s.r.l.	National Research Council (CNR)	2019	Information Extraction from INDIRE educational documents	Coordinator	10.000,00	
Minister of University and Research	National Research Council (CNR)	2016- 2018	Cultural Heritage Resources Orienting Multimodal Experiences	Collaborator	410.000,00	http://www.chrome.u nina.it/
Tuscany Region	National Research Council (CNR)	2016- 2018	Social Sensing for breaking news	Collaborator	654.861,00	
Minister of University and Research	National Research Council (CNR)	2013- 2016	Short writings, Linguistic simplification, social inclusion: models and applications	Collaborator	328.500,00	



PNRR: M6/C2\_CALL 2022 Full Proposal



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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Source website Funded by Researcher inst. where Position in Year Title Fund (euro) Institution Projects grant listed grant is/was performed Minister of University National Research Council (CNR) 2013- The Administration of Collaborator 900.000,00 and Research 2014 Justice in Italy: the case of neurogenetics and neuroscience, a multidisciplinary approach 2012- Legal Text Mining: building Collaborator **Tuscany Region** National Research Council (CNR) 30.000,00 2014 semantic networks to support advanced queries in legal textual corpora **European Commision** National Research Council 2007-Drafting Legislation with Collaborator 387.568,00 https://joinup.ec.euro 2008 Ontology-based pa.eu/collection/justic e-law-andsecurity/document/d alos-project-dalos **European Commision** National Research Council (CNR) Bootstrapping of Ontologies Collaborator 3.600.000,00 2006-2009 and Terminologies Strategic Research Project

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** * * ****	Finanziato dall'Unione euro NextGenerationEU	opea	
Project Code: PNRR-MAD-2022-12376692	Call section:	Malattie Croniche non	Trasmissibili (MCnT) ad alto imp	oatto sui siste	mi sanitari e
Applicant Institution: Lazio	Applicant/PI	Coordinator: VADA	LÀ GIANLUCA		
2.5 Research Collaborators n.	4				
Last Name: D'AGUI' First Name: GIUSEPPINA		Last name at t Gender: F	birth:		
Title: Development of AI algorithms		Country of res	idence: ITALY		
Nationality: Italiana		Country of Bir	th: ITALY		
Date of birth: 18/11/1979		Place of Birth:	Soveria Mannelli		
Official H index (Scopus or Web of Science)	: 15.0				
Scopus Author Id:57209715337	DRCID ID:000	00-0003-2080-818	1 RESEARCH ID:AIA-	0104-2022	
Contact address					
Current organisation name: Università degli st	udi di Messina				
Current Department / Faculty / Institute / La	boratory nar	ne: Dipartimento	di Ingegneria		
Street: c/da Di Dio (S. Agata)					
Postcode / Cedex: 98166		Town: Messina			
Phone:+393492386856		Phone 2:			
Education / training					
Educational institution and location		Degree	Field of study	From	To year

Educational institution and location	Degree	Field of study	From year	To year
University of Messina	PhD	Mathematics	2005	2009
University of Messina	Single-cycle master's degree / Laurea	Mathematics	2000	2004

#### **Personal Statement:**

The researcher is an expert in nonlinear analysis and in particular in nonlinear differential equations as well as difference equation. The link between the approximate determination of solutions of differential equations in complex geometries, discrete equations and the use of artificial neural networks runs deep. Differential equations play a fundamental role in all fields of applied sciences. Analytical solutions of differential equations may not be obtained easily, so numerical methods can be developed to handle them.

## **Positions and honors**

Mínístero della Salute
Direzione generale della ricerca e dell'innovazione in sanità



# Finanziato dall'Unione europea NextGenerationEU

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PNRR: M6/C2\_CALL 2022 Full Proposal

Project Code: PNRR-MAD-2022-12376692

Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Positions					
Institution	Division / Research group	Location	Position	From year	To year
University of Messina	Department of Engineering	Messina	Associate Professor	2021	2022
University of Messina	Department of Engineering	Messina	Researcher SENIOR	2018	2021
University of Messina	Department of Engineering	Messina	Researcher JUNIOR	2011	2018
University of Reggio Calabria	Department DIMET of Engineering Faculty	Reggio Calabria	Research Contract	2010	2011
University of Reggio Calabria	Department DIMET of Engineering Faculty	Reggio Calabria	Research fellowship	2009	2010

#### Other awards and honors

Applicant Institution:

She obtained the National Scientific Qualification for full professor on 29 June 2020 in Mathematical Analysis, Probability and Mathematical Statistics.

She obtained the National Scientific Qualification for associate professor on 28 march 2017 in Mathematical Analysis, Probability and Mathematical Statistics.

Award for "Recent developments in Mathematical Sciences "of the Gioenia Academy of Catania 2012

Grant						
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
MUR	University of Messina	2017	PRIN 2017 Title: Nonlinear Di erential Problems via Variational, Topological and Set-valued Methods	Collaborator	76.904,00	https://prin.mur.gov.it /Pages/Index/2
INdam, gnampa	University of Messina	2017	Existence, multiplicity and properties qualitative solutions of nonlinear differential problems.	Collaborator	1.600,00	https://www.altamate matica.it/gnampa/atti vita/progetti-di- ricerca/
INdam, gnampa	University of Messina	2016	Teoria dei punti critici e applicazioni.	Coordinator	1.700,00	https://www.altamate matica.it/gnampa/atti vita/progetti-di- ricerca/
INdam, gnampa	University of Messina	2015	Equazioni differenziali non lineari e applicazioni	Coordinator	1.100,00	https://www.altamate matica.it/gnampa/atti vita/progetti-di- ricerca/
INdAM, GNAMPA	University of Messina	2014	Problemi differenziali non lineari con crescita non standard.	Coordinator	4.900,00	https://www.altamate matica.it/gnampa/atti vita/progetti-di- ricerca/

Mínístero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		****	Finanziato dall'Unione euro NextGenerationEU	pea	
Project Code: PNRR-MAD-2022-12376692	Call section:	Malattie Croniche non	Trasmissibili (MCnT) ad alto impa	tto sui sistem	ii sanitari e
Applicant Institution: Lazio	Applicant/PI 0	Coordinator: VADA	LÀ GIANLUCA		
2.6 Research Collaborators n.	5				
Last Name: Fogolari		Last name at b	pirth:		
First Name: Marta		Gender: F			
Title: Biomarkers analysis	Country of residence: ITALY				
Nationality: italiana		Country of Bir	th: ITALY		
Date of birth: 31/07/1988		Place of Birth:	Livorno		
Official H index (Scopus or Web of Science)	: 11.0				
<b>Scopus Author Id</b> :56672860700	ORCID ID:000	00-0002-0218-5884	4 RESEARCH ID:X-194	5-2019	
Contact address					
Current organisation name: Fondazione Policli	nico Universita	ario Campus Bio-Meo	dico		
Current Department / Faculty / Institute / Lak	poratory nan	ne: UOC di Ortop	edia e Traumatologia		
Street: Via Alvaro del Portillo 200					
Postcode / Cedex: 00128		Town: Roma			
Phone:+393663697588		Phone 2:			
Education / training					
Educational institution and location		Degree	Field of study	From year	To year
Università Campus Bio-Medico di Roma	Ph		Osteo oncological pathology	2021	

			-	
Università Campus Bio-Medico di Roma	PhD	Osteo oncological pathology	2021	0
Policlinico Universitario Campus Bio-Medico di Roma	Specialization / Specializzazione	Clincal Pathology	2014	2019
Università Campus Bio-Medico di Roma	Single-cycle master's degree / Laurea magistrale a ciclo unico	Medicine and Surgery	2007	2013

## **Personal Statement:**

The overall goals of the project is to collect multimodal data of patients affected by LBP to develop an AI system to guide spine care. The researcher will be in charge of analyzing biomarkers. Indeed, biomarkers are biological characteristics that can be used to indicate health or disease. Increasingly, studies suggest that the presence of inflammatory mediators can be measured systemically in the blood. These biomarkers may serve as novel tools for directing patient care.

# **Positions and honors**

Positions					
Institution	Division / Research group	Location	Position	From year	To year
Policlinico Universitario Campus Bio-Medico di Roma	Laboratory Division	Rome, Italy	MD specialized in Clinical Pathology	2020	2022

## Other awards and honors

Mínístero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal			**** * * ***	Finanziat dall'Unic NextGener	<b>to</b> one europ rationEU	ea	
Project Code: PNRR-MAD-2022-12376692 Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e						o sui sistemi sanitari e	
Applicant Institution: Lazio			Applicant/PI Coordinator: VADALÀ GIANLUCA				
Grant							
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed	

0,00

Collaborator

Mínístero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		****	Finanziato dall'Unione euro NextGenerationEU	opea	
Project Code: PNRR-MAD-2022-12376692	Call section:	Malattie Croniche nor	n Trasmissibili (MCnT) ad alto imp	oatto sui sistem	ii sanitari e
Applicant Institution: Lazio	Applicant/PI	Coordinator: VAD	ALÀ GIANLUCA		
2.7 Research Collaborators n.	6 - Under	r 40			
Last Name: RUSSO First Name: FABRIZIO		Last name at Gender: M	birth:		
Title: Clinical data collection		Country of re	sidence: ITALY		
Nationality: Italiana		Country of Bi	rth: ITALY		
Date of birth: 25/06/1988		Place of Birth	: Reggio Calabria		
Official H index (Scopus or Web of Science)	: 16.0				
Scopus Author Id:55220439500	RCID ID:000	00-0002-8566-895	52 RESEARCH ID:K-55	557-2018	
Contact address					
Current organisation name: Fondazione Policli	nico Universita	ario Campus Bio-Me	edico		
Current Department / Faculty / Institute / Lal	poratory nar	me: UOC di Orto	pedia e Traumatologia		
Street: Via Alvaro del Portillo 200					
Postcode / Cedex: 00128		Town: Roma			
Phone:+393493601908		Phone 2:			
Education / training					
Educational institution and location		Degree	Field of study	From year	To year
Campus Bio-Medico University, Rome, Italy	P	hD	Osteo-oncology	2018	2021

Campus Bio-Medico University, Rome, Italy	PhD	Osteo-oncology	2018	2021
Campus Bio-Medico University, Rome, Italy	Specialization / Specializzazione	Orthopedics and Trauma Surgery	2013	2018
Campus Bio-Medico University, Rome, Italy	Single-cycle master's degree / Laurea magistrale a ciclo unico	Medicine	2006	2012

## **Personal Statement:**

The overall goal of the research project is to develop an AI platform for personalized LBP care. The researcher will assist in the multimodal data collection for the development of the AI system and its validation.

# **Positions and honors**



PNRR: M6/C2\_CALL 2022 Full Proposal



# Finanziato dall'Unione europea NextGenerationEU

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Project Code: PNRR-MAD-2022-12376692

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

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	100115

Institution	Division / Research group	Location	Position	From year	To year
Campus Bio-Medico University	MED33 \ Orthopaedics	Rome, Italy	Assistant Professor (RTDA)	2021	2024
Fondazione Policlinico Universitario Campus Bio- Medico	UOC Ortopedia e Traumatologia	Rome, Italy	Orthopaedic and Trauma Surgeon	2018	2022
University of Maryland	R Adams Cowley Shock Trauma Center	Baltimore, Maryland - USA	AOTrauma Fellow	2017	2017
Stanford University	Department of Orthopaedic Surgery	Palo Alto, California - USA	Research Fellow	2013	2013
University of Pittsburgh	Department of Orthopaedic Surgery - Ferguson Laboratory for Orthopaedic and Spine Research	Pittsburgh, Pennsylvania - USA	North America Spine Society (NASS) Research Fellow	2012	2012
AO Research Institute (ARI)	Musculoskeletal Regeneration Program - Intervertebral Disc Regeneration	Davos, Switzerland	Medical Fellow	2011	2011

## Other awards and honors

2019 AOSpine Clinical Fellowship Award

2019 ON/ICORS Education Scholarship

2017 and 2018 American Academy Orthopaedic Surgeons (AAOS) Honorary Mention 2016 AOTrauma Clinical Fellowship Award

2016 2nd Level Scholarship Italian Society Orthopedic and Traumatology (SIOT) 2016 Best Paper Award International Society for the Study of the Lumbar Spine

2015 1st Level Scholarship SIOT

2013 Biospina Award Italian Society Spinal Surgery

2012 North American Spine Society Research Fellowship Award

Grant						
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Italian Workers Compensation Authority (INAIL)	Campus Bio-Medico University of Rome	2021	Development of an innovative, multidisciplinary and integrated approach for workers suffering from degenerative pathologies of the lumbar spine based on advanced technologies, capacity building, and feasibility analysis for the creation of a reference center for prevention, diagnosis, treatment, and professional reintegration (SPINE 4.0)	Collaborator	1.196.000,00	https://www.inail.it/cs /internet/attivita/ricerc a-e- tecnologia/finanziam enti-per-la- ricerca/bando-bric- 2021.html



PNRR: M6/C2\_CALL 2022 Full Proposal



# Finanziato dall'Unione europea NextGenerationEU

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Project Code: PNRR-MAD-2022-12376692

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Italian Minister of Education, University and Research	Campus Bio-Medico University of Rome	2019	Advanced injectable nano- composite biomaterials with dual therapeutic/regenerative behaviors for bone cancer (ACTION).	Collaborator	142.556,00	https://prin.mur.gov.it /Iniziative
Italian National Institute for Insurance against Accidents at Work (INAIL)	Campus Bio-Medico University of Rome	2018	Development of a Multidisciplinary and Integrated Approach, for the management of the worker affected by degenerative spine pathBRIC2018ologies: study of the occupational aspects and an innovative regenerative treatment of the intervertebral disc to favor return to work (ACTIVE).	Collaborator	630.000,00	https://www.inail.it/cs /internet/attivita/ricerc a-e- tecnologia/finanziam enti-per-la- ricerca/bando-bric- 2018.html
European Commission (Horizon 2020)	Campus Bio-Medico University of Rome	2018	Induced pluripotent stem cell-based therapy for spinal regeneration (iPSpine)	Collaborator	557.975,00	https://cordis.europa. eu/project/id/825925
European Commission (Horizon 2020)	Campus Bio-Medico University of Rome	2017	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lumbar SPINE unresponsive to conventional therapy (RESPINE)	Collaborator	331.362,00	https://cordis.europa. eu/project/id/732163/ it

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** * * ***	Finanziato dall'Unione europ NextGenerationEU	pea				
Project Code: PNRR-MAD-2022-12376692	Call section: N	Malattie Croniche non	Trasmissibili (MCnT) ad alto impat	tto sui sisten	ni sanitari e			
Applicant Institution: Lazio	Applicant/PI C	coordinator: VADAL	LÀ GIANLUCA					
2.8 Research Collaborators n. 7 - Under 40								
Last Name: BRUNATO		Last name at b	pirth:					
First Name: DOMINIQUE PIERINA		Gender: F						
Title: Development of AI platforms	Country of residence: ITALY							
Nationality: Italiana		Country of Birt	th: ITALY					
Date of birth: 29/08/1982		Place of Birth:	Vicenza					
Official H index (Scopus or Web of Science):	4.0							
Scopus Author Id:55237740200 O	RCID ID:000	0-0003-3256-4794	RESEARCH ID:AIB-8	573-2022				
Contact address								
Current organisation name: Consiglio Nazionale	e delle Ricerch	e						
Current Department / Faculty / Institute / Lab	oratory nam	e: Istituto di Ling	guistica Computazionale "A. Za	ampolli" (IL	.C)			
Street: Via G. Moruzzi, 1								
Postcode / Cedex: 56124		Town: Pisa						
Phone:+393402356841		Phone 2:						
Education / training								
Educational institution and location		Degree	Field of study	From year	To year			

Educational institution and location	Degree	Field of study	year	To year
University of Siena, Italy	PhD	Linguistics, Cognitive Sciences	2010	2015
University of Siena, Italy	Master's Degree / Laurea Magistrale	Theoretical and Applied Linguistics	2007	2010
University of Padua, Italy	Bachelor Degree / Laurea Triennale	Communication Sciences	2001	2005

#### **Personal Statement:**

Dominique Pierina Brunato as a member of the Italian Natural Language Processing Laboratory (ItaliaNLP Lab) of CNR will provide her expertise on the development of multilingual NLP-based technologies to extract and dynamic structure the linguistic peculiarities and the semantic content embedded in natural language corpora. For the specific scope of the project, she will carry out activities focused on the development and customization of information extraction tools aimed at analyzing the different typologies of healthcare textual resources collected in the project and she will be involved in the development of assessment tools devoted to checking the stylistic form of medical reports and their compliance to the standard way of writing.

## **Positions and honors**

Mínístero della Salute
Direzione generale della ricerca e dell'innovazione in sanità



# Finanziato dall'Unione europea NextGenerationEU

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

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Project Code: PNRR-MAD-2022-12376692

Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Positions					
Institution	Division / Research group	Location	Position	From year	To year
National Research Council (CNR)	Institute of Computational Linguistics ¿A. Zampolli¿	Pisa (Italy)	Research fellow	2014	2021
National Research Council (CNR)	Institute of Computational Linguistics ¿A. Zampolli¿	Pisa (Italy)	Research fellow	2014	2021

## Other awards and honors

2020 Outstanding Paper award for the paper ¿Linguistic Profiling of a Neural Language Model¿ presented at the 28th International Conference on Computational Linguistics (COLING 2020).

2015 Distinguished Young Paper mention award for the paper ¿ISACCO: a corpus for investigating spoken and written language development in Italian school-age children; at the II° Italian Conference on Computational Linguistics (CliC-it).

2010-2013 Phd fellowship sponsored by University of Siena, Italy.

Grant						
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed
Tuscany Region (Progetti Congiunti di Alta Formazione - POR FSE 2014-2020 Asse A ¿ Occupazione).	Institute of Computational Linguistics ¿A. Zampolli¿, CNR, Pisa	2018- 2020	PERFORMA - Personalizzazione di pERcorsi FORMativi Avanzati	Collaborator	37.800,00	http://www.ilc.cnr.it/e n/content/performa- arco-cnr
Tuscany Region (Bando POR FESR 2014-2020)	Institute of Computational Linguistics ¿A. Zampolli¿, CNR, Pisa	2017- 2018	UBIMOL ¿ UBIquitous Massive Open Learning	Collaborator	540,00	https://www.gruppom eta.it/it/ubimol
Tuscany Region (Bando FAR FAS 2014)	Institute of Computational Linguistics ¿A. Zampolli¿, CNR, Pisa	2015- 2017	Social Sensing for breaking news (SMART NEWS)	Collaborator	654.861,00	http://www.ilc.cnr.it/it/ content/smartnew
Minister of University and Research	Institute of Computational Linguistics ¿A. Zampolli¿, CNR, Pisa	2015- 2016	SCRIBE ¿ Short writings, Linguistic simplification, social inclusion: models and applications"	Collaborator	328.500,00	http://www.ilc.cnr.it/it/ content/scribe
Tuscany Region (POR CReO FESR 2007- 2013)	Institute of Computational Linguistics ¿A. Zampolli¿, CNR, Pisa	2013- 2015	"iSLe" (Intelligent Semantic Liquid eBook);	Collaborator	1.038.917,00	http://www.progettois le.it/

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		**** * * ****	Finanziato dall'Unione euro NextGenerationEU	pea		
Project Code: PNRR-MAD-2022-12376692	Call section:	Malattie Croniche non	Trasmissibili (MCnT) ad alto impa	tto sui sisten	ni sanitari e	
Applicant Institution: Lazio	Applicant/Pl	Coordinator: VADA	LÀ GIANLUCA			
2.9 Additional Research Collab	orators n	. 2 - Under 4(	) to hire			
Last Name: MURESU First Name: FRANCESCO		Last name at b Gender: M	irth: MURESU			
Title: Clinical data collection		Country of residence: ITALY				
Nationality: Italiana		Country of Birth: ITALY				
Date of birth: 10/06/1982		Place of Birth: Sassari				
Official H index (Scopus or Web of Science):	1.0					
Scopus Author Id:53983215600 O	RCID ID:000	00-0001-9727-356	B RESEARCH ID:53983	215600		
Contact address						
Current organisation name: Università degli Stu	udi di Sassari					
Current Department / Faculty / Institute / Lab	oratory nar	ne: UOC di Ortop	aedia e Traumatologia			
Street: Viale San Pietro						
Postcode / Cedex: 07100		Town: Sassari				
Phone:+393491023499		Phone 2:				
Education / training						
Educational institution and location		Degree	Field of study	From	To year	

Educational institution and location	Degree	Field of study	From year	To year	
University of Sassari	Specialization / Specializzazione	Orthopedics and Traumatology	2009	2014	
University of Sassari	Single-cycle master's degree / Laurea magistrale a ciclo unico	Medicine and Surgery	2002	2008	

## **Personal Statement:**

The researcher will support clinical data collection for the development of the AI system

# **Positions and honors**

Positions									
Institution	Division / Research group	Location	Position	From year	To year				
University Hospital of Sassari	U.O.C. of the Orthopedic Clinic	Sassari	Orthopedic Medical Director	2020	2022				
U.O.C. Marino Hospital Regina Margherita - ATS	Orthopedics and Traumatology Department	Alghero (SS)	Orthopedic Medical Director	2015	2020				
U.O.C. Single Hospital Alto Vicentino -ULSS 4	Orthopedics and Traumatology Department	Santorso (VI)	Orthopedic Medical Director	2014	2015				

# Other awards and honors

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal			**** **** ****	Finanziat dall'Unic NextGener	<b>to</b> one europ rationEU	ea	
Project Code: P	NRR-MAD-2022-12376692	tion: Malattie Croniche non T	rasmissibili (MCn	T) ad alto impatto	o sui sistemi sanitari e		
Applicant Institution:	Lazio	Applica	Applicant/PI Coordinator: VADALÀ GIANLUCA				
Grant							
Funded by Institution	Researcher inst. where grant is/was performed	Year	Title	Position in Projects	Fund (euro)	Source website grant listed	

Collaborator

0,00

Ministero della Salute Direzione generale della ricerca e dell'innovazione in sanità PNRR: M6/C2_CALL 2022 Full Proposal		****	Finanziato dall'Unione europ NextGenerationEU	oea				
Project Code: PNRR-MAD-2022-12376692	Call section: N	Malattie Croniche non	Trasmissibili (MCnT) ad alto impat	to sui sistem	ii sanitari e			
Applicant Institution: Lazio	Applicant/PI C	coordinator: VADA	LÀ GIANLUCA					
2.10 Additional Research Collaborators n. 3 - Under 40 to hire								
Last Name: GUARNOTTA First Name: UMBERTO	Last name at t Gender: M	birth:						
Title: Development AI algorithms		Country of res	idence: ITALY					
Nationality: Italia		Country of Birth: ITALY						
Date of birth: 31/12/1994		Place of Birth:	Catania					
Official H index (Scopus or Web of Science):	3.0							
Scopus Author Id:57210147872 O	RCID ID:000	0-0003-4768-642	8 RESEARCH ID:AIA-10	)55-2022				
Contact address								
Current organisation name: Università degli stu	di di Messina							
Current Department / Faculty / Institute / Lab	oratory nam	e: Dipartimento	di Ingegneria					
Street: Via Archirafi, 34								
Postcode / Cedex: 90123		Town: Palermo						
Phone:+393485460313		Phone 2:						
Education / training								
Educational institution and location		Degree	Field of study	From year	To year			
Univeristy of Palermo	Ph	D	Mathematics and Computational Sciences	2018	2021			

## Personal Statement:

University of Catania

University of Catania

Thanks to the increase in computational resources and the availability of huge datasets for learning, neural networks have led to new techniques for solving partial differential equations (PDEs). At the same time, some deep neural networks have recently started to be interpreted as nonlinear (partial) differential equations, leading to a new frontier for gaining theoretical knowledge and designing new algorithms for deep learning. The researcher has good knowledge regarding nonlinear partial differential equations that will enable new results of this new connection between applied mathematics and data science.

Master's Degree /

Laurea Magistrale

Bachelor Degree /

Laurea Triennale

Mathematics

Mathematics

# **Positions and honors**

Positions								
Institution	Division / Research group	Location	Position	From year	To year			
University of Palermo	Department of Mathematics and Computer Science	Palermo	Research Fellow	2021	2022			

2016

2013

2018

2016

Mínístero 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-MAD-2022-12376692	Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e				
Applicant Institution: Lazio	Applicant/PI Coordinator: VADALÀ GIANLUCA				

#### Other awards and honors

Grant									
Funded by Institution	Researcher inst. where grant is/was performed		Title	Position in Projects	Fund (euro)	Source website grant listed			
MUR	University of Palermo	2017	Nonlinear Di erential Problems via Variational, Topological and Set-valued Methods	Collaborator	39.357,00	https://prin.mur.gov.it /Pages/Index/2			



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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

# 2.17 Expertise Research Collaborators

Selected pe	Selected peer-reviewed publications of the Research Group / Collaborators										
Collaborato	Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*		
GUARNOTTA UMBERTO	Singular Quasilinear Elliptic Problems With Convection Terms	Article	NOT_FO UND	2425	2022	10.1063/5.0082998		0	С		
GUARNOTTA UMBERTO	Singular quasilinear convective elliptic systems in R <sup>N</sup>	Article	741-756	11	2022	10.1515/anona-2021- 0208		0	0		
BRUNATO DOMINIQUE PIERINA	Linguistically-Based Comparison of Different Approaches to Building Corpora for Text Simplification: A Case Study on Italian	Article	1-19	13	2022	10.3389/fpsyg.2022.707 630	35350726	0	F		
Fogolari Marta	SARS-CoV-2 AY.4.2 variant circulating in Italy: Genomic preliminary insight	Article	1689- 1692	94	2021	10.1002/jmv.27451		1	0		
RUSSO FABRIZIO	Artificial Intelligence and Computer Aided Diagnosis in Chronic Low Back Pain: A Systematic Review	Review	5971	19(10)	2022	10.3390/ijerph19105971		0	С		
d'agui' Giuseppina	Two positive solutions for a nonlinear parameter- depending algebraic system	Article	10-17	14	2021	10.14658/pupj-phrg- 2021-2-3		3	0		
GUARNOTTA UMBERTO	Infinitely many solutions to singular convective Neumann systems with arbitrarily growing reactions	Article	849-863	271	2021	10.1016/j.jde.2020.09.02 4		0	0		
BRUNATO DOMINIQUE PIERINA	A NLP-based stylometric approach for tracking the evolution of L1 written language competence	Article	71-105	13(1)	2021	https://doi.org/10.17239/j owr-2021.13.01.03		2	0		
Fogolari Marta	High value of mid-regional proadrenomedullin in COVID- 19: A marker of widespread endothelial damage, disease severity, and mortality	Article	2820- 2827	93	2021	10.1002/jmv.26676	33200824	12	0		
RUSSO FABRIZIO	Artificial intelligence and computer vision in low back pain: A systematic review	Review	10909	18	2021	10.3390/ijerph18201090 9	34682647	3	С		
DORIA CARLO	Efficacy and safety of minimally invasive axial presacral I5-s1 interbody fusion in the treatment of lumbosacral spine pathology: A retrospective clinical and radiographic analysis	Article	1-9	91	2020	10.23750/abm.v91i14- S.11103	33559626	0	L		
GUARNOTTA UMBERTO	On a Singular Robin Problem with Convection Terms	Article	895-909	20	2020	10.1515/ans-2020-2093	NOT_FOUND	3	0		

Sent date: 08/07/2022 16.45



PNRR: M6/C2\_CALL 2022 Full Proposal



Applicant/PI Coordinator:

# **Finanziato** dall'Unione europea

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NextGenerationEU

Project Code: PNRR-MAD-2022-12376692

**Applicant Institution:** Lazio Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e VADALÀ GIANLUCA

Collaborato	Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**
Venturi Giulia	Waiting time information in the Italian NHS: A citizen perspective	Article	796-804	124	2020	10.1016/j.healthpol.2020 .05.012	32624247	
BRUNATO DOMINIQUE PIERINA	Profiling-UD: a Tool for Linguistic Profiling of Texts	Article	7145- 7151	-	2020	10.5281/zenodo.655308 9		14
Fogolari Marta	Best diagnostic accuracy of sepsis combining SIRS criteria or qSOFA score with Procalcitonin and Mid- Regional pro-Adrenomedullin outside ICU	Article	16605	10	2020	10.1038/s41598-020- 73676-у	33024218	11
Fogolari Marta	Preservation of microvascular barrier function requires CD31 receptor-induced metabolic reprogramming	Article	3595	11	2020	10.1038/s41467-020- 17329-8	32681081	ę
GUARNOTTA UMBERTO	Multiple nodal solutions to a Robin problem with sign- changing potential and locally defined reaction	Article	269-294	30	2019	10.4171/RLM/847		10
RUSSO FABRIZIO	The Role of Type i Diabetes in Intervertebral Disc Degeneration	Article	1177- 1185	44	2019	10.1097/BRS.00000000 00003054	30973512	18
Venturi Giulia	Inferring quantitative typological trends from multilingual treebanks	Article	33	18	2019	10.1418/95391		2
DORIA CARLO	Minimally Invasive Far Lateral Lumbar Interbody Fusion: A Prospective Cohort Study	Article	512-516	8	2018	10.1177/2192568218756 908	30258758	1
BRUNATO DOMINIQUE PIERINA	Is this sentence difficult? Do you agree?	Article	2690- 2699	-	2018	10.18653/v1/D18-1289		15
Fogolari Marta	Distribution and characterization of Shiga toxin converting temperate phages carried by Shigella flexneri in Hispaniola	Article	321-328	65	2018	0.1016/j.meegid.2018.07 .038	75254	
DORIA CARLO	Intradural lumbar disc herniations associated with cauda equina syndrome:	Review	167-172	30	2017	10.23736/S0394- 9508.17.04638-1		(

383-397

E193-

E201

447

42

2017

2017

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00001762

10.1016/j.jmaa.2016.10.

10.1097/BRS.0000000

p-Laplacian

Report of two cases and review of literature Positive solutions for a

discrete two point nonlinear boundary value problem with

Biomechanical Evaluation of

Transpedicular Nucleotomy with Intact Annulus Fibrosus

D'AGUI' GIUSEPPINA

RUSSO

FABRIZIO

Article

Article

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# **Finanziato** dall'Unione europea

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Lazio

Applicant Institution:

Applicant/PI Coordinator: VADALÀ GIANLUCA

Collaborato	Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
d'agui' Giuseppina	Constant sign solutions for parameter-dependent superlinear second-order difference equations	Article	649-659	21	2015	10.1080/10236198.2015. 1045891		10	0
RUSSO FABRIZIO	Intervertebral disc regeneration: From the degenerative cascade to molecular therapy and tissue engineering	Article	679-690	9	2015	10.1002/term.1719	23512973	68	0
MURESU FRANCESCO	Dynamic Stabilization of the Lumbar Spine: Current Status of Minimally Invasive and Open Treatments	Book chapter	209-227		2014	10.1007/978-1-4471- 5280-4		1	F
MURESU FRANCESCO	Dynamic Stabilization of the Lumbar Spine: Current Status of Minimally Invasive and Open Treatments	Book Chapter	209-227		2014	10.1007/978-1-4471- 5280-4_10		0	0
d'agui' Giuseppina	Variational methods on finite dimensional Banach spaces and discrete problems	Article	915-939	14	2014	10.1515/ans-2014-0406		40	0
Venturi Giulia	Assessing document and sentence readability in less resourced languages and across textual genres	Article	30	2	2014	10.1075/itl.165.2.03del		15	F
Venturi Giulia	T2K: a System for Automatically Extracting and Organizing Knowledge from Texts	Article	8	-	2014	10.5281/zenodo.655283 9		0	F
MURESU FRANCESCO	The corpectomy using minimally invasive access in thoracolumbar fractures	Article	44621	1 (3)	2012	10.4172/2161- 0533.1000108		0	0
BRUNATO DOMINIQUE PIERINA	Does gender make a difference? Comparing the effect of gender on children's comprehension of relative clauses in Hebrew and Italian	Article	1053- 1069	122	2012	10.1016/j.lingua.2012.02 .007		80	0
DORIA CARLO	Nucleus disc arthroplasty with the NUBAC¿ device: 2-year clinical experience	Article	S36-S40	20	2011	10.1007/s00586-011- 1752-3	21416380	16	L
MURESU FRANCESCO	Skeletal fragility definition	Short Survey	41579	8(2)	2011		22461808	30	0
d'agui' Giuseppina	Three solutions to a perturbed nonlinear discrete Dirichlet problem	Article	594-601	375	2011	10.1016/j.jmaa.2010.09. 050		39	0
Venturi Giulia	The BioLexicon: A large-scale terminological resource for biomedical text mining	Article	29	12	2011	10.1186/1471-2105-12- 397	21992002	40	F





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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Collaborato	Title	Туре	Pag	Vol	Year	DOI	PMID	Cit.**	P.*
DORIA CARLO	Percutaneous techniques in the treatment of osteoporotic, traumatic and neoplastic fractures of thoraco-lumbar spine: Our institutional experience	Article	1136- 1139	41	2010	10.1016/j.injury.2010.09. 032	20951992	9	F

\* 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)?	
Does your research involve the use of human embryos?	
Does your research involve the use of human foetal tissues / cells?	
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?	
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?	
Does your research deal with endangered fauna and/or flora and/or protected areas?	
Does your research involve the use of elements that may cause harm to humans, including research staff?	
7. DUAL USE	
Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an	No

Ministero della Salute
Direzione generale della ricerca e dell'innovazione in sanità

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# Finanziato dall'Unione europea NextGenerationEU

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Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

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Applicant/PI Coordinator: VADALÀ GIANLUCA

## 8. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

Could your research raise concerns regarding the exclusive focus on civil applications?

## 9. MISUSE

Does your research have the potential for misuse of research results?

## 10. OTHER ETHICS ISSUES

Are there any other ethics issues that should be taken into consideration? Please specify

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.

# 4 - Call-specific questions

## Eligibility

I acknowledge that I am aware of the eligibility requirements for applying as specified in the Call-PNRRXXX\_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.

I confirm that the proposal that I am about to submit draws substantially don't repeat on an existing or recently finished GRANT funded.

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.

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?

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 Project Code:
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 Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

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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?

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?

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

This project aims to develop and establish the clinical use of a novel Artificial Intelligence (AI)-based platform to assess the risk and the progression of low back pain (LBP), promoting patient-specific personalized and enhanced spine care. The project will establish an evidence-based approach to collecting multifactorial data in patients affected by LBP. A multidimensional strategy using different AI technologies will be used to assess the multifactorial etiology of LBP, distinguish specific LBP phenotypes and provide a Decision Support System (DSS) for the prediction of a specific treatment The specific aims are to: 1) Validate a platform for the physician to estimate the risk of LBP onset, predict outcomes and foster personalized LBP care based on the patients; phenotypes; 2) Develop a platform for patients for the evaluation of the progression of LBP and the effect of treatments; 3) Test the platforms in the real-world clinical setting and compare with the standard cares.

## Background / State of the art

LBP is a major global problem that affects more than 500 million people, approximately 7.5% of the world population. Since the first Global Burden of Disability study in 1990, LBP has been considered the leading global cause of disability. Nowadays, diagnosing and treating LBP requires and is based on several data, such as radiological images, patient-reported outcome evaluation questionnaires, biomarkers, etc. Therefore, the ultimate therapeutic decision is often guided by elaborating a vast body of information using an algorithmic approach. However, given the contribution of multiple factors in the definition of LBP, a personalized, multidimensional, and precision medicine approach is urgently needed to improve the care and outcomes of patients with LBP. In the last decade, the use of AI is being increasingly investigated in medical research. To date, AI-based methods have been proposed in the LBP prevention and management framework on different types of data. Although the recent advances in the application of AI in LBP are noteworthy, some concerns still exist. This project aims to integrate several heterogeneous data sources into an AI model and developing two interfaces to improve the disease management of both the patients and the physicians. An innovative, multidisciplinary and integrated tool for managing LBP will be created by considering the individuals genotypes, phenotypes, occupational/environmental stressors and socioeconomic and behavioral characteristics.

## Description and distribution of activities of each operating unit

The consortium comprises a multidisciplinary team with expertise in the care of LBP and the development of AI tools and their translation to the clinical setting.

UO1 will be the coordinator of the project and together with UO2 they will guarantee access to a large number of patients and multimodal clinical data. Data regarding the phenotypes a d genotypes of LBP patients will be analyzed at UO1 thanks

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to a multidisciplinary team including the Laboratory Divsion. Furthermore, both UO1 and UO2 will carry out the data labeling phase, necessary for training the algorithms and the validation of the AI system.

UO3 will carry out the feature extraction phase on image processing and textual data. It will work on the data fusion and the feature selection phases. It will develop the IT infrastructure to store the data collected and they will be responsible for the development of the Explainable, the phenotyping analysis and the validation of the platform.

UO4 will help developing the AI algorythms given its expertise in artificial neural networks.

# 5.4 Specific Aims and Experimental Design

## Specific aim 1

To develop a virtual platform for the physician to estimate the risk of LBP onset and progression, monitor its course, and identify peculiar patient subgroups based on their treatment-responder profile.

The medical platform will allow the analysis of the development and progression of the pathology. This aim to overcome the limitations related to the poor integration of different medical data, poor interpretability and explainability of AI methods used, and a reduced analysis of the patients' therapeutic process. For these reasons, the AI medical tool will be based on the development and application of data fusion techniques to integrate different data types and acquisition frequency. Both structured data (radiological data, clinical data, and sensor data) and unstructured data (medical report) will be analyzed.

## Specific aim 2

To develop a virtual platform for the physician to estimate the risk of LBP onset and progression, monitor its course, and identify peculiar patient subgroups based on their treatment-responder profile.

The medical platform will allow the analysis of the development and progression of the pathology. This aim to overcome the limitations related to the poor integration of different medical data, poor interpretability and explainability of AI methods used, and a reduced analysis of the patients' therapeutic process. For these reasons, the AI medical tool will be based on the development and application of data fusion techniques to integrate different data types and acquisition frequency. Both structured data (radiological data, clinical data, and sensor data) and unstructured data (medical report) will be analyzed.

## Specific aim 3

To test and validate the performance of the AI platforms in the real-world setting and compare their performance to the established practice.

The team will perform proof-of-concept clinical studies

## Experimental design aim 1

## Multimodal Data collection

Multimodal data on patients affected by LBP will be obtained by previously acquired databases of clinical trials carried out at UCBM [1, 2] and in a retrospective review of prospectively collected data.

The prospective study will be conducted at UCBM. Adult patients aged between 18-80 years old with a clinical diagnosis of non-specific LBP and candidates either for conservative, surgical or regenerative treatments (allogenic and autologous mesenchymal stem cells) will be included. Exclusion criteria include: trauma, cancer, severe spine deformity, infection, or previous spine surgery. All patients will be asked for written informed consent for participation in the study. Once included, patients will undergo a multidimensional evaluation to identify data elements characterizing important phenotypic features determining LBP (analysis of lifestyle, occupational, environmental, socio-economic, and behavioral features; physical examination; clinical imaging; biomarkers) at timepoint 0, 1, 3 and 6 months.

Feature extraction from different medical sources

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With respect to reports from EMG, MRI, X-Ray, PE and Medical History, AI technologies based on NLP and Machine Learning will be developed to extract relevant information [3,4]. The information will be codified in a vector, where each component identifies the presence (or absence) of elements characterizing important features determining LBP, which are defined by physicians. In particular, the information extraction tool will be implemented as a supervised entity classifier that, given a set of features and a training corpus, creates a statistical model using the feature statistics extracted from the training corpus. The classifier analyses the words of a new text to verify the presence or absence of a specific entity. The training corpus will be produced by physicians during the Data collection phase, who will annotate the presence of specific entities. The feature vector extracted from the text will be combined with the vectors extracted from the other modalities. They will represent the input of the Explainable (DSS) for the automated detection and prediction of treatment. Find and characterize distinct LBP phenotypes and develop an Explainable DSS for the automated detection and prediction of treatment.

Patient data extracted from the different sources will be concatenated to obtain the feature space representation of the patient. Techniques of Time Series analysis will be used, being the patient representation composed of time-series observations. We will develop a type of clustering or phenotyping over time in which patients are grouped based on similarity of future outcomes, rather than on similarity of observations. The combination of techniques of supervised feature selection such as Relief, Fisher score, Correlation-based feature selection, and Fast correlation-based filter will be used to detect the best representation. Furthermore, we will use a developed simultaneous feature selection and clustering algorithm to confirm the characterization of the identified phenotypes as well as to detect possible sub phenotypes [5]. Algorithms of Machine Learning and Deep Learning for forecasting time series will be investigated and tested to build the classifier to predict the correct treatment. The DSS will be based on classifier and on results of phenotyping. For this scope, the DSS will be based on methods and approaches of the Explainable Artificial Intelligence such as attention mechanism and/or feature importance estimation algorithms to physicians the explanation of the decision made by the DSS [6]. Cross validation (K-fold and leave one-out) with and without data augmentation techniques will be used to archive the DSS performance. All algorithms will be implemented in the Python programming language. The performance in terms of accuracy, sensitivity and precision will be calculated.

#### Experimental design aim 2

ERRATA CORRIGE of Specific aim 2: To develop a virtual platform for the patient, whereby he/she will be aware of the evolution of his/her conditions and the effect of active treatments in real-time. To help the patient be more aware of the evolution of the disease and therapy, an automatic frequently asked questions (FAQ) answering system will be developed. It will support patients by providing the most appropriate answer for their questions typed in natural language in the digital helper. The system, offering information about their pathology and possible treatments, will improve patients awareness of their health condition and therapies.

Question Answering (QA) is typically addressed by relying on NLP systems able to search for the most suitable answer to a question from a collection of textual documents. However, considering the context of the project, QA will be implemented as a Frequent Question Answering (FAQ) system that seeks the most suitable answer for a question from a predefined and validated set of question-answer pairs uploaded on the system. Precisely, FAQ answering first matches the query typed by the user with the most similar question in the predefined set; then, it shows the answer associated with the selected question to the user. If there is no match between the users query and the questions in the set, the user request is answered by a healthcare expert to guarantee the highest possible accuracy of the answer.

The FAQ answering system for QA developed in the project thus comprises two main phases. In the first phase, the system performs a linguistic analysis of the users question using the linguistic annotation pipeline developed at the Institute of Computational Linguistics "A. Zampolli" (ILC-CNR). This step is meant to acquire the underlying linguistic structure of the question, and it creates the premises for automatic knowledge extraction. In the second phase, FAQ answering computes the semantic similarity between the users query and the questions uploaded on the system to find the most appropriate answer. Currently, the uploaded question-answers comprise FAQs referring to therapies and hospital services dealing with

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LBP. The set also includes some of its possible paraphrases to improve system robustness for each question. The methodology for computing semantic similarity between questions exploits distributional semantics models based on DL approaches. Specifically, the model builds a n-dimension vector for each question, creating its semantic representation. The similarity between questions is measured by computing the cosine distance between the vector of the user¿s question and the vector of the questions uploaded on FAQ answering.

## Experimental design aim 3

The clinical partners will perform a proof-of-concept study to test and validate the performance of the AI platforms in the real-world setting and compare their performance to the established practice.

To evaluate the XAI multimodal platform as a real support to clinical activity, we will develop an experimental test that aims to evaluate the efficacy of the proposed system. In this experimental setting, several stakeholders (physicians and experts of LBP working in different centers) will blindly evaluate a data set of patients for which the most suitable therapy is known. They will first be asked to annotate with labels the proposed therapy based on the data visualization without the support of the platform. After one month (at least), to avoid bias, the same experts will be asked to annotate the support of the platform in the decision making process.

Next, to analyze this experiment, we will compare the labels provided by physicians in the two phases of the experiment. The following will then be assessed: (1) the performance of individual physicians; (2) the agreement between them. For the first point, performance in terms of accuracy, sensitivity and precision will be calculated. For the second point, several measures of agreement among physicians such as Cohen's Kappa and overall agreement will be calculated. In order to assess whether using the algorithm produces more standardized reports, a system able to compare the stylistic form of different reports will be developed. The system will rely on NLP-based technologies. Specifically, we will use Profiling-UD, a linguistic profiling system described by Brunato et al. (40) that implements a set of rules to extract and quantify the linguistic properties of document collections that are used as a text profile. The linguistic properties will include the distribution of a wide range of raw (e.g. sentence length), lexical (e.g. lexical richness), morpho-syntactic (e.g. noun/verb ratio) and syntactic characteristics (e.g. clause types, embedded structures, ordering patterns of syntactic elements). This linguistic profile. The distance between these vector representations will be used to assess the stylistic similarity between reports produced by physicians using (or not) the Al multimodal platform. Such a comparison will highlight specific linguistic usage which do not adhere to a standard way of writing.

#### Picture to support preliminary data

Project copy copy.png

#### Hypothesis and significance

We hypothesize that an AI platform can aid in the profiling of different phenotypes of patients affected by LBP and predict outcomes after different treatments based on patients; characteristics supporting the medical decision.

The project will overcome the existing limitations concerning the application of AI to LBP by integrating several heterogeneous data sources into an AI model and developing an interface to improve disease management. The project will expand the available knowledge on LBP by 1) recognizing multidimensional factors (regarding lifestyle, occupational, environmental, socio-economic, behavioral, clinical, imaging, biomarkers, and biosensors features) that may affect the clinical response to treatments fostering personalized patient care, 2) combine different AI technologies to analyze the data and recognize specific LBP phenotypes 3) developing and validating a novel AI platform for the physician to phenotype patients with LBP and predict outcomes, 4) creating an AI patient platform, offering information about their pathology and possible treatments, to improve patients¿ awareness of their health condition and therapies. 5) validate and test the AI platforms in the real-world setting compared to the standard of care.

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# 5.5 Methodologies and statistical analyses

#### Methods of data collection

Study subject confidentiality and welfare will always be maintained as the highest priority. For all work involving data collections of human information, electronic or otherwise, we will adhere to the law laid down in the European Directive 95/46/EEC Patient information will be held anonymous and confidential. The investigator will only use such information for the purpose of conducting the research described in this protocol, and the investigator will not disclose such information to any third party except those of his/her colleagues and employees who are assisting in the conduct of the study and who are bound by the obligations of confidentiality.

- PROMs: lifestyle, occupational, environmental, socio-economic, behavioral, and clinical features of LBP will be investigated through the administration of globally validated scales such as Oswestry Disability Index (ODI), visual analogue scale (VAS), short form-36 (SF-36), and Becks Depression Inventory (BDI), Work Ability Index (WAI), WHO Well Being Index, Pittsburgh Sleep Quality Index (PSQI).

- Medical history

- Physical examination (PE) notes

- X-Ray imaging: Meyerding classification for spondylolisthesis. Disc height (DH).

- Magnetic resonance imaging (MRI): modified Pfirrmann grading system for the severity of IDD. The presence of a disc bulge, protrusion, herniation, or sequestration will be assessed at T2 images and its location. Radicular compression will be classified as `contact, `displacement, or `compression, depending on their extent. The severity of stenosis will be assessed on the 7-grade Schizas classification. Facet arthropathy. Modic changes.

- Biomarkers: linflammatory, structural, angiogenic and pain mediators as well as growth factors by targeted proteomics ELISA and Luminex technologies will be assessed

- Electromyography (EMG): normal results or the presence of either an acute or chronic neuropathy with corresponding nerve root will be recorded.

## Statistic plan

All statistical analyses will be performed using SAS® (SAS Institute, Cary, NC, USA). All confirmatory statistical tests will be analyzed using 2-sided significance tests at the 0.05 alpha level. P-values will be presented to 3 decimal places.

#### **Statistical analysis**

The normality of data distribution will be assessed upon confirmation of the central limit theorem and determined with the Wilk-Shapiro text. All continuous datapoints will be expressed as the arithmetic mean ± standard deviation. For categorical data, proportions will be illustrated. To analyze intergroup differences, a two-way ANOVA will be performed to test for statistical significance with Dunnetts and Tukeys post-tests for multiple comparisons to evaluate continuous outcome measures changes from baseline to each follow-up timepoints. For categorical data, Chi square will be performed. Furthermore, within each group, outcome measure differences between timepoints in the same individuals will be evaluated using the paired t test for continuous outcomes and Chi square for categorical outcomes. The correlation between multiple continuous and categorical data will be evaluated using multiple linear regression and multiple logistic regression at each timepoint, respectively. Statistical analysis will be conducted using the STATA software (v. 17.0, Statacorp). A p value < 0.05 will be considered statistically significant.

#### Timing of analysis data

The study duration is 24 months. The enrollment in the prospective study will start after ethical approval at M3 till M18. Follow up period will be up to 6 months after treatment and will last until M24. All patients will be assessed pretreatment

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(M0), 1 (M1), 3 (M3) and 6 (M6). In addition, extra visits will be scheduled upon patients clinical needs. Data will be recollected at each planned visit. Biostatistical analysis and dissemination will be carried out between M20 and M24

# 5.6 Expected outcomes

#### Aim 1

Following data collection, we expect to own multidimensional information from a significantly numerous sample size of patients with diverse LBP presentation, intensity, pathophysiological contributors, and proposed treatments. We expect to obtain data on at least 70 patients treated with regenerative treatments, 200 patients treated with conservative treatments and 100 patients treated with surgery. This will allow us to provide a wide dataset for subsequent feature extraction, algorithm analysis and further elaboration for the development of the AI tool. After the development of the feature extraction algorithms, we expect to have all the necessary tools to represent and identify the different phenotypes in correlation with the proposed treatments. In addition, we expect to be able to define a standard protocol for the collection and analysis of multimodal data. Selection of features identifying changes in the series dynamics with respect to medical diagnosis and phenotyping. Development of an Explainable Decision Support System for the detection and prediction of medical treatments.

#### Aim 2

The development of the FAQ answering system is aimed at supporting a high-quality human-computer interaction thus enabling the patients to have personalized assistance. Specifically, we expect that the virtual platform based on NLP technologies will allow patients to be more aware of the evolution of her/his condition and the therapy she/he is following.

#### Aim 3

The validation of the physician platform is used for identifying the most appropriate treatment for the patient. It will involve the results of phenotyping and it will support physician decision-making through a high degree of explainability of the DSS results.

## 5.7 Risk analysis, possible problems and solutions

If few data will be collected during the data collection phase, Data Augmentation and Data Generation techniques will be exploited to create synthetic data.

# 5.8 Significance and Innovation

The project is expected to significantly expand knowledge on how LBP is generated, propagated, and treated. The project aims to establish a significant contribution to the development of evidence-based, multidimensional, patient-centered care for LBP. It may potentially revolutionize the treatment of patients affected, who are frequently dissatisfied due to poorly individualized and symptom-oriented therapies. Using AI and the identification of multiple LBP phenotypes, we will be able to 1) assess the risk of onset or progression and 2) indicate the most appropriate treatment strategy for every specific patient, 3) monitor the clinical course, and possibly 4) intervene to adjust it whenever ineffective and 5) foster prevention strategies before onset. The project will provide novel insights into LBP pathophysiology and pose a new basis for the future treatment of this pandemic condition decreasing the socio-economic burden on the National Health System.

## 5.9 Bibliography

 Efficacy of Intradiscal Injection of Autologous BM-MSC in Worker Patients Affected by Chronic LBP Due to Multilevel IDD (ACTIVE). ClinicalTrials.gov Identifier: NCT04759105 [Available from: https://clinicaltrials.gov/ct2/show/NCT04759105.
 Efficacy of Intradiscal Injection of Autologous BM-MSC in Subjects With Chronic LBP Due to Multilevel Lumbar IDD

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(DREAM). ClinicalTrials.gov Identifier: NCT05066334 [Available from: https://clinicaltrials.gov/ct2/show/NCT05066334. 3. Matthew N. O. Sadiku, Omobayode I. Fagbohungbe, and Sarhan M. Musa (2020), Artificial Intelligence in Healthcare: An Overview. In: International Journal of Engineering Research and Advanced Technology (IJERAT), 6(12), DOI: 10.31695/IJERAT.2020.3670.

4. Kamal Jain and Vishal Prajapati (2021), NLP/Deep Learning Techniques in Healthcare for Decision Making. In: Primary Health Care, 11(3, 373)

5. Merone, Mario, et al. "Discovering COPD phenotyping via simultaneous feature selection and clustering.(BIBM). IEEE,2018.

6. Samek, W., et al.(2017). Explainable artificial intelligence: Understanding, visualizing and interpreting deep learning models. arXiv preprint arXiv:1708.08296.

# 5.10 Timeline / Deliverables / Payable Milestones

The experimental work has been divided in 3 Work Packages (WPs) corresponding to the different Specific Aims of the proposed research and resulting from the integrated collaboration of units. The WPs are divided in Tasks (T).

WP1

- T1.1 Ethics and multimodal data collection (M1 -M20)
- T1.2 Development and validation of feature extraction algorithms (M2-M9)
- T1.3 Phenotypes analysis (M7 M14)
- T1.4 Development of DSS (M12, M18)
- D1.1 Ethical approval (M3)
- D1.2 Report on the prospective clinical study (21)
- D1.3 Report of feature extraction algorithms (M8)
- D1.4 DSS Algorithm software (M12)

WP2

- T2.1 Collection of a dataset composed of question-answer pairs and its multi-level linguistic annotation (M1-M6)
- T2.2 Development of the FAQ answering system (M6-M18)
- D2.1 Dataset of linguistically annotated question-answer pairs (M6)
- D2.2 FAQ answering system algorithm (M14)

#### WP3

T3.1 Validation of DSS and medical interaction (M12 - M24) D3.1 Evaluation report of DSS (M18)

## Milestones 12 month

- All patients recruited
- Release Feature Extraction Algorithms
- Software in python code and report of feature extraction algorithms for image data
- Midterm presentation of innovation activities
- Technical report concerning the development and application of clustering and feature selection techniques for phenotyping analysis.
- Dataset of question-answer pairs

#### **Milestones 24 month**

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- Closing meetings

- FAQ answering system algorithm

- Release of validation phase of DSS

## Gantt chart

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## 5.11 Equipment and resources available

## **Facilities Available**

- UCBM is an internationally-renowned center of education, health services and scientific research. The close link among the Departments of Medicine (UCBM-ORTO) and Engineering (UCBM-ENG) and the modern hospital provide an optimal environment to develop and apply patient-oriented technologies, and to perform multidisciplinary preclinical and clinical research. The UCBM Spine Clinic is dedicated to the conservative and surgical care of more than 1000 patients affected by LBP every year adopting a multimodal approach. The tight coexistence of scientists, radiologists and surgeons provides an optimal environment to develop and apply patient-oriented translational research. Blood draws for biomarker assessment will be performed at the Laboratory of our Institution and later analyzed at our Regenerative Orthopaedics Laboratory. The Engineering department will be involved in this project through the unit of Computer Systems and Bioinformatics. The unit leader in this project will be Mario Merone (RTDA). This unit operates in the field of machine learning and deep learning, with reference to signal and image processing with particular reference to methods and techniques for Decision Support System and Radiomics.

- The Institute of Computational Linguistics Antonio Zampolli of CNR operates in the field of computational linguistics and has a consolidated position as a leading center at both the national and international levels. ILC will participate with the Italian Natural Language Processing Lab that focuses on the development of multilingual NLP-based technologies aimed at extracting and dynamically structuring the linguistic peculiarities and the semantic content embedded in corpora. Therefore, the CNR will specifically focus on the development of information extraction tools to analyze the different typologies of medical textual sources and the FAQ answering system.

- UniSA is an internationally-renowned center of Spine Care highly focused on LBP

- UniME will be involved in mathematical modelling. The research unit has skills and abilities concerning set-valued analysis, calculus of variations, fixed point theory, and application to various types of boundary problems for ordinary differential equations and partial differential equations as well as discrete difference equations. The link between the approximate determination of solutions of differential equations in complex geometries, discrete equations and the use of artificial neural networks runs deep.

## Subcontract

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

Together, the partners provide complementary expertise and technologies to develop novel platforms that will enable and enhance the development of AI technologies for LBP and implement it in the clinic scenario to foster personalized care. UO1 and UO2 are internationally renewed clinical centers for spinal care and with a high volume of patients focus on LBP prevention, diagnosis, and treatment. UO1 with its Laboratory Division masters genotypes and biomarkers analysis. UO3 and UO4 master explainable AI in terms of deep learning, machine learning, computer vision, time series analysis, and process mining.

To facilitate and ensure integration and collaboration will be organized periodic and extraordinary meetings to improve communication between partners by sharing information on individual organizations and contributions to the project.

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

#### What is already know about this topic?

The use of AI in spine care has been exploited for different tasks and several algorithms have been developed in recent years in order to speed up the diagnostic process and optimize patients recovery. The latest AI improvements allows to develop autonomous and accurate models to provide decision support to the physician.

#### Details on what is already know about this topic

LBP is one of the most frequently observed clinical conditions, and degenerative spine disease seems to be a leading driver of low

back pain. The global prevalence of low back pain increased from 377.5 million in 1990 to 577.0 million in 2017. Medical healthcare is driven by an incredible increase in the amount of data generated through various diagnostic tools and nodes within the healthcare systems. Decisions are based on patterns across these datasets that guide towards the right diagnosis.

Moreover, prognosis healthcare providers utilize these datasets to justify a specific treatment approach. Therefore, the correct

interpretation of these datasets is crucial and directly impacts patient outcomes and the operations of healthcare systems.

#### What this reasearch adds?

The AI system developed will consist of two platforms, one for the patient and the doctor. These will consist of AI technologies that will be used in fusion for the extraction of information related to the progression of the disease, as well as estimate the risk of developing the disease as well as monitoring the patient's response to therapy.

#### Details on what this reasearch adds

In our vision, the treatment of LBP should be tailored in a personalized, multidimensional, holistic, precision medicine framework in

which every contributing aspect needs to be carefully evaluated and addressed. In this proect, we aim to develop an Albased system to integrate all the heterogeneous data generated during managing patients affected with LBP. These will include light phenotyping, data extraction from clinical notes, imaging, and other biomarkers (namely deep phenotyping). This will generate an integrated database through which our AI platform, via the collaborative efforts of the multidisciplinary group in our consortium, aims to recognize different LBP phenotypes and identify which one will benefit more from a specific treatment than others.

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

The project aims to establish a significant contribution to the development of an evidence-based, multidimensional, patientcentered care of LBPI. This approach may potentially revolutionize the treatment of patients affected by this condition and reduce the socio-economic burden for public health.

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

This innovative approach will have a substantial impact on multiple aspects related to LBP with the following objectives: - To assess the risk of LBP, providing continuous, personalized, integrative, and comprehensive care: the AI system outputs will

assist the physicians in recognizing which aspects primarily contribute to LBP in a specific patient. In this way, the proposed treatment will be tailored to each patient to maximize outcomes while reducing associated economic losses and fostering a therapeutic alliance. Indeed, in the framework of continuing individualized LBP care, the direct and indirect costs will be

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Applicant Institution: Lazio	Applicant/PI Coordinator: VADALÀ GIANLUCA	

significantly

reduced for Public Health Systems and patients.

- To develop innovative, precision medicine-driven, effective interventions for LBP.

- To identify new psychosocial, physical, working, economic, and biomechanical factors predictive of a specific outcome or needing a

particular treatment approach.

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Applicant/PI Coordinator:

dinator: VADALÀ GIANLUCA

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# 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	19.000,00	19.000,00	not permitted	0,00
2 Researchers' Contracts	600.000,00	0,00	600.000,00	60,00
3a.1 Equipment (Leasing -	63.000,00	0,00	63.000,00	6,30
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	17.000,00	0,00	17.000,00	1,70
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts *	0,00	0,00	0,00	0,00
5 Patient Costs	110.000,00	0,00	110.000,00	11,00
6 IT Services and Data Bases	25.000,00	0,00	25.000,00	2,50
7 Travels	29.000,00	0,00	29.000,00	2,90
8 Publication Costs	37.000,00	0,00	37.000,00	3,70
9 Dissemination	29.000,00	0,00	29.000,00	2,90
10 Overheads *	70.000,00	0,00	70.000,00	7,00
11 Coordination Costs	20.000,00	0,00	20.000,00	2,00
Tota	1.019.000,00	19.000,00	1.000.000,00	100,00

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

Report the Co-Funding Contributor:

Budget Justification		
1 Staff Salary	Pro-quota salary of personel involved in the project	
2 Researchers' Contracts	New contracts for personal involved in the project	
3a.1 Equipment (Leasing - Rent)	Work stations	
3a.2 Equipment (buying)		
3b Supplies	Consumables necessary for project activities	
3c Model Costs		

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4 Subcontracts	
5 Patient Costs	Orthopedic visits and clinical exams
6 IT Services and Data Bases	Software Licenses
7 Travels	Conferences
8 Publication Costs	Open access publications on high impact peer reviewed journals
9 Dissemination	National and international conferences
10 Overheads	Administrative costs
11 Coordination Costs	Shipping costs, Coordination meetings

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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

# Proposed total budget UO1 Institution: Fondazione Policlinico Universitario Campus Bio-Medico (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	10.000,00	10.000,00	not permitted	0,00
2 Researchers' Contracts	240.000,00	0,00	240.000,00	60,00
3a.1 Equipment (Leasing - Rent)	10.000,00	0,00	10.000,00	2,50
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	2.000,00	0,00	2.000,00	0,50
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts	0,00	0,00	0,00	0,00
5 Patient Costs	70.000,00	0,00	70.000,00	17,50
6 IT Services and Data Bases	5.000,00	0,00	5.000,00	1,25
7 Travels	8.000,00	0,00	8.000,00	2,00
8 Publication Costs	9.000,00	0,00	9.000,00	2,25
9 Dissemination	8.000,00	0,00	8.000,00	2,00
10 Overheads	28.000,00	0,00	28.000,00	7,00
11 Coordination Costs	20.000,00	0,00	20.000,00	5,00
Total	410.000,00	10.000,00	400.000,00	100,00

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Applicant/PI Coordinator: VADALÀ GIANLUCA

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Budget Justification		
1 Staff Salary	Pro-quota salary of person involved in the project.	
2 Researchers' Contracts	New contracts of personal involved in the project to be hired	
3a.1 Equipment (Leasing - Rent)	Work stations	
3a.2 Equipment (buying)		
3b Supplies	Consumable necessary for project activities	
3c Model Costs		
4 Subcontracts		
5 Patient Costs	Orthopedic visits and clinical exams	
6 IT Services and Data Bases	Software licenses	
7 Travels	Travels for project meeting and international conferences and symposia.	
8 Publication Costs	Costs for project open access journal publications.	
9 Dissemination	Costs for participation to scientific conferences for results dissemination.	
10 Overheads	Costs requested from institutions.	
11 Coordination Costs	Costs for projects meeting and samples shipments.	

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 Applicant Institution:
 Lazio
 Applicant/PI Coordinator:
 VADALÀ GIANLUCA

# Proposed total budget UO2 Institution: Università degli Studi 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	2.000,00	2.000,00	not permitted	0,00
2 Researchers' Contracts	120.000,00	0,00	120.000,00	60,00
3a.1 Equipment (Leasing - Rent)	3.000,00	0,00	3.000,00	1,50
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	5.000,00	0,00	5.000,00	2,50
3c Model Costs	0,00	0,00	0,00	0,00
4 Subcontracts	0,00	0,00	0,00	0,00
5 Patient Costs	40.000,00	0,00	40.000,00	20,00
6 IT Services and Data Bases	0,00	0,00	0,00	0,00
7 Travels	5.000,00	0,00	5.000,00	2,50
8 Publication Costs	8.000,00	0,00	8.000,00	4,00
9 Dissemination	5.000,00	0,00	5.000,00	2,50
10 Overheads	14.000,00	0,00	14.000,00	7,00
11 Coordination Costs	not permitted	not permitted	not permitted	0,00
Total	202.000,00	2.000,00	200.000,00	100,00

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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Call section: Malattie Croniche non Trasmissibili (MCnT) ad alto impatto sui sistemi sanitari e

Budget Justification		
1 Staff Salary	Pro-quota salary of person involved in the project.	
2 Researchers' Contracts	New contracts of personal involved in the project for both declared researchers to higher and person to be recruited.	
3a.1 Equipment (Leasing - Rent)	Work stations	
3a.2 Equipment (buying)		
3b Supplies	Consumable necessary for project activities	
3c Model Costs		
4 Subcontracts		
5 Patient Costs	Orthopedic visits and clinical exams	
6 IT Services and Data Bases	Software licenses	
7 Travels	Travels for project meeting and international conferences and symposia.	
8 Publication Costs	Costs for project open access journal publications.	
9 Dissemination	Costs for participation to scientific conferences for results dissemination.	
10 Overheads	Costs requested from institutions.	
11 Coordination Costs		

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 Applicant Institution:
 Lazio
 Applicant/PI Coordinator:
 VADALÀ GIANLUCA

# Proposed total budget UO3 Institution: Consiglio Nazionale delle Ricerche (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	5.000,00	5.000,00	not permitted	0,00
2 Researchers' Contracts	120.000,00	0,00	120.000,00	60,00
3a.1 Equipment (Leasing - Rent)	25.000,00	0,00	25.000,00	12,50
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	5.000,00	0,00	5.000,00	2,50
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	10.000,00	0,00	10.000,00	5,00
7 Travels	8.000,00	0,00	8.000,00	4,00
8 Publication Costs	10.000,00	0,00	10.000,00	5,00
9 Dissemination	8.000,00	0,00	8.000,00	4,00
10 Overheads	14.000,00	0,00	14.000,00	7,00
11 Coordination Costs	not permitted	not permitted	not permitted	0,00
Total	205.000,00	5.000,00	200.000,00	100,00

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Applicant/PI Coordinator: VADALÀ GIANLUCA

Budget Justification		
1 Staff Salary	Pro-quota salary	
2 Researchers' Contracts	New contracts of personal involved in the project for both declared researchers to higher and person to be recruited.	
3a.1 Equipment (Leasing - Rent)	Computer equipment	
3a.2 Equipment (buying)		
3b Supplies	Consumable necessary for project activities	
3c Model Costs		
4 Subcontracts		
5 Patient Costs		
6 IT Services and Data Bases	Software licenses	
7 Travels	Travels for project meeting and international conferences and symposia.	
8 Publication Costs	Costs for project open access journal publications.	
9 Dissemination	Costs for participation to scientific conferences for results dissemination.	
10 Overheads	Costs requested from institutions.	
11 Coordination Costs		

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 Applicant Institution:
 Lazio
 Applicant/PI Coordinator:
 VADALÀ GIANLUCA

# Proposed total budget UO4 Institution: Università degli studi di Messina (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	2.000,00	2.000,00	not permitted	0,00
2 Researchers' Contracts	120.000,00	0,00	120.000,00	60,00
3a.1 Equipment (Leasing - Rent)	25.000,00	0,00	25.000,00	12,50
3a.2 Equipment (buying)	0,00	0,00	0,00	0,00
3b Supplies	5.000,00	0,00	5.000,00	2,50
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	10.000,00	0,00	10.000,00	5,00
7 Travels	8.000,00	0,00	8.000,00	4,00
8 Publication Costs	10.000,00	0,00	10.000,00	5,00
9 Dissemination	8.000,00	0,00	8.000,00	4,00
10 Overheads	14.000,00	0,00	14.000,00	7,00
11 Coordination Costs	not permitted	not permitted	not permitted	0,00
Total	202.000,00	2.000,00	200.000,00	100,00

<i>Mínístero della Salute</i>	Finanziato
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Applicant Institution: Lazio

Applicant/PI Coordinator: VADALÀ GIANLUCA

Budget Justification	
1 Staff Salary	Pro quota salary
2 Researchers' Contracts	New contracts of personal involved in the project for both declared researchers to higher and person to be recruited.
3a.1 Equipment (Leasing - Rent)	Computer hardware and software
3a.2 Equipment (buying)	
3b Supplies	Consumables necessary for project activities
3c Model Costs	
4 Subcontracts	
5 Patient Costs	
6 IT Services and Data Bases	Software licenses
7 Travels	Travels for project meeting and international conferences and symposia.
8 Publication Costs	Costs for project open access journal publications.
9 Dissemination	Costs for participation to scientific conferences for results dissemination.
10 Overheads	Costs requested from institutions.
11 Coordination Costs	



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Applicant/PI Coordinator: VADALÀ GIANLUCA

# Principal Investigator Data

Cognome: VADALÀ Nome: GIANLUCA Genere: M Codice fiscale: VDLGLC79C14I874J Documento: Carta d'identità, Numero: AU7552603 Data di nascita: 14/03/1979 Luogo di nascita: Soveria Mannelli Provincia di nascita: CZ Indirizzo lavorativo: Via Alvaro del Portillo 200 Città: Roma CAP: 00128 Provincia: RM Email: g.vadala@gmail.com Altra email: g.vadala@policlinicocampus.it Telefono: +393389831497 Qualifica: Ricercatore Universitario Struttura: Unita Operativa Complessa di Ortopedia e Traumatologia Istituzione: Policlinico Universitario Campus Bio-Medico di Roma Datore/ente di lavoro? Yes Datore/ente di lavoro SSN? No Nome datore/ente di lavoro non SSN: Univerasità Campus Bio-Medico di Roma Nome istituzione SSN: Fondazione Policlinico Universitario Campus Bio-Medico Tipo contratto: Ricercatore RTD-A 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.

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# **Project validation result**