TIMESPAN

Management of chronic cardiometabolic disease and treatment discontinuity in adult ADHD patients

H2020 – 965381

D8.2. – Communication and Outreach Plan

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This Communication and Outreach Plan has been reviewed by the TIMESPAN Impact and Innovation Board (IIB).

Abbreviations

ADDISS	ADD INFORMATION SERVICE
ADD	Attention Deficit Disorders
ADHD	Attention Deficit Hyperactivity Disorders
ART	ADHD Remote Technology
AU	AARHUS UNIVERSITET
CAD	Coronary Artery Disease
DLNN	Deep Learning Neural Network
EASO	THE EUROPEAN ASSOCIATION FOR THE STUDY OF OEBSITY
EDAC	Ethics and Data Management Advisory Committee
EDMB	Ethics and Data Management Board
ECNP	European College for Neuropsychopharmacology
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EMA	European Medicine Agency
EU	European Union
Eunethydis	EUropean NETwork for HYperkinetic DISorders
GA	General Assembly
GWAS	Genome-wide association studies
HKU	THE UNIVERSITY OF HONG KONG
iDEAS	High Dimensional Empirical Bayes Screening
IPR	Intellectual Property Rights
KCL	KING'S COLLEGE LONDON
KI	KAROLINSKA INSTITUTET
ML	Machine learning
ORU	OREBRO UNIVERITY
PI	Principal Investigators
PMO	Project Management Office
PRS	Polygenic risk scores
RMT	Remote Measurement Technology
SDK	Software Development Kit
SC	Steering Committee

SUNY	THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK
UCL	UNIVERSITY COLLEGE LONDON
UiB	UNIVERSITETET I BERGEN
UMCG	ACADEMISCH ZIEKENHUIS GRONINGEN
UNSW	UNIVERSITY OF NEW SOUTH WALES
UoI	HASKOLI ISLANDS
VHIR	FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA
QC	Quality Check

Table of Contents

1 Executive Summary

This document deals with the dissemination and communication measures, that are crucial for the TIMESPAN project. In the following chapters, the overall objectives, stakeholders and channels of dissemination and communication for the TIMESPAN project are summarized and clearly explained. The document sets the foundation and stable framework for the implementation of all dissemination and communication activities, exploitation, training activities, as well as publications. The stakeholder analysis was performed by the Impact and Innovation Board (IIB) and concentris in consultation with the consortium partners. concentris will measure and report on a 6-monthly basis the success of the chosen communication channels using the most appropriate measurements. Based on the collected data, concentris will propose strengthening or weakening of certain communication channels.

2 Deliverable Report

2.1 Introduction and definition

This document sets the outline of the TIMESPAN communication and outreach plan. It covers the overall objectives, stakeholders and channels of dissemination and communication for the TIMESPAN project. Moreover, it establishes exploitation, training activities and procedures for performance evaluation. Last but not least, it will facilitate the implementation of the TIMESPAN publication rules as outlined in the TIMESPAN Grant Agreement (965381) and the TIMESPAN Consortium Agreement.

For the purpose of this document, the terms “Communication”, “Dissemination”, and “Exploitation” are defined as follows:

Communication:

“Communication on projects is a strategically planned process that starts at the outset of the action and continues throughout its entire lifetime, aimed at promoting the action and its results. It requires strategic and targeted measures for communicating about (i) the action and (ii) its results to a multitude of audiences, including the media and the public and possibly engaging in a two-way exchange.”

Dissemination:

“The public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium.”

Exploitation:

“Means to make use of the results produced in an EU project in further activities (other than those covered by the project, e.g. in other research activities; in developing, creating and marketing a product, process or service; in standardization activities).” [1]

[1] EC Research & Innovation Participant Portal Glossary/Reference Terms

2.2 Objectives

The objectives of this Dissemination, Communication and Exploitation Plan are the following:

- To make TIMESPAN known to all stakeholders
- To make TIMESPAN results accessible in clear and customized formats to reach the scientific, clinical and public health community, guideline committees and the general public, particularly focusing on patient groups (ADHD Europe via ADDISS and EASO)
- To identify and valorise the intellectual property rights (IPR) generated within WP1-6
- To train the next generation of scientists (master-classes, e-learning, mentoring scheme etc.)

2.3 Communication strategy

Table 1: Target groups, communication goals, multipliers and communication tools to reach them

Target group	Communication goals, i.e. what we want our target groups to do / understand etc.	Communication tools, i.e. how we want to reach them									
		Publications	Conferences	Guidelines	Data sharing	Website	Social media	Videos	Press releases	Newsletters	Training
(1) Scientific community											
• Doctors / clinicians	– Use the RMT for detailed data collection and monitoring – Improved identification of ADHD patients at risk for cardiometabolic outcomes and thus optimized multidisciplinary and personalized treatment approaches	x	x	x		x	x		x	x	x
• Academic sector (universities, general hospitals and research groups) in the fields of: ○ Mental health specialists and cardiologists	– Further discovery and development of novel treatment approaches for ADHD and co-occurring cardiometabolic-diseases via the RMT – Re-use TIMESPAN data for own research	x	x	x	x	x	x	x	x	x	
• Early career scientists	– Advance their careers using available expertise and new knowledge from TIMESPAN – Establish a Mentor-Mentee program and thus educate the next generation of scientists	x	x		x	x	x	x		x	x
(2) Commercial sector											
• Companies ○ Targeted start-ups ○ Investors	– Benefit from wearable device (EmbracePlus) and thus develop new tools for data collection – Real-world screening for drug-drug interactions – Further translate TIMESPAN results into marketable products, thus making new knowledge sustainable and available for use.	x	x			x	x			x	

Target group	Communication goals, i.e. what we want our target groups to do / understand etc.	Communication tools, i.e. how we want to reach them									
		Publications	Conferences	Guidelines	Data sharing	Website	Social media	Videos	Press releases	Newsletters	Training
	– Understand economic benefits and invest into research for patients with ADHD and co-occurring cardiometabolic diseases – Strengthen the research and innovation landscape in Europe by ensuring knowledge transfer										
(3) Government / Regulatory decision makers											
• National agencies o European Medicines Agency o National health authorities	– Lobby for including and adapting clinical guidelines based on new TIMESPAN findings – Develop specifications for a European electronic health record exchange format	x		x		x	x		x		
• European level o European Commission (Directorate Health Authority)	– Spread general news about TIMESPAN in the large community of the H2020 programme. – Raise awareness, educate, disseminate results at patient and laymen's events	x	x				x			x	
(4) General public											
• Patients o Patients with ADHD and co-occurring cardiometabolic diseases o National patient organisations Patients' families and care givers	– Better understand ADHD and co-occurring cardiometabolic diseases, gain acceptance of this condition and decrease stigmatization – Giving feed-back and engaging in dialogue – Publication of results in patient journals and presentation at patient events – Support changed treatment practice based on TIMESPAN results – Raise awareness, educate, disseminate results at patient events	x	x			x	x	x	x		
• General public	– Better understand ADHD and co-occurring cardiometabolic diseases, gain acceptance of this condition		x			x	x	x	x		

Table 2: TIMESPAN List of stakeholders

Category	Stakeholders	Website	Comment
Industry			Interested in EMPATICA product
Multiple Stakeholders	European College of Neuropsychopharmacology ECNP	https://www.ecnp.eu	Brings together research and treatment / public health.
Multiple Stakeholders	European Brain Council EBC	https://www.braincouncil.eu	Brings together researchers, patients, policy makers and industry
Multiple Stakeholders	National Institute for Health and Care NICE	https://www.nice.org.uk/	Brings together research and healthcare
Multiple Stakeholders	Innovative Medicines Initiativse IMI	https://www.imi.europa.eu/	EU-funded public-private partnership funding health research and innovation; aimed to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. Relevant for exploitation (i.e. new projects/ proposals that come from the current research)
Multiple Stakeholders	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)	http://www.encepp.eu/	Coordinated by the European Medicines Agency
Multiple Stakeholders	EUNETHYDIS European NETwork for Hyperkinetic DISorders	https://eunethydis.eu	Brings together researchers, clinicians and early career scientists as well as government agencies and the pharmaceutical industry.
Multiple Stakeholders	European Association for the Study of Obesity (EASO)	www.easo.org	The leading voice of obesity science, medicine, and community in Europe, representing scientists, health care professionals, physicians, public health experts and patients.

Category	Stakeholders	Website	Comment
Multiple Stakeholders	ECNP Nutrition Network	https://www.ecnp.eu/research-innovation/ECNP-networks/List-ECNP-Networks/Nutrition	ECNP´s mission is to better understand the bidirectional links between mental health and nutrition, including the mediating systems and psychopharmacology and to use this knowledge to identify novel neuropsychological and neuropharmacological intervention strategies. The Chairs of the Network are Suzanne Dickson, University Medical Centre Utrecht, and Roger Adan, University of Utrecht.
Multiple stakeholders	CIBER of Mental Health (CIBERSAM)	https://www.cibersam.es/en/about-us	Spanish research network on mental health. The mission consists in providing answers and solutions to enable mental illnesses to be treated, as a way to improve citizens' quality of life.
Public Agency	AQuAS	https://aquas.gencat.cat	Catalan Agency for Health Quality and Evaluation (AQuAS): The mission of the AQuAS is to generate relevant knowledge, through the evaluation and analysis of data for decision-making, in order to contribute to the improvement of the health of citizens and the sustainability of the health system in Catalonia.
Patient organisation	International Diabetes Federation IDF Europe	https://idf.org/	Umbrella organization of over 240 national diabetes associations in 168 countries and territories. It represents the interests of the growing number of people with diabetes and those at risk. The mission is to promote diabetes care, prevention and a cure worldwide.
Patient organisation	European Society of cardiology	https://www.escardio.org/	Disseminates evidence-based scientific knowledge to cardiovascular professionals so they can better care for their patients.
Patient organisation	ADHD Europe	www.adhdeurope.eu	The voice of Europeans with ADHD.
Patient organisation	Deutsche Diabetes Hilfe	https://www.diabetesde.org	German Diabetes Aid (DDH) leading German health organisation for more than 8 million people with diabetes.

Category	Stakeholders	Website	Comment
Patient organisation	Adipositas Hilfe Deutschland	https://www.adipositashilfe-deutschland.de/aktuelles.html	German patient and caregiver association that works to establish a therapy for obesity.
Patient organisation	Diabetes Denmark	https://diabetes.dk	Danish Diabetes Aid
Patient organisation	Adipositas Denmark	http://adipositasforeningen.dk	
Patient organisation	Riksförbundet Attention	https://attention.se/	Swedish ADHD organisation
Patient organisation	Diabetes Sweden	https://www.diabetes.se/om-oss/	Swedish Diabetes Aid
Patient organisation	Riksförbundet Hjärtlung	https://www.hjart-lung.se/	Swedish Association for heart and lung diseases
Patient organisation	Riksförbundet HOBS	https://www.hobs.se	Swedish Association for obesity
	ECNP Nutrition Network	https://www.ecnp.eu/research-innovation/ECNP-networks/List-ECNP-Networks/Nutrition	ECNP mission is to better understand the bidirectional links between mental health and nutrition, including the mediating systems and psychopharmacology and to use this knowledge to identify novel neuropsychological and neuropharmacological intervention strategies. The Chairs of the Network are Suzanne Dickson, University Medical Centre Utrecht, and Roger Adan, University of Utrecht.
Payers for Health Care	European Health Care insurances		Examples: German (AOK, DAK, Techniker, Barmer; Italy: Generali, Intesa Sanpaolp Vita, Poste Vita; France: CNP Assurances, Crédit Agricole Assurances, BNP Cardif; Netherlands: AEGON, Achmea
Pharma-Industry	Takeda Pharma	https://www.takeda.com	(Metformin) (collaborations in many ADHD-trials)
Pharma-Industry	Medice, Laboratorios Rubió, Bial	https://www.laboratoriosrubio.com/en/	ADHD Drugs
Government / Regulatory decision makers	Socialstyrelsen	https://www.socialstyrelsen.se/en/	National Board of Health and Welfare. Swedish governmental agency under the Ministry of Health and Social Affairs that regulates treatment guidelines for medical conditions.
Government / Regulatory decision makers Policy makers	MEP Alliance for Mental Health	https://www.gamian.eu/activities/mep-alliance-mental-health/	Brings together various Members of the European Parliament (MEPs) that work more generally on mental health issues.
Category	**Stakeholders**	**Website**	**Comment**

Government / Regulatory decision makers Policy makers	EFNA MEP group, Brain Mind & Pain	http://www.brainmindpain.eu/register-of-supporters/	The following MEPs seem to be quite active regarding health and nutrition: Roza Thun (Poland, EPP), Biljana Borzan (Croatia, S&D), Pascal Arimont (Belgium, EPP), MEP Sirpa Pietikäinen (EPP, FI), MEP Tomislav Sokol (EPP, HR), MEP Petra De Sutter (Greens, BE), MEP Frédérique Ries (Renew, BE)
Government / Regulatory decision makers	European Federation of Neurological Associations (EFNA)	https://www.efna.net	Brings together European umbrella organisations of neurological patient advocacy groups, to work with other associations in the field of neurology, including the European Federation of Neurological Societies (EFNS), in what has been termed a "Partnership for Progress".
Government / Regulatory decision makers	EMA	https://www.ema.europa.eu/en	Agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
Government / Regulatory decision makers	World Health Organisation	https://www.who.int	
Government / Regulatory decision makers	EU Research Council	https://erc.europa.eu	
Government / Regulatory decision makers	EU Commission	https://ec.europa.eu/info/index_en	
Politicians	EU Parliament	https://www.europarl.europa.eu/portal/en	
Professional associations	European Network Adult ADHD	https://www.eunetworkadultadhd.com/	Brings together European psychiatrists, psychologists, clinicians as well as researchers.
Category	**Stakeholders**	**Website**	**Comment**
Professional associations	World Psychiatric Association	https://www.wpanet.org	Collaborative work with international agencies, leading non-government and civil

			society organisations, and research institutions in many countries. WPA has a formal relationship with the World Health Organization (WHO) and a joint work programme with the WHO's Department of Mental Health.
Professional associations	Diabetes Nutrition Study Group of the European Association for the Study of Diabetes (EASD).	https://dnsg-easd.eu/	
Professional associations	Associació Catalana de Diabetis	http://www.acdiabetis.org	
Professional associations	Associació de Diabetes Catalunya	https://adc.cat/es/	
Professional associations	Asociación Nacional de Personas Obesas	https://www.asepo.es/	
Professional associations	Federación Española de Diabetes	https://fedesp.es/	Representative association for people with diabetes in Spain.
Professional associations	The Danish Association For The Study Of Obesity	https://dsaf.dk/en/	
Professional societies	Steno Diabetes Center Copenhagen	https://www.sdcc.dk/english/research/Pages/default.aspx	
Professional societies	Deutsche Diabetes Gesellschaft	https://www.deutsche-diabetes-gesellschaft.de/home.html	The German Diabetes Society (DDG) is one of the largest medical and scientific societies in Germany. The tasks are the research, therapy and prevention of diabetes mellitus. DDG offers service and advice for physicians as well as for non-medical professionals and those active in politics and society.
Professional societies	FENS	https://www.fens.org	Federation of European Neuroscience Societies
Professional societies	Joint Programmeming Initiative a Healthy Diet for a Healthy Life (JPI HDHL)	https://www.healthydietforhealthylife.eu	Coordinating research in the area of nutrition, diet, health and physical activity
Professional societies	Human Brain Project HBP	https://www.humanbrainproject.eu/en/	The Human Brain Project (HBP) is building a research infrastructure to help advance neuroscience, medicine, and computing
Category	**Stakeholders**	**Website**	**Comment**
Professional societies	Network of European Funding for	https://www.neuron-eranet.eu	Mission to advance research on the human brain and its

	Neuroscience Research NEURON		diseases; create European research networks.
Professional societies / Health care providers	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. AWMF	https://www.awmf.org/awmf-online-das-portal-der-wissenschaftlichen-medizin/awmf-aktuell.html	Scientific-based medicine (all healthcare disciplines)
Professional societies / Health care providers	European Academy of Neurology (EAN)	https://www.ean.org/	EAN is the organization that unites and supports neurologists across the whole of Europe. Currently, 45 European national neurological societies as well as 800 individuals are registered members of the EAN. Thus the EAN represents more than 21,000 European neurologists.
Professional societies / Health care providers	European Psychiatric Association (EPA)	https://www.europsy.net	EPA is the main association representing psychiatry in Europe. EPA's activities address the interests of psychiatrists in academia, research and practice throughout all stages of career development. EPA deals with psychiatry and its related disciplines and it focuses on the improvement of care for the mentally ill as well as on the development of professional excellence.
Professional societies / Health care providers	European Psychiatric Association (EPA)	https://www.europsy.net	EPA is the main association representing psychiatry in Europe. EPA's activities address the interests of psychiatrists in academia, research and practice throughout all stages of career development. EPA deals with psychiatry and its related disciplines and it focuses on the improvement of care for the mentally ill as well as on the development of professional excellence
Category	**Stakeholders**	**Website**	**Comment**
Professional societies / multiple	Pan European Regional Committee (PERC) of the International Brain	http://www.ibro.org	A global organization resulting from the union of neuroscience organizations with the aim to promote and support

stakeholders (bridges)	Research Organization (IBRO)		neuroscience training and collaborative research around the world. The IBRO-PERC is a PanEuropean Regional Committee supporting the IBRO mission and helping to plan and implement IBRO activities in Europe. In the last few years, IBRO-PERC has established collaborations with European organizations to promote neuroscience in Europe at all levels, including the training of the next generation of European neuroscientists as well as stimulation of using scientific knowledge to develop and improve treatments of disease
Trainees / Early Career Researchers	TIMESPAN Early Career Scientists and Medical Doctors	-	

Dissemination of Results

2.4 Expected results

The following Table (Table 3) displays the expected results (i.e. deliverables) of all work packages, the month they are due for submission to the European Commission, the dissemination level according to the Grant Agreement, target groups and users, and the relevance of contents for them.

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D1.1.	Report package on pharmacological and non-pharmacological cardiometabolic treatment adherence related to (subthreshold and high risk) ADHD	1	5- UMCG	CO	34	NO				
D1.2.	Report package on worsening of cardiometabolic risk profile related to (subthreshold and high risk) ADHD	1	5- UMCG	CO	38	NO				
D1.3.	Report package on psychosocial and wellbeing outcomes in terms of (a) work and societal participation (b) depression, anxiety, and stress-related outcomes and (c) substance use and substance use disorders) related to (subthreshold and high risk) ADHD		11-UoI	CO	46	NO				
D1.4.	Report package on morbidity, health deterioration and early death related to (subthreshold and high risk) ADHD	1	2-KI	CO	48	NO				

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D1.5.	Manuscript on causal effects pertaining to the associations established in D1.1 to D1.4	1	5-UMCG	CO	60	NO				
D2.1.	Report package on ADHD medication and cardiometabolic risk in patients with ADHD and cardiometabolic disease (Task 2)	2	5-UMCG	CO	38	NO				
D2.2.	Report package on ADHD medication and adherence to treatment of cardiometabolic disease (Task 2)	2	4-UiB	CO	40	NO				
D2.3.	Report package on ADHD medication and the prognosis of cardiometabolic diseases (Task 3)	2	9-UCL	CO	54	NO				
D2.4.	Report package on socio-demographic and clinical modifiers on the effects of ADHD medication (Task 4)	2	3-AU	CO	60	NO				
D2.5.	Report package on drug-drug interactions between ADHD medications and medications for cardiometabolic diseases (Task 5)	2	2-KI	CO	60	NO				

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D3.1.	Report package (incl. manuscript): Harmonizing definitions of treatment discontinuity and non-adherence across different countries and databases (Task 2)	3	2-KI	CO	30	NO				
D3.2.	Report package (incl. manuscript): Longterm ADHD medication trajectories across and between health care systems and countries based on real-world data. (Task 3)	3	1-ORU	CO	42	NO				
D3.3.	Report package (incl. manuscript): Age, sex, socioeconomic status, dosage of ADHD medication, psychiatric comorbidity and level of care as modifiers of ADHD treatment discontinuity (Task 4)	3	4-UiB	CO	54	NO				
D3.4.	Report package (incl. manuscript): Level of ADHD treatment discontinuity in adults with co-occurring chronic obesity, cardiovascular disease and/or diabetes (Task 5)	3	12-UNSW	CO	60	NO				

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D4.1.	Report on the primary GWAS analyses and summary results for use in WP6 (Task 2)	4	3-AU	CO	20	NO				
D4.2.	Report on the secondary GWAS analyses (e.g. heritability and genetic correlations)	4	3-AU	CO	20	NO				
D4.3.	Manuscript on causality of ADHD medication discontinuation on obesity, CAD and TYDM	4	6-VHIR	CO	30	NO				
D4.4.	Lists of top-ranking causal variants and genes for WP6 (Task 3)	4	3-AU	CO	30	NO				
D4.5.	Manuscripts on GWAS and the genetic architecture of ADHD medication discontinuation (Task 1, 2, 3, 5)	4	3-AU	CO	35	NO				
D4.6.	Manuscripts on the impact of deleterious rare variants on ADHD medication discontinuation (Task 4)	4	3-AU	CO	45	NO				
D4.7.	Manuscript on PRS analyses to predict ADHD medication discontinuation (Task 6)	4	2-KI	CO	60	NO				

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D5.1.	First study subject approvals package (Task 2)	5	7-KCL	CO	12	NO				
D5.2.	Midterm recruitment report (Task 3)	5	7-KCL	CO	32	NO				
D5.3.	Overview of planned publications incl. short outlines (Task 5)	5	7-KCL	CO	48	NO				
D5.4.	ART-CARMA SDK (Task 4)	5	7-KCL	CO	60	NO				
D5.5.	Report on final status of posting results (Task 3)	5	7-KCL	CO	60	NO				
D5.6.	Summary report on major WP5 publications (Task 5)	5	7-KCL	CO	60	NO				
D6.1.	DLNN algorithms (freely available via GitHub) (Task 1)	6	10-SUNY	PU	6	YES	x	x		x
D6.2.	DLNN algorithms (freely available via GitHub) (Task 4)	6	10-SUNY	PU	15	YES	x	x		x
D6.3.	Report package (incl. manuscript) on predicting cardiometabolic outcomes and treatment discontinuity using clinical and epidemiological data sets (Task 3)	6	10-SUNY	CO	30	NO				

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D6.4.	Report package (incl. manuscript) on predicting cardiometabolic risk using genomic data (Task 7)	6	10-SUNY	CO	60	NO				
D6.5.	Report comparing accuracy across datasets	6	10-SUNY	CO	60	NO				
D7.1.	Report on Ethics Monitoring Strategy	7	13-HKU	PU	3	YES	x	x		
D7.2.	Data management plan	7	13-HKU	CO	6	NO				
D7.3.	Repository of all ethics and access documents (human studies, incl. existing datasets) in the TIMESPAN intranet	7	13-HKU	CO	14	NO				
D7.4.	EDMB report (incl. EDAC feedback) on TIMESPAN ethics and data management implementation (incl. evaluation of the independent ethics advisor) (Month 18)	7	13-HKU	PU	18	YES	x	x		
D7.5.	EDMB report (incl. EDAC feedback) on TIMESPAN ethics and data management implementation (Month 36)	7	13-HKU	PU	36	YES	x	x		

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D7.6.	EDMB report (incl. EDAC feedback) on TIMESPAN ethics and data management implementation (incl. evaluation of the independent ethics advisor) (Month 54)	7	13-HKU	PU	54	YES	x	x		
D8.1.	Go-online of the public project website	8	17-concentris	PU	4	YES	x	x	x	x
D8.2.	Communication and Outreach plan	8	17-concentris	PU	6	YES		x		
D8.3.	Project brochure and professional templates	8	17-concentris	PU	6	YES	x	x	x	x
D8.4.	Systematic review covering the available evidence on ADHD and cardiometabolic disease	8	6-VHIR	PU	24	YES	x			x
D8.5.	Training course in pharmaco-epidemiological analyses using real-world data for relevant stakeholders	8	2-KI	PU	48	YES	x	x	x	x
D8.6.	Patient and layman event	8	14-ADDISS	PU	50	YES			x	x

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D8.7.	Recommendations for clinical practice guideline and consensus statement on ADHD and cardiometabolic diseases	8	6-VHIR	PU	60	YES	x	x	x	x
D8.8.	Report on interactions with health authorities /regulators	8	6-VHIR	CO	60	NO				
D8.9.	Video explaining new knowledge on management of ADHD and co-occurring cardiometabolic diseases	8	17-concentris	PU	60	YES	x	x	x	x
D8.10.	Final exploitation and sustainability plan (including sustainability roadmap)	8	17-concentris	CO	60	NO				
D8.11.	Summary report on major publications/findings	8	1-ORU	PU	60	YES		x		
D8.12.	Summary report on the success of the chosen communication channels	8	17-concentris	PU	60	YES		x		
D9.1.	Go-online of the public project website	9	17-concentris	PU	4	YES	x	x	x	x
D9.2.	Establishment and composition of the acronym committees and boards	9	17-concentris	PU	12	YES		x		

Del No	Deliverable name	WP No	Short name of lead participant	Dissemination level	Delivery date (month)	External relevance? (YES/NO)	Target groups			
							(1) Scientific audience	(2) Government / Regulator	(3) Commercial sector	(4) General public
D10.1	H - Requirement No. 1	10	1-ORU	CO	12	NO				
D10.2.	POPD – Requirement No. 2	10	1-ORU	CO	14	NO				
D10.3.	NEC - Requirement No. 4	10	1-ORU	CO	15	NO				
D10.4.	M - Requirement No. 6	10	1-ORU	CO	12	NO				
D10.5.	POPD – Requirement No. 8	10	1-ORU	CO	6	NO				

2.5 Peer-reviewed publications, posters and conference talks

2.5.1 Principle of authorship

The TIMESPAN General Assembly considers that the project was successful in receiving funding, and that the project will only achieve its final goal if there is a broad collaboration between the different disciplines and institutions involved. Therefore, credit is due to all contributors to the programme. On this basis, all peer-reviewed publications resulting directly from the work of TIMESPAN (both journal and conference) will have shared authorship, i.e. at least one representative of all TIMESPAN partners involved directly in that work will be invited to be included as co-author (see authorship rules below).

The TIMESPAN Consortium aligns itself with following rules for authorship:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it has been critically for important intellectual content of the manuscript; AND
3. All authors must provide approval of the final version of a manuscript to be published; AND
4. The authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

2.5.2 Review and approval procedure

Pre-submission review and approval procedure

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before planned submission of the manuscript to the respective journal. The main author has to follow the following procedure (Figure 1, p.27):

1. The main author fills out the manuscript synopsis document (which can be downloaded from KEYWAYS) and send it to the PMO. The synopsis summarises on 1-2 pages the proposed title, involved WPs, proposed authors, abstract / hypothesis (if applicable), analysed variables (if applicable), used methods (if applicable), and key references.
2. The PMO will forward the synopsis to the Impact & Innovation Board (IIB) who will review it within 14 days.
3. Once approved by the IIB, the planned manuscript will be entered into the TIMESPAN dissemination tracker by the PMO.
4. The main author then sends the draft manuscript to the PMO who will forward it to the team leaders. The team leaders officially have 30 days to provide feedback and / or approve the manuscript. This means the sooner all team leaders approve, the sooner the manuscript can be submitted for publication.
5. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

An objection is justified if

(a) the protection of the objecting Party's Results or Background would be adversely affected

(b) the objecting Party's legitimate interests in relation to the Results or Background would be significantly harmed.

The objection has to include a precise request for necessary modifications.

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted.

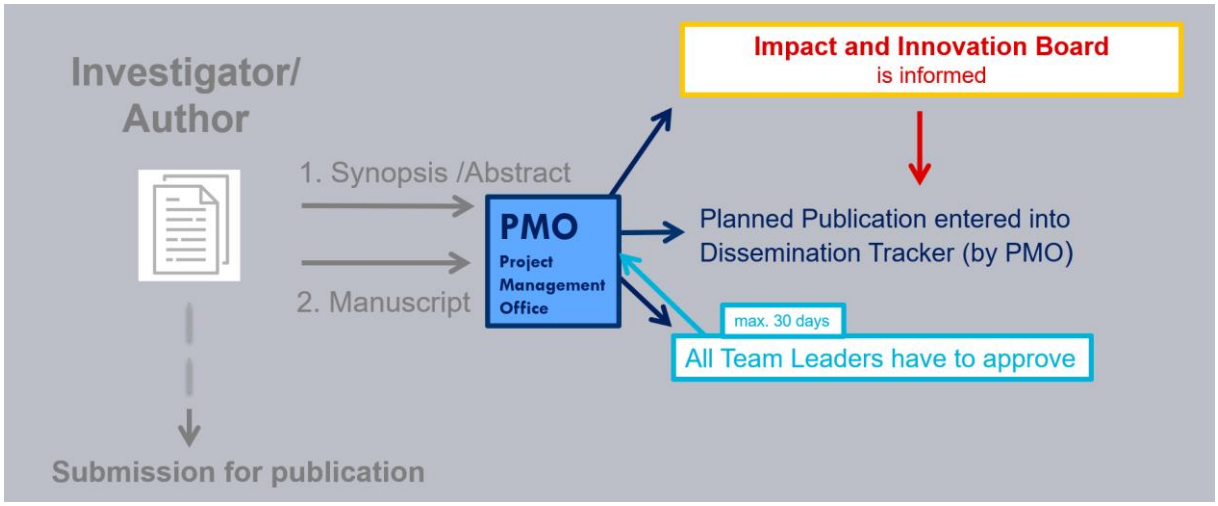


Figure 1: Pre-submission review and approval procedure

2.6 Conferences and events

2.6.1 Conferences and events organised by TIMESPAN

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Event	Patient and laymen event	PU	50	14-ADDISS
Masterclass	TIMESPAN Masterclasses for ESC	PU	13,25,37,49,60	17-concentris

2.6.2 Relevant other scientific conferences as a platform for showcasing TIMESPAN results

The following scientific conferences are known to date as potential platforms for TIMESPAN talks, posters and symposia:

Name of conference	Frequency/Date	Internet Link
Eunethydis	Yearly	https://eunethydis.eu/news-events/events/
ECNP	Yearly	https://www.ecnp.eu/Congress2021/ECNPcongress
World Congress on ADHD	Yearly	https://www.adhd-congress.org/
World Congress of Psychiatric Genetics	Yearly	https://ispg.net/wcpg-2021/
European Congress on Obesity	Yearly	https://easo.org/
European Society of Cardiology congress	Yearly	https://www.escardio.org/
UK Adult ADHD Network	Yearly	https://www.ukaan.org/
International Conference on Pharmacoepidemiology & Therapeutic Risk Management	Yearly	https://www.pharmacoepi.org/meetings/annual-conference/
Asian Conference on Pharmacoepidemiology	Yearly	https://www.pharmacoepi.org/meetings/asian-conference/
International Society of Pharmacovigilance	Yearly	https://isoponline.org/annual-meetings/

3 Communication Tools and Activities

3.1 Project Identity and communication material

3.1.1 TIMESPAN communication toolkit

Logo:

Color definition:

Letterhead:

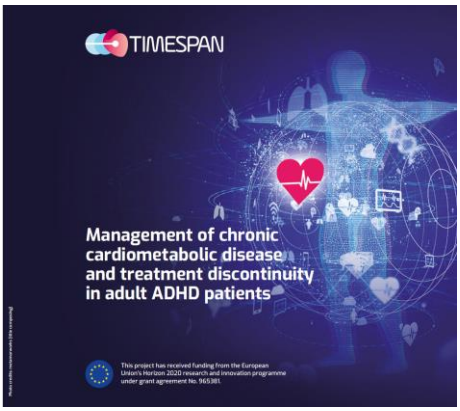
A template for a letterhead is available and can be downloaded from KEYWAYS.

PowerPoint template:

A PowerPoint template is available and can be downloaded from KEYWAYS.

Brochure:

The project brochure is available and can be downloaded on the TIMESPAN website.



3.1.2 Target release times

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Communication material	Logotypes RGB, CMYK, grayscale	PU	01	concentris
Communication material	Letterhead	CO	01	concentris
Communication material	PowerPoint template	CO	01	concentris
Communication material	Project Brochure	PU	06	concentris

3.2 Project website

3.2.1 Link

The TIMESPAN website can be found at https://www.timespan.eu and also via the QR-Code.

TIMESPAN Website QR-Code

3.2.2 Who is in charge

All partners are responsible for their own contents, for generating news items and informing the WP8 leader and PMO on any updates to be made.

The WP8 leader in consultation with the coordinator authorizes any content updates requested by the partners or generated by WP8 and informs concentris accordingly.

concentris is responsible for implementing updates of the project website using the content management system word press.

The Impact and Innovation Board monitors the website and notifies the WP8 leader and PMO in case of any change requests.

3.2.3 Quality management activities is in charge

concentris performs half-yearly, technical quality checks of the website. This includes (among other things) testing links and technical features of the website, updating plug-ins, checking whether there are any error messages coming up, correct display of all graphical elements (incl. cell phone and tablet views), GDPR notice, and download features.

The WP8 team supported by the **Impact and Innovation Board** is responsible for content related quality management of the TIMESPAN website, e.g., correct citations, scientific contents and presentation of results.

3.2.4 Target release times

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Website	Information about the project, for scientists, governments / regulators, commercial sector, patients and public	PU	08	concentris
Website	Updates (content)	PU	continuously	concentris
Website	Updates (technical QC)	PU	half-yearly	concentris

3.3 Social media

3.3.1 Overview social media accounts

At the time of issuing this document, TIMESPAN holds three social media accounts:

Twitter: @TIMESPAN_H2020 https://twitter.com/TIMESPAN_H2020

Facebook: @TIMESPANhorizon2020 https://www.facebook.com/TIMESPANhorizon2020

LinkedIn: TIMESPAN Horizon2020 https://www.linkedin.com/company/timespan-horizon2020

3.3.2 Who is in charge ("social media manager")

The following people have access to the social media TIMESPAN accounts:

- Henrik Larsson (Örebro)
- Veronika Picmanova (concentris)
- J.A. Ramos-Quiroga (VHIR)
- Ameli Schwalber (concentris)

All TIMESPAN partners are encouraged to

- Inform the social media managers about any news which can be shared.
- Re-tweet TIMESPAN messages as much as possible.
- To put in contact their institutional social managers in order to share their communication strategies with the TIMESPAN social media manager.

3.3.3 Social media audience

With messages shared via the TIMESPAN social media accounts, we aim to reach the following audiences:

Researchers, companies and entrepreneurs, policymakers, the EU Commission, patients, patient families, the general public, and early career scientists.

3.3.4 Hashtags and handles to be used

The following hashtags (#) and handles (@) shall be included in our tweets as much as possible and as appropriate for each individual message:

European Commission / general public / scientific platforms

@EU_H2020 / @horizon2020

@ADHD_Europe / @ukaan_org

TIMESPAN partners:

@orebrouni

@karolinskainst

@AarhusUni

@UiB

@researchumcg

@vallhebron

@KingsIoPPN

@unitartu

@eResearch_UCL, @ucl, @School_Pharmacy

@UpstateNews

@Haskoli_Islands

@UNSWMedicine

@hkumedChan

@UK_ADHD

@EASOobesity

@empatica

@concentris_EU

Thematic hashtags:

#h2020 #Horizon2020 #EU

#timespan # TIMESPAN

#ADHD

#AdultADHD #ADHDawareness

#cardiometabolicdisease

#cardiovasculardisease

#metabolichealth

#Obesity #Type2Diabetes

#PsychiatricDisorders

#QualityOfLife

#digitalhealth #wearables #research #mentalhealth

#RealWorldData #RMT

3.3.5 Connection between social media accounts, project website and other communication means of TIMESPAN

The Twitter, Facebook, and LinkedIn Icons that link to each TIMESPAN social media account are to be used as much as possible on all means of communication of TIMESPAN. A maximum of cross-referencing is wanted to improve search engine ranking.

3.3.6 TIMESPAN code of social media conduct

TIMESPAN partners agree on the following principles for social media conduct:

- Content owner decides what to post and share. No unauthorized sharing of pictures and information about others without prior consent.
- No information leakage to prevent loss of intellectual property.
- No spread of negative messages.
- No posting of EU classified information (e.g. confidential deliverables).
- No fake messages or spam, only accurate news is posted.
- Use of appropriate, inoffensive language.

3.3.7 Flexible time of postings

We strive to post news at the moment they are taking place, for example:

- when there is a project breakthrough, such as a major publication
- when TIMESPAN is featured at a conference or event
- when TIMESPAN is presenting at an exhibition fair stand

Events and conferences:

The following timeline applies for posting about TIMESPAN events and conferences:

- Ideally, 6 weeks in advance: Informing about the event, deciding hashtags to be used and start sharing content alongside.
- Ideally, 1 month in advance: Creating web content and starting to promote it on TIMESPAN social media accounts using the event hashtag; preparing an event image to share on tweets.
- Before the event: Preparing a list of useful, relevant Twitter handles for participants to engage with before and during the event, such as event speakers and participants; creating a list of posts to tweet during the event.
- During the event: Live-tweeting with interesting pictures, tagging/mentioning people, promoting the relevant hashtag and asking participants to join the conversation; tweeting related content, scientific studies, published papers, web content, always including relevant hashtags.
- After the event: During the days following the event, monitoring impact and keeping tweeting relevant content with your own hashtag (if any).

3.4 Newsletter

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Newsletter (external)	Information about – TIMESPAN – Latest scientific developments & publications – Personnel developments – Success stories	PU	Half-yearly	concentris

3.5 Videos/ TV spots / Broadcasting

TIMESPAN aims to produce a video about explaining new knowledge on management of ADHD and co-occurring cardiometabolic diseases at the end of the project. Target group for this video are patients and the general public. The video will be published on YouTube and promoted via the project website and TIMESPAN social media channels.

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Video	Video explaining new knowledge on management ADHD and co-occurring cardiometabolic diseases	PU	60	concentris

TIMESPAN welcomes any further opportunities for broadcasting or promotion of results on TV. Whenever such an opportunity arises, the WP8 team will discuss details with relevant teams.

TIMESPAN considers to promote results in the web-video/-radio show “GoToHealth” (weekly hour-long internet talk-show featuring health and medical information)
Link: https://gotohealthmedia.com/video/

3.6 Press release / public media article

TIMESPAN will inform the general public about major news in a timely manner. Press releases will be distributed to announce TIMESPAN key publications and other important news (i.e. public events). These will be prepared by the project management office together with the press office of ORU and authors. For papers where KCL takes the lead, the preparation will be done by the IoPP press office.

4 Exploitation of Results

Key Exploitable Results of TIMESPAN have been defined at the proposal stage (see Table 4). This may change during the course of the project.

4.1 Key exploitable results

Table 4: Key exploitable results

Key Exploitable Results	Concept, Target groups, Benefits
Advanced knowledge on the total burden of ADHD and unmet needs (WP1)	**WHAT?** We will create the world largest ADHD dataset to identify new insights into burden and unmet needs of patients with ADHD and co-occurring cardiometabolic disease. **FOR WHOM?** Scientists (pharma & academic) ➔ clinicians ➔ patients ➔ general public **WHY?** Increase awareness in psychiatric and somatic clinics as well as in society **HOW/When?** Open access publication (e.g., consensus statement), online material for patient organisations and consensus statement conference during the project period, and large-scale data sources for future research.
Detection of potential protective and harmful real-word drug-drug interactions (WP2)	**WHAT?** TIMESPAN will use iDEAS analyses, a novel screening approach for identification of drug-drug interactions in real-world data, to create a list of potential **protective and harmful real-world drug-drug interactions.** **FOR WHOM?** EMA & scientists (academia and pharma) ➔ clinicians ➔ patients. **WHY?** TIMESPAN will advance the understanding of risks and benefits of combined pharmacological treatment approaches and polypharmacy in the management of adult ADHD and co-occurring cardiometabolic disease. **HOW/When?** Open access publication and reports to health authorities, such as EMA networks (e.g., EudraVigilance), during the project period and further exploitation opportunities after the project period. See 2.2.2
New technological tools and platforms for advanced data management (WP3)	**WHAT?** New tool for advanced data management (combined use of ML and language processing techniques; WP3) with a focus on approaches that can transform the massive amount of text variables in electronic health records into quantitative measures for research. **FOR WHOM?** SME's, Scientists and health authorities ➔ clinicians ➔ patients. **WHY?** This can be further developed into viable products with a strong impact on the digitalization of health care systems, developments in research and clinical applications using electronic health records, such as specifications for a European electronic health record exchange format. **HOW/When?** TIMESPAN partners will after the project period continue the approach in collaboration with health analytic companies (SME's). See 2.2.2
Identify the genetic architecture of ADHD medication discontinuation (WP4)	**WHAT?** Use multiple data-sources with genome-wide data to create the world-largest pharmacogenomics dataset to identify genetic variants associated with ADHD treatment discontinuity. **FOR WHOM**? Scientists (pharma & academic) ➔ health authorities' ➔ clinicians ➔ patients. WHY? Identifying specific biological mechanisms involved in treatment response is critical for developing personalized treatment approaches and drug development. HOW/When? Open access publications during the project period and to facilitate replication and further genomic research outside TIMESPAN, GWAS summary statistics will be made available to other consortia (e.g., IMpACT and PGC).
Development of ADHD Remote Technology (ART) assessment and monitoring battery (WP5)	**WHAT?** ART assessment and monitoring battery. **FOR WHOM?** Scientists and health authorities' ➔ clinicians ➔ patients **WHY?** RMT helps to better understand the relationship between ADHD medication and cardiometabolic disease as well as optimizing and personalizing clinical management to improve outcomes.

Key Exploitable Results	Concept, Target groups, Benefits
	HOW/When? Open access publications during the project period. TIMESPAN partner KCL will further develop the ART assessment and monitoring battery and work towards bringing it to the clinicians and patients. See 2.2.2
Validation of digital outcomes from RMT devices (WP5)	**WHAT?** Identify novel digital endpoints using wearable devices for patients with ADHD. **FOR WHOM?** Scientists (Academia/Pharma) and Regulators ➔clinicians ➔ patients **WHY?** Provide remote insight to scientific regulators and triallists to objective clinical outcomes, collected through a non-invasive wearable sensor in real-time reducing reliance on hospital visits. **HOW/When?** TIMESPAN partner EMPATICA developed the device and will during and after the project period continue to improve it and bring it to the market incorporating it with its remote monitoring platform made available worldwide. See 2.2.2
Development of risk stratification algorithms (WP6)	**WHAT?** TIMESPAN develops risk stratification algorithms using DLNN for identification of individuals at risk for poor cardiometabolic outcomes and treatment discontinuity. **FOR WHOM?** Scientist, Pharmaceutical, biotech, medical device, diagnostic, eHealth companies, health care authorities' ➔ health care system/clinicians➔ patients. **WHY?** Help clinicians identify high-risk patients who need more intensive treatment monitoring. **HOW/When?** WP6 partners aim to further develop this into viable products which will be of interest to pharmaceutical, biotech, medical device, diagnostic, eHealth, and other companies to develop new personalized strategies, products, and services. All of our DLNN algorithms will be made freely available via GitHub. See 2.2.2
New knowledge about safety, quality and effectiveness of personalized multidisciplinary treatment interventions (WP2, WP5, WP6),	**WHAT?** TIMESPAN will identify risks and benefits of ADHD monotherapy as well as combined pharmacological and non-pharmacological treatment for patients with ADHD and co-occurring cardiometabolic disease, by applying advanced pharmaco-epidemiological analyses and ML approaches to existing (e.g., large-scale register data) and newly acquired data (RMT data) **FOR WHOM?** Scientists ➔ clinicians ➔ patients. **WHY?** Provide appropriate evidence-based care for patients with ADHD and co-occurring cardiometabolic disease that reduce morbidity, mortality and societal costs. **HOW/When?** Open access publications & recommendations for clinical guidelines during the project period.
Predictors for treatment discontinuity (WP3, WP4, WP5, WP6)	**WHAT?** Based on findings from WP3-6, TIMESPAN will identify predictors (e.g., side-effects and genomic factors) for treatment discontinuity. **FOR WHOM?** Scientists ➔ health care system/clinicians ➔ patients. **WHY? A**dvance the management of adults with ADHD and co-occurring cardiometabolic disease. **HOW?** Open access publications, online material, interaction with health authorities, recommendations for clinical guidelines during the project period.
Recommendations for clinical guidelines & consensus statement (WP8)	**WHAT?** TIMESPAN will deliver optimized and personalized multidisciplinary treatment approaches that minimise harm and maximise positive changes in disease progression and improved treatment discontinuity. **FOR WHOM?** Regulators ➔ health care system & clinicians ➔ patients. **WHY?** Updated consensus statements and treatment guidelines on ADHD and co-occurring cardiometabolic disease will lead to better patient care and disease management. **HOW?** TIMESPAN's collaboration with the appropriate stakeholders ensure that the results regarding optimized and personalized multidisciplinary treatment approaches will be incorporated in clinical guidelines for ADHD and cardiometabolic disease. TIMESPAN partners and Scientific Advisors are leaders in international organizations issuing recommendations and guidelines such as the WFA, EUNETHYDIS, ENAA, ECNP adult ADHD network.

4.2 Path to deliver the innovation to the market

Towards the end of the project, the TIMESPAN tools will be translated into marketable products. Given a positive evaluation by the Impact and Innovation Board, in conjunction with the valorisation departments of the academic partners involved and in line with the TIMESPAN Consortium Agreement, we have two ways of placing output on the market: a) SME partner EMPATICA and b) approach additional SMEs interested.

• **Developments of a new technology for data analytics**: This TIMESPAN result based on an iDEAS approach can identify real-word signals from protective and harmful drug-drug interactions. TIMESPAN WP2 can assess risks and benefits of combined pharmacological treatment and polypharmacy in the management of adult ADHD and co-occurring cardiometabolic disease specifically. This can result in a list of potential harmful real-word drug-drug interactions that can be implemented in the European database of suspected adverse drug reaction reports (EudraVigilance). Findings of protective drug-drug interactions represent targets for drug repurposing. Moreover, this technology can be adapted to other fields of research and also by health authorities and pharmaceutical companies. The major available report systems across the world (e.g., EudraVigilance in Europe and FDA-based MedWatch in US) are based on spontaneous reports of adverse events. This is problematic for several reasons (e.g., unclear if the adverse event is caused by the medication or underlying factors). Partners KI and ORU will during and after the project period further validate the analytical approach and also work with regulatory bodies (EMA networks) to identify processes and standards for implementation and approach SMEs.

• **Development of risk stratification tools:** This TIMESPAN innovation meets a market need and – depending on results - will be further developed into a viable product. This will be of interest to pharmaceutical, biotech, medical device, diagnostic, eHealth, and other companies to develop new personalized strategies, products, and services. TIMESPAN partners SUNY and ORU will lead this together with key stakeholders, including scientific organizations (e.g., EUNETHYDIS), health analytical companies (e.g., IQ-VIA), to develop risk stratification tools in the context of ADHD and cardiometabolic disease based on ML and electronic health records. We will also approach national and international health authorities (e.g., EMA) and other European commission networks in this process.

• **New technological tools and platforms for advanced data management**: Sophisticated analysed of electronic health record information has unparalleled potential benefits for research, health care systems and patients, but it is an extremely complex task. Several TIMEPSAN partners will consider initiating spin-off research projects using this approach involving small companies and SME's, in particular for advanced coding and standardization. ORU and KI have already at this early stage approached a health analytic company (i.e., IQ-VIA) and a pharmaceutical company (i.e., TAKEDA) to discuss further developments in relation to text mining of electronic health records in Sweden.

• **ADHD Remote Technology (ART) assessment and monitoring battery**. This TIMESPAN innovation meets an unmet need for patients and clinicians and - depending on results - will be further developed into viable products for use in health care systems. This has the potential to transform clinical practice, by offering clinicians and patients easy, time-saving, access to frequent detailed data on symptoms and impairments during the titration process and subsequent long-term monitoring of treatment effects. Further application could involve smartphone-based feedback directly to the patient, to promote behaviors that can contribute to improvement in ADHD symptoms. TIMESPAN work aims to feed into a subsequent phase, where KCL will test the utility of the remote measures for clinical

decision making, optimization of treatment effects and supporting self-management. This will require mixed methods implementation research to explore user perspectives and needs, methods for integration into clinical work flows and information systems, and identifying anticipated benefits to users.

• **Validated outcomes from wearable device:** Validated digital endpoints are much needed, but currently lacking in the field of ADHD (and other mental disorders). TIMESPAN partner Empatica has vast experience in developing medical and research wearables that feed into Empatica's platform that uses a combination of biosensors to detect unique components of human physiology that are distilled in AI-based algorithms to continuously and remotely monitor autonomic activity, movement, sleep and cardiac activity. As such, Empatica's legacy in building user-friendly medical technology makes the market for this platform expansive. If successful, the algorithms developed through TIMESPAN can be valuable not only to ADHD patients, but to anyone at risk for heart disease. Empatica will use a combination of digital marketing tools including SEO, search ads, press releases, email marketing, paid social media advertisement, blog posts and affiliate marketing to capture the target audience's attention and grow the market for this product.

In any case, preference will be given to commercial formats rather than scientific publications in order to support sustainability by generating income, which can be used to foster market entry and promotion of use in the future. In this context, the exploitation agreement of TIMESPAN will provide a clear, reliable and robust policy in protection and use of TIMESPAN IPR.

• **Sustainability Plan/Roadmap:** A detailed sustainability plan will be evaluated and present throughout the TIMESPAN project and a final version will be submitted at the end of the project (D8.10, WP8) showing how the key deliverables and results from the action will become accessible beyond the funded action, and how any key results will be made openly accessible within the EU legal framework. We will follow the FAIR guidelines to ensure that all data and results from TIMESPAN ensure that data or any digital object are Findable, Accessible, Interoperable and Reusable in compliance with all local, national and international legal obligations. Data sustainability will be accomplished by placing all the data management and analyses code (ie., Github) in an online repository and by providing a description of how to access raw data of each data source. TIMESPAN will also maximize transparency and enable future research (e.g., meta-analyses) by presenting GDPR-conform aggregated raw data for all study variables (i.e., made available in the appendix of all publications). The sustainability plan will take into consideration the identification of results that may need sustainability solutions, and the identification of potential end-users for these results.

4.3 Innovation management

The practical approach to innovation management will be as follows: Each partner will assign one person responsible for IP-related issues, who will discuss IPR matters on a regular basis with the site leader. The site leader will be asked to report on IP-related issues at the regular WP TCs and the WP-leader will report those to the Steering Committee and the IIB. Innovation management will be a permanent topic on the agenda of GA and SC meetings in order to discuss knowledge protection and IPR issues, progress and outcome of dissemination and exploitation activities.

In addition, the innovation manager (chair of IIB) will interview the site PIs at every GA meeting to regularly update the draft IIB with and support of the PMO will thoroughly monitor that all regulations as defined by the Consortium Agreement will be adhered to by the project partners. In the case of

evolving conflicts that cannot be solved by the IP representatives, the Steering Committee will be involved in order to find an agreement acceptable and practicable for all concerned partners.

Type	Content	Dissemination level	Timepoint (Month)	Responsible (Lead)
Yearly Check	IP issues	CO	12, 24,36,48,60	Innovation Manager

4.4 Clinical Guidelines

WP8 (17–concentris and 6-VHIR) will advance the dissemination the TIMESPAN results by sharing them with the scientific and medical community, healthcare and policy sectors and patient organisations. Newly developed clinical tools of TIMESPAN will be incorporated into (inter)national clinical guidelines.

Type	Content	Dissemination level	Timepoint (Month)	Responsible (Lead)
Report	Recommendations for clinical practice guideline and consensus statement on ADHD and cardiometabolic diseases	PU	60	6-VHIR

5 Educational activity

5.1 Portfolios

TIMESPAN will require and support the early career researchers to develop personal portfolio's specifying their training needs and wishes. These portfolios should reflect the multidisciplinary nature of the research and provide a future generation with a basis in both fundamental research and translational approaches towards clinical and societal use of research findings. The portfolio's will be updated each year and will be discussed by each early career scientist with the supervisor and his/her mentor (see 5.3).

Templates for the portfolios are available on KEYWAYS.

5.2 Training courses and master classes

TIMESPAN will disseminate knowledge by training (young) scientists. Training covers two areas: a) training of study personnel, b) training early career scientists in science dissemination and other relevant topics through courses and involvement in the planning and implementation of dissemination activities.

At each of the yearly TIMESPAN General Assembly meetings, concentris will schedule a master class for early career scientists. These master classes, which will be given by top experts from inside and outside the consortium as selected by the early career scientists themselves, will cover the latest advances in key areas of research within the TIMESPAN programme. Master classes will be recorded and the video clips will be provided online via YouTube and the TIMESPAN website.

5.3 Secondments and Internships

Training will include secondments to other sites within TIMESPAN which can vary from brief visits of approx. one week to longer visits of 2-3 months. This format will support the optimal integration of the research performed in TIMESPAN.

If sufficient budget is available (there is no budget specifically set aside for this, so this depends on the budget of the respective partner institute), training can include secondments at partner sites within the TIMESPAN consortium.

Activities funded: Secondment / internship – up to 3 months of duration.

Criteria for selection:

- Early career scientist (any trainee who is not yet not an independent investigator)
- Internship must support TIMESPAN objectives, and has to result in a report
- Covers travel and subsistence only
- Budget source to be decided individually for each case

Decision-making:

The decision for funds being spent on secondments / internships will be taken by the members of the Impact and Innovation Board.

The applicant needs to send a request to the members of the Impact Board, cc to the Coordinator and the PMO. The request needs to address the four criteria for selection as outlined above for the Impact and Innovation Board members to be able to validly decide.

Voting rules and quorum: The Impact Board shall not decide validly unless two-thirds (2/3) of its members are present or represented. Each member present or represented in the meeting shall have one vote. Decisions shall be taken by simple majority.

5.4 Mentorship scheme

Early career researchers will be offered the possibility to choose a mentor (a senior academic) from another site within TIMESPAN. The mentors will meet with their mentees about four times a year, with at least one in-person meeting (during the COVID-19 pandemic via Zoom/Skype etc.) annually and additional Zoom/Skype or telephone meetings. They will also be available for further advice and discussion via email. Importantly, female junior researchers will be offered the option of choosing, as their mentor, a female senior academic from within TIMESPAN. One of the key aims of mentoring of the female early career researchers is to enhance the retention of female researchers in academic research.

5.5 Target release times

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Training activity	Masterclass	PU	13	17-concentris
Training activity	Masterclass	PU	25	17-concentris
Training activity	Masterclass	PU	37	17-concentris
Training activity	Masterclass	PU	49	17-concentris
Training activity	Masterclass	PU	60	17-concentris

6 Open access

6.1 Definitions

"**Open access** (OA) refers to the practice of providing online access to scientific information that is free of charge to the end-user and reusable. 'Scientific' refers to all academic disciplines. In the context of research and innovation, 'scientific information' can mean: 1. peer-reviewed scientific research articles (published in scholarly journals) or 2. research data (data underlying publications, curated data and/or raw data).

Self-archiving / 'green' open access – the author, or a representative, archives (deposits) the published article or the final peer-reviewed manuscript in an online repository before, at the same time as, or after publication. Some publishers request that open access be granted only after an embargo period has elapsed.

Open access publishing / 'gold' open access - an article is immediately published in open access mode. In this model, the payment of publication costs is shifted away from subscribing readers. The most common business model is based on one-off payments by authors. These costs, often referred to as Article Processing Charges (APCs) are usually borne by the researcher's university or research institute or the agency funding the research. In other cases, the costs of open access publishing are covered by subsidies or other funding models."

Source: Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020

6.2 Contractual requirements about open access publications

6.2.1 Open access to scientific publications

According to Art. 29.2 of the Grant Agreement,

"Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms "European Union (EU)" and "Horizon 2020";
- the name of the action, acronym and grant number;

- the publication date, and length of embargo period if applicable, and
- a persistent identifier."

6.2.2 Open access to research data

According to Art. 29.3 of the Grant Agreement,

"Regarding the digital research data generated in the action ('data'), the beneficiaries must:

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;

(ii) data which is relevant for addressing a public health emergency, if specifically requested by the Commission and within the deadline specified in the request;

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardized by making those specific parts of the research data openly accessible.

In this case, the data management plan must contain the reasons for not giving access.

As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the Commission agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge."

7 Sustainability measures after the end of the project

The TIMESPAN project receives funding and has a run-time of 5 years. Sustainability measures will be discussed at a later point, e.g. two years before the end by the GA.

Topics to be discussed in the frame of sustainability are:

- What will happen to the website?
- Exploitation of results after the project end
- Foundation of a new company
- Continued funding

8 Monitoring of Dissemination and Communication activities

8.1 Roles and responsibilities

The Coordinator has the ultimate responsibility for tasks defined in the Grant Agreement and represents the Consortium vis-à-vis the Commission. He is responsible for submitting deliverables and reports to the Commission (Grant Agreement, Art. 19 and 20). Publication of deliverables must therefore be signed off by the coordinator prior to submission.

The Project Management Office supports the coordinator with monitoring of project progress and reporting (WP9). Any dissemination, communication or exploitation activity should be notified to the PMO.

The Work Package 8 team directs the work programme of WP8 and is responsible for the implementation of tasks, milestones and deliverables as described in WP8. The WP8 leader should be informed about any dissemination, communication or exploitation activity.

All partners are responsible for timely dissemination and communication of results in line with the provisions of the Grant Agreement (Art. 29), Consortium Agreement (Art. 8.4 and 8.5) and decisions taken by the General Assembly or the Steering Committee. All partners have experienced legal officers at their institution who can assist in IPR aspects. Individual partners will make sure that their discoveries with commercial potential are appropriately transferred and fully exploited – as peer-reviewed publications, new software or specific patents.

The Innovation and Impact Board is responsible for designing a structured communication plan for dissemination and the exploitation of results and will monitor the steps being taken. Together with the Project Management Office it will oversee the comprehensive internal and external dissemination of project results and knowledge.

The Impact and Innovation Board represented by the **Innovation Manager** will interview TIMESPAN partners at the annual GA meetings concerning their IPR and dissemination plans for the next year, and whether intellectual property will have to be protected. The board reports to the Steering Committee. In case intellectual property has to be protected, the Impact Board will provide advice regarding the responsibility for filing and protecting IPRs.

8.2 Performance evaluation

8.2.1 Process of performance evaluation

WP8 and the Innovation and Impact Board have created this Communication and Dissemination Plan and have defined the key messages of the project for each target and stakeholder group. The success and impact will be evaluated each 12 months and, based on the results, messages and activities adjusted (see Figure 2).

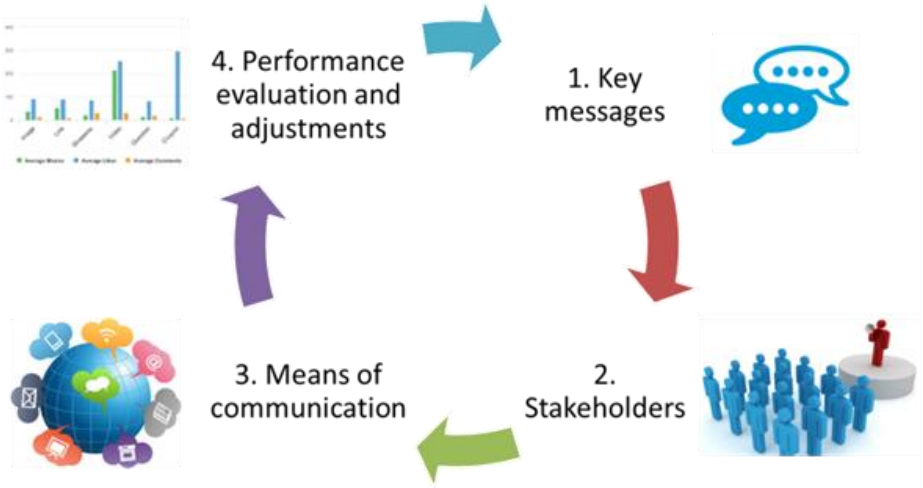


Figure 2: Process of continued improvement of communication performance

8.2.2 Key performance indicator

Quantitative:

Scientific performance

- Number of scientific articles published
- Number of talks and posters at conferences

Social media

The following measurements will be reported on a monthly basis:

- Number of followers
- Number of likes
- Number of shares

Training

- Number of early career scientists participating in master classes
- Number of internships / secondments taken place
- Number of views per video of masterclass

Reaching the public

- Number of articles published in general press
- Number of website visits
- Number of event attendees for events aimed at general public

Type	Content	Dissemination level	Timepoint (Month)	Responsible (Lead)
Report	Summary report on the success of the chosen communication channels	PU	60	17-concentris

8.2.3 Target release times

Type	Content	Dissemination Level	Timepoint (Month)	Responsible (Lead)
Performance evaluation	Performance evaluation of website, social media and other dissemination and communication activities	CO	18, 30, 42, 54	17-concentris

9 Tracking and reporting of Dissemination and Communication activities

TIMESPAN has to submit periodic reports to the European Commission at the following time points:

- RP1: from month 1 to month 18

- RP2: from month 19 to month 36

- RP3: from month 37 to month 48

- RP4: from month 49 to month 60

In order to collect and prepare content for reporting dissemination and communication activities, the TIMESPAN dissemination tracker has been developed and will be made available for download on KEYWAYS.

The tracker record plans for journal publications and presentations at conferences, other dissemination activities geared towards the relevant stakeholders, e.g. press releases, interviews and consultation meetings with agencies, and exploitation of generated IP, e.g. patents.

Process for dissemination and communication tracking:

In order to keep the process as easy as possible, the Steering Committee agreed on the following process:

1. Bottom-up approach (permanent): Whenever somebody disseminates anything about TIMESPAN, also if he/she only mentions the project, an **email shall be sent to the Innovation and Impact Board and the WP8 leader** (veronika.picmanova@concentris.de). In that email, the date, event and place, the title and author of the piece of dissemination shall be mentioned. If possible, the slides, the poster or a link shall be included, so that it can be uploaded to KEYWAYS.

2. Top-down approach (yearly): The Innovation and Impact Board will interview TIMESPAN partners shortly before the annual GA meetings concerning their IPR and dissemination plans for the next year (see Section 5.3). With assistance by the PMO, the Innovation and Impact Board will trace the planned dissemination and exploitation activities including journal publications in the TIMESPAN at least once a year at the occasion of the GA meeting.

NB: For peer-reviewed publications additional rules apply – see Section 2.5.

10 Standard acknowledgement

According to Art. 29.4 of the Grant Agreement any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

“The TIMESPAN project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 965381. This reflects only the author`s view, and the European Commission is not responsible for any use that may be made of the information it contains. “

Link to EU emblem and guidelines for use.

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