Join Us to Optimize Health Through Cohort Research

Deliverable 7.1 Monitoring and evaluation (M&E) framework

Version 1.0

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Author	Birgit Schauer (UMG)
Contributors	Ana Barbosa Mendes (EUR), Simon Ruegg (University of Zurich), Sabine Schipf, Antje Witt (UMG), Maria Szlachta, Pawel Sowa (MUB), Silvan Licher, Natalie Terzikhan (EMC)
Reviewer	-

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Abbreviations

D	Deliverable
EC	European Commission
KPI	Key Performance Indicator
M	Month
M&E	Monitoring and Evaluation
MS	Milestone
PMT	Project Management Team
RPO	Research Performing Organisation
RRI	Responsible Research and Innovation
SwafS	Science with and for Society
WP	Work Package

Partner abbreviations

EUR	Erasmus University of Rotterdam
EMC	Erasmus Medical Centre
M&E	Monitoring and Evaluation
MUB	Medical University of Bialystok
SocLab	Fundacja Soclab - Laboratorium Badań i Działań Społecznych
UMG	University Medicine Greifswald
UwB	University of Bialystok, Social Science Department
UoZ	University of Zurich
WB	WhiteBits

Executive summary

JoinUs4Health aims to combine Responsible Research and Innovation (RRI) and crowdsourcing as converging approaches to promote inclusive innovation and citizen engagement in cohort research. This deliverable outlines the status of the Monitoring and Evaluation (M&E) framework at the time of submission. After summarizing aims and relevant background information (Section 0), we provide an overview of the aim, ambition and expected outcomes of the project (Section 2). Section 3 (Monitoring) provides background information on indicators (Appendix I) and two questionnaires, which are being used to gather feedback on the platform (see Appendix II) and assess the effect of the project on cohort participation in the Study of Health in Pomerania (SHIP)[1] (Appendix III).

Section 4 (Evaluation) proposes evaluation objectives, evaluation questions, assessment criteria, and the application of the NEOH evaluation framework to guide the collection, analysis and reporting the data used for evaluation purposes. First, we describe details and structure of the Theory of Change-based NEOH evaluation framework (Section 4.1). Then we outline potential advantages of this framework (Section 4.2) and the envisaged application to JoinUs4Health (Section 4.3). In preparation for the in-country baseline evaluation in the three countries (Section 4.4), a one-day workshop will be organized on 24 June 2022 with partners, cohort representatives and invited stakeholders.

Section 5 outlines links to MoRRI and SDG indicators as described in the Grant Agreement. Discussions as part of the baseline evaluation shall inform whether to use RRI keys or RRI process dimensions or both to operationalize RRI as part of the project. Finally, Section 6 summarizes details on methodological aspects including next steps.

[1] Newly invited participants were divided into an intervention group (information about JoinUs4Health: two thirds of participants) and a control group (no information on JoinUs4Health: one third)

1 Introduction

1.1 Aims of the monitoring and evaluation framework

The M&E framework aims to

- monitor processes and progress towards objectives of the project
- measure quality of activities, products and outputs as well as user satisfaction
- assess the achievement of planned objectives and impacts and
- demonstrate how the project contributes, amongst other aspects, to the community and identity building of local and European RRI communities

In this document we also define aspects such as:

- boundaries of the initiative (target population, cohort regions and institutions)
- expected impact and
- implemented operations and infrastructures

The contents are based on initial, internal exchanges with Work Package leaders to reflect on outputs and outcomes and specific input from Simon Ruegg (University of Zurich) and Ana Barbosa Mendes (EUR) to discuss the potential of applying the NEOH framework[2] for the evaluation of the JoinUs4Health project, which focus on implementation of RRI.

1.2 RRI keys

The five key elements of RRI (sometimes also referred to as the pillars or key dimensions of RRI) include gender, ethics, open science, public engagement, science education, and governance. Table 1 outlines original statements of the Description of Action how the RRI keys are to be addressed via JoinUs4Health. This M&E framework is based on and elaborates on this original vision. Governance (6th RRI key) will also be considered. Deliverable 4.1 ("Report on the concept of RRI institutionalization under JoinUs4Health project") outlines a roadmap how institutional changes are implemented in the cohort institutions of the JoinUs4Health consortium based on these RRI key dimensions.

1.3 RRI process dimensions

The introduction of the four process dimensions anticipation, reflexivity, inclusion and responsiveness provide framework conditions for the process of RRI (Owen, Macnaghten et al. 2012, Stilgoe, Owen et al. 2013). These process dimensions set out conditions for research and innovation processes to be responsible. Hence, practicing a more responsible research and innovation requires that processes are (source: https://rri-tools.eu/; access date: 29 November 2021):

- diverse & inclusive: involve early a wide range of actors and publics in R&I practice, deliberation, and decision-making to yield more useful and higher quality knowledge. This strengths democracy and broadens sources of expertise, disciplines and perspectives
- anticipative & reflective: envision impacts and reflect on the underlying assumptions, values, and purposes to better understand how R&I shapes the future. This yields to valuable insights and increase our capacity to act on what we know

[2] http://neoh.onehealthglobal.net

- open & transparent: communicate in a balanced, meaningful way methods, results, conclusions, and implications to enable public scrutiny and dialogue. This benefits the visibility and understanding of R&I
- responsive & adaptive to change: be able to modify modes of thought and behaviour, overarching organizational structures, in response to changing circumstances, knowledge, and perspectives. This aligns action with the needs expressed by stakeholders and publics

Table 1. Extract from the Description of Action of how the five keys of Responsible Research and Innovation (RRI) are to be covered through JoinUs4Health

RRI key	Description how this dimension is to be covered
Public engagement	
	a platform is established promoting low-level interactions between citizens, other actors of society and researchers via crowdsourcing
	based on prioritisations of collated research questions high-level interactions are facilitated by means of mentored working groups
Ethics	
	the process is transparent and democratic
	the citizen science board reflects on ethics-related aspects
	inclusion of citizens in cohort research will open the option to shape the informed consent process of study participation more perspicuous for medical laypersons
	mentoring of citizen science groups by professional researchers or students and the revision of proposals through the citizen science and scientific management boards promote research integrity
Learning and education	
	citizen engagement and targeted online training materials offer new skills to citizens; summer schools (pupils) and master programme (postgraduate)
	RRI and science online courses (researchers, citizens) (Tasks 4.3 – 4.4) provide further opportunities for formal and informal science education
Gender equality	
	the implementation of crowdsourcing and citizen science attracts input from all strata of society regardless of age, gender, ethnic or cultural background and education
	emphasis will be placed on encouraging peer-learning so that less educated participants benefit from the expertise of more advanced peers
Open access	
	all engaged actors can apply to access customized results of research data given their result application is supported by the citizen science and scientific management boards
	a statistical pipeline allows generating customized result outputs based on specifications of the applicants
	authors will strive to publish the results of JoinUs4Health in open access form
	outcomes will be communicated via website and social media
	other institutions will be able to use algorithms and standard operating procedures developed within this enterprise
	the platform created for JoinUs4Health will be modular and open source to facilitate tailoring it to the specific needs of future users (institutions and participants)

2 Aim, ambition and expected outcomes

Table 2 outlines the overall aim and ambition of the JoinUs4Health project. Expected outcomes from merging crowdsourcing and RRI approaches encompass different areas:

1. awareness raising: Due to the different periods of implementation, local societies in the three cohort regions will have a different level of awareness of the cohort studies in their region. But even if awareness exists, currently little is known about details of activities and outputs from the cohort studies
2. networking:
    a. the platform has the potential to serve as a connector between existing bubbles between and within RRI groups. For instance citizens are often trapped in their own sometimes very small bubble. But also professionals (scientists, policy makers) face many barriers to exchange knowledge, information and experiences. The platform offers opportunity to connect in a safe and controlled environment, which is set up to foster RRI approaches and generate tangible benefits for local societies
    b. the cohorts can contribute their networks they are embedded in as well as their reputation when approaching external networks to mobilise specific stakeholder- or expert groups
3. collation: the collation of suggestions provides a long-term accessible knowledge-base
4. democratization: by allowing submission of own suggestions, voting on suggestions of others and contributing to activities whilst having a choice between topics, time commitments and types of activities
5. empowerment: by providing access to structures, processes and outputs developed as part of JoinUs4Health as well as aggregated results or even individual-level data of cohort studies
6. knowledge generation and innovation: targeted linkages between community- and team-level interactions have the potential to result in cross-fertilization and innovation (Gimpel, Graf-Drasch et al. 2020)
7. generation of tacit knowledge: the advantage of combining input from society as much as from science is the generation of tacit knowledge. “An engineer has to check the geological context of where to build the bridge.” (Simon Ruegg, 16.09.2021)
8. learning: comprises learning opportunities but also mutual learning between groups and individuals
9. dissemination: the concept allows more targeted dissemination of information that matters to people

Besides such expected outcomes a variety of unexpected outcomes may arise and will be documented throughout the project.

Table 2. Overall aim and ambition of JoinUs4Health

Overall aim	To combine Responsible Research and Innovation (RRI) and crowdsourcing as converging approaches to promote inclusive innovation and citizen engagement in cohort research.
Ambition	To engage cohort participants, citizens and other groups of societal actors (i.e. policy makers, business/industry, non-governmental organisations, education community) in a more co-creative manner to • make cohort research more sensitive to societal expectations and concerns • promote equal access to science, especially in the field of health and life sciences.
Vision	We want people to live better and healthier lives thanks to trust, understanding, and engagement in science.

3 Monitoring

3.1 Overview

The monitoring framework provides the means for determining if a programme is on course to achieve its aims. Table 3 shows an overview of existing instruments used for monitoring:

- two questionnaires (see sections 3.2 and 3.2.2)
- indicators of webpage usage
- indicators of platform usage

Table 3. Overview of existing instruments applied as part of JoinUs4Health

Instrument	Details
Questionnaire to obtain feedback on the platform	Target group: Anyone aged 16 years or older accessing the task "Feedback on the JoinUs4Health platform"[3] on the JoinUs4Health platform has access to questionnaire links in four languages (Dutch, English, German, Polish) See Appendix II for details
Questionnaire on awareness, use and perception of JoinUs4Health	Target group: Participants of the Study of Health in Pomerania who were divided into • an intervention group (⅔ of participa□ts; i□formatio□ o□ JoinUs4Health and JoinUs4Health stamps) and • a control group (⅓ of participants; no prior information on JoinUs4Health and SHIP stamps) See Appendix III for details on the questionnaire and Appendix IV on the stamp design for these two groups
Website	Key performance indicators have been defined for the website and social media (see M5.2); details remain to be discussed as part of Work Package 3
Platform	Platform indicators have not yet been developed in detail But basic indicators such as number of new registrations, number of submitted suggestions, number of topics etc. per given time interval (e.g. per month) can be generated upon request

[3] https://platform.joinus4health.eu/ju4htask/feedback-to-the-joinus4health-platform/

3.2 Details on existing instruments

3.2.1 Questionnaire to obtain feedback on the platform

The Limesurvey questionnaire is accessible via the JoinUs4Health platform without requiring prior registration. Therefore, platform registration is not a barrier for providing feedback on the platform. The full questionnaire is shown in Appendix II.

3.2.2 Questionnaire to assess effect of JoinUs4Health on cohort response

Background: Our hypothesis is that making the value of cohort research more tangible to the local populations may lead to a higher willingness to participate within the study region and thus increase cohort response. This hypothesis is tested by evaluating the effect of knowing about the project on the baseline response of the third SHIP-cohort NEXT. The potential positive effect of the JoinUs4Health project on cohort response is a major “business argument” for cohort institutions. If a pronounced effect can be quantitatively shown, then the cohort institutions have more incentive to carry the work on after the end of the project.

Design: From May onwards, ⅔ of the invitees of the randomly selected SHIP NEXT sample receive information on JoinUs4Health (intervention group), while the other third only receives the standard invitation documents. Initially, the project is relatively unknown, so most of the invitees have not heard of JoinUs4Health. Over time, the level of awareness of the project will increase.

Both groups receive a short self-completion questionnaire when they are at the SHIP examination centre in order to collect general reasons for participation, the extent of use of JoinUs4Health services and expectations.

Primary outcome: Participation in SHIP yes/no

Exposure (control or intervention group): Information on JoinUs4Health via

- cover letter explaining the project
- project flyer
- four JoinUs4Health stamps (control group: SHIP-stamps

The questionnaire includes 10 questions (see Appendix III for detailed contents):

- reason for participating in SHIP (Question 1)
- awareness (level) of the project (Questions 2-4)
- if project is known: Level of interaction with the project (Questions 5-8)
    - website,
    - platform visit,
    - platform registration,
    - contribution: submission suggestion, contribution to task, engagement in team, participation in event
- impression (Question 9) and expectations (Question 10) of the project

4 Evaluation

4.1 NEOH framework for evaluation of integrated health approaches

Impact indicators for RRI are difficult to develop as there is often a time-lag between the 'causal' events and the emerging impacts. Impact assessment thus requires a conceptual framework. A variety of framework exist, which have been developed by other projects (European Commission 2018). Several frameworks and roadmaps have been published with specific focus on Responsible Research (RRI) activities (European Commission 2020, National Advisory Council on Innovation 2020, European Commission 2021).

We envisage the application of the NEOH evaluation framework for integrated health approaches, which was developed during work of the EU COST action TD 1404 "Network for Evaluation of One Health" (NEOH, http://neoh.onehealthglobal.net; Ann Lindberg, Ruegg et al. (2015) and Ruegg, McMahon et al. (2017). This framework has since evolved into a leading evaluation tool in the One Health (OH) community. The application of the framework has been published covering in a range of case studies (Buttigieg, Savic et al. 2018, Sandberg, Hesp et al. 2021). Furthermore, the framework has been further developed and applied to specific contexts, such as the evaluation framework for governance mechanisms, which served as basis for the evaluation of 15 OH initiatives in 16 African, Asian and European countries (Hitziger, Aragrande et al. 2019). Thus, the application as part of JoinUs4Health also allows an assessment to what extent it is applicable in an RRI context.

Integrated health approaches allow the integration of knowledge across sectors, disciplines and stakeholders. The key goal is to generate tacit knowledge in relation to a given health challenge. Tacit knowledge can only be generated through open exchanges with different stakeholders. A key aspect is to flatten hierarchies and value societal input as equally relevant as scientific input, which also generates opportunities to "learn and evolve in a collective process" (Rüegg, Häsler et al. 2018).

The **NEOH evaluation framework** is based on a systems approach to address intrinsic complexities of integrated health approaches, which are regarded as subsystems of the context within which they operate in.

Four overarching elements form the basis of the NEOH evaluation framework (Figure 1):

1. the definition of the initiative and its context
2. the description of the theory of change with an assessment of expected and unexpected outcomes
3. the process evaluation of operational and supporting infrastructures (the "OH-ness") and
4. an assessment of the association(s) between the process evaluation and the outcomes produced

The mixed methods approach combines

- a descriptive and qualitative assessment
- a semi-quantitative evaluation (scoring) for the evaluation of the degree (OH-index) and structural balance (OH-ratio) of "OH-ness" and
- conventional metrics for different outcomes in a multi-criteria-decision-analysis

An important question to clarify is to what extent the OH-index is applicable to RRI initiatives.

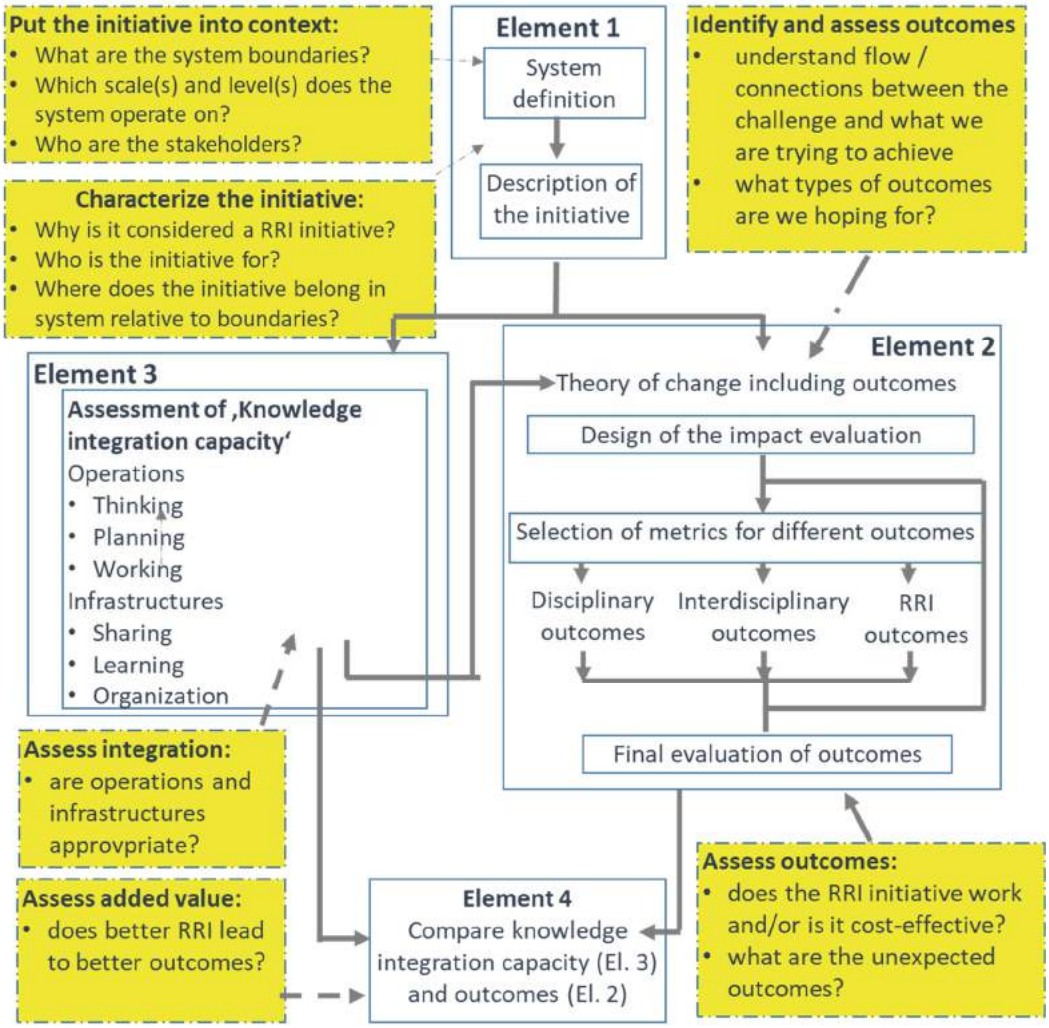

Figure 1. Flow chart of elements to be considered during the JoinUs4Health evaluation (clear boxes) with their purpose and the associated questions to be answered (yellow boxes).

In Element 1, the JoinUs4Health initiative and its context are described to inform Elements 2 and 3. Element 2 relies on a Theory of Change to identify expected outcomes and collects unexpected outcomes through non-linear impact assessment. In Element 3, the implementation of operations and infrastructure contributing to the RRI initiative is assessed. The two assessments are compared in Element 4. Adapted from Rüegg, Nielsen et al. (2018)

4.2 Potential advantages and disadvantages of applying the NEOH framework

Potential advantages

1. The NEOH evaluation framework
    a. is highly versatile, its application has been documented in a series of case studies and it been applied to new contexts (Hitziger, Aragrande et al. 2019)
    b. has been developed for integrated health approaches addressing complex problems
    c. shares key elements, which are very similar to RRI
2. Parallels between RRI and OH are very striking
    a. assessment of the OH-index could be transferred almost 1:1 to RRI

b. shift from deficit- to dialogue framework is strongly present in both approaches

Simon Ruegg (University of Zurich), one of the main authors of this framework, is prepared to contribute to the evaluation with the aim to explore the applicability in the RRI context. Besides the potential benefit of a shared publication, this also provides opportunities to

- apply the framework in a new context thus testing its flexibility to accommodate our specific needs
- bring RRI and OH communities closer as both operate on very similar philosophies.

Potential disadvantages

The framework has not been specifically developed for RRI initiatives, even though RRI and OH appear to have a lot in common. This is regarded as a productive challenge, which will be addressed as follows:

1. an assessment of similarities and differences between RRI and OH is planned to address questions such as
    a. what are the overlapping parts between OH and RRI?
    b. is OH a sub-unit of RRI or does RRI fit within the framework of OH?
2. an adaptation of the framework to RRI approaches will be explored

4.3 Envisaged application to JoinUs4Health

Role of the cohorts: Subsystem within the overall context

The JoinUs4Health project including its components such as the cohort institution, the platform and innovative methodological approach of combining crowdsourcing and RRI approaches is regarded as a subsystem in the context of the local communities of the cohort study regions. Based on this perspective, the cohort do not form the central point around which activities need to be based on, but rather as one component of the overall system.

Role of the management cycles: Sub-units

The JoinUs4Health initiative aims to influence the overall system in which it operates and thus cannot place cohort research at the sole centre. Initially, a cohort chooses a new featured topic every three months, so that each month a new featured topic will be promoted once the platform and interactions are fully operational (from May 2022 onwards). These so called management cycles are regarded as sub-units within the project, which allow exploring factors that influence under which circumstances the JoinUs4Health project provide tangible value to science and society compared to traditional approaches.

Differences between countries

An important aspect to consider is the comparison of the three participating cohort study regions, where the project is implemented. Hence, an impact evaluation is planned for the overall project and each cohort region.

4.4 Baseline evaluation

We foresee three workshops:

1) online workshop to align the facilitators of the national workshops,

2) national (physical or online) workshops to determine the local theory of change and objectives, and
3) online workshop to integrate the outcomes of the national workshops at the level of JoinUs4Health.

Simon Ruegg will participate at the first and third workshops, whilst the second is organized by the national partners.

The 1st workshop is organized on 24 June 2022 with the aim to co-produce the methods that will be used to facilitate the co-production of the theory of change. Participants will be one experienced facilitator (in citizen science or system thinking) and 3-4 junior scientists from each county. System mapping (e.g. causal loop diagrams) will be used to relate the different elements relevant to health in a graphical web of these elements. The method is based on an incremental process, where each participant first maps their own concept, then integrates it with 2-3 others, then with 6 and finally with a group of up to 30. The resulting map should reveal drivers and recipients (out-degree and in-degree in social network analysis) of health. The 1st workshop will establish a harmonized methodology in the three countries and initiate the junior participants to system thinking and co-production. It will be structured as a first ½ day of introduction to system thinking for juniors and a whole day workshop of co-production with all facilitators.

The facilitators will then implement the national workshops (2nd workshop), during which the national groups can elaborate objectives that should be addressed by the local JoinUs4Health implementation (e.g. better access to family health care, shorter distance to green space, etc.). The national group can then prioritize these objectives and on the systems map, options for interventions can be co-designed, e.g. defining space for urban gardening. These are composing the theory of change, i.e. what interventions will lead to what kind of outcome and impact in health. In a final step, the measuring points are identified to create accountability. These will be used for the evaluation of JoinUs4Health.

A subgroup of the national workshops will participate in a joint 3rd workshop at the JoinUs4Health-level to integrate those national system maps. The idea being to identify generic elements of the theory of change and characterize the differences between countries. The workshop will be facilitated according to the same principles as the national workshops. The outcome is expected to be a generic theory of change with generic indicators for evaluation as well as locally specific objectives and indicators.

4.5 Element 1: Description of the initiative and context

4.5.1 Scales and levels the project operates on

The conceptual evaluation framework

- is built around the
    - six RRI key dimensions (Section 1.2) and
    - four RRI process dimensions (see Section 1.3) and
- shall address different perspectives: individuals, cohort institutions, local communities (cohort study regions) and international community (SwafS, EU, world)

4.5.2 Boundaries of the initiative

One point of discussion was whether to centre the project around the cohort studies or the cohort regions at large thus,

- including other stakeholder groups / projects / initiatives and
- allowing suggestions / topics / working teams to go forward without an explicit link to cohort research.

This is a rather fundamental decision, which shouldn't be made pre-maturely without gaining experiences first. Therefore, we design the first featured topic to be open in terms of suggestions that will be considered during the first months of the pilot test.

4.5.3 Target population / geographical focus

The project focusses on the three cohort study regions as this is where the cohort data is being collected, and where we specifically want return tangible value to the local societies. The cohort regions are located in the three Member States Germany (SHIP), the Netherlands (Rotterdam Study) and Poland (Bialystok PLUS). Details on the cohorts and participating partner institutions can be found on the JoinUs4Health project website. The following sections outline differences between the three study regions.

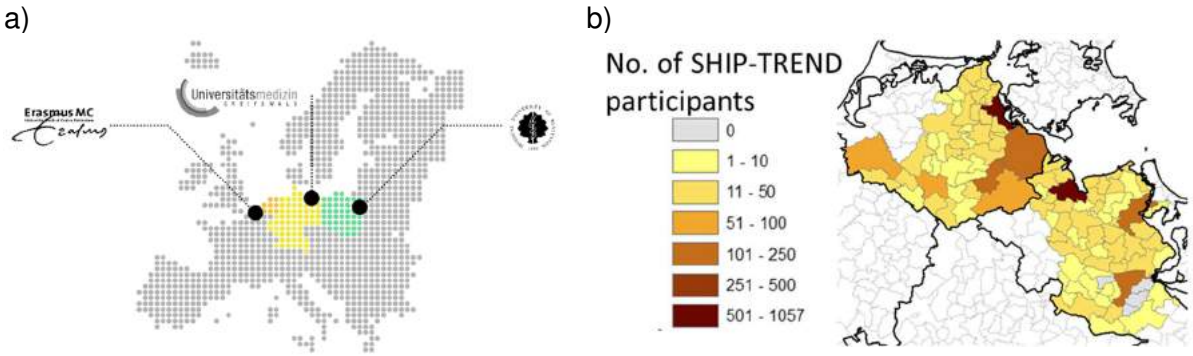

Figure 2a and b. Location of the three cohort partners (a) and number of SHIP-TREND participants per commune in the SHIP study region (b); SHIP-TREND is the 2nd of three SHIP cohorts.

4.5.4 Cohort study regions

The total population of the study regions of SHIP, the Rotterdam Study and Bialystok Plus comprises an estimated number of 244, 630 and 300 thousand inhabitants. The study regions of the Rotterdam Study and Bialystok PLUS are larger cities. On the contrary, the SHIP study region covers

- two rural districts with two cities (Greifswald and Stralsund, both with almost 60,000 inhabitants)
- three towns (Grimmen, Anklam and Wolgast, with 10,000 to 12,000 inhabitants each) and
- 99 rural communes with median population densities of 26 inhabitants per km^2 (interquartile range: 17 – 50)

Both the SHIP and Bialystok study regions are border regions (SHIP: Poland; Bialystok: Belarus) and belong to the economically less developed regions in their country.

4.5.5 Cohort institutions

A prospective, population-based cohort study is an observational study, which recruits community-dwelling individuals in which baseline data are collected on characteristics, health outcomes and other potential exposures of all participants at study initiation are determined. Data collection procedures are designed carefully, in order to have information about exposures before disease manifests in any of the participants. This 'cohort' of participants is subsequently monitored over time to determine disease events. Hence, this study type allows assessing incidence of disease, disease risks associated with the measured exposures as well as long-term consequences of disease.

Since cohort research generates large amounts of population-representative data regarding a wide range of diseases and potentially modifiable risk factors associated with such diseases, the results from cohort studies are often used to guide public health policies and to inform clinical practice.

Medical strongholds

The cohort implementing institutions are all part of strong medical universities. Population-based cohort research is tightly linked with medical departments (sharing staff, instruments, expertise, etc.). The set-up and implementation of cohort research requires highly sophisticated processes and structures as well as strong financial backup.

Social inequality and divide in science literacy is therefore expected to play a role. Partners debated several times to what extent differences in science literacy affect the interest of locals to actively engage in JoinUs4Health. Therefore, this is an important aspect to consider as part of the evaluation.

Table 4. Overview of the three cohort studies implemented by the three JoinUs4Health partners UMG (SHIP), MUB (Bialystok PLUS) and EMC (Rotterdam Study)

Cohort study	Country	(Sub-)Cohort	Start	N
Study of Health in Pomerania (SHIP) [a]	Germany	SHIP	1997	4,308
		TREND	2003	4,420
		NEXT	2021	[4,400]
Bialystok Polish Longitudinal University Study [b]	Poland	PLUS	2018	637
Rotterdam Study	Netherlands	RS-I	1989	7,983
		RS-II	1999	3,011
		RS-III	2006	3,932
		RS-IV	2016	3,006
Total				27,297

[a] Examinations of SHIP-NEXT started in June 2021 with the aim or enrolling 4400 new participants until 2026
[b] Examinations of PLUS started in late 2019

Duration of cohort implementation and size of cohorts

The three cohort institutions have long-standing experience in population-based cohort research with in total 58 years of data, from over 28,000 participants (Table 4). Until 12/2023 approximately 5,000 additional participants will be enrolled as part of SHIP (n ≈ 3,000) and PLUS (n ≈ 2,000).

The coordinated approach between the three cohort partners offers specific advantages regarding organizational learning with public involvement, since all cohorts are prospective and repeatedly examine study participants approximately every five years. This creates a strong bond with many participants who therefore are on average more likely to engage in research and contribute to change than locals without any link to an ongoing study.

Furthermore, cohorts are embedded in extensive local, regional, national and international networks, communities and consortia, which can be mobilized depending on the respective focus area.

Effects of the COVID-19 pandemic

The extent of the societal shake-up has and will be strongly felt by many individuals and societal groups. As part of cohort research, the effects of the pandemic will be seen in measures of population health as well as participation in medical examinations due to lockdowns, distancing requirements, safety measures, reluctance of participants to be exposed, or self-isolation requirements. The pandemic may hopefully also contribute to a shift in thinking of previously "more traditionally thinking" scientists towards stronger openness to RRI approaches in association with cohort research in the longer term.

Familiarity with RRI

Neither of the cohort partners have had in-practice experience with RRI, systems thinking, transdisciplinary or participatory research. Since the start of the project, cohort partners have not yet managed to engage deeply with RRI or engaged their institutional colleagues deeply with the concept yet. For many cohort representatives (outside the consortium), a potentially attractive benefit of JoinUs4Health is the potential to enhance participation (response) in cohort research, which would justify long-term investment into this concept.

4.6 Element 2: Assessment of expected and unexpected outcomes based on the Theory of Change

- What does the JoinUs4Health initiative do
    - Provide opportunities for structured exchange in a controlled environment
    - Participatory democracy
    - networking … (see rough list of bullet points in section 2)
- how does the initiative do it: In a responsible manner (according to principles of RRI)
- 1st order impact
    - innovation: Through cross-fertilization and diversity
    - empowerment of citizens: Through participatory democracy
    - integration of knowledge: Through valuing diverse inputs
    - …
- 2nd order impact
    - Increased trust and interest in science

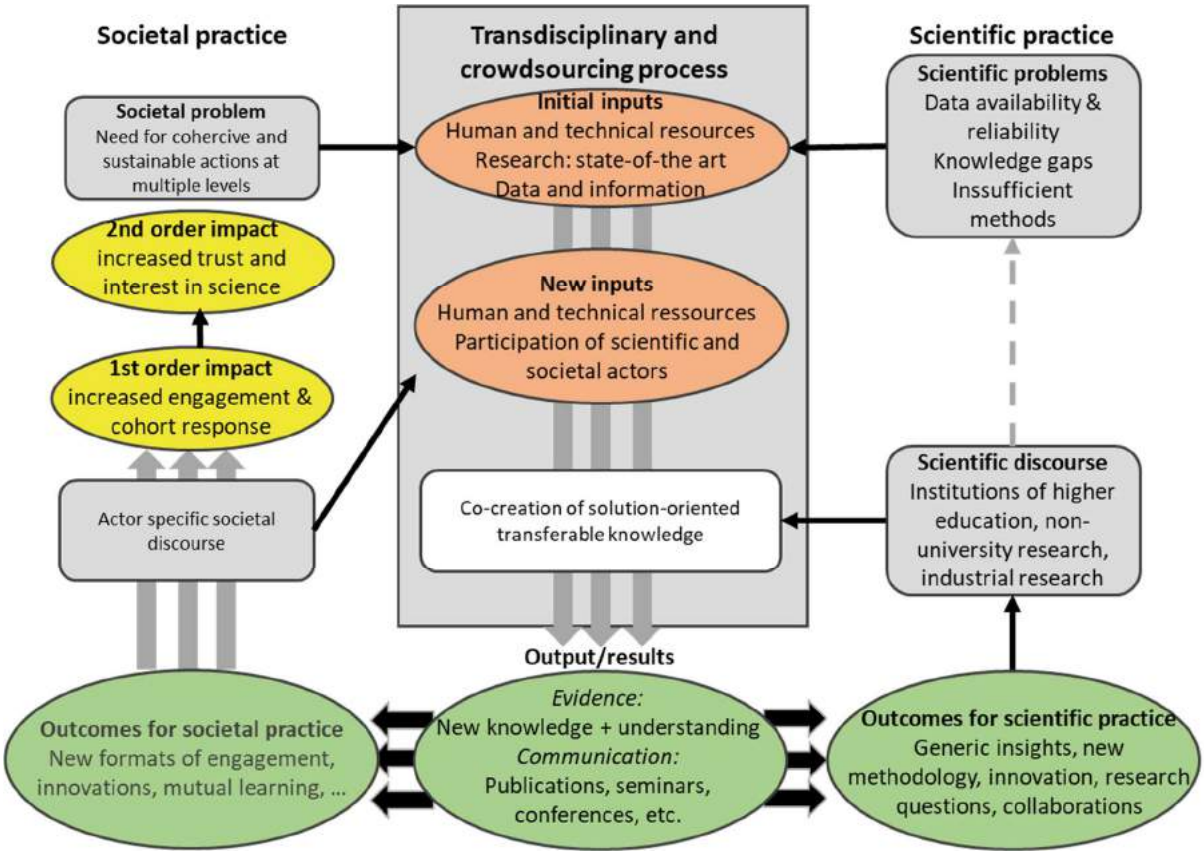

Figure 3. The change pathway for the JoinUs4Health project adapted from Rüegg, Häsler et al. (2018)

4.7 Element 3: Assessment of the implementation of operations and infrastructures

The aspects of operations are captured via the "dimensions" Thinking, Planning, and Working, whilst the supporting infrastructure is evaluated via the dimensions "Systemic organisation", "Learning", and "Sharing". All these six areas are summarised as process characteristics, originally termed as "OH-ness"). We aim to apply this framework to JoinUs4Health, ideally also to assess the "RRI-ness" of the initiative.

4.8 Element 4: Comparison of the assessments carried out in Elements 2 and 3

This fourth Element shall compare the outcomes and the index (RRI-ness) as well as different ways of applying the framework.

5 Relation to MoRRI and SDG indicators

MoRRI indicators and SDGs provide frameworks for common indicators.

Table 5. Specifications of MoRRI indicators which are envisaged to be addressed based on the JoinUs4Health Description of Action

ID	Description
PE	**Public engagement**
PE3	Citizen preferences for active participation in S&T decision making / assessments of working packages

ID	Description
PE5	Generating means and providing resources (cohort results, staff time) to support low- and high-level interactions as part of the platform
PE6	Dedicated resources for Public Engagement / platform, cohort data, educational materials etc.
PE7	Public engagement activities are directly and indirectly embedded in the funding structure of the cohort and associated institutions relating to activities about a) disseminating research to citizens or societal stakeholders, b) involving citizens or societal stakeholders in research activities and c) on public engagement.
PE7	Promotion of RRI activities within the organization by encouraging staff to contribute to working groups is an indirect investment, and this will be sustained after the end of the project.
PE7	Generation and translation of educational materials as well as staff time paid via the project is not fully budgeted so that in-kind contributions by all research partners are envisaged.
PE7	Uptake of citizens' ideas and suggestions into cohort research and assessment of the effects of engagement via questionnaires are covered via non-project funds.
PE7	Performance-based incentives (e.g. annual pot of 10,000 Euros to be distributed to the most active institutions / researchers) are envisaged but cannot be guaranteed without prior in-depth consultations with the university's management body, especially in times of coronavirus. But this indicator will be promoted and evaluated as part of the project.
PE8	One citizen science board per cohort institution, which revises working group proposals
PE8	Encouraging scientific staff to present their ideas to platform users before submitting data access applications and funding proposal
PE9	R&I democratization index / democratic and transparent engagement
ETH	**Ethics**
E1	Ethics at the level of Universities / recognition of contribution, pyramid system - upgrade in experience levels, ethics advisors from various groups of stakeholders)
GOV	**Governance**
GOV2	Establish processes for managing RRI-related governance mechanisms in terms of ethics, citizen engagement, open access and open science, gender equality, responsible research and innovation and formal, informal and non-formal science education in various ways
GOV3	Encourage researchers to address these fields
GOV3	Encourage other institutions to address these fields.
SLSE	**Learning and education**
SLSE2	RRI related training / e.g. training of researchers and PhD students)
SLSE3	Science communication / targeted communications and disseminations
SLSE4	Citizen science activities in RPOs / measured by number of platform users and working groups
GE	**Gender equality**
GE10	Number and share of female inventors and authors
OA	**Open access**
OA3	Social media outreach
OA6	RPO support structures for researchers / incentives for data sharing, RRI training and engagement via the platform and other means).

6 M&E methodology

6.1 Levels of evaluation

Level of evaluation: M&E can be carried out at different levels:

1. JoinUs4Health platform
2. cohort institutions
3. management cycles
4. overall project

Evaluations carried out at levels 1-3 will be based on the Indicator Matrices such as the WP3 example in Appendix I. For the impact evaluation of the overall project, we consider applying the NEOH project, which will be discussed with stakeholders during a M&E workshop in mid-2022.

6.2 Timing and process of evidence collection

Starting in Quarter 3 of 2022, M&E will be performed via continuous as well as regular, interim assessments (Table 6). Continuous collection of evidence can be achieved through automated reporting via

- the platform
- facilitators of working and study teams and
- questionnaire-based assessments of cohort participants (level of awareness and perception of the project and prior engagement) as cohort examinations are carried out continuously over time

Besides such objective (e.g. factual, quantitative) evidence, we will also include subjective (e.g. opinion-based, qualitative) evidence such as interim questionnaires and focus group discussions.

Table 6. Target groups, means and frequency of assessment of evidence collected for monitoring purposes

Target group	Means of assessment	Frequency of assessment
Platform users	General platform indicators[a]	Continuously
Active platform users	Facilitators' reports; moderators' and mentors' assessments, feedback by other users, …	Continuously
Cohort scientists and other cohort staff members	Internal monitoring systems[b]	Continuously
General population in the cohort study regions	Interview questions assessed during cohort examinations	Continuously
General public	Questionnaires or opinion polls	Quarterly
Platform users	Questionnaires or opinion polls	Quarterly
Citizen science board and monitoring members	Focus group discussion	Quarterly
Public health officials	Questionnaires or opinion polls	Biannually

[a] e.g. no. of submitted questions, no. of items open for voting, no. of votes, no. of likes/follows/shares, no. of active votes, no. of active contributors, no. of working teams, no. of study teams, …
[b] e.g. no. of data applications with prior/planned engagement of / dissemination to community; publications, which were opened for discussion prior to submission, …

6.3 Costs

The cost of collecting these data is relatively low. Some platform-based indicators can be automatically collected. Institutional-level data need to be collected to monitor the level of institutional integration of RRI methodologies as an institutional change. Details to collection institutional-level data need to be discussed with cohort representatives during the M&E workshop in January 2022.

The costs of collecting cohort-associated data collections depends on the type and duration of assessments. At this stage only a short self-administered questionnaire is planned to assess whether cohort participants have already heard of the project and accessed the website of platform to assess whether awareness of the JoinUs4Health platform influences the preparedness to participate in cohort research.

6.4 Project self-assessment & reflection

This deliverable will be used as a basis for future reflection not just for project partners, but also the members of the M&E groups. Indicators need to be elaborated on to capture the success criteria for the project objectives in more detail. Questionnaires, interviews and workshops allow further capturing input from different stakeholder groups and experts. Based on the feedback, a revised version of the M&E framework will be provided with the first evaluation report, which is planned after the evaluation workshop was held mid-2022.

6.5 Responsibilities

The coordinator is responsible for gathering feedback from all WP leaders to complete the evaluation and finalize the report. Work Package leaders contribute to all stages of the evaluation process in regard to their own Work Package. The M&E groups of the three cohort institutions and additional representatives from all stakeholder groups will be engaged in the planning of the evaluation process and revision of the evaluation reports.

Appendix I. Details on evaluation criteria for Work Package3

Table 7. Preliminary indicator matrix for Work Package 3 “Technical implementation” (lead: UMG)

Criterion ID	Activities	Assumptions	Outputs / impacts	Measures	Means of gathering	Risks
3.1	Co-design of platform requirements	All RRI groups are engaged in co-design activities	A clearly defined set of requirements JoinUs4Health platform that meets the needs of all RRI groups	Satisfaction of different stakeholders with the requirements list (or features) of the platform	Individual and group interviews Workshops with consortium partners, platform users, representatives from cohort institutions and other stakeholders	Expectations and interests of the stakeholder groups differs widely Challenge to structure, merge diversified feedback
3.2	Engagement via the platform	All RRI groups are engaged in platform activities	All RRI groups engage in low- and high-level interactions of the platform	Usability of the platform	Individual and group interviews Workshops with consortium partners, platform users, representatives from cohort institutions and other stakeholders	The platform is not intuitive and user-friendly The platform does not meet users' expectations
3.3	Community building via the platform	JoinUs4Health platform is up and running Requirements clearly defined	Diverse community receives regular updates (newsletters, social media), visits the platform and engages in low- and high-level interactions		User survey and user testing Usability evaluation with gender balance and W3C accessibility in mind	

Criterion ID	Activities	Assumptions	Outputs / impacts	Measures	Means of gathering	Risks
3.4	Community and platform management	JoinUs4Health platform is up and running Requirements clearly defined	Communication in social media and newsletters Low-level interactions on the platform High-level interactions via the platform (facilitated study and working teams)	Feedback from newsletter recipients, social media users receiving communications and platform users engaging in low- or high level interactions		
3.5	Platform maintenance (during and beyond the project funding period)	JoinUs4Health platform is up and running Requirements clearly defined	Development (M&E report I) plan for the platform Sustainability and maintenance plan for the platform (M&E report II and final M&E report)	Ongoing development of the platform beyond pure maintenance (M&E report I) Commitment from UMG to invest into the platform beyond the project (M&E report II and final M&E report)	Development plan available considering budget constraints Interview with key stakeholders from UMG	Lack of skills or resources within Science4People (within project period) Lack of skills or resources within UMG (beyond end of project)

Appendix II. Questionnaire to obtain feedback to the online platform

Access to questionnaires: German: https://ship.limequery.org/614216?lang=de; English: https://ship.limequery.org/614216?lang=en; Dutch: https://ship.limequery.org/614216?lang=nl; Polish: https://ship.limequery.org/614216?lang=pl

English version

Please note: Layout differs from layout of online version in Limesurvey; numbers are the value categories specified in Limesurvey (not visible as part of the online version)

1. What is your overall impression of the JoinUs4Health platform?

   ** Please choose the appropriate response for each item:*

	very good	good	neutral	not good	not good at all	not specified
Visual design	☐	☐	☐	☐	☐	☐
Navigation	☐	☐	☐	☐	☐	☐
User-friendliness	☐	☐	☐	☐	☐	☐
Wording - platform	☐	☐	☐	☐	☐	☐
Interface	☐	☐	☐	☐	☐	☐
Wording – platform contents	☐	☐	☐	☐	☐	☐

2. How can we improve the visual design?

   Please write your answer here: ……

   Condition: Answer was 'not good at all' or 'not good' or 'neutral' or 'good' in Question 1 / Visual design

3. How can we improve navigation on the platform?

   Please write your answer here: ……

   Condition: Answer was 'not good at all' or 'not good' or 'neutral' or 'good' in Question 1 / Navigation

4. How can we improve general user-friendliness?

   Please write your answer here: ……

   Condition: Answer was 'not good at all' or 'not good' or 'neutral' or 'good' in Question 1 / User-friendliness

Home page

5. What is your impression of the landing page?

   ** Please choose the appropriate response for each item:*

	fully agree	agree	neutral	don't agree	don't agree at all	not specified
After a short time, I had a reasonable idea of what this project was about.	☐	☐	☐	☐	☐	☐
The landing page invites me to look further into the platform.	☐	☐	☐	☐	☐	☐

6. Did you register on the platform?

   ** Please choose only one of the following:*

1	yes
0	no
999	not specified

7. Do you have suggestions on how to improve the registration form?

   ** Please choose only one of the following:*

   Condition: Answer was 'yes' in Question 6

1	yes
0	no
999	not specified

8. namely:

   Please write your answer here: ……

   Condition: Answer was 'yes' in Question 7

9. Have you received an activation email after your registration on the platform?

   ** Please choose only one of the following:*

   Condition: Answer was 'yes' in Question 6

1	yes
0	no
999	not specified

Suggestions

10. Do you have any comments on the page 'Suggestions'?

    ** Please choose only one of the following:*

1	yes
0	no
999	not specified

11. namely:

    Please write your answer here: ……

    Condition: Answer was 'yes' in Question 10

12. How can we improve the filter variables and filtering options?

    Please write your answer here: ……

    Condition: Answer was 'yes' in Question 10

Topics

13. Do you have any comments to the page 'Topics'?
    ** Please choose only one of the following:*

1	yes
0	no
999	not specified

14. namely:
    Please write your answer here: ……:

    Condition: Answer was 'yes' in Question 13

Tasks

15. Do you have any comments to the page 'Tasks'?
    ** Please choose only one of the following:*

1	yes
0	no
999	not specified

16. namely:
    Please write your answer here: ……

    Condition: Answer was 'yes' in Question 15

Teams

17. Do you have any comments to the page 'Teams'?
    ** Please choose only one of the following:*

1	*yes*
0	*no*
999	*not specified*

18. namely:
    Please write your answer here: ……

    Condition: Answer was 'yes' in Question 17

Profile

19. Do you have any comments to the page 'Profile' (click on user icon top right)?
    ** Please choose only one of the following:*

    Condition: Answer was 'yes' in Question '6

1	*yes*
0	*no*
999	*not specified*

20. namely:
    Please write your answer here: ……

    Condition: Answer was 'yes' in Question 19

Closure

21. Which of the following devices would you preferably use when accessing the platform?

** Please choose only one of the following:*

1	*desktop*
2	*laptop*
3	*tablet*
4	*smartphone*
999	*not specified*

22. Were the questions of this survey easy to understand?

** Please choose only one of the following:*

1	*yes*
0	*no*
999	*not specified*

23. Here you can add any further comments to the project, platform or testing.

Please write your answer here: ……

Personal details

This is an anonymous survey. However, your information on age group and gender supports the evaluation of the feedback in the course of the platform testing.

24. Which age group do you belong to?

** Please choose only one of the following:*

1	*16-20 years*
2	*21-30 years*
3	*31-40 years*
4	*41-50 years*
5	*51-60 years*
6	*61-70 years*
7	*>70 years*
999	*not specified*

25. What is your gender?

** Please choose only one of the following:*

1	male
2	female
3	diverse
999	not specified

Thank you very much for your feedback to the JoinUs4Health platform!

Appendix III. Questionnaire for SHIP-participants

Translated from German to English

Please note: Layout differs from layout of online version in Limesurvey; numbers are the value categories specified in Limesurvey (not visible as part of the online version)

1. For what reasons are you taking part in the SHIP examination? *(multiple selection possible)*

1	to learn more about my own health
2	to do something for the common good
3	to support research
4	because of the expense allowance
5	to experience how a scientific study works
6	to please my family / friends / acquaintances (I was "persuaded")
7	other reasons, namely: .....
999	don't know

2. Have you noticed this project flyer in the invitation?

1	yes *(go to Question 4)*
0	no

3. Have you heard or read about the JoinUs4Health project?

Condition: Answer was 'yes' in Question 2

1	*yes*
0	*no* (go to Question 5)
999	*not specified* (go to Question 5)

4. How did you find out about JoinUs4Health? (multiple choice)

Condition: Answer was 'yes' in Question 3

1	*online search (for example Google search)*
2	SHIP website
3	*Facebook*
4	*radio*
5	*television*
6	*online recommendation from friends, family, acquaintances or work circle*
7	*personal recommendation (conversation or telephone call) from friends, family, acquaintances or work circle*
8	*newspaper / magazine*
9	*other, namely* .....

5. Have you looked at the JoinUs4Health content on the website?

Condition: Answer was 'yes' in Question 3

1	*yes*
0	*no*
998	*I didn't know that a website existed*
999	*not specified*

6. Have you looked at JoinUs4Health content on the platform?

   Condition: Answer was 'yes' in Question 3

1	*yes*
0	*no*
998	*I didn't know that a platform existed*
999	*not specified*

   If answer is b, c or d and answer was 'no' or 'not specified' in Questions 5 and 6: Then end of questionnaire

7. Have you ever registered on the platform?

   Condition: Answer was 'yes' in Question 6

1	*yes*
0	*no*
999	*not specified*

8. Have you used the JoinUs4Health platform to ...

   (yes / no option for each sub-question)

   Condition: Answer was 'yes' in Question 7

1	*... submitted a proposal?*
2	*... voted on the proposals of others?*
3	*... participated in a group exchange?*
4	*... worked on a task?*
5	*... participated in an online event?*

9. What is your impression of the project so far?

   Condition: Answer was 'yes' in Question 5 OR Question 6

1	*very positive*
2	*positive*
3	*neutral*
4	*negative*

10. What do you expect from the JoinUs4Health project for yourself personally or for the Western Pomerania region?

    Condition: Answer was 'yes' in Question 5 OR Question 6

    Free text: .....

Appendix IV. Stamps handed out to the intervention group

Figure 4. Stamps received by the intervention group who is informed about JoinUs4Health

Figure 5. Stamps received by the control group who is not informed about JoinUs4Health

Glossary

Baseline	a) in relation to cohort research: baseline examination means the first examination of a cohort participant; b) in relation to indicators: the value of the indicator before the JoinUs4Health project has been undertaken, i.e. the situation within the local societies of the cohort study regions and beyond before the JoinUs4Health intervention
Common indicators	a list of indicators with agreed definitions and measurement units to be used where relevant, permitting aggregation to the national and EU level.
Evaluation	the systematic collection and analysis of information about programmes and projects, their purpose and delivery; it derives knowledge on their impact as a basis for judgments. Evaluations are used to improve effectiveness and inform decisions about current and future programming
Impact	the change that can be credibly attributed to an intervention. Same as “effect” of intervention or “contribution to change”
Indicator	a variable that provides quantitative or qualitative
Method	families of evaluation techniques and tools that fulfil different purposes. They usually consist of procedures and protocols that ensure systemisation and consistency in the way evaluations are undertaken. Methods may focus on the collection or analysis of information and data; may be quantitative or qualitative; and may attempt to describe, explain, predict or inform action. The choice of methods follows from the nature of the intervention, the evaluation questions being asked and the mode of enquiry – causal, exploratory, normative etc. (European Commission 2014)
Monitoring	observe whether intended products are delivered and whether implementation is on track (European Commission 2014)
Output	direct product of a programme intended to contribute to results. (European Commission 2014)
Output indicator	an indicator describing the “physical” product of spending resources through policy interventions. Examples are: the length, width or quality of the roads built; the number of hours of extra-teaching hours provided by the intervention; the capital investment made by using subsidies. (European Commission 2014)
Result	the specific dimension of the well-being of people that motivates policy action, i.e. that is expected to be modified by the interventions designed and implemented by a policy. Examples are: the mobility in an area; the competence in a given sector of activity (European Commission 2014)
Result indicator	an indicator describing a specific aspect of a result, a feature which can be measured. Examples are: the time needed to travel from W to Y at an average speed, as an aspect of mobility; the results of tests in a given topic, as an aspect of competence; the share of firms denied credit at any interest rate, as an aspect of banks’ rationing. (European Commission 2014)

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