

945345 – H2O

Health Outcomes Observatory

WP7 – Scientific Coordination & Project Management

D7.3 Scientific Publication Plan

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1. Definitions

Participants of the H2O Consortium are referred to herein according to the following codes:

1. **MUW.** Medizinische Universitaet Wien.
2. **Charité.** Charite – Universitaetmedizin Berlin
3. **EMC.** Erasmus Universitair Medisch Centrum Rotterdam
4. **ICS-HUVH.** Institut Catala De La Salut – Hospital Universitari Vall d’Hebron
5. **KCL.** King’s College London
6. **KUL.** Katholieke Universiteit Leuven
7. **EPF.** Form Europeen des Patients / European Patients’ Forum
8. **I-HD.** The European Institute for Innovation through Health Data
9. **The Hyve.** The Hyve BV
10. **TEAMIT.** TEAM IT Research SL
11. **KUH.** Karolinska Universitetssjukhuset
12. **UniSR.** Universita Vita-Salute San Raffaele
13. **IKNL.** De Stichting Integraal Kankercentrum Nederland
14. **TAKEDA.** Takeda Pharmaceuticals International AG
15. **NVS.** Novartis Pharma AG
16. **ABBVIE.** AbbVie INC
17. **Lilly.** Ali Lilly and Company Limited
18. **MDT.** Medtronic International Trading SARL
19. **Pfizer.** Pfizer Limited
20. **ROCHE.** F. Hoffman-La Roche Limited
21. **SARD.** Sanofi-Aventis Recherche & Development
22. **JDRF.** JDRF International
23. **Trial Nation.** Trial Nation

Grant Agreement. (Including its annexes and any amendments) The agreement signed between the beneficiaries of the action and the IMI2 JU for the undertaking of the H2O project (Grant Agreement No. 945345).

Project. The sum of all activities carried out in the framework of the Grant Agreement.

Consortium. The H2O Consortium, comprising the above-mentioned legal entities.

Consortium Agreement. Agreement concluded amongst H2O participants for the implementation of the Grant Agreement. The agreement shall not affect the parties’ obligations to the Community and/or to one another arising from the Grant Agreement.

2. Abbreviations

- **KPIs** Key Performance Indicators
- **LOINC** Logical Observation Identifiers Names and Codes
- **ML** Machine learning
- **NCI** National Cancer Institute
- **OHDSI** Observational Health Data Sciences and Informatics
- **OMOP** Observational Medical Outcomes Partnership
- **PAB** Patient Advisory Board
- **PREM** Patient-reported experience measures
- **PRO-CTCAE** Patient-Reported version of the widely used Common Terminology Criteria for Adverse Events
- **PROFILES** Patient Reported Outcomes Following Initial treatment and Long-term Evaluation of Survivorship
- **PROMs** Patient-Reported Outcome Measures
- **PROMIS** Patient-Reported Outcomes Measurement Information System
- **PROs** Patient-Reported Outcomes
- **SAB** Scientific Advisory Board
- **SES-CD** Simple Endoscopic Score for Crohn Disease
- **SME** Small Medium Enterprise
- **VMU** Vrije Universiteit Medisch Centrum
- **WHO** World Health Organisation

3. Abstract

Peer-reviewed publications and presentations on conferences are essential to establish credibility and show thought leadership in the scientific community. The deliverable D7.3 Scientific Publication Plan outlines the Health Outcomes Observatory (H2O) project's planned efforts to support and promote scientific publications and presentations at conferences. It details current and anticipated research activities at the time of submission (M12; September 2021) and their associated dissemination through publication and/or presentation. This document will be updated and supplemented as needed with specific publication tactical plans over the duration of the project.

The main objective of this document is to provide a guideline and reference for the scientific dissemination of H2O's results. It complements the efforts of the Work Packages and the project deliverables, ensuring that project results are disseminated to their fullest potential.

The following areas are included in this document:

- An assessment of the scientific context of the project and analysis of potential publishing factors.
- An analysis of target audiences for the project's scientific communication.
- An overview of the overall publication strategy for the project, including known publications at the time of submission.
- Identification of target journals and conferences for H2O communication and dissemination.

4. Introduction

H2O is the first ever unified attempt to collect and incorporate patient-reported outcomes into health care decision-making at individual and population levels across multiple locations in Europe. By capturing and integrating new information from the patient perspective, the H2O project represents an innovative opportunity to advance health research as well as healthcare systems, using real-world evidence based on data reported from patients combined with clinical data. Scientific manuscripts on the value of PRO's, data registries, the philosophy of value-based healthcare, as well as the selection process for outcomes are expected to be published. Furthermore, papers on the development of new structures and organizational models intended for use with health data will be published. These will focus more on change management and business innovation. Additionally, as a public-private partnership focused on enhancing patients' role within healthcare delivery, H2O will provide valuable insight into the legal and public policy dimensions of innovative patient-centred healthcare, as well as the development of novel patient-centered healthcare business models. Manuscripts on these topics are also expected to be published.

“Dissemination” in the consortium agreement (Chapter 1 – Definitions) is defined as any public disclosure by a Beneficiary of project results by any appropriate means (other than public disclosure from seeking protection for and/or exploiting such results), including but not limited to scientific publications (in any medium), press releases, content on a website, or presentations at a conference. In this deliverable, we focus on scientific publications only.

5. Scientific communication assessment

5.1. Context

As a large-scale multi-stakeholder and multi-jurisdictional ecosystem incorporating patient-reported and other health outcomes into health care decision-making across Europe, H2O is uniquely positioned to analyze and report on the interactions between healthcare delivery, medicines, patient comorbidities, and patient-reported outcomes. These data will provide unprecedented visibility into the relationship between the delivery of healthcare services and their effects on patient-reported outcomes. Furthermore, the infrastructure and governance of H2O across a multi-jurisdictional ecosystem will position H2O to disseminate knowledge on best practices associated with legal requirements, public policy, data governance and business modelling within patient-centered healthcare ecosystems. Publications from the H2O project will provide evidence for the value of outcome-focused care to health professionals, policy makers, financiers and other stakeholders, as well as document the procedures and practices for the development, deployment and maintenance of multi-stakeholder, multi-jurisdictional healthcare ecosystems.

5.2. SWOT/Situation analysis

There is a distinct possibility to include brief literature assessment/gap analysis. A large consortium with its many experts and viable network is a strength to get publications accepted, while the huge volume of submissions to journals is a threat. To mitigate potential delays and the unpredictability of the publication process, Zenodo will be utilized for the purpose of collecting pre-publication deliverables without diminishing their peer-reviewed value.

5.3. Target audiences

The target audience for the scientific publications is the scientific and academic communities. The language will be written closer to an expert manner. The topics will focus on outcomes research, value-based healthcare, the results of the Delphi studies, and other technical topics. The writing will be tailored to professional researchers, clinicians, and institutional scholars as well as policy makers, industry leads, and the broader legal community.

6. Scientific key messages

- To raise the profile of PROs in the three disease areas and beyond
- To widely socialize the outcome sets in healthcare in the four H2O Tier One Countries, but also outside Europe
- To generate evidence on whether the use of PROs leads to improved general health outcomes
- To disseminate the H2O governance principles which have been described in the NEJM Catalyst publication: <https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0146>
- To determine criteria for stratification based of PROs
- To build a basis for outcome transparency and re-use of health data for research and other legitimate purposes

7. Publication plan

A mixture of deliverable-associated and additional publications on various topics are planned. Additionally, a mixture of presentations/abstracts/posters/papers. The scope of release is noted below. Some of this is known now and some will develop as the project progresses.

Note: to be filled out with known publications & further information added throughout project. Specific authors to be selected by assigned work package. The listed items are the predetermined deliverables agreed upon by the consortium. Additional publications are possible but require approval and consortium review.

7.1. Concept paper and project plan (already published)

The aim of this publication was to disseminate the concept and project plan of the H2O project.

<https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0146>

Stamm, T., Bott, N., Thwaites, R., Mosor, E., Andrews, M. R., Borgdorff, J., ... & Styliadou, M. (2021). Building a Value-Based Care Infrastructure in Europe: The Health Outcomes Observatory. NEJM Catalyst Innovations in Care Delivery, 2(3).

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Concept & project plan	Stamm et al.	External stakeholders	NEJM Catalyst	MUW/Takeda	-

7.2. Delphi results/core outcome sets

The Delphi studies will help build on existing standards of outcome sets using a multi-stakeholder approach. A key feature is the inclusion of patients in their development from the onset. Through this

iterative process each of the three disease WP's can produce an outcome set specific to their disease type, as reflected in the outcome items chosen in the Delphi rounds.

In addition, a generic patient-reported outcome set will be developed independent of the three disease areas. There are several reasons for the additional development of a generic set. To begin, it helps flush out common generic outcomes across the WP's, as well as highlight potential gaps in a disease-specific set. For instance, a WP may hyper focus on items relevant to a specific disease while overlooking equally important generic indicators like general health status or overall health-related quality of life. Furthermore, the generic PROs could serve as the first interface of the developed app. That is, patients across disease types would be first asked about generic PROs such as their overall well-being, mood or pain and then be given an option to answer more disease or symptom specific PROs. Users may be willing to answer short generic PROMs more often than comprehensive disease-specific PROMs too. While the latter can be used for adjusting actual treatments and measuring treatment goals, short generic PROs may be useful in self-monitoring or improving patient-doctor communications. Third, a generic Delphi survey relevant to chronic diseases in general is also meaningful given that H2O plans to expand beyond the three diseases in the future. Finally, as outlined in WP2 (Task 2.10), one of the important aspect of the H2O project is to ensure the interoperability of data collected across the three diseases. Different PROMs which are used to measure same or similar PROs across the three diseases will be ultimately calibrated into a single common metric using the item response theory (IRT) method. For this to happen, it is important to identify key generic domains/PROs that are relevant across different diseases.

The planned publications in the table below are results from the following deliverables:

D3.2 Report on initial core outcome set for diabetes WP3 5 - KCL Month 12 (new: 18)

D4.1 Report on the initial core outcome set for IBD WP4 6 - KUL Month 12 (new: 18)

D5.1 Report of cancer patients prioritized for inclusion and initial outcome set WP5 13 - IKNL Month 12 (new: 18)

D5.5 Report of further evaluated core outcome set with newly developed PROMs WP5 13 - IKNL Month 60 – planned as **short communication rather than a full publication**

D7.5 Publication on the generic outcome set of all three diseases WP7 1 - MUW Month 30

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Diabetes Delphi/ outcome set (D3.2)	Porth et al.	Internal and external stakeholders (Int/Ext) + a lay version for patients	Leading diabetes journal	MUW, supported by KCL	M18+
Literature review regarding the diabetes core outcome set (Part of D3.2)	Hopkins et al.	Int/Ext	Standard diabetes journal	KCL	M18+
IBD Delphi/ outcome set (D4.1)	Fierens et al.	Int/Ext + a lay version for patients	Leading IBD journal	KUL	M18+
Metastasized breast cancer Delphi/outcome set (Part of D5.1)	De Rooji et al.	Int/Ext + a lay version for patients	Leading oncology journal	INKL	M18+

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Lung cancer Delphi/outcome set (Part of D5.1)	De Rooji et al.	Int/Ext + a lay version for patients	Leading oncology journal	INKL	M18+
Up-dated version of outcome set in a cancer type (to be determined) (D5.5)	De Rooji et al.	Int/Ext	Planned as short communication, rather than a full publication; <i>Cancer Discovery</i> or other Leading Oncology Journal	INKL	M60+
Generic Delphi/outcome set (D7.5)	Seidler et al.	Int/Ext + a lay version for patients	Leading journal in general health	MUW	M18+

7.3. Requirements specifications

We plan to publish the requirements specifications from the perspective of patients and health professionals which are gathered alongside our co-creation process.

The planned publications in the table below are results from the following deliverables:

D3.1 Report on requirements specification, WP3 – KCL Month 9 (new: 18)

D4.2 Report on requirements specification, WP4 – KUL Month 12 (new: 18)

D5.2 Report on requirements specification, WP5 – IKNL Month 12 (new: 18)

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Requirements specification (D3.1, D4.2 and D5.2)	To be determined	Int/Ext	Technology journal	MUW	M18+

7.4. Observatories blueprint

The aim of this publication is to disseminate the Observatories' blueprint. This could be used for scaling up in other countries and other disease areas.

The planned publications in the table below are results from the following deliverables:

D7.4 Publication on the blueprint of the national and the pan-European H2O Observatories WP7 1 - MUW ORDP: Open Research Data Pilot Public 24

Topic/Publication	Authors	Target Group	Target Journal	Lead	Month
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				partner	
H2O Blueprint	To be determined	External	OpenAIRE	MUW	24+

7.5. Architecture specification

Similar to the blueprint, we will publish the architecture specification.

The planned publications in the table below are results from the following deliverables:

D2.2 Development of an architecture blueprint Charité Month 12

D2.1 Development of a cross-calibration method to be used in all three disease areas, and exploration of a cross-calibration approach between all core outcome sets and PRO tools Charité Month 36

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Architecture blueprint	Prasser et al.	Internal	Zenodo	Charité	12+
Cross-calibration method	To be determined	Int/Ext	Medical informatics journal	Charité	36+

7.6. Patient stratification based on PROs/framework for personalized prediction tool

According to what we outlined in the project proposal, we will use the data generated in H2O for stratification in the three disease areas.

The planned publications in the table below are results from the following deliverables:

D3.6 Research agenda for further research and new treatment recommendations on patient stratification/ segmentation (WP3) WP3 1 - MUW Month 36

D3.8 Academic paper that explores the possibility of patient stratification based on PROs and describes the framework to build the personalized prediction tool (WP3) WP3 5 - KCL Month 60

D4.5 Research agenda and plan for further research on patient stratification WP4 6 - KUL Month 36

D4.7 Academic paper that explores the possibility of patient stratification based on PROs and describes the framework to build the personalized prediction tool (WP4) 6 - KUL Month 60

D5.6 Academic paper that explores the possibility of patient stratification based on PROs and describes the framework to build the personalized prediction tool, including necessary characteristics and access to data and/or programming code (WP5) WP5 13 - IKNL Month 60

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
Research agenda PRO Stratification Diabetes (D3.6)	To be determined	Int/Ext	<i>Health Data Science</i> or a leading diabetes journal	MUW	M36+
Stratification based on PROs Diabetes (D3.8)	To be determined	Int/Ext	To be determined	KCL	M60+
Research	To be	Int/Ext	<i>Gut</i> or a	KUL	M36+

Topic/Publication	Authors	Target Group	Target Journal	Lead partner	Month
agenda PRO Stratification IBD (D4.5)	determined		leading diabetes journal		
Stratification based on PROs IBD (D4.7)	To be determined	Int/Ext	To be determined	KUL	M60+
Stratification based on PROs Cancer (D5.6)	To be determined	Int/Ext	Leading oncology journal	INKL	M60+

8. Additional actions to achieve scientific excellence and thought leadership

8.1. Prepublications

Zenodo provides a community account for H2O pre-publications. It serves the purpose of pre-publication collection which enables the project members to share deliverables (only the ones which are intended to be published in a peer-reviewed journal later) on Zenodo while seeking an appropriate journal to publish in externally. This process offers a central hub for the collection of publications and deliverables sourced from H2O to undergo review without formal publication or premature public release.

Details on the H2O Zenodo account

Account creds:

Username- preston.long@meduniwien.ac.at

Password- Research123!

Collection URL:

https://zenodo.org/communities/h2o_publication_community/

Above address links directly to your community collection.

Upload URL:

https://zenodo.org/deposit/new?c=h2o_publication_community

Above address will automatically ensure people who use it will have their record added to your community collection.

Curation URL:

https://zenodo.org/communities/h2o_publication_community/curate/

Above address links to your private curation URL. You will find all uploads pending your curation.

Harvesting URL:

https://zenodo.org/oai2d?verb=ListRecords&set=user-h2o_publication_community&metadataPrefix=oai_dc

Above address links to a OAI-PMH feed, which can be used by other digital repositories to harvest this community.

8.2. Promotion of publications on social media

We will promote accepted publications on social media. This will be done via posts and blogs on LinkedIn, Twitter and the project's website.

8.3. Promotion of citations

We take actions to increase the number of citations of the H2O publications. This includes

- Asking consortium partners to refer to H2O publications on conference presentations,
- Including links to scientific publications if we report about the projects and its results in other media,
- Journal clubs of our young outcomes researchers/managers network

8.4. Conference abstracts (ANNEX 1.0)

We will encourage the authors of the above described publications to submit a conference abstract prior to the acceptance of a certain paper in a journal. Target conferences include disease-specific meetings, but also congresses in the area of health informatics, data protection, data science, health services management, legal and ethical issues, value based-care and outcome research. In addition, we will continue to present H2O and its progress on conferences and meetings.

9. Publication approval process

With some exceptions, publications commonly include project results. The approval process for publications on project results is described in the consortium agreement in Chapter 7.5 - Dissemination of results.

10. Conclusion

This deliverable will be devoted to support the WP and task leaders with regard to publications in scientific journals and participation to scientific conferences. In this task, we will focus on dissemination activities related to more than one WP, e.g. the generic outcome set of all three diseases. We plan publish the blueprint of the national and the pan-European H2O Observatories and the generic outcome set of all three diseases. A scientific publication plan will be developed based on this outline. Participation in scientific conferences and conducting workshops for disseminating H2O results and process success models will be encouraged.

ANNEX. Publications Policy

Note: see D7.1 Project Handbook

ANNEX 1.0 Planned Conference Submissions

Date (2022)	Event	Organisation
4 February 2022	World Cancer day - various events	Union for International Cancer Control (UICC)
23-25 March 2022	European Breast Cancer Congress (EBCC)	EORTC, EUSOMA
30 March-2 April 2022	European Lung Cancer Congress (ELCC)	European Society for Medical Oncology (ESMO)
May 2022?	ESMO Breast	European Society for Medical Oncology (ESMO)
29-31 May 2022	SMDM Biennial European Conference	Society for Medical Decision Making (SMDM)
3-7 June 2022	ASCO Annual meeting	American Society for Clinical Oncology (ASCO)
June 2022?	MASCC/ISOO Annual meeting	Multinational Association of Supportive Care in Cancer (N
9-13 September 2022	ESMO Annual congress	European Society for Medical Oncology (ESMO)
September 2022?	European Cancer Rehabilitation & Survivorship S	Acta Oncologica & Danish Cancer Society
19-22 October 2022	ISOQOL Annual conference	International Society for Quality of Life Research (ISOQO
5-9 November 2022	ISPOR Europe	ISPOR (The Professional Society for Health Economics a
6-10 December 2022	San Antonio Breast Cancer Symposium (SABCS)	American Association for Cancer Research (AACR), May