

Media Release

Health Outcomes Observatory (H2O) collaborating with public health partners to lead and advise the first pan-European Observatory, a milestone in H2O's ambition to transform the use of Patient Reported Outcomes in value based health care decision-making across Europe

Vienna, 09.02.2022: The Health Outcomes Observatory (H2O) consortium members are delighted to announce their collaboration with the Dutch National Health Care Institute, The Danish Medicines Agency, Danish Health Data Authority and Aarhus University Hospital to set up the Pan-European H2O Health Outcomes Observatory, a virtual 'hub' for the collation and sharing of Patient Reported Outcomes (PROs) with patients, providers, regulators and healthcare decision-makers.

This is a vital step towards achieving the mission of the H2O; to establish standardized outcomes sets, so clinicians and patients can speak the same 'language', thereby strengthening the voice of patients and informing and enriching shared decision making in healthcare delivery across Europe as well as informing health technology assessment.

The pan-European Observatory will lead on;

- Implementation of outcome standards for measuring PROs in a way which is practical and simple to apply within clinical practice
- Establishing governance principles for H2O, such as data governance, design of the overall network architecture and technology platform and sustainability as a not-for-profit Enterprise
- Holding metadata (not identifiable patient data) securely and ethically

"We are delighted to be appointed to this role within H2O. The Danish Medicines Agency, like all Medicines Agencies, is interested in bringing forth the patient voice. This is an important step in that direction. We are particularly impressed by the Pan-European scope of this project, as it expands the gathering of PROs and sharing of insights to an international level," said Jesper Kjær, Head of The Danish Medicines Agency's Data Analytics Centre.

"Having lead the national Danish effort on Patient Reported Outcomes for several years, we are more than happy to be able to share and learn. This initiative offers a mechanism for knowledge to flow across countries in a way we have never seen before. This matters, because measuring on a common scale is critical for creating change," said Lisbeth Nielsen, Director General of the Danish Health Data Authority.

"Shared decision making is intimately embedded in the Dutch healthcare system and closely linked to our effort to keep the standard health insurance package accessible for everyone in the Netherlands. Outcomes data is vital for shared decision making. Preferably real time, and from

validated sources, as intended by H2O. We are also highly intrigued by the idea of using data from the H2O project for HTA assessments. Once a drug is on the market it would be great to be able to follow up with the use of international outcomes data,” said Diana Delnoij, Chief Scientific Officer, Dutch National Health Care Institute.

“In Denmark, we have been going ‘from data to knowledge to action’ for a while now as we have been sharing the hospital and regional data. We know from experience that sharing this data generates debate and ultimately improves quality. This project enables us to expand this principle across a range of European sites,” said Jørgen Schøler Kristensen, Medical Director of Aarhus University Hospital.

The H2O expects to be shortly announcing National H2O Observatories; independent data repositories for PROs with links to national hospitals where standardized clinically captured outcomes are being hosted, as well as the managers of patient identifier system in collaboration with partner hospitals.

-ENDS-

-NOTES TO EDITORS-

About H2O

The Health Outcomes Observatory (H2O) is a public-private consortium drawing together patients, providers, regulators and healthcare decision-makers who share an interest in putting patients at the heart of value-based healthcare. The aim is to bring Patient Reported Outcomes (PROs) into decision-making by giving patients the tools to measure PROs in a standardised way. If clinicians and patients speak a standardized PRO ‘language’, this opens up a new world of possibilities, including;

- improved access to data informing clinical decisions
- Real World Evidence showing the status and dynamics of patient populations
- higher quality and sustainability of care through more transparent evidence of outcomes
- support for the design and direction of new treatment development

All of which will bring benefits for individual patients, as well as the broader population. H2O is currently being established across multiple locations in Europe To learn more, visit www.health-outcomes-observatory.eu

About The Danish Medicines Agency

The Danish Medicines Agency (DKMA) is the supreme pharmaceutical authority in Denmark and is placed under the Danish Ministry of Health. It has a key role in the current and future use of PRO data in Denmark, primarily as they are tasked with monitoring effects and side effects from medical products, but also in the implementation of PRO data in clinical trials and evaluation of pharmaceuticals. DKMA is focused on integrating the voices of the patients in these evaluations

which may occur through access to PROs. The establishment of the DKMA's Data Analytic Centre (DAC) makes Denmark a strong contributor to making Real World Evidence a trusted and accepted source of evidence.

<https://laegemiddelstyrelsen.dk/en/>

About the Danish Health Data Authority

DHDA is responsible for creating a coherent health data and digital solutions for the benefit of patients and clinicians, as well as research and administrative purposes in the health care system. DHDA was established on 1 November 2015 and is part of the Ministry of Health and translates health policy objectives into concrete solutions that promote a healthier Denmark.

<https://sundhedsdatastyrelsen.dk/da/english>

About the Dutch National Health Care Institute

On behalf of the government, the National Health Care Institute works to ensure that everyone in the Netherlands has access to good care, now and in the future. The National Health Care Institute is responsible for advising the Minister of Health, Welfare and Sport regarding the content of the basic health insurance benefits package. It promotes the quality, affordability, and accessibility of care by identifying opportunities for innovations and improvements in the care sector and providing relevant guidance accordingly. In addition, the Institute develops information standards, encourages the utilisation of digital care and explores the potential opportunities for applying new technologies. Furthermore, the Institute manages the funds for the Health Insurance Act and the Long-term Care Act, and implements risk equalization among health insurers.

<https://www.zorginstituutnederland.nl>

About Aarhus University Hospital

Aarhus University Hospital (AUH) is the largest hospital in Denmark and one of the largest in Europe. AUH develops and provides highly specialized treatment together with research and education at an international standard. AUH covers all clinical expertise with its 41 clinical departments, and in recent years these departments have been successfully involved in more than 26 collaborative EU projects. In 2021, *Newsweek* magazine ranked AUH as number 19 among 250 hospitals worldwide that best avail themselves of the most advanced technologies and lead in their use of AI, robotic surgery, digital imaging, telemedicine, smart buildings, information technology infrastructure and EHRs.

www.en.auh.dk

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