

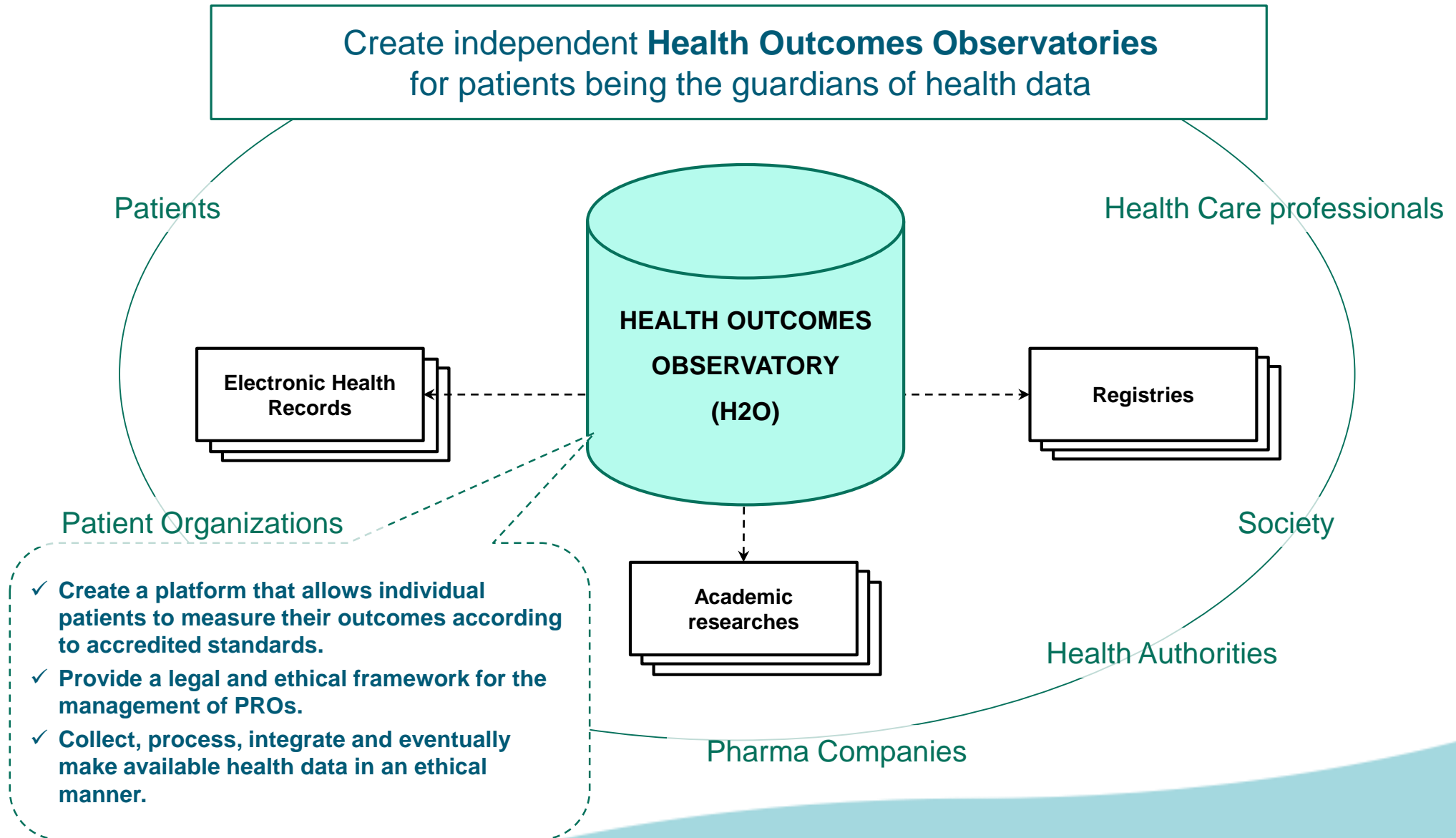
**Health Outcomes Observatories:
Empower patients with tools to
measure their outcomes in a
standardised manner creating
transparency of health outcomes**

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Our Vision and Objectives



Provide transparency of Health Outcomes to Patients, Patient Organizations, Health Authorities, Health Care Professionals, Society and Pharmaceutical Companies



Specific challenges to be addressed

- There is general agreement on the need for increased patient centricity in healthcare provision
 - Current measures of disease and outcomes often fail to completely capture disability, symptoms, HRQOL and the experience of health care from the patient's perspective
- A reward system that truly focuses on value requires measurement and transparency of patient outcomes
 - Structured and standardised outcomes data will enable patients to have more productive interactions with providers and will facilitate the establishment of systems that reward innovators on the basis of value created for patients
- There is a lack of models for capturing and managing patient-reported health data in an ethical and sustainable way
 - There are few examples of incorporating structured patient-reported data into clinical care

Need for public-private collaboration (1)

- The lack of standardisation and integration of data across health care remains an obstacle to fully realising the benefits of the digital revolution
- Measurement methodologies and outcome standards need to be endorsed by those generating the data and by those using the data
- The complexity of the challenge is such that it requires action that is collective, innovative and nurtured in an environment where sensitive information can be shared securely

Need for public-private collaboration (2)

Patient associations...to develop tools and approaches, and to build trust and patient engagement

Regulatory authorities and agencies...for use of novel endpoints, data requirements and evidence

Life sciences companies...for expertise, commitment to long-term research and innovation, and funding for long-term sustainability

Experts (eg medical, ethicists, social scientists, statisticians, digital)...to develop measures, tools and methods for data capture

Privacy and legal experts...to set up governance models and access terms to allow data sharing and, therefore, support sustainability

SMEs and other innovators...to develop the appropriate tools and technologies

Objectives of the topic

- Identify appropriate standards for capturing the patient perspective when measuring health outcomes and patients' experience of care
- Implement technology solutions for individual patients to record and measure their outcomes
- Establish platform(s) to process data for the benefit of multiple stakeholders, in compliant ways
- Create a sustainable model for continuous collection of data and for providing access to data for researchers
- Establish health outcomes observatories in the three disease areas, collecting data in three different countries for each disease

Pre-competitive nature

- The observatories, and the activities they pursue, will be open to all participants (despite the fact that some participants might have competing products in the disease area)
- The tools and methods developed will be available to all participants during the project and will be made available to observatories that are subsequently established (beyond the life of the project)

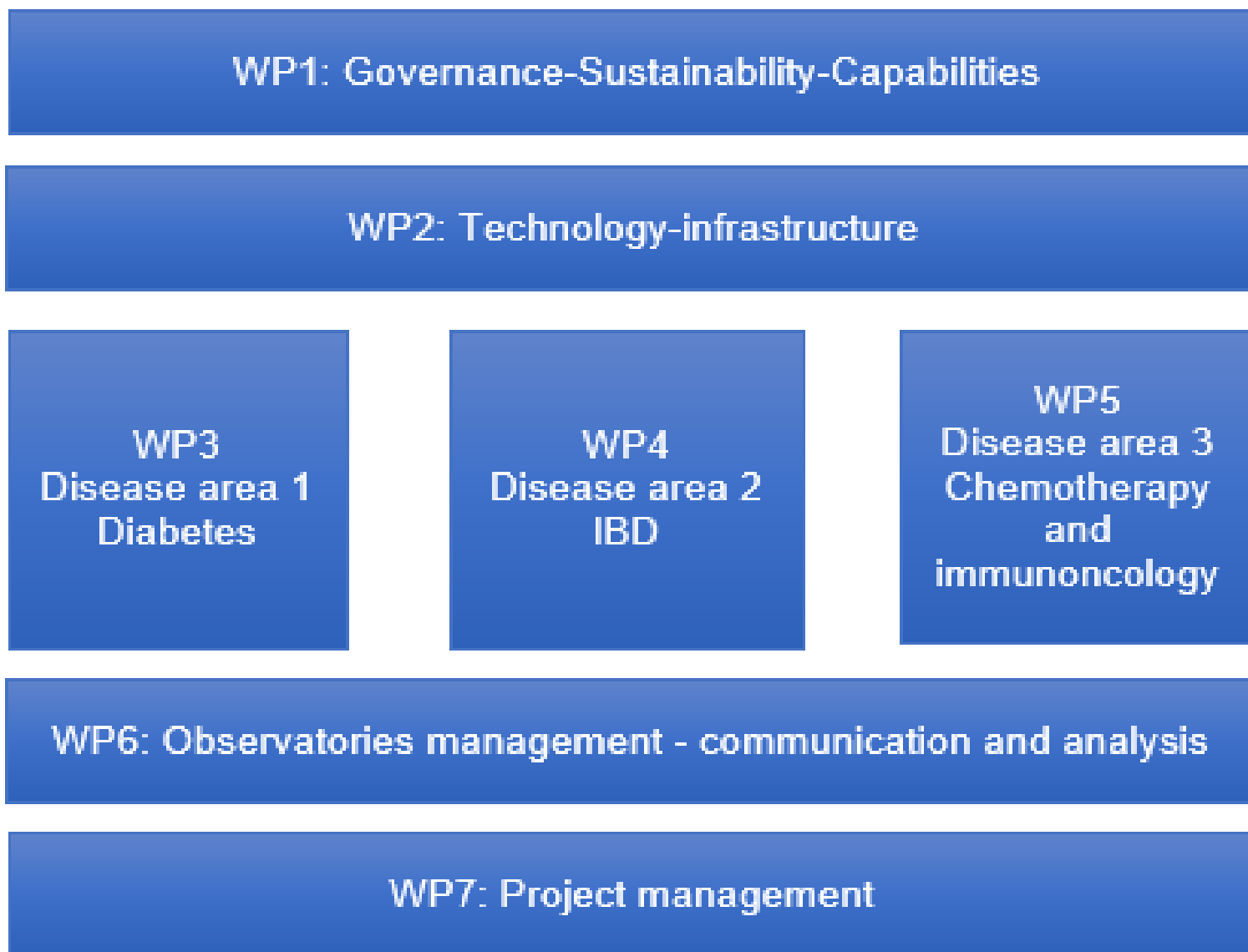
Expected impact (at the level of the individual)

- Enable individual patients to:
 - receive close to real-time information on their disease status
 - hold more informed discussions with healthcare professionals
 - understand how their status compares with other patients'
 - share their data and help the broader patient community
- Allow healthcare professionals to:
 - track the evolution of their patients
 - conduct a different, outcome-based, conversation with patients
 - better inform and enhance clinical decisions based on the patient perspective

Expected impact (at group/population level)

- Allow patient organisations to:
 - assess the status and dynamics of their patient population
 - increase engagement with other healthcare stakeholders in evidence-based advocacy
- Enable health authorities and healthcare providers to:
 - improve quality of care through better patient-centric measures
 - ensure sustainability of healthcare systems through more effective allocation of resources
- Allow pharma and other innovative companies to use data to:
 - generate insights that can be used to support the design and direction of the development of new treatments
 - generate robust evidence that can be used in submissions to regulators, HTA agencies and other decision makers

Suggested architecture of the project



Expected contributions of the applicants

- Skills in measurement and research in health outcomes and registries
- Access to existing real-world data and technology
- Ability to build strong relationships with a range of relevant partners
- Legal skills including data governance and healthcare law
- Digital architecture and technical skills, including data linkage skills
- Expertise in data mining, machine learning, computational biology
- Expertise in epidemiology and biostatistics
- Medical expertise across the disease areas
- Social science expertise for models of data collection
- Communications and project management expertise

plus

Participation by (or willingness to contribute as experts) patient advocacy groups and national health-related bodies

Expected (in kind) contributions of industry consortium

- Skills in measurement and research in health outcomes and RWE
- Ability to build strong relationships with a range of relevant partners
- Legal expertise
- Financial and business planning expertise
- Digital technologies expertise
- Expertise in epidemiology and biostatistics
- Medical knowledge for the disease areas
- Regulatory expertise
- Expertise in public-private partnerships related to clinical and RWE research
- Communications and project management expertise

What's in it for you?

- Academic researchers will benefit from participating in this work by:
 - participating in ground-breaking, multi-country research
 - gaining visibility for their work through publications, impact on society, and collaboration with multiple stakeholders
- SMEs will be benefit from taking part by:
 - Building working relationships with leading experts and organisations
 - opening the door to further partnerships in future observatories
- Patients' organisations will benefit by:
 - Better understanding the status and dynamics of their patient population
 - New opportunities for engagement with other healthcare stakeholders in evidence-based advocacy

Key deliverables of the project

- Establishment and sustainable operation of the observatories:
 - in three countries; integrated into the national health ecosystems
 - all legal and ethical requirements in place for data collection, data management and data access
- Infrastructure for data generation and use functioning from Year 3:
 - Outcome measures identified with broad stakeholder acceptability
 - Digital tools designed, tested and launched
 - Technologies to link the patient-generated data with existing patient-level health care data
- Communication materials:
 - Annual reports after Year 3 comparing health outcomes/experience
 - Publications on: outcomes measures and validation; analyses for patient stratification and ideal levels of care; and on lessons learned



Thank you

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