

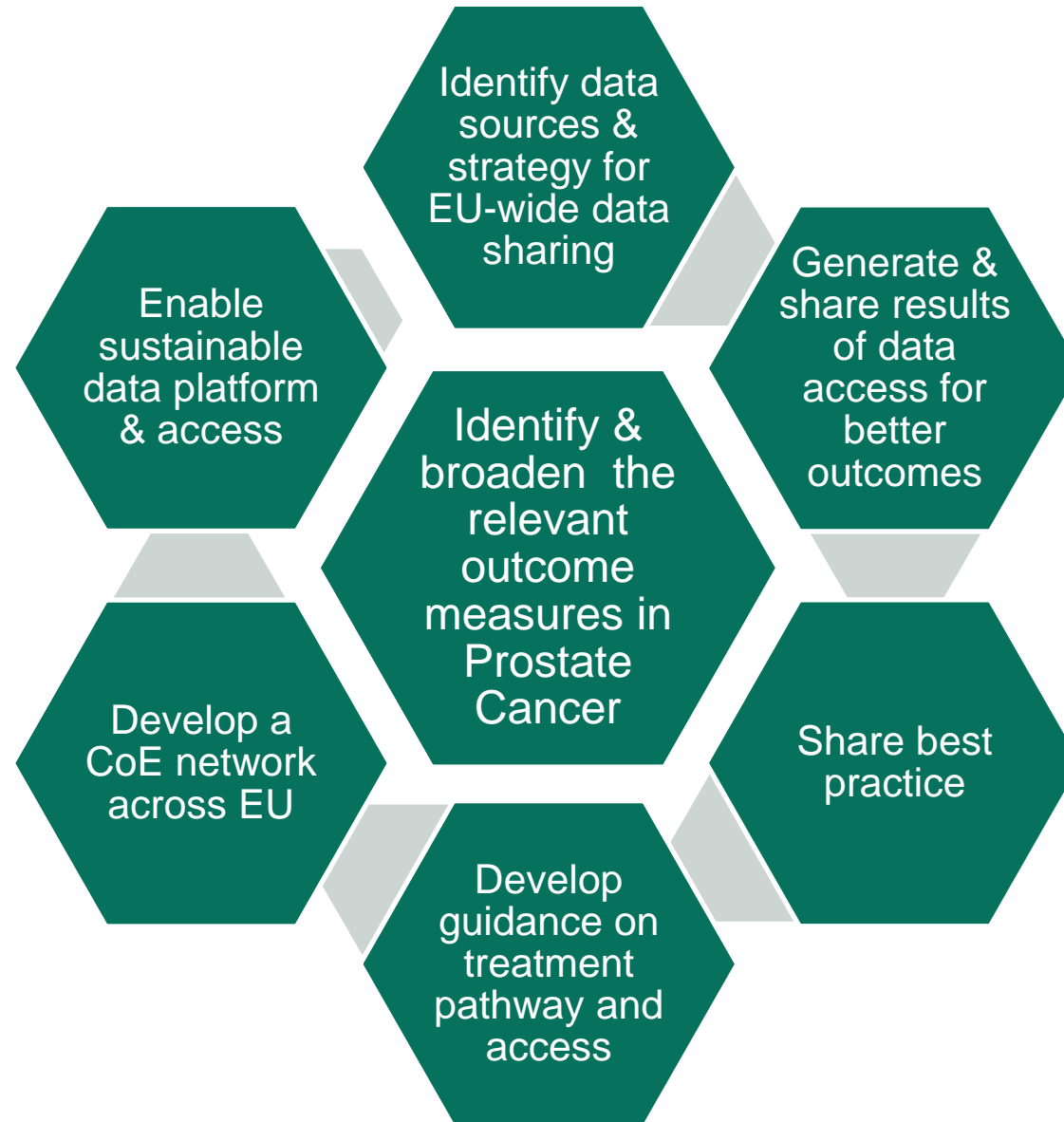
How Big Data could support better diagnosis and patient-centred treatment outcomes for Prostate Cancer

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Need for public-private collaboration

- The majority of the prostate cancer research consortia focus on clinical trial inputs, tools, and operational efficiencies,
 - relatively few efforts are focused on how PCa-related outcomes could be incorporated into the broader health and social care system.
 - This type of effort additionally relies on academic groups, subject matter experts and additional IT.
 - Patient, caregiver, and advocacy organizations will be crucial in understanding outcomes of relevance, and approaches.
- The Innovative Medicines Initiative 2 (IMI2) allows pharmaceutical companies to collaborate with payer, regulatory, and other important stake-holder partners to understand the best path forward to improve health/social care and data systems for treatment of PCa.

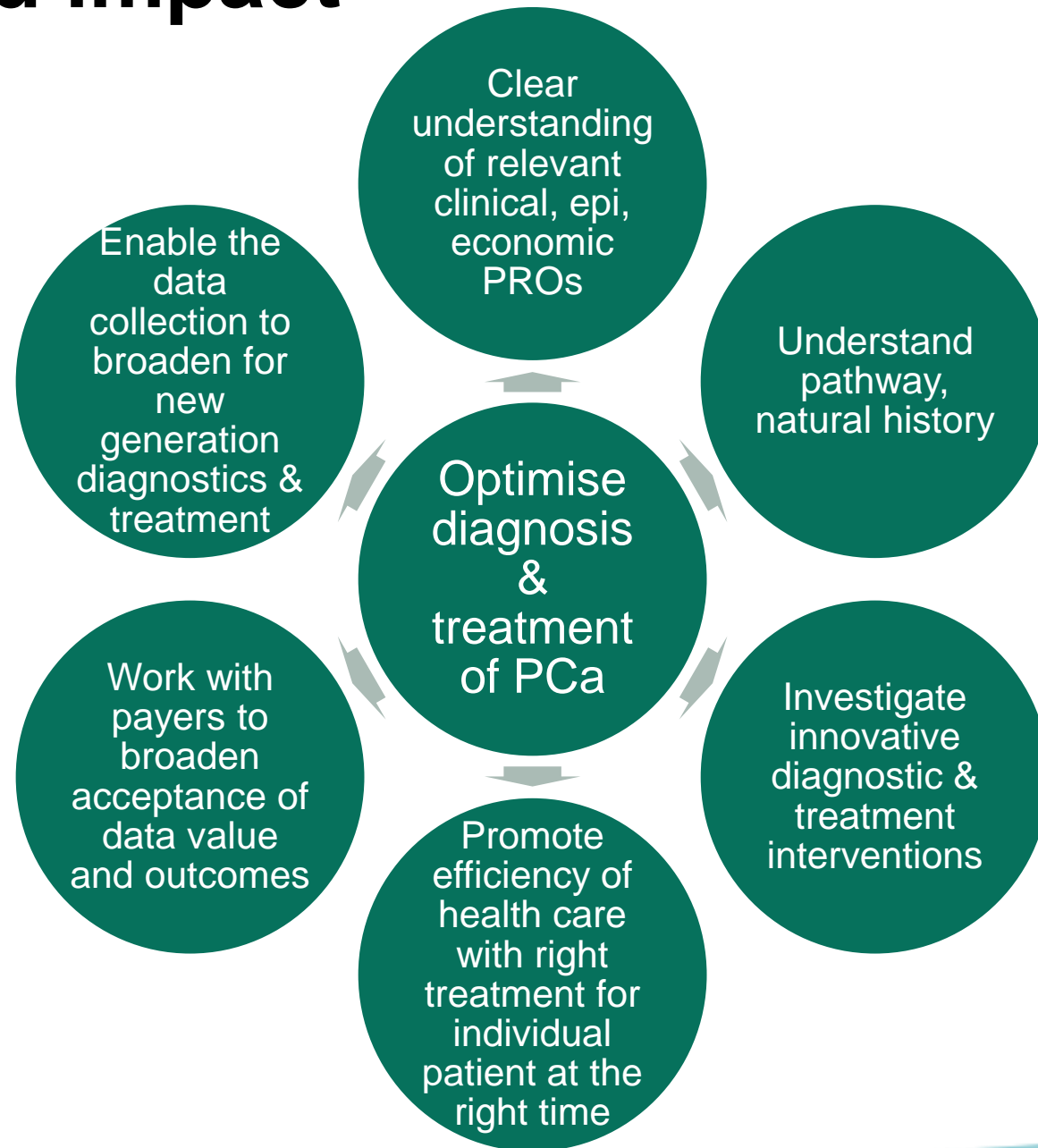
Objectives of the full project



Pre-competitive nature

- The neutral platform of IMI design allows pharma companies to collaborate with academia, payer, regulatory, patient organisations and other important stakeholder partners to facilitate discussions and recommendations on how to improve prostate cancer patient outcomes
- Value based health care with increased health outcome focus is expected to allow a better use of scarce resources within the health care budgets of member states

Expected impact



Suggested architecture of the project

WP 1: Project Management and administration

WP 2: Disease understanding and Outcome definition

WP 3: Data access and sources

WP 4: Data platform

WP 5: Data analytics

WP 6: HTA – EMA - payer integration

WP 7: Dissemination and communication

WP 8: Legal, ethics and governance

Expected contributions of the applicants

- The **ability to engage with and manage multiple disciplines** to deliver on the stated objectives of the proposal.
- **Access to real world datasets** that have not yet been used in this context
- The ability to **engage partners across multiple geographies** is also expected.
- To encompass all key dimensions and to include the insight of the relevant stakeholders, the applicant consortium involve the following:
 - HTA/payers;
 - Academic networks;
 - Cancer registries and information systems.
 - Patient associations (Several organisations would allow for a well-rounded independent group allowing for robust input);
 - Cancer reference centres;
 - Genomic sequencing groups;
 - Medical societies for information on guidelines and to disseminate results;
 - Big data companies;
 - Innovative SMEs

Expected (in kind) contributions of industry consortium

- Facilitate collaborations and partnerships across geographies and specialties
- Provide relevant data sets (existing & future) on treatments and outcomes in PCa
- Expertise in:
 - The performance of clinical trials in prostate cancer with or without involvement of advanced therapies;
 - The capture and analysis of outcomes research including Real World Data, biomolecular samples, etc.;
 - Statistics, in data mining and in merging large data sets from various sources;
 - Project and result communications, and legal and regulatory requirements relevant to the project.

What's in it for you?

Influence

- Opportunity to drive and shape the agenda

Networks

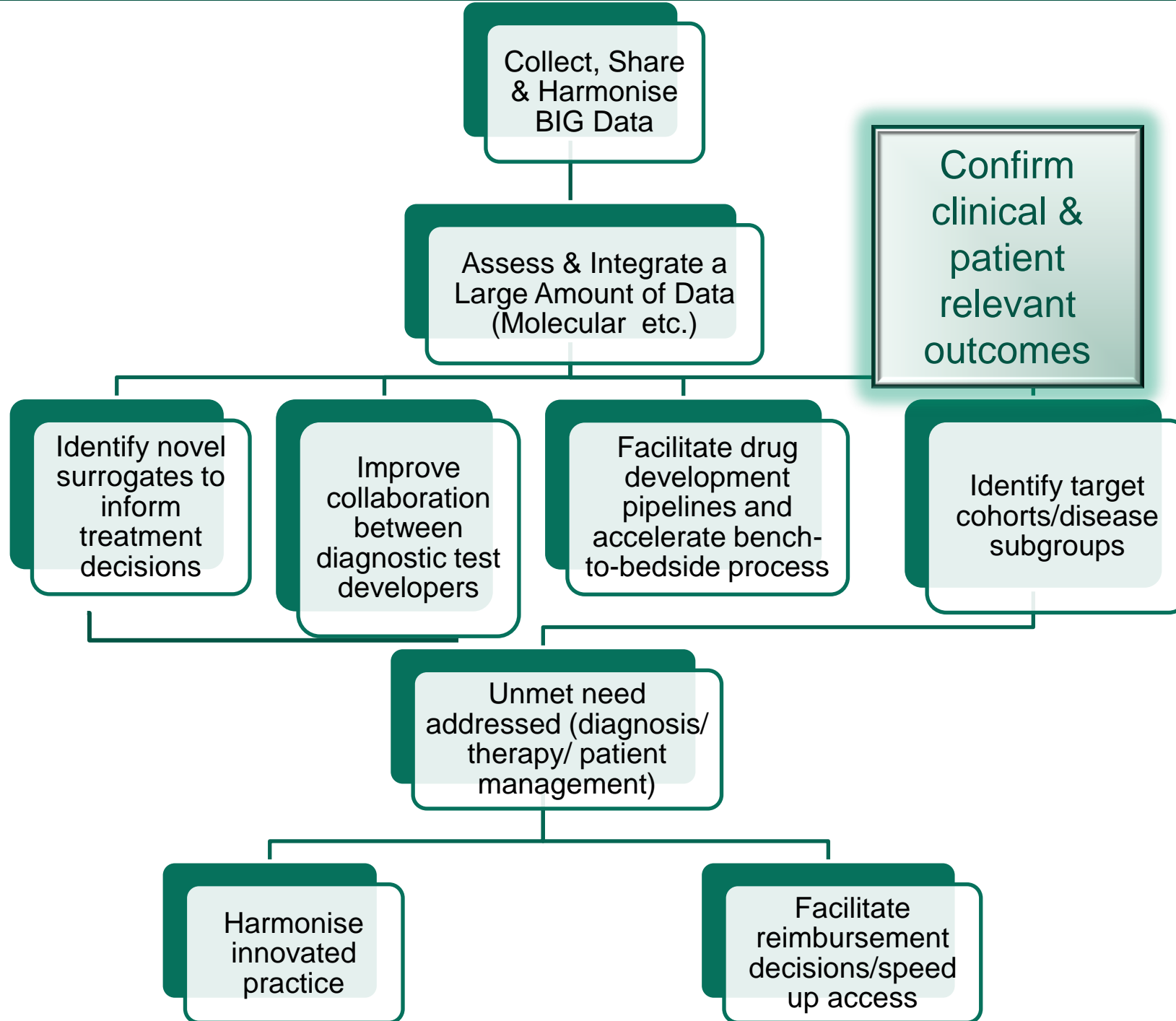
- Facilitates access to decision makers and subject area experts (Methods and TA)
 - HTA
 - Regulators
 - Academics

Capabilities

- Develop in house capabilities as part of broader consortium
 - Methods expertise
 - TA expertise

Data Access

- Through the project
- Through building trusting relationships



Key deliverables of the full project 1/5

- 1) Mapping of available data sources and key clinical, economic and quality of life/patient reported outcomes (QoL/PRO) measures;
- 2) Develop a data integration strategy:
 - Leveraging expertise from previous IMI projects including EMIF, EHR4CR, and all current BD4BO projects including the CSA;
 - Evaluation of suitability for combining different data sources (incl. white paper / publication). Assessment of benefits of combining data sources;
 - Evaluation of technical and legal feasibility of combining data sources.

Key deliverables of the full project 2/5

- 3) Integration of multiple data sources into a multi-country data sharing platform and new electronic endpoint proposal (e.g. Mapping of digital solutions / options across outcomes clinical and pharmacoeconomic), potentially including:
- Demonstration (pilot) project based on results from evaluation of suitability;
 - Peer-reviewed publications of validated innovative end-points, outcomes and technologies;
 - Portable data capture protocols and modules for implementation in health-care system electronic medical records;
 - Data governance framework to address quality and privacy concerns of data integration (building on other existing IMI projects);
 - Definition of data integration model to be potentially implemented in phase 2 of the project.

Key deliverables of the full project 3/5

- 4) Assessment of prostate cancer epidemiology, disease course and progression and burden (e.g. prevalence, incidence, mortality, clinical, economic, and humanistic factors):
- Definition of relevant endpoints linked to PCa;
 - Literature review of relevant topics in PCa with a focus on cognition, functional, behavioural, and diagnostic outcome measures across the different PCa stages;
 - Alignment of key stakeholders (including patients) on relevance of those outcomes for different uses (e.g. reimbursement, assessments, etc.);
 - Assessment of those outcomes in current data sources and expansion for additional data items where currently not available;
 - Build on new knowledge developed during the project to guide and propose best-practice outcomes.

Key deliverables of the full project 4/5

- 5) Identification of the patients' pathways and the sequences and modalities of treatments used by physicians, and associated health outcomes ;
- 6) Make recommendations on personalized screening strategies and treatment plans based on knowledge learned from this project;
- 7) Recommendations on validated instruments of patients reported outcomes to be collected in future studies and registries as determined in number four above;
- 8) Identify what represents value for prostate cancer patients;
- 9) Collection of genomic data available in databases to better inform treatment choices and novel predictive and prognostic markers;
- 10) Collection of economic endpoints such as costs and resource utilization and understand how economic burden of the disease increases as PCa progresses;

Key deliverables of the full project 5/5

11) Developing analytic methods and tools to describe the natural history, and inform epidemiological and HE models:

- Publications on model archetypes that characterize the patient journey across the spectrum of disease using existing data sources to compare methodologies such as Time to event, Markov modeling, Linear Regression and Mixed-effect Model Repeated Measure (MMRM);
- Peer-reviewed recommendation of disease modelling approaches, based on different methodologies.

12) To gain advice/alignment on all recommendations, frequent engagement and in-person symposiums with representatives of Health Technology Assessment (HTA) & regulator agencies, and payers responsible for making access and reimbursement decisions will be considered.

Questions?

Contact the IMI Programme Office
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