

## **PIONEER General Assembly Meeting November 2020**

### **PIONEER reaches the halfway mark of the project**

PIONEER convened its Annual General Assembly Meeting virtually on November 23<sup>rd</sup> and 24<sup>th</sup>, with over 60 members gathering online to report on the progress of their work packages and to exchange ideas. Discussion were focused on prioritisation of datasets for on-boarding to the PIONEER platform to answer the projects prioritised research questions.

### **Halfway highlights across the project**

#### **WP2: Disease understanding and outcome definitions**

- Systematic reviews completed for the core outcome sets (COS) for the different prostate cancer stages (localised, locally advanced, metastatic and non-metastatic castration resistant prostate cancer). Manuscript is drafted and will be submitted for peer review once the qualitative interviews are completed.
- Four expert group meetings, combination of face-to-face and virtual, conducted in support of the COS work.
- Qualitative interviews with men with metastatic PCa ongoing in the UK, Germany and EU wide via patient organisations.
- Systematic review and COSMIN assessment of patient reported outcome measurements (PROMs) developed for PCa.

#### **WP3: Data access and sources**

- Identification of 82 potential prostate cancer data sources from 16 countries.
- Thirty five completed data fact sheets included in the PIONEER EMIF catalogue.
- Eight datasets available in the PIONEER platform: 2 academic datasets PRIAS and ERSPC; 1 external dataset from Active Biotech AB and five industry datasets from three EFPIA partners (Bayer, Astellas & IQVIA).
- Six additional datasets currently being mapped to OMOP, the European Common Data Model, with 18 further datasets prioritised for mapping.
- Development of the PIONEER Dataset Screener which allows PIONEER members to assess which data sources contain the most relevant information for the research question they wish to answer.

#### **WP4: Data platform**

- EMIF catalogue with information on the PIONEER datasets (<https://emif-catalogue.eu/>)
- Centralised data platform consisting of:
  - OHDSI OMOP environment for sharing and analysis of real-world data (<https://pioneer-atlas.thehyve.net/>).
  - JupyterHub environment to enable combined analysis on real-world population health (or clinical data) and omics data (<https://pioneer-jupyter.thehyve.net/>). Temporary hackathon environment on Amazon supporting OMOP-Atlas, JupyterHub and SAS analytics tooling.
- Pilot with RadboudUMC for ways to feed in live electronic health record data into the PIONEER platform..

#### **WP5: Data analysis**

- WP5 have worked closely with WP4 to define the data model (OMOP) to be used for PIONEER and have developed a generic data analysis plan and study protocol template for use by the consortium.

- PIONEER 1-day hackathon that was held on the 11<sup>th</sup> of May. The hackathon demonstrate the full potential of the PIONEER platform with over 50 attendees exploring the PIONEER datasets with the ODHSI ATLAS toolbox; producing preliminary analyses using ATLAS, Python, R & SAS functionalities; and setting goals for future data analyses.
- Upcoming PIONEER study-a-thon March 8<sup>th</sup> to 12<sup>th</sup>, 5 days focused on Which are the long-term outcomes of prostate cancer patients undergoing non-interventional management (i.e., watchful waiting) and what is the impact of comorbidities and life expectancy?

#### WP6: HTA regulator-payer integration

- Expert Committee Policy Stakeholder Feedback Forum (ECPSFF) established. The ECPSFF will be expanded over the coming months to ensure it has the right expertise in place to move forward with the objectives of the work package.
- First PIONEER Policy Paper published which outlines the key problems and challenges in the HTA field today.
- High level overview of HTA outcomes in prostate cancer in UK, Sweden, France and Germany defined to date.
- Visual map of prioritised HTA issues grouped according to how challenging it will be to find solutions defined. WP6 will use this visual representation to guide their work moving forward.
- Commitment to engage with WP5 to assess the available evidence around inequalities in PCa care across Europe.

#### WP7: Dissemination and communication

- Development of a comprehensive and periodically updated communication and dissemination strategy for the project.
- Completion of external PIONEER communication tools: Project [brochures](#) scientific and patient versions; PIONEER project [interviews](#); PIONEER animated [video](#); Infographics; and Quarterly PIONEER [newsletter](#).
- Completion of internal and external communication surveys
- Set-up of the PIONEER [website](#) and social media channels including [Twitter](#), [LinkedIn](#) and [YouTube](#).

#### WP8: Legal, ethics and governance

- Ongoing support to PIONEER on legal, ethical and governance matters.
- Drafting and finalisation of two standard form template Data Sharing Agreements to reflect both the Centralised and Federated Database Models).
- Preparation of a Data Processing Agreement in order to allow data conversion by the consortium.
- Drafting a Data Sub-Processor Agreement for use with Helmholtz to cover their hosting support pending accession to the Consortium
- Providing additional information/analysis to the PIONEER Ethics Advisory Board.

#### Active PIONEER Research Questions

The PIONEER consortium performed a prioritisation survey among two stakeholder groups healthcare professionals including pharmaceutical companies and prostate cancer patients to identify and prioritise the top 56 research questions applicable to both stakeholder groups. PIONEER has begun to work a number of these research questions including:

*Research question 1:* What are the relevant tumour-specific and patient-specific variables that affect prognosis of prostate cancer patients suitable for active surveillance? A four phase study plan has been developed to address this question with a qualitative component added to explore the factors influencing men's adherence to active surveillance. First publication coming soon!

*Research question 7:* What is the clinical benefit of determining patients' genetic risk profile regarding prostate cancer management, especially in the screening setting? Systematic review and meta-analysis completed on the use of polygenic risk scores on evaluating risk of prostate cancer in Caucasian men. For the protocol see: <https://bit.ly/361Lxge>.

### **Molecular Data Working Group**

There is an unmet clinical need for diagnostic and/or prognostic tools that facilitate personalised prostate cancer treatment. The long-term burden of disease could be reduced by development and increased use of genomic profiling tools, which may help to reduce the over-treatment of indolent tumours; however, the OMOP common data model not suitable for storing high-dimensional omics data. To date the working group have defined six potentially relevant and accessible questions along with PIONEER datasets and publically available external patient-centred prostate cancer datasets required to answer these questions.

For more information: [www.prostate-pioneer.eu](http://www.prostate-pioneer.eu)

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