PIONEER General Assembly Meeting May 2020 Summary

PIONEER convened its 3rd Annual General Assembly Meeting virtually with over 50 members gathering online to report on the progress of their work packages and to exchange ideas. In particular, attendees were asked to focus on how PIONEER can develop and implement an effective sustainability plan to ensure that the PIONEER platform is utilised well beyond the lifetime of the project.

Year 2 highlights per work package

Overseeing the functioning and outputs of all PIONEER work packages is WP1: Project management and administration. WP1 have worked hard to ensure that a collaborative relationship between all partners, both public and private, has been established. WP1 have continued to implement PIONEER's management structure and establish effective communication channels to ensure all potential challenges are identified and either avoided or overcome.

WP2: Disease understanding and outcome definitions

- Four 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). Systematic review manuscript is drafted and will be submitted for peer review once the qualitative interviews are completed.
- Qualitative interviews are ongoing in the UK and Italy. Final ethical approval is outstanding in Germany and Netherlands with a potential delay due to COVID-19.
- Four expert group meetings, combination of face-to-face and virtual, were conducted in support of the COS work.
- Ethical approval for qualitative interviews granted in the UK and the interviews have started. Final ethical approval is outstanding in Germany and Netherlands with a potential delay due to COVID-19.
- WP2 is also assessing the available patient reported outcome measurements (PROMs) identified in systematic reviews in terms of psychometric properties using the COSMIN criteria.
- Systematic review on the diagnostic and prognostic factors (DPF) for the four prostate cancer stages started. Review protocol has been finalised and is ready for publication.

WP3: Data access and sources

- Identification of 82 potential prostate cancer data sources from 16 countries. Currently, 34 of these datasets have completed their associated data fact sheets and are included in the PIONEER EMIF catalogue.
- First two academic datasets made available in the PIONEER Big Data platform by PIONEER partner Erasmus University Medical Centre (MC). Erasmus MC have contributed two of the most well-known European datasets to the PIONEER Big Data platform:
    1. The Prostate Cancer Research International Active Surveillance (PRIAS).The primary objective of PRIAS is to provide evidence-based recommendations on how to select and follow men with low-risk prostate cancer on active surveillance.
    2. The European Randomised study of Screening for Prostate Cancer (ERSPC) Rotterdam. The aim of ERSPC is to investigate the effect of regular prostate-specific antigen (PSA) screening on prostate cancer mortality.
- First Data Sharing Agreement signed with external data contributor Active Biotech AB. Active Biotech AB has now shared data collected in a phase 3 randomised, double blind, placebo controlled study of tasquinimod in men with metastatic castrate-resistant prostate cancer.
- Five industry datasets from three EFPIA partners (Bayer, Astellas & IQVIA) have been made available for the platform.

- 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/).
  - JupytherHub environment to enable combined analysis on real-world population health (or clinical data) and omics data (https://pioneer-jupyter.thehyve.net/). Jupyter supports many programming languages, including Python and R, to be used by WP5 for data analysis. The OHDSI-OMOP and JupyterHub instances are secured via authentication methods and access is managed via Keycloak.
- Temporary hackathon environment on Amazon supporting OMOP-Atlas, JupyterHub and SAS analytics tooling.
- Preparations together with RadboudUMC for pilot ways to feed in live electronic health record data and additional diagnostic biomarkers such as imaging and genomics into PCa clinical research and diagnostics in an academic hospital setting.

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.
- Now that the PIONEER platform is operational WP5 have switch their focus to training in the use of the PIONEER 'Big Data' platform, starting with the PIONEER 1-day hackathon that was held on the 11th of May.
- The hackathon demonstrate the full potential of the PIONEER platform with the 50 attendees exploring the PIONEER datasets with the ODHSI ATLAS toolbox; producing preliminary analyses using ATLAS, Python, R & SAS functionalities; and settinh goals for future data analyses.

WP6: HTA regulator-payer integration
- Expert Committee Policy Stakeholder Feedback Forum (ECPSFF) members identified and recruited. Aim of WP6 is to work with the ECPSFF to identify and address evidence gaps which can delay decision-making by regulatory agencies and health technology assessment (HTA) bodies and payers, which ultimately compromise timely patient access to innovative treatments for prostate cancer.
- 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 to date in UK, Sweden, France and Germany.
- Stakeholder face to face discussion at EMUC Nov 2019.
- Based on the above activates WP6 have finalised a visual map of prioritised HTA issues grouped according to how challenging it will be to find solutions. WP6 will use this visual representation to guide their work and engage stakeholders in the development of the groups 2nd policy paper.

WP7: Dissemination and communication
- Project brochures – scientific and patient versions which can be download from the PIONEER website.

- PIONEER project interviews – listen to the PIONEER consortium members discussing why they are part of PIONEER and what their respective work packages will deliver (https://prostate-pioneer.eu/publications/videos/).
- PIONEER animated video. A short 2 minute video for those new to PIONEER or unsure of what exactly Big Data in healthcare is or how it is relevant to prostate cancer research. The video explains in basic terms how PIONEER will use Big Data for prostate cancer while keeping this data safe & secure.
- Quarterly PIONEER newsletter (https://prostate-pioneer.eu/publications/newsletters/).

WP8: Legal, ethics and governance
- Drafting and finalisation of two standard form template Data Sharing Agreements which allow transfer and processing of data in accordance with legal, regulatory and ethical requirements (with different versions of the Data Sharing Agreement to reflect both the Centralised and Federated Database Models).
- Preparation of a Data Processing Agreement in order to allow data conversion by the consortium.
- Continued monitoring of the effect of Brexit negotiations on the PIONEER project to put in place any necessary documentation or process changes which may be required as the UK transitions out of Europe to ensure that this does not unduly impact the PIONEER project and to support both the consortium members based in the UK and the wider consortium in minimising and mitigating any difficulties in data transfer which this may cause.

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 the top 5 research questions applicable to both stakeholder groups. PIONEER has begun to work prioritised 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.

For more information: www.prostate-pioneer.eu
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