

PIONEER Management Board Meeting – London calling

PIONEER partner King's College London hosted PIONEER's 2nd Management Board meeting at Guys Cancer Centre at the beginning of November. Work package leads from both the public and private sides of the consortium gathered to report on PIONEER's progress. The focus of the discussion was on effective sustainability planning to ensure that PIONEER's outputs are utilised well beyond the lifetime of the project.

The meeting was opened by James N'Dow (EAU PIONEER coordinator) and Alex Asiimwe (EFPIA PIONEER lead). The opening remarks all touched upon the importance of continuing to develop and strengthen the consortiums relationship with data contributors. The attending members of PIONEER's Scientific and Ethical Advisory Boards were also introduced to the consortium.

Milestones across the PIONEER Work Packages (WP)

WP2: Disease understanding and outcome definitions

WP2 have updated an earlier 2013 systematic review on outcomes for localised prostate cancer and completed a further two systematic reviews for outcome definitions for locally advanced and metastatic prostate cancer. At the upcoming EMUC19 meeting in November WP2 will hold an expert group meeting, including all relevant stakeholders, to discuss the definitions of the identified outcome sets for localised and metastatic prostate cancer and to define a feasible outcome measurement instrument for each. The expert group meeting will be supported by qualitative interviews in the UK, Germany and the Netherlands. In the coming year WP2 will begin to focus on the diagnostic and prognostic factors for all stages of the disease.

WP3: Data access and sources

WP3 have identified 79 potential prostate cancer data sources from 16 countries. Each data source has an associated data fact sheet which allows PIONEER members to assess which data sources contain the most relevant information for the research question they wish to answer. Twenty three data sources are ready for conversion and import into the PIONEER 'Big Data' platform. In order to enable quick and effective on boarding of data it has been recognised that a number of data contributors will require additional support. In the coming 6 months WP3 will work on an effective solution to this with PIONEER partners IQVIA and The Hyve. WP3 will also continue to finalise outstanding Data Access Agreements.

WP4: Data platform

The main aim of WP4 is to deliver a data repository and analytics platform that is secure, sustainable and enables PIONEER to meet its objectives. To this end WP4 has setup the OMOP/OHDSI platform for population-based registries and epidemiological research (both federated and centralised models), and is currently setting up an omics analysis platform for cohort and clinical trial data. WP4 also has ATLAS, an analysis tool for the OMOP/OHDSI software, running for PIONEER, complete with a synthetic data set for ATLAS testing. WP4 will now begin to train PIONEER members in how to use PIONEER's 'Big Data' platform.

WP5: Data analysis

For WP5 their main tasks are yet to begin as they require WP3 and WP4 to deliver both the data and the data platform to begin data analysis. Over the first year 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. Given that the PIONEER platform is now operational WP5 will switch their focus to training in the use of the PIONEER 'Big Data' platform.

WP6: HTA regulator-payer integration

The main aim of WP6 is 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. WP6 has brought together the expert committee of stakeholders (ECPSFF), which resulted in PIONEER's 1st policy paper which outlined the key problems and challenges in the HTA field today. Based off this WP6 have created 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

Over the course of the last 6 months WP7 have been working on the development of a scientific and patient brochure for the project, both of which can be download from the PIONEER [website](#). WP7 have also conducted a number of informative interviews with members of the consortium, which can be watched [here](#). Interested in knowing more about the project be sure to follow us on Twitter or subscribe to the PIONEER quarterly newsletter. In the coming months WP7 will finalise and launch a short animated video explaining PIONEER and 'Big Data'.

WP8: Legal, ethics and governance

WP8 has continued to provide general legal support to the PIONEER programme as and when questions arise, including confidentiality arrangements under which discussions have commenced regarding the possibly of new partners joining PIONEER, and on contractual arrangements around how the central database may be hosted. WP8 is also monitoring the effect of Brexit on the PIONEER project. In the event of a deal then little will change for PIONEER during the transition period (until Jan 2021). In the event of no-deal, and hence no transition period, then there are two principal impacts for PIONEER:

1. UK recipients will no longer be generally eligible to receive funding from the EU for research programmes such as PIONEER; however, the UK Government will pay the amounts which the UK based PIONEER beneficiaries would have expected to receive. WP8 has written to the UK beneficiaries flagging the need them to ensure that their institutions have registered the PIONEER project on the UK Government's Portal.
2. It will be more difficult to transfer personal data between the UK and EU in the event of no-deal and similar mechanisms and contracts will need to be put in place as when, for example, transferring data to the US or other non-EU locations. However, as our strategy is based on avoiding the use of identifiable personal data, there should be no real impact on sharing of patient datasets. There may be some minor impacts on how we communicate as a consortium, but these can be addressed if necessary, by putting in place short contracts to allow for this.

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.

For more information: www.prostate-pioneer.eu

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