

PIONEER 2nd General Assembly - Greetings from Berlin!

PIONEER convened its 2nd Annual General Assembly Meeting at the beginning of May in Berlin with over 50 members gathering to report on the progress of their work packages and to exchange ideas. In particular, work packages were asked to reflect on their first year progress and any challenges they encountered. The focus of the discussion was on effective solutions to existing or potential roadblocks in the project, as well as methods to increase alignment between the different work packages. The meeting was opened by Matthias Gottwald (Head of Research and Development Policy and Networking at Bayer Pharma), Michael Devoy (Chief Medical Officer at Bayer AG), Alex Asiimwe (EFPIA PIONEER lead) and James N'Dow (EAU PIONEER coordinator). The opening remarks all touched upon the importance of continuing to develop and strengthen the public-private partnerships within PIONEER. IQVIA, the newest member of PIONEER, was also welcomed to the consortium.

As PIONEER's focus shifts to the preparation of its first periodic report for the IMI all work packages reflected on their progress to date and their expectations for year two.

WP2: Disease understanding and outcome definitions

The aim of WP2 is to develop standardised definitions of prioritised prostate cancer outcomes and diagnostic and prognostic factors across the different stages of prostate cancer. To date WP2 have updated an earlier systematic review from 2013 on outcomes for localised prostate cancer and completed a further two systematic reviews of the literature for outcome definitions for locally advanced and metastatic prostate cancer. For localised prostate cancer the identified outcome sets have been integrated following the Williamson and Clarke taxonomy. At EMUC19 in November WP2 will hold an expert group meeting, including all relevant stakeholders, to discuss the definitions of the identified outcome set for localised prostate cancer and to define a feasible outcome measurement instrument for each.

WP3: Data access and sources

To date WP3 have identified 66 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. Thirteen of these have been prioritised for inclusion in the PIONEER data platform based on the two prioritised pilot research questions identified through an extensive Delphi process which involved all stakeholders, including patients. WP3 have defined 2 data sharing models a federated model for remote data which may not leave the source's repository and a centralised model for data which may leave the source's repository. Currently, WP3 are piloting both models and their associated Data Access Agreements with the projects first prioritised data contributor. The aim of WP3 is to have all Data Access Agreements for the 13 prioritised data sources completed by November 2019.

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. In the first 12 months of PIONEER WP4 have setup an EMIF data catalogue containing the meta data of PIONEER's available data sets. WP4 have also developed a modern user interface which supports the full transSMART 17.1: Glowing Bear. Moving forward WP4 will complete a proof of concept study for both OMOP and transSMART Glowing Bear using the first two pilot data sets from PIONEER's first data contributor, once the Data Access Agreements are complete.

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.

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. In the first year WP6 has setup a stakeholder forum referred to as expert committee policy stakeholder feedback forum (ECPSFF). This ECPSFF includes patients, clinicians, regulators, HTA and payers as well as stakeholders involved in evidence generation. The ECPSFF will be consulted on a regular basis over the lifetime of the project with the aim of mitigating potential implementation barriers for PIONEER's results.

WP7: Dissemination and communication

To date WP7 have developed a detailed communication and dissemination strategy for PIONEER as well as establishing a strong visual identity for the project. This is a living document that will be periodically reviewed and updated as the communication needs of PIONEER evolve over time. In addition, WP7 have developed and launched the PIONEER-specific website and Twitter accounts and have created a PIONEER communications toolkit with easy to use templates and guides for project dissemination activities.

WP8: Legal, ethics and governance

In the first year WP8 ensured that PIONEER adhered to all applicable laws and ethics. WP8 achieved this by providing and reviewing all legal documents and by giving timely advice and support to all WPs regarding any legal or ethical issues they faced. Examples of this support included review of PIONEER's Advisory Agreements, drafting of PIONEER's Data Access Agreements and Data Access Policy, production of Memorandums of understanding as well as liaising with other BD4BO projects. In the coming year WP8 will continue to work closely with all WPs to ensure PIONEER develops a sustainable data governance structure which addresses patient confidentiality and data ownership concerns.

Overseeing the functioning and outputs of all PIONEER work packages is **WP1: Project management and administration**. In the first 12 months of the project WP1 have worked hard to ensure that a collaborative relationship between all partners, both public and private, has been established. WP1 have implemented PIONEER's management structure and established effective communication channels to ensure all potential challenges are identified and either avoided or overcome. In addition, WP1 have overseen PIONEER's first Grant Agreement Amendment and the establishment of PIONEER's Scientific and Ethical Advisory Boards.

During the course of the meeting WP7 also took the opportunity to talk in detail to PIONEER's coordinators, the different work package leads and co-leads as well as number of PIONEER's researchers. This short informative video interviews will all be made available over the coming months on the project's website. Overall, the general take home message from the meeting was that yes we have had a productive first year, but we must keep this momentum up with particular focus on engaging all possible data contributors.

For more information: www.prostate-pioneer.eu

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