

Title: PIONEER: European Commission Innovative Medicines Initiative funded BD4BO (Big data for better outcome) project on prostate cancer

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Introduction & objectives: Prostate Cancer DlagnOsis and TreatmeNt Enhancement through the Power of Big Data in EuRope (PIONEER) is a BD4BO project initiated by the EAU and supported by Innovative Medicines Initiative 2. This pan-European partnership brings together 32 public and private stakeholders in prostate cancer (PCa) research and clinical care from 9 countries across Europe. PIONEER is motivated by the desire to address some of the most important research questions in the field of PCa that have not yet been answered using single data sources. PIONEERs vision is to re-orient the management and clinical practice of PCa towards a more outcome-driven, value-based and patient-centric healthcare system for all European men living with PCa.

Methods & materials: PIONEER is made up of 8 teams built into individual work packages (WPs) handling tasks including: project management and administration (WP1), defining core outcomes (WP2), data access and sources (WP3), data platform delivery and maintenance (WP4), data analytics (WP5) and HTA/regulator/payer integration (WP6). WP7 disseminates and communicates PIONEER information and results and WP8, made up of dedicated teams of lawyers, ethicists and data specialists, addresses the barriers related to data sharing and data protection. Target contributors to the PIONEER platform are: Academics focused on PCa, large clinical practices and medical centres, life science companies, data aggregators and payers/governments. Based on the cohorts and datasets that will be available in PIONEER, and to offer more flexibility to data providers, PIONEER has chosen to use both the Federated model where remote data remains at the source's servers or repository and the Central model, where the data is moved outside of the environment of the data controller to a central data warehouse for research.

Results: Since the start in May 2018, over 60 databases have been identified. PIONEER has actively engaged in outreach and as of September 2019, PIONEER has started collating and mapping data for the PIONEER platform. To date, PRIAS is being mapped for Federated data sharing, ERSPC Rotterdam, Malmö Diet and Cancer and Malmö Preventative Medicine are being prepared for data sharing via the Central model. Industry partners like IQVIA, Bayer, Astellas, Sanofi and COVANCE have agreed to share databases they hold. Negotiations are underway for access to additional cohorts from European and non-European countries.

Conclusions: The PIONEER platform is being built using European and non-European datasets. Big data approaches using real-life data show great potential to fuel a new era in PCa care and management. By harnessing the power of big data through collecting high-quality real-world data into a single innovative platform, health outcomes and healthcare systems in Europe can be maximized for men with prostate cancer.