Title: PIONEER: a BD4BO (Big data for better outcome) prostate cancer project

Authors: Susan Evans-Axelsson[a], Thomas Abbott[b], Louise Fullwood[c], Muhammad Imran Omar[d] Marinel Cavelaars[e], Maxim Moinat[e], Kees van Bochove[e], Carl Steinbeisser[f], Alex Asiimwe[f], John-Edward Butler-Ransohoff[f], Monique Roobol[g], Maria J. Ribal[h], Charles Auffray[i], Zsuzsanna Devecseri[j], *Amit Kiran[j],* Emma Smith[h], Mieke Van Hemelrijck[k], Steven MacLennan[d], Denis Horgan[l], Fredrik Moen[m], Christian Reich[n], Kishore Papineni[j], Sonia Araujo[n], Billy Franks[j], Bertrand De Meulder[i], Femke van Diggelen[o], Doron Lancet, James N'Dow[h], Anders Bjartell[a] and PIONEER Consortium*

Affiliations: a. Lund University, b. Astellas, c. Pinsent Masons, d. University of Aberdeen, e.The Hyve, f. Bayer AG, g. Erasmus, h. European Association of Urology, i. EISBM, j. Sanofi, k. King's College London, l. European Alliance for Personalised Medicine (EAPM), m. IHE, n. IQVIA, o. ttopstart, p. Weizmann Institute, Rehovot, Israel

Background: Prostate Cancer DIagnOsis and TreatmeNt Enhancement through the Power of Big Data in EuRope (PIONEER) is an Innovative Medicines Initiative 2 pan-European partnership bringing together 32 public and private stakeholders, in prostate cancer 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 prostate cancer that have not yet been answered using single data sources. PIONEERs goal is to ensure the optimal care for all European men living with prostate cancer by unlocking the potential of Big Data and Big Data analytics.

Methods: PIONEER is made up of 8 teams built into individual work packages (WPs). Project management and administration is handled by WP1. WP2 aims to define core outcome sets for prostate cancer in the context of the patient's treatment pathway. WP3 team aims to identify, approach and negotiate appropriate data sharing agreements with holder of high-quality, real-life prostate cancer-based datasets worldwide. WP4 aims to deliver a data repository and analytics platform that is secure, sustainable and meets PIONEERs objectives. WP5 will carry out analyses of the data sources identified and collated by WP3 and WP4 based on the core outcome sets identified by WP2. WP6 is responsible for HTA regulator-payer integration. WP7 will run in parallel with the other packages to disseminate and communicate PIONEERs aims, objectives and results. PIONEER is highly sensitive to the legal, regulatory and ethical concerns around sharing of patient data, therefore the PIONEER project includes dedicated teams of lawyers, ethicists and data specialists whose role is to oversee data sharing and ensure that all data sharing and data processing is done in compliance with law and with established good practice, and that the privacy of patients is respected (WP8).

Results: Since the start in May 2018, PIONEER has actively engaged in outreach and now has over 60 potential data sources identified. As of September 2019 datasets from academic and industrial partners are in the process of being mapped to formats for subsequent analyses. Negotiations are underway for access to additional cohorts from non-European countries.

Conclusions: The PIONEER platform is being built using European and non-European datasets. PIONEER will harness the power of big data to develop a data platform of unparalleled scale, quality and diversity. This Big Data statistical power will transform the field of prostate cancer care by empowering

meaningful improvements in clinical practice, prostate cancer disease-related outcomes and health economic outcomes.

Conflict of Interest: No conflicts of interest related to this presentation.

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