

The European perspective at the EAU-RF

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Disclosures/Conflict of Interest

Scientific Advisory Board and/or speaker honoraria
Accord, Astellas, AstraZeneca, Bayer, Ferring, IPSEN, Janssen, MSD, Sandoz

Research grants

Astellas, Bayer, Ferring

Co-founder

Glactone Pharma AB

Board Member

Glactone Pharma AB, Noviga AB

Shareholder

LIDDS AB, Glactone Pharma AB, WntResearch AB,





Agenda

• EAU Research Foundation

Previous and ongoing studies/registries

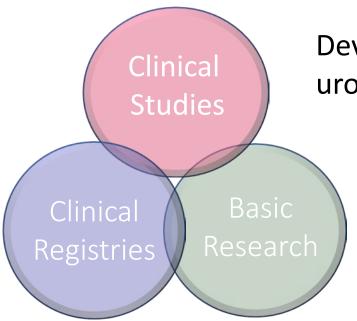
- Future strategies
 - Big Data, Al and Data Haven





EAU Foundation for Urological Research

The mission of the EAU Research Foundation (EAU RF) is to promote, facilitate and stimulate clinical and basic research in European urology. We set out to achieve this mission by acting as a bridge between urological centres, research organisations and the EAU.



Development of a European network of urological research centres





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EUSP Axel Merseburger Lubeck (DE)



YAU G. Cacciamani Los Angeles (US)









Previous studies

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

MAY 10, 2018

VOL. 378 NO. 19

MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis

V. Kasivisvanathan, A.S. Rannikko, M. Borghi, V. Panebianco, L.A. Mynderse, M.H. Vaarala, A. Briganti, L. Budäus, G. Hellawell, R.G. Hindley, M.J. Roobol, S. Eggener, M. Ghei, A. Villers, F. Bladou, G.M. Villeirs, J. Virdi, S. Boxler, G. Robert, P.B. Singh, W. Venderink, B.A. Hadaschik, A. Ruffion, J.C. Hu, D. Margolis, S. Crouzet, L. Klotz, S.S. Taneja, P. Pinto, I. Gill, C. Allen, F. Giganti, A. Freeman, S. Morris, S. Punwani, N.R. Williams, C. Brew-Graves, J. Deeks, Y. Takwoingi, M. Emberton, and C.M. Moore, for the PRECISION Study Group Collaborators*

The use of risk assessment with MRI before biopsy and MRI-targeted biopsy was superior to standard transrectal ultrasonography—guided biopsy in men at clinical risk for prostate cancer who had not undergone biopsy previously.

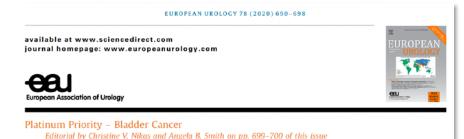






Previous studies

2013 – 2019 STOPPED for safety reason after 359 pts:



Treatment of High-grade Non-muscle-invasive Bladder Carcinoma by Standard Number and Dose of BCG Instillations Versus Reduced Number and Standard Dose of BCG Instillations: Results of the European Association of Urology Research Foundation Randomised Phase III Clinical Trial "NIMBUS"

Marc-Oliver Grimm^{a,*}, Antoine G. van der Heijden^b, Marc Colombel^c, Tim Muilwijk^d, Luis Martínez-Piñeiro^e, Marko M. Babjuk^f, Levent N. Türkeri^g, Joan Palou^h, Anup Patel^f, Anders S. Bjartell^{f,k}, Christien Caris^f, Raymond G. Schipper^f, Wim P.J. Witjes^f, for the EAU Research Foundation NIMBUS Study Group[†]

Conclusions:

The reduced frequency schedule was inferior to the standard schedule regarding the time to first recurrence.

Further recruitment of patients was stopped immediately to avoid harm in the reduced frequency BCG arm.

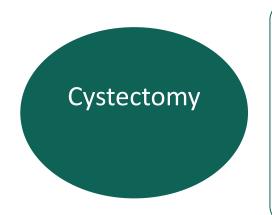




Study designOpen-label Phase 2. High-risk UTCa



Received
Neoadjuvant
cisplatin-based
chemotherapy
or ineligible for
Neo Cisplatinbased CT



- pT3-4 and/or pN1-3 stage
- FGFR3 alterations (FoundationOne test)

Adjuvant pemigatinib for 12 months

PI Andrea Necchi Funding: Incyte

Primary Objective: Evaluate relapse-free survival

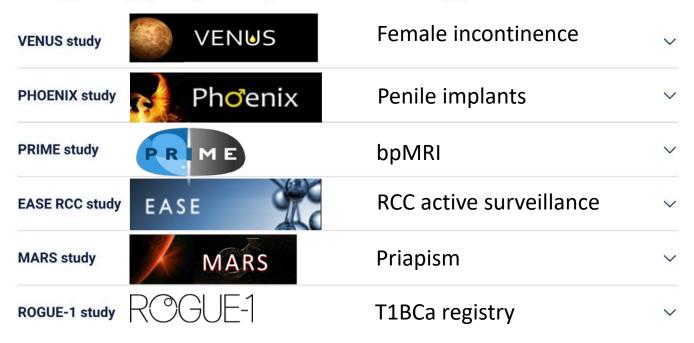
Secondary Objectives: Evaluate safety, tolerability and overall survival

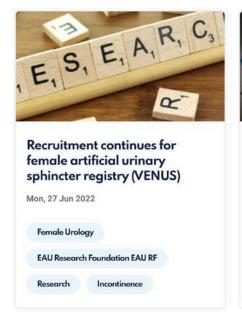
Study restricted to Italy but now stopped. Only 5/43 pat pos genetic FGFR3 test (>10%)

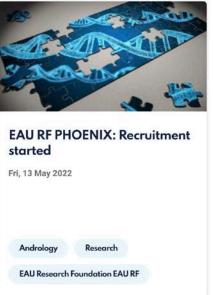




Ongoing projects (still recruiting)

















PRIME: 500-patient prospective, international, within-patient, multicentre, level 1-evidence

available at www.sciencedirect.com



European Association of Urolog

Platinum Opinion

Is It PRIME Time for Biparametric Magnetic Resonance Imaging in Prostate Cancer Diagnosis?

Alexander Ng a,b, Pramit Khetrapal c,d, Veeru Kasivisvanathan b,c,*

^aUCL Medical School, University College London, London, UK; ^b BURST Research Collaborative, London, UK; ^c Division of Surgery and Interventional Science, University College London, London, UK; ^d Department of Urology, Whipps Cross Hospital, Barts Health NHS Trust, London, UK



Prof Caroline Moore



Dr Veeru Kasivisvanathan

University College London Hospital, UK

AIM: To assess whether bpMRI is non-inferior to mpMRI in detecting csPCa

FIRST 200 DAYS

9

SITES OPENED

142

PATIENTS RECRUITED







Upcoming studies/registries





PI Andrea Necchi. PM Fillipo Pedersoli



A prospective multicentre registry for patients undergoing focal therapy for localised prostate cancer.

PI: Eric Barret Paris Juan I. Martinez-Salamanca, Madrid





OLIGOMET: Outcomes of local treatment for oligometastatic prostate cancer diagnosed using PSMA-PET

Principal investigators:

Prof. Shahrokh Shariat, Dr. Pawel Rajwa,

Department of Urology, Medical University of Vienna, Vienna, Austria

Dr. Giorgio Gandaglia, Prof. Alberto Briganti

Department of Urology, Ospdedale San Raffaele IRCCS, Milan, Italy

Study Phase	Prospective
Objectives	Primary: To analyze the time to castration-resistant prostate cancer (CRPC) in patients treated with local therapy for oligometastatic prostate cancer diagnosed using PSMA-PET imaging
Study Design	Prospective, multicenter, observational study
Number of centers	12
Planned Sample Size	Approximately 250 patients
Planned start date	May 1st 2023











PIONEER & the BD4BO mission



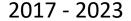
Prof James N'Dow

- PIONEER is part of the Innovative Medicine Initiative's (IMI's) "Big Data for Better Outcomes" (BD4BO) programme
- The BD4BO mission is to improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data











PIONEER consortium

PIONEER is:

- A network of 35 public and private stakeholders
- who collaborate closely with internal and external data providers
- to build a prostate cancer Big
 Data & analytics platform.





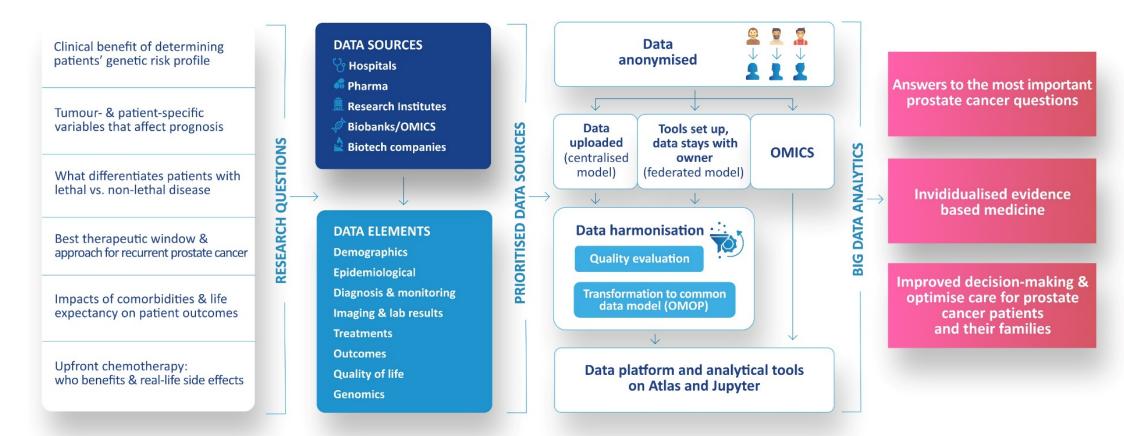




BIG DATA PLATFORM

THE EUROPEAN NETWORK OF EXCELLENCE FOR BIG DATA IN PROSTATE CANCER

Together we can ensure each individual patient receives the right treatment for them at the right time.



KNOWLEDGE GAPS

DATA SOURCES

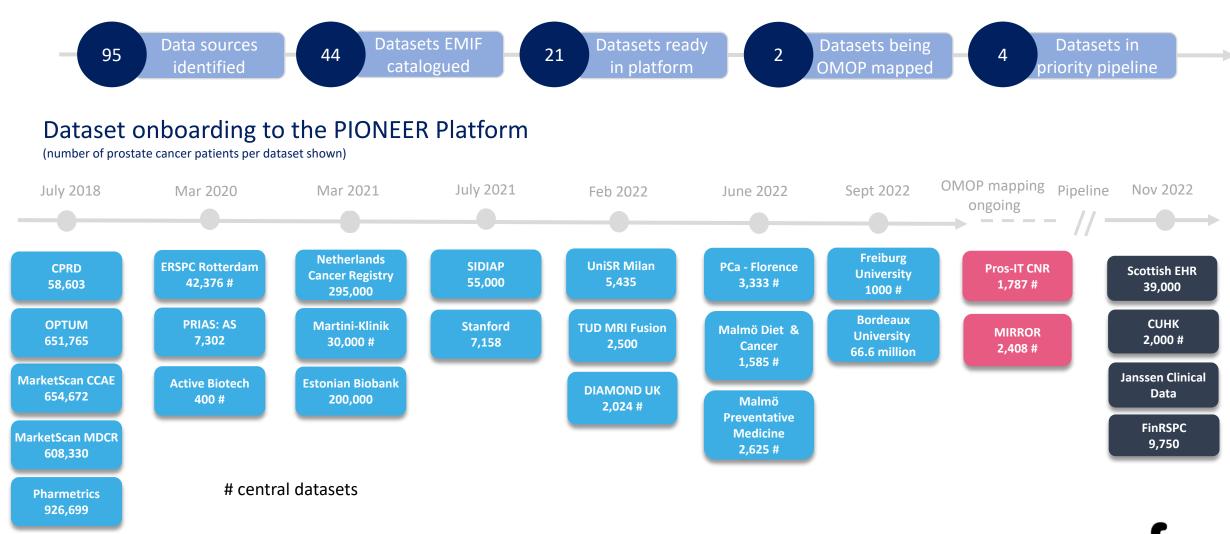
BIG DATA PROCESSING

PIONEER OUTCOMES





PIONEER Data sources and access overview

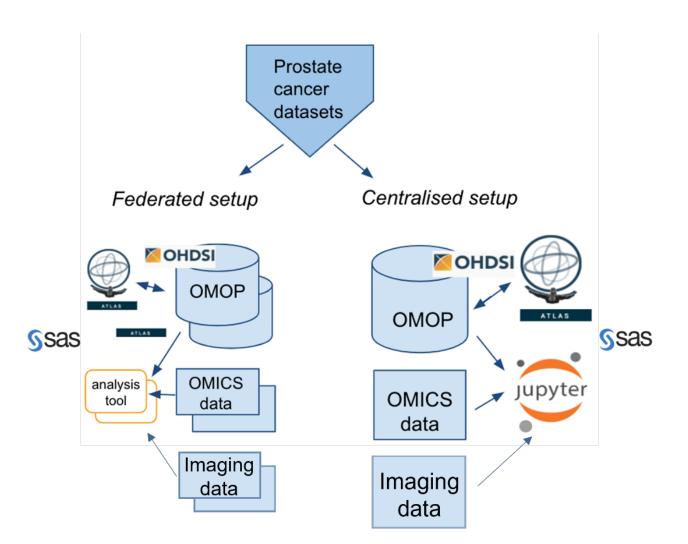




European

of Urology

PIONEER Big Data Platform



- PIONEER Big Data platform at CASUS / HZDR launched and active
- Federated & centralised model
- Integrated analytics applications







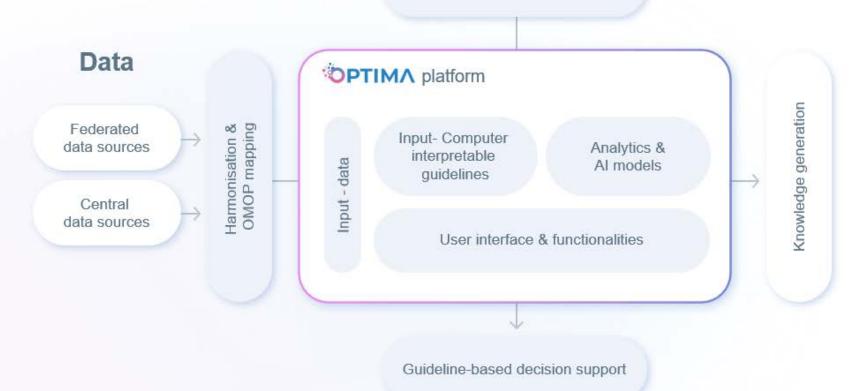
OPTIMA – PCa, lung & breast cancer



What we want to achieve

2021 - 2026

Two pillars form the foundation of OPTIMA-AI: Clinical decision support based on computer-interpretable guidelines and AI-discovery of new knowledge from real-world data



Prioritised knowledge gaps





















38 Partners across 9 countries in the following fields:

- IMI experienced researchers / SMEs
- Professional medical societies
- Cancer key opinion leaders
- Leading guideline developers
- Patient organisations
- Committed industry partners
- EMA steering group members
- AI in healthcare experts
- Implementation scientists



































































Transforming urology care

New EAU data innovation project

Data Haven: Real World Data Real World Evidence Big Data analytics
Artificial Intelligence
Services

Novel guidance of decisions by urologists

Personalised treatment of urology Patients











Why focus on Real World Data (RWD)?

- Evidence gaps not filled fast enough with high quality RCTs
- Mistake to think published outcomes from Centres of Excellence representative of practice in general
- Evidencing the purpose of EAU demands collecting RWD systematically

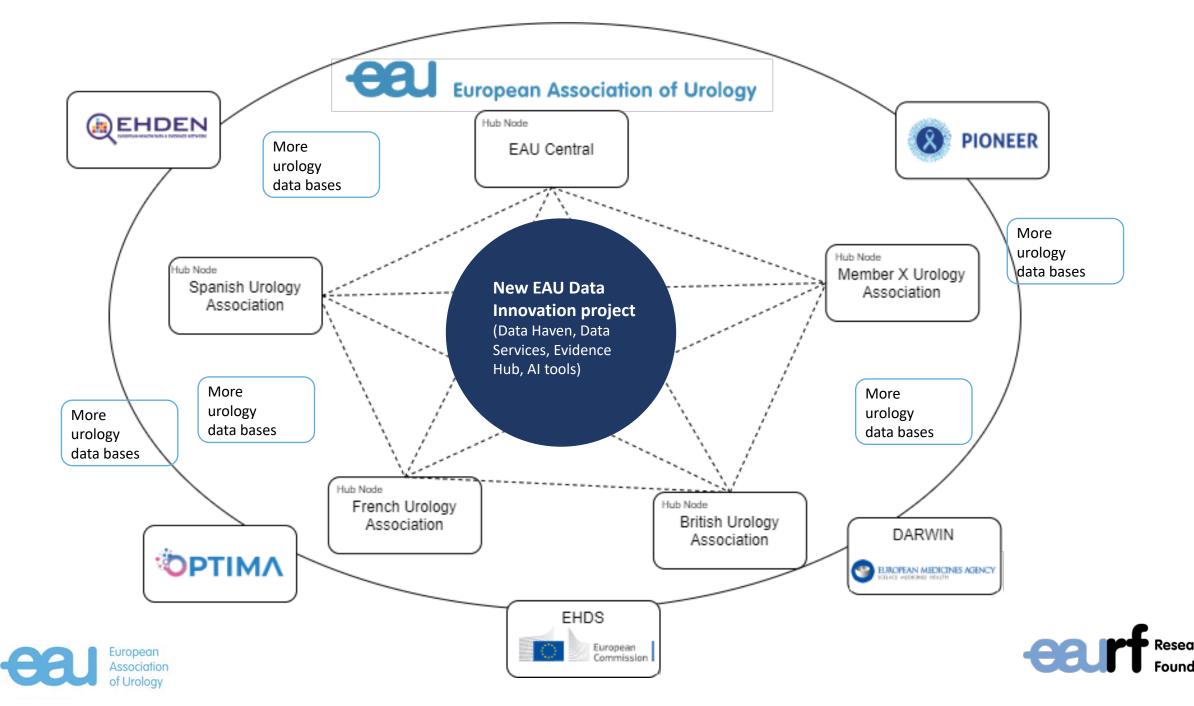


Evidence Based Medicine is evolving to include Real World Evidence (RWE)









FUTURE AIMS

Expand the portfolio of investigator-initiated clinical research projects and registries through seeding grants and other set-ups

Supporting Young Academic Urologists (EAU - YAU)

Consensus meetings and broad collaborations to fill gaps of knowledge

Focus on Big Data, Real-World Data, Data Haven

https://uroweb.org/offices/eau-foundation-for-urological-research





