



PIONEER's update and integration of a metastatic PCa COS

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About PIONEER

Harmonising assessment of men with PCa is key for both clinical research and practice.



- PIONEER is an IMI2 funded pan-European public private partnership consisting of 32 stakeholders from across 9 countries.
- PIONEER's goal is to ensure the optimal care for all European men diagnosed with prostate cancer (PCa) by unlocking the potential of big data and big data analytics.
- Work package 2 aims to define core outcome sets (COS) for PCa in the context of the patient's treatment pathway.

Introduction



- A standard set of metastatic PCa outcomes for clinical audit has been developed by the International Consortium for Health Outcomes Measurement's (ICHOM).
- By collaborating with ICHOM, we updated the systematic review to ascertain whether any new outcomes have been reported.
- The PIONEER Consortium will use the integrated and updated COS as a basis to harmonise data across diverse big data resources. The COS can also be recommended for effectiveness trials, systematic reviews, guidelines and clinical practice.

Methods

The methodology of the project is split into three phases:



A systematic review of systematic reviews which included randomised controlled trials (RCTs) of any intervention for men with metastatic PCa published between 1st January 2014 and 21st of December 2018 was conducted.



We compared the identified outcomes with the outcomes in the ICHOM outcome sets.



The newly identified outcomes have been prioritised by a multidisciplinary expert group.



The Williamson and Clarke taxonomy (2018) was used to integrate the outcome set and to recategorise the outcomes to a common taxonomy which is used and supported within research and practice in Europe.

Results and Discussion

We identified new primary and secondary outcomes in the RCTs.

These outcomes were not part of the ICHOM outcome set and a multidisciplinary expert group of patients, clinicians and researchers further evaluated the outcomes.

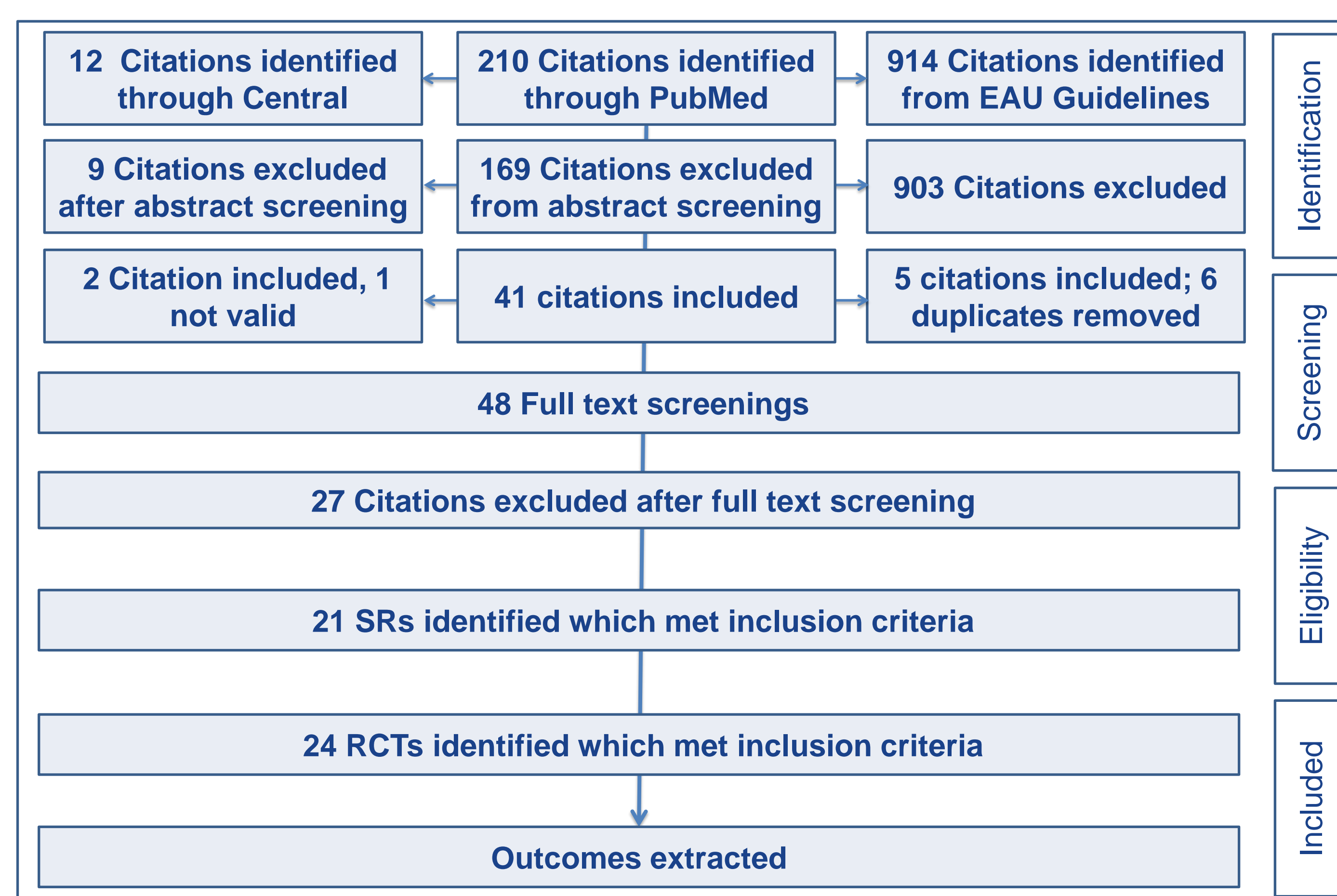
Table 1: Prioritised newly identified outcomes

Prioritised new outcomes
Biochemical progression-free survival
Bone progression free survival rate
Clinical progression free survival
Cost-effectiveness
Death from causes other than PCa
PSA response
Radiographic progression-free survival
Response Evaluation Criteria In Solid Tumours objective response rate
Time to PSA progression

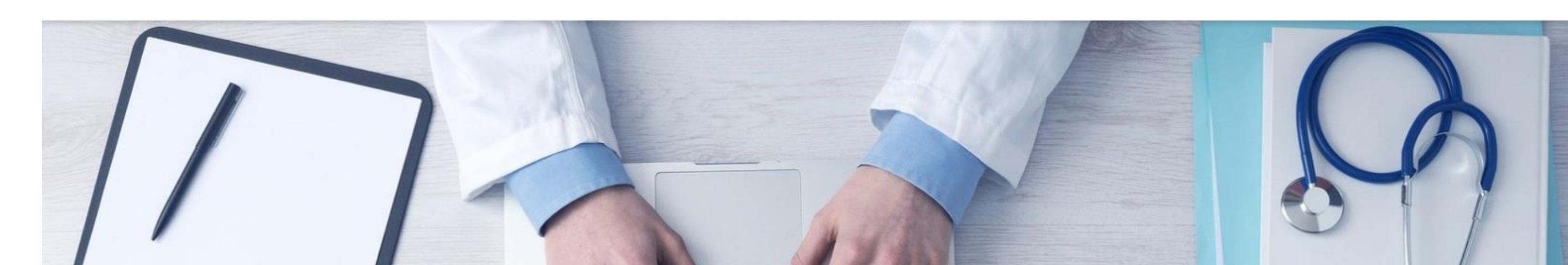
Results and Discussion

Literature searches identified 1,136 references and 24 RCTs were included.

Figure 1: PRISMA flowchart



Conclusions



The next steps will focus on a qualitative part for metastatic PCa COS, which has not been included in previous research by ICHOM. This aims to better understand patient perspectives.



In addition, PIONEER will aim to reach consensus on the most appropriate definitions of clinician observed outcomes and the psychometric properties and feasibility of the outcomes identified.

We would like to thank the PIONEER multidisciplinary expert group for their support.