#896TiP - ProBio: An outcome-adaptive, multi-arm, open-label, multiple assignment randomised controlled biomarker-driven trial in patients with metastatic castration-resistant prostate cancer

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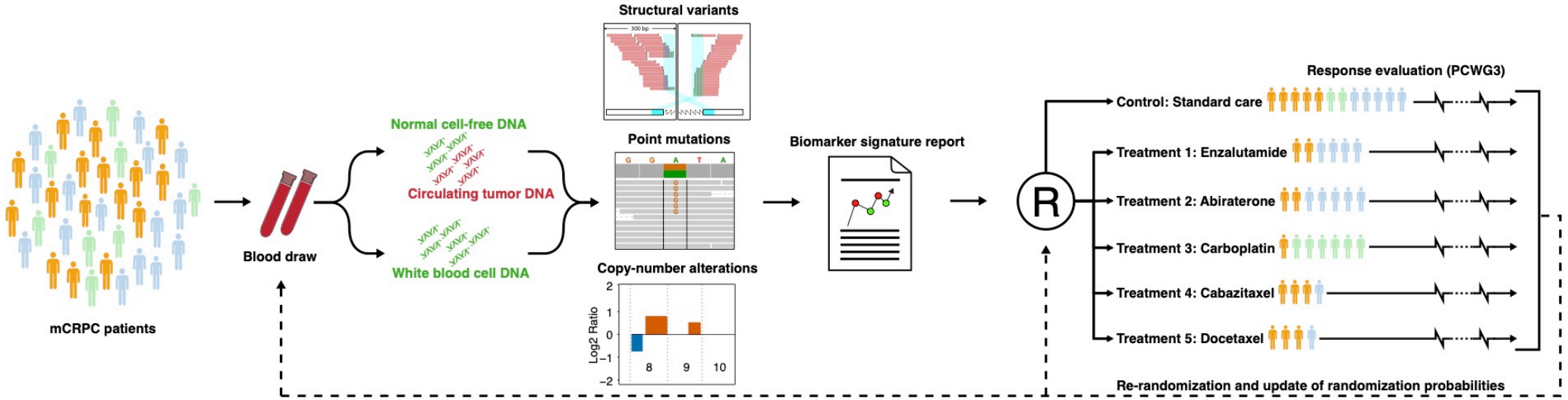
on behalf of the ProBio Investigators

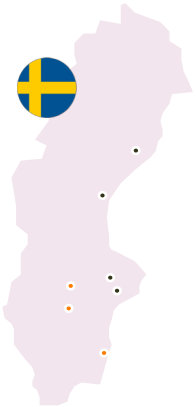


The Prostate Biomarker (ProBio) trial

- EudraCT: 2018-002350-78 / NCT03903835
- Hypothesis: Biomarker guided treatment decisions will increase progression-free survival (primary endpoint), which would result in prolonged overall survival and improved quality-of-life (secondary endpoints).
- Novelty:
  - Prospective **liquid biopsy** profiling for therapy selection
  - **Platform** design with **adaptive** randomisation
  - **Re-randomization** of progressing patients

Trial design

- Adaptive, multi-arm, open-label, multiple assignment randomized controlled biomarker driven phase 3 trial.
- Men with mCRPC (n=750) will be randomized to receive either standard of care or experimental treatment based on a molecular biomarker signature inferred from circulating tumor DNA.
- A mini-genome (1.48 Mb), tailored for metastatic prostate cancer
  - mutations (78 genes), structural rearrangements (11 genes), genome-wide copy number alterations, microsatellite instability, mutational burden



Interested in joining the ProBio trial?

Contact us!

Probiotrial.org

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The authors declare that they have no conflicts of interest.

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