

# New transrectal prostate biopsy approach may improve tolerability and safety



# my conflict of interest

- DEBN Sp. z o. o.\* shareholder

\* company established to develop and implement a new method of preventing infectious complications in patients undergoing prostate biopsy

# prostate biopsy

- over 4 million procedures a year in U.S. and Europe and growing<sup>1</sup>
- still the standard
- transrectal means risk of infection
- fluoroquinolone: overuse, side effects and “prohibition”<sup>2</sup>
- change the route to transperineal<sup>3</sup>
- need for troubleshooting?



1. Estimation based on Z. Tandogdu model presented at the EAU Annual Congress Madrid, Spain 2019  
2. EMA. Quinolone- and fluoroquinolone-containing medicinal products - European Medicines Agency. European Medicines Agency. Published September 17, 2018  
3. EAU Guidelines. Edn. presented at the EAU Annual Congress Amsterdam, the Netherlands 2022. ISBN 978-94-92671-16-5

# strategies for better prostate biopsy

## non-antibiotic strategies



rectal povidone-iodine

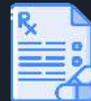


transperineal route

## systemic antibiotic strategies



targeted prophylaxis



augmented prophylaxis

# non-antibiotic: rectal povidone-iodine



## pros

- reduction of infections rate
- reduction of re-hospitalisation

## cons

- insufficient measure
- standardisation problem

# non-antibiotic: transperineal route



## pros

- 1st choice and best measure to reduce infections

## cons

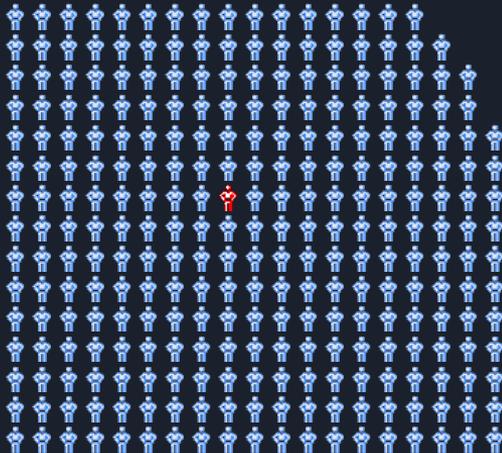
- more painful
- more urinary retention
- more ED?
- more expensive

1. Berry B, Parry MG, Sujenthiran A, et al. Comparison of complications after transrectal and transperineal prostate biopsy: a national population-based study. *BJU International*. 2020;126(1):97-103. doi:10.1111/bju.15039
2. Pradere B, Veeratterapillay R, Dimitropoulos K, et al. Nonantibiotic Strategies for the Prevention of Infectious Complications following Prostate Biopsy: A Systematic Review and Meta-Analysis. *Journal of Urology*. 2021;205(3):653-663. doi:10.1097/jju.0000000000001399
3. EAU Guidelines. Edn. presented at the EAU Annual Congress Amsterdam, the Netherlands 2022. ISBN 978-94-92671-16-5

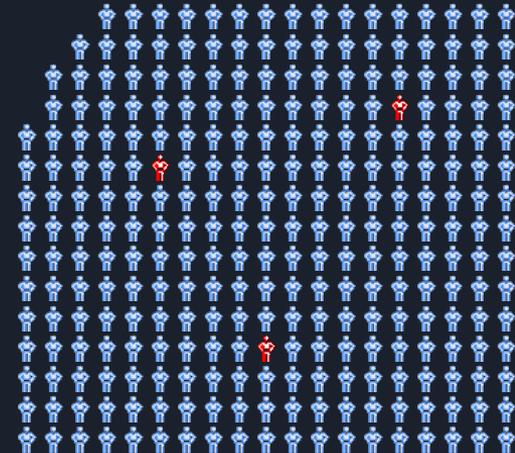
# non-antibiotic: transperineal route



transrectal biopsy  
re-admission: sepsis



transperineal biopsy  
re-admission: urinary retention



*transperineal route would prevent **one** readmission for **sepsis** in 278 patients  
at the cost of **three** additional patients readmitted for **urinary retention***

# antibiotic: targeted prophylaxis



## pros

- may reduce infections
- may be cost-effective

## cons

- complicates practicalities
- no RCTs on non-fluoroquinolones

1. Taylor AK, Zembower TR, Nadler RB, et al. Targeted Antimicrobial Prophylaxis Using Rectal Swab Cultures in Men Undergoing Transrectal Ultrasound Guided Prostate Biopsy is Associated With Reduced Incidence of Postoperative Infectious Complications and Cost of Care. *Journal of Urology*. 2012;187(4):1275-1279. doi:10.1016/j.juro.2011.11.115
2. Singh P, Kumar A, Yadav S, et al. "Targeted" prophylaxis: Impact of rectal swab culture-directed prophylaxis on infectious complications after transrectal ultrasound- guided prostate biopsy. *Investigative and Clinical Urology*. 2017;58(5):365. doi:10.4111/icu.2017.58.5.365

# antibiotic: augmented prophylaxis



## pros

- reduce infections

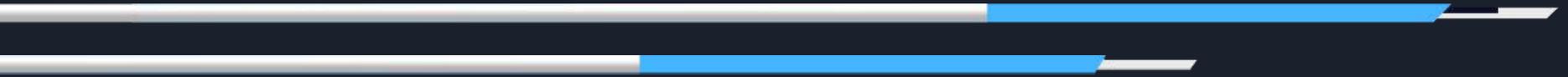
## cons

- may contradict the principles of antibiotic stewardship
- no standard combination



new approach:  
DEBN<sup>®</sup> antimicrobial prostate biopsy device

prostate biopsy & anesthesia needles + **amikacin** coating





## potential benefits and goals

- first local antibiotic prophylaxis for prostate biopsy
- tool for easy augmented prophylaxis
- reduction of total antibiotics use
- microbiome protection with less side effects
- easy use of antimicrobial agents available only parenterally
- the possibility of using antibiotics that penetrate poorly into the prostate
- reduction of infectious complications related to prostate biopsy

# what has been done

- coating formulation
- proof-of concept studies
- IP protection: patents granted in EU, US, Canada, Brazil, Japan and Australia
- technology transfer from lab to clean room
- packaging validation
- sterilisation validation
- biocompatibility
- stability
- ready for clinical trial: EC approved

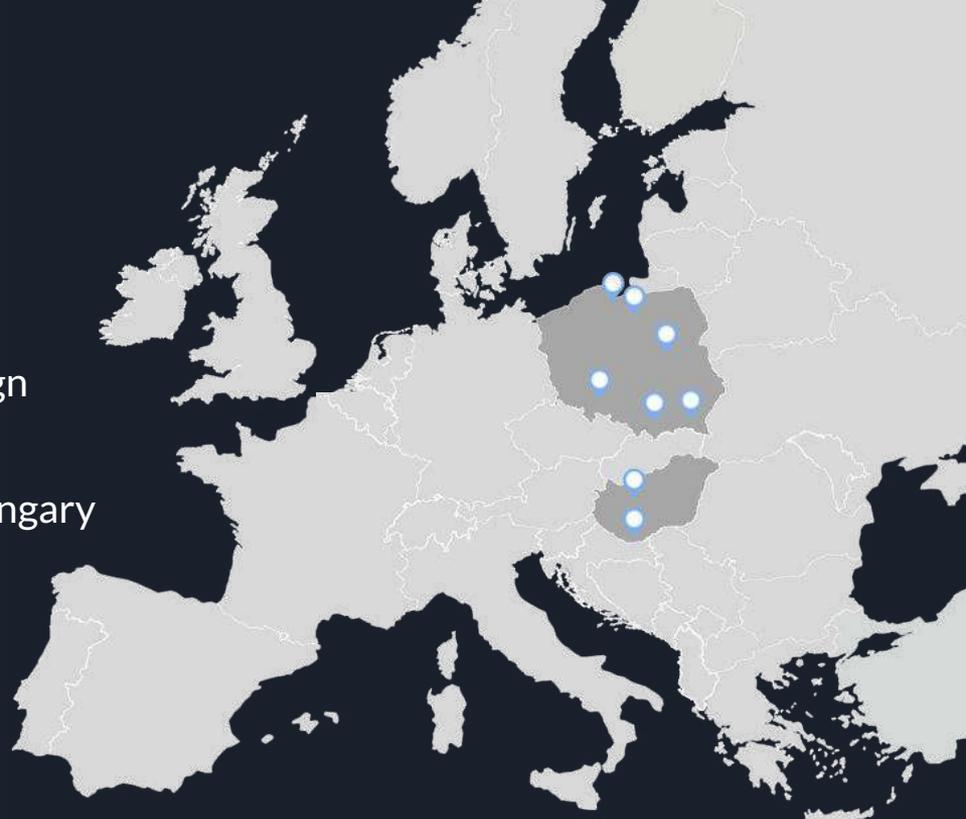




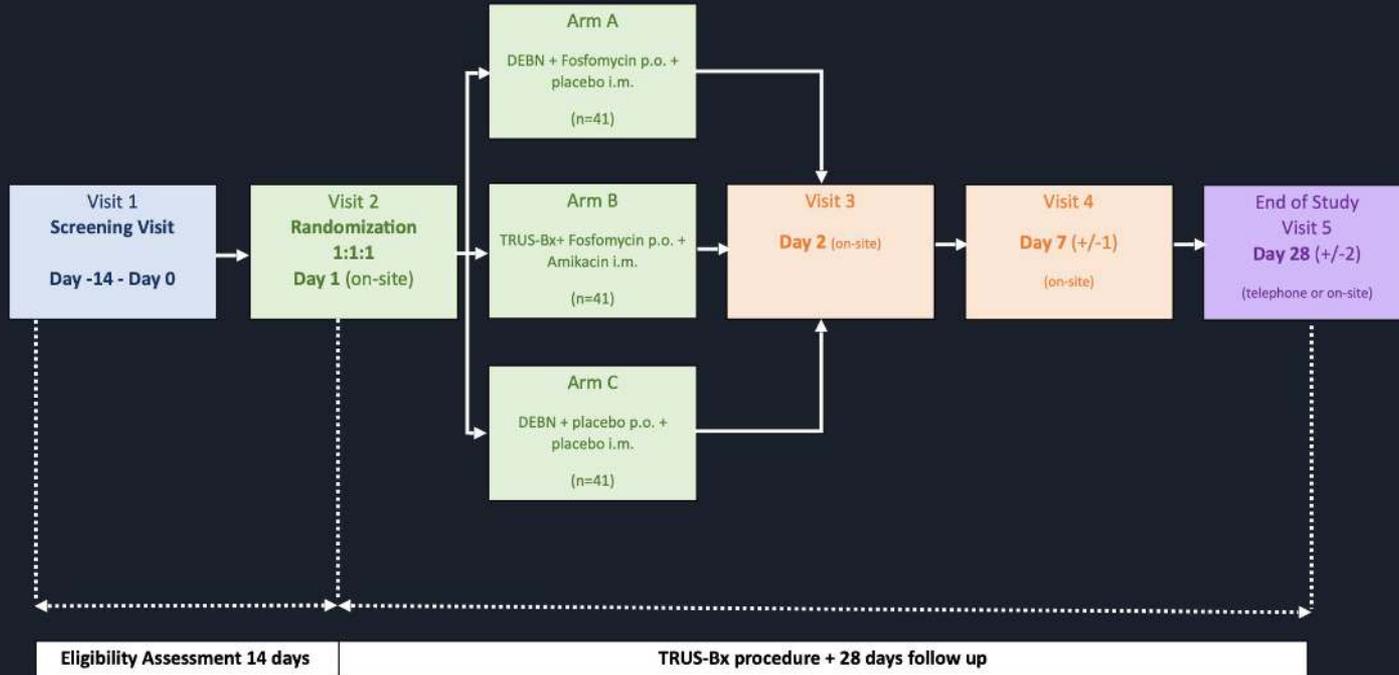
# DEBN<sup>®</sup> clinical trial

- randomised, non-inferiority design
- double-blind
- 8 study centers in Poland and Hungary
- approx. 123 patients
- 3 study arms
- 5 study visits
- primary hypothesis:

*transrectal prostate biopsy performed with DEBN is non-inferior to standard transrectal prostate biopsy combined with augmented prophylaxis*

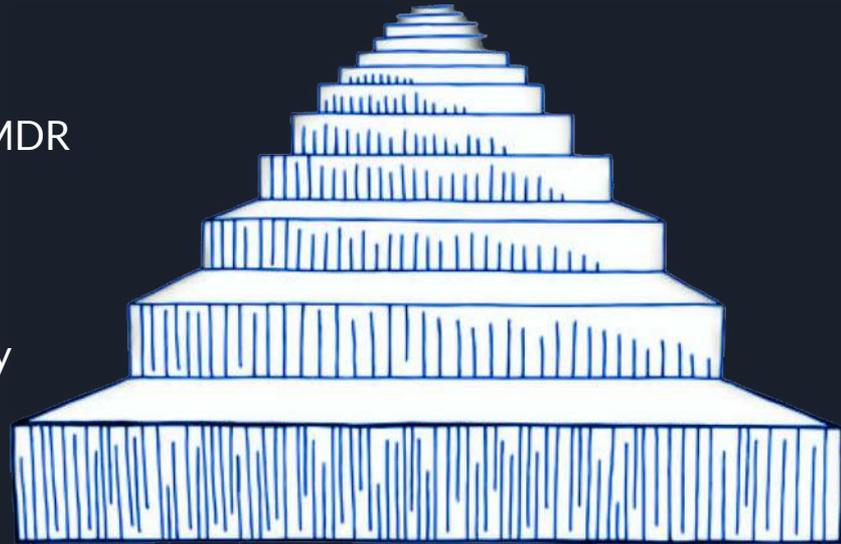


# DEBN<sup>®</sup> trial design scheme



# next steps after RCT

- EU certification process according to MDR
- EU market entry
- further post-approval trials
- FDA certification and U.S. market entry



thank you for your attention