MONITORING PLAN

Study name:	Multi-IMPROD2.0
Study code:	T326/2019
EurdraCT number:	Not applicable
Sponsor / Investigator:	Turku University Hospital
Name of study site:	Turku University Hospital
Duration of the study:	02/2020-02/2026
Planned No. of subjects:	600

EXTENT OF MONITORING

Minimum monitoring as specified by the organisation to implement the obligations of quality policy and good clinical practice.

ITEMS TO BE MONITORED (detailed description)

- **Study initiation visit**

- **1st monitoring in the beginning of the study:**

Items to be checked are:
Study documentation in investigator's trial file
Informed consents of screened and enrolled study subjects
CRFs completed by the date of monitoring visit of 1-2 first enrolled subjects.
Timing for the visit is Feb-2021.

- **2nd monitoring visit after the recruitment has been completed:**

Items to be checked are:
Informed consents of all screened and enrolled patients
Main parameters in CRFs of all study subjects:
Inclusion and exclusion criteria
Overall PI-RADS-score of the prostate
If TRUs-guided biopsies are performed, the overall histopathological gleason grade of the prostate
(Serious) Adverse events
Study documentation in investigator's study file.
Planned timing for the visit is Feb-2022.

- **3rd monitoring visit after last patient has completed the study:**

Items to be checked are:
study documentation of investigator's study file.
Planned timing for the visit is Feb-2026.

Estimated time used for monitoring

- *1st monitoring visit 10h*
- *2nd monitoring visit 40h*
- *3rd monitoring visit 10h*

The monitoring plan is valid until further notice and it can be updated by mutual consent.

Ilkka Nikulainen		
Name of Monitor	Date	Signature
Peter Boström		
Name of Sponsor/Investigator	Date	Signature

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