

Aiforia[®] Clinical Suite for Prostate Cancer: A Holistic Assistive Tool for Prostate Cancer Diagnostics

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PROSTATE CANCER

- According to WHO, there were more than 1.4 million new cases of prostate cancer in 2020. (1)
- Prostate cancer is the second most common cancer in men, and it caused globally more than 375 000 deaths in 2020. (1)
- Early intervention based on correct characterization of the tumor is a key element of treatment planning and survival. (2)
- Analysis of biopsies is time-consuming and prone to interobserver variability. (3)

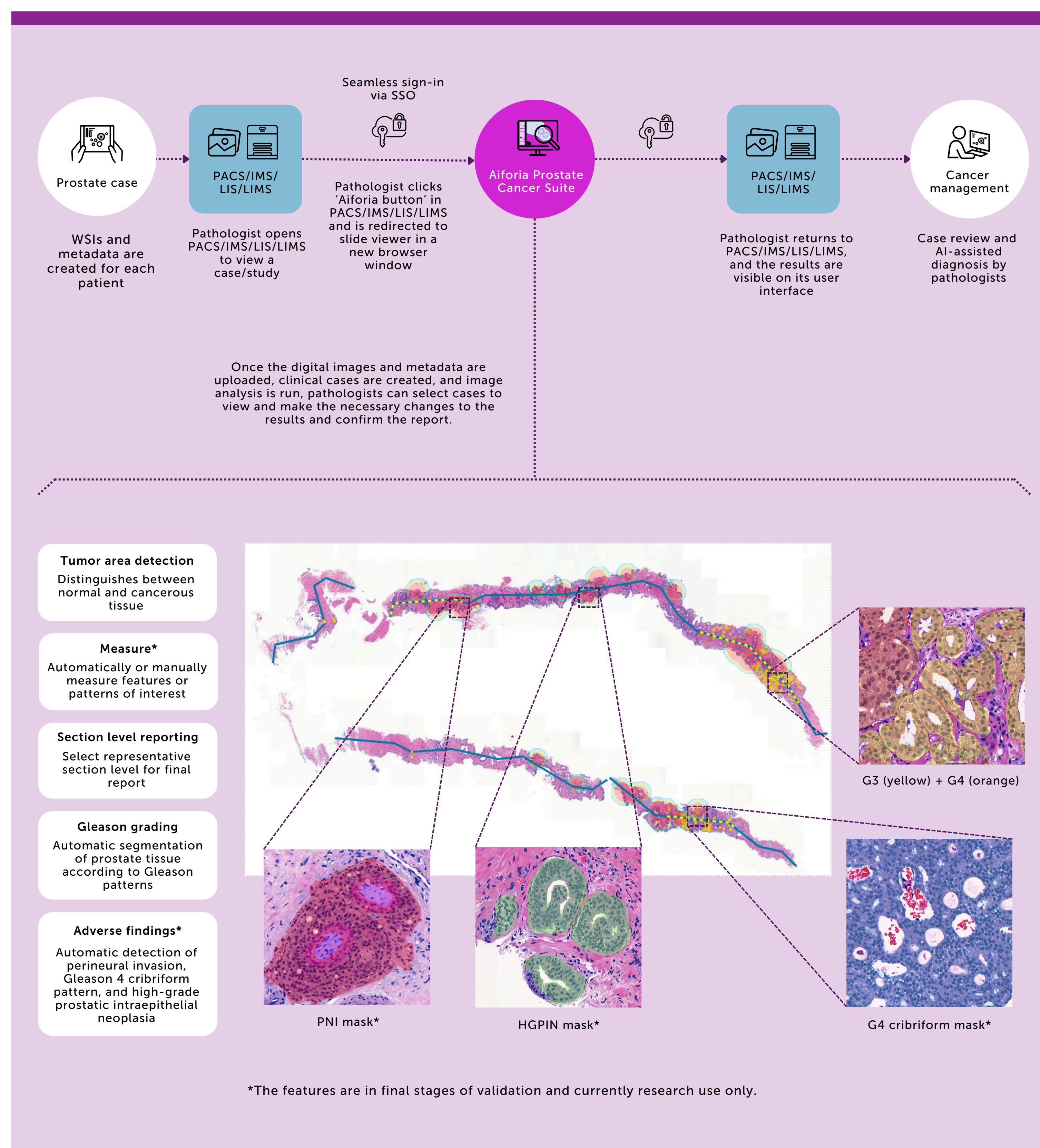
TECHNOLOGY

Computational pathology and artificial intelligence (AI)-based tools have enabled the objective diagnosis of whole slide images (WSIs) along with the access to necessary clinical information and case-related images. Aiforia[®] Clinical Suite for Prostate Cancer is a CE-marked software product consisting of a case and image viewer and AI-trained image analysis algorithms. It produces automated analysis detecting tumor epithelium, Gleason patterns, length measures* and adverse findings* from H&E stained prostate biopsy slides.

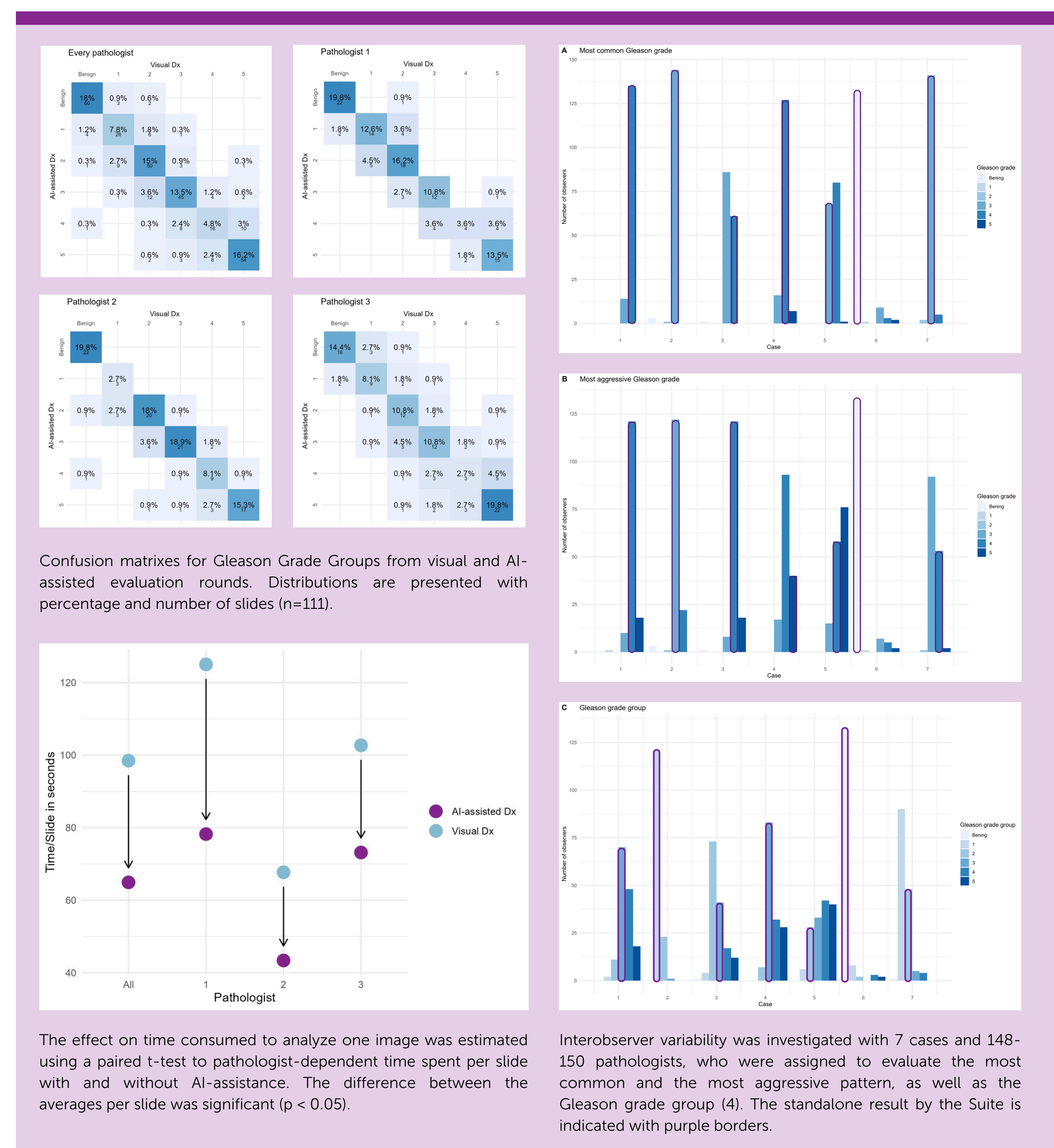
STUDIES

Whole slide images of routine H&E slides from 111 prostate cancer patients were digitized. The images were analyzed in two independent rounds: with and without the assistance of the product (4-week washout period), and a variety of statistical characteristics were calculated. 7 WSIs were also analyzed by 148-150 pathologists in 15 countries, and the consensus was compared to the result of the product. The measurement of tissue and tumour lengths, and the performance of the adverse findings are at the last phases of clinical validations.

AIFORIA PROSTATE CANCER SUITE WORKFLOW



STUDY RESULTS



STUDY RESULTS

- The model can predict positive observations with 96.8 % recall ratio for the combined dataset, ranging from 93 to 100 % for individual pathologists. Precision ranged from 86.9 to 93.9 % per pathologists, being 89.8 for the combined dataset. Overall accuracy (F1) ranged from 89.8 to 96.6 % per pathologist, being 93.2 % on average.
- The reliability of agreement between visual Dx and AI-assisted Dx was 0.846 (Cohen's weighed kappa) for the combined dataset, and the range for pathologists was 0.788-0.878.
- Time spent for Gleason pattern analysis per slide was significantly reduced during AI-assisted Dx; on average each slide took 34% less time ($p < 0.05$).

BENEFITS OF AI-ASSISTED ANALYSIS

- Improved treatment efficacy with more precise diagnosis
- Faster time to diagnosis and less waiting time for patients
- Samples are reviewed consistently and efficiently ensuring everyone is treated the same
- Time savings and reduction in error while improving treatment accuracy results in faster work and lower costs

CONCLUSIONS

- AI-assisted Gleason grading is very well in concordance with the analysis performed without its assistance.
- The AI methodology reduced the needed time for grading by 34 % versus eyeballing method.
- Inter-observer variability that is present among pathologists can be reduced by AI-assisted support. The suite may serve as a second opinion or as a triage tool for medical centers.
- With digital tools and automated workflow the increasing burden of prostate diagnostics may be reduced significantly.
- The CE-marked suite will be complemented soon with the measurement and adverse findings features.
- Performance will be further investigated with third-party clinical performance evaluations at real-world settings.

1) Cancer Today - IARC. (2023, February 2nd). Online analysis table. WHO. <https://gco.iarc.fr/today/>

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3) Melia J. et al. A UK-based investigation of inter- and intra-observer reproducibility of Gleason grading of prostatic biopsies. Histopathology. 2006 May;48(6):644-54.

4) van Leenders GJLH et al. ISUP Grading Workshop Panel Members. The 2019 International Society of Urological Pathology (ISUP) Consensus Conference on Grading of Prostatic Carcinoma. Am J Surg Pathol. 2020 Aug;44(8):e87-e99.