

European Prostate Cancer Awareness Day

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An industry perspective on the MRI diagnostic pathway

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Clinical impacts of the MRI diagnostic pathway

mpMRI pathway vs. TRUS-bx pathway	PRECISION ¹ (500 men)	MRI-FIRST ²	4M Study ³	PROMIS ⁴
Increase in detection of significant cancers [%]	+12%	No difference in significant cancer (+2%)	No difference in significant cancer (+2%)	No difference in significant cancer (+2%)
Diagnosis of insignificant cancer	-13%	-14%	-11%	-5%
Avoid biopsy after negative mpMRI in [%] of patients	28%	18-21%	49%	27%
Reduction of Biopsy cores per patient (relevant for infections and side effects)	11 → 4 (= -64%)	12 → 3 (= -75%)	12 → 3 (= -75%)	n.a.

¹ Kasivisvanathan V, et al. PRECISION Study Group Collaborators. MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis. N Engl J Med. 2018; 378(19):1767-1777

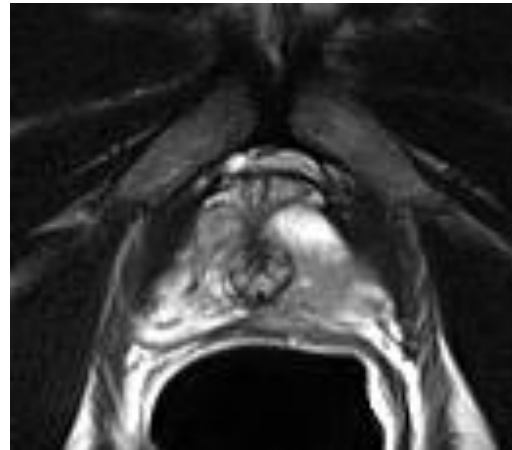
² Rouvière O, Puech P, Renard-Penna R, et al. Use of prostate systematic and targeted biopsy on the basis of multiparametric MRI in biopsy-naïve patients (MRI-FIRST): a prospective, multicentre, paired diagnostic study. Lancet Oncol 2018; [http://dx.doi.org/10.1016/S1470-2045\(18\)30569-2](http://dx.doi.org/10.1016/S1470-2045(18)30569-2).

³ van der Leesta M, Cornelis E, Israël B, et al. Head-to-head comparison of transrectal ultrasound guided prostate biopsy versus multi-parametric prostate resonance imaging with subsequent MR-guided biopsy in biopsy-naïve men with elevated PSA; a large prospective multicenter clinical study. Eur Urol 2018 in press

⁴ Ahmed HU, et al. Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. Lancet 2017; 389: 815–22

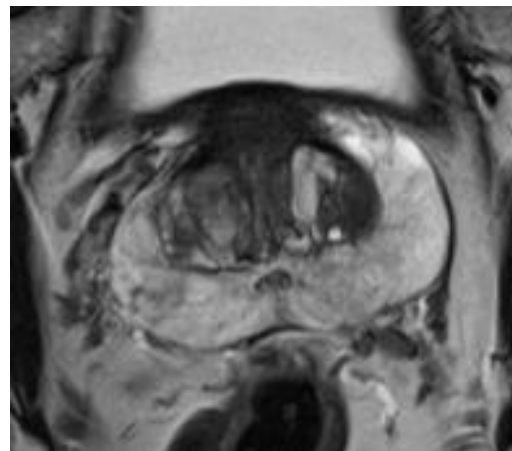
Advancements in technology improving patient comfort, speed and quality

2010



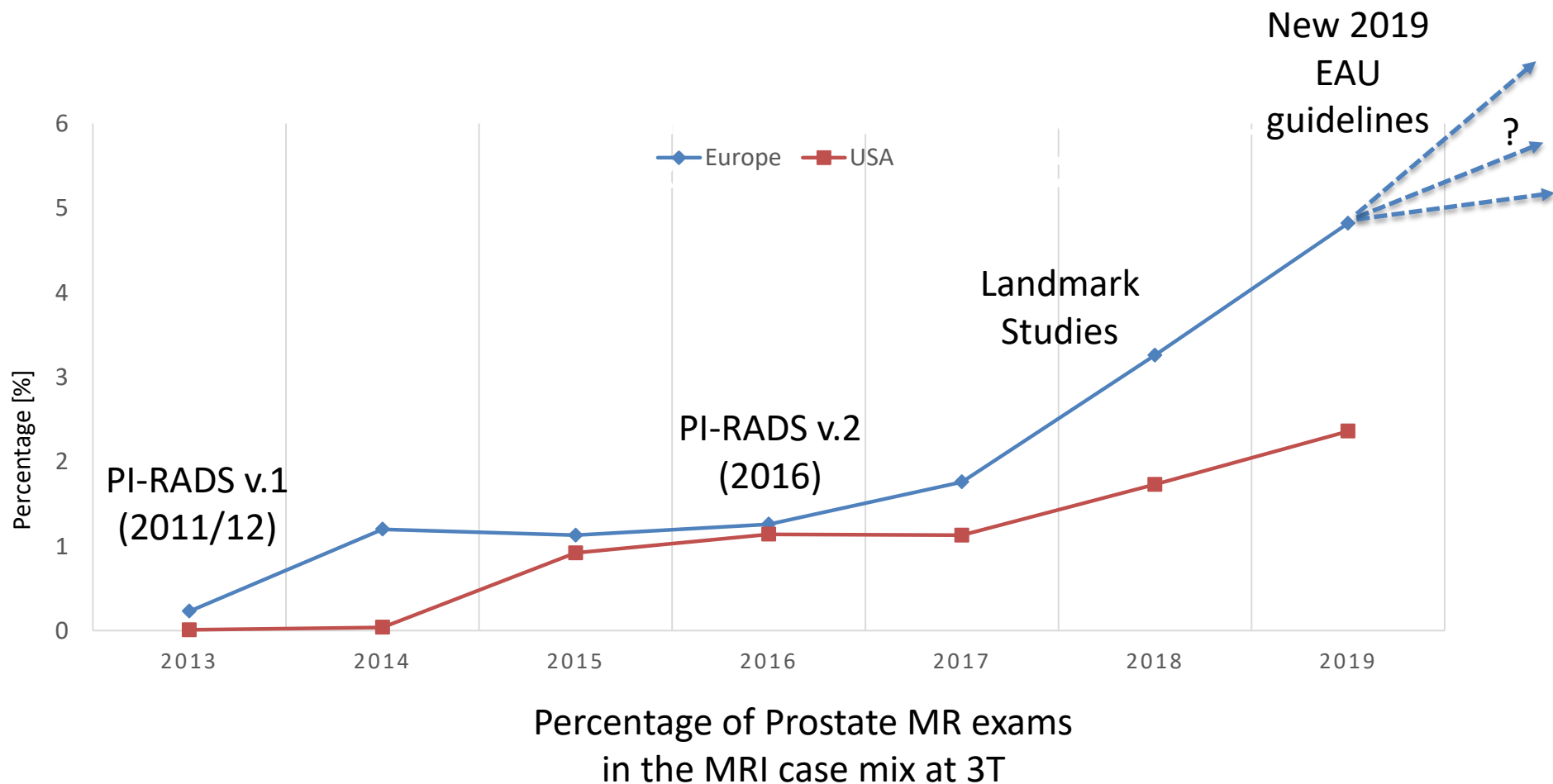
45-60 min

2020



20-30 min

Development of prostate MRI exam numbers in clinical practice



Challenges with the MRI pathway for prostate cancer detection

ORIGINAL RESEARCH • SPECIAL REPORT

Radiology

PI-RADS Steering Committee: The PI-RADS Multiparametric MRI and MRI-directed Biopsy Pathway

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Conflicts of interest are listed at the end of this article.

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High-quality evidence shows that MRI in biopsy-naïve men can reduce the number of men who need prostate biopsy and can reduce the number of diagnoses of clinically insignificant cancers that are unlikely to cause harm. In men with prior negative biopsy results who remain under persistent suspicion, MRI improves the detection and localization of life-threatening prostate cancer with greater clinical utility than the current standard of care, systematic transrectal US-guided biopsy. Systematic analyses show that MRI-directed biopsy increases the effectiveness of the prostate cancer diagnosis pathway. The incorporation of MRI-directed pathways into clinical care guidelines in prostate cancer detection has begun. The widespread adoption of the Prostate Imaging Reporting and Data System (PI-RADS) for multiparametric MRI data acquisition, interpretation, and reporting has promoted these changes in practice. The PI-RADS MRI-directed biopsy pathway enables the delivery of key diagnostic benefits to men suspected of having cancer based on clinical suspicion. Herein, the PI-RADS Steering Committee discusses how the MRI pathway should be incorporated into routine clinical practice and the challenges in delivering the positive health impacts needed by men suspected of having clinically significant prostate cancer.

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Online supplemental material is available for this article.

The current version of the Prostate Imaging Reporting and Data System (PI-RADS) was formulated on experience gained from PI-RADS version 1, accumulated scientific evidence, and expert consensus (1). The release of PI-RADS version 2.1 is expected to further improve observer variability (2). A recent publication evaluated multiple clinical studies, systematic analyses, and professional guidelines on their use of multiparametric MRI in prostate cancer detection (3). It showed that the test performance of multiparametric MRI-directed biopsy in the detection of prostate cancer is superior to that of systematic transrectal US-guided biopsy. High-level evidence has now established multiple benefits of MRI-directed biopsy over systematic transrectal US-guided biopsy of the prostate (4). These benefits include (a) a reduction in the number of men who need to undergo biopsy (5–9); (b) a reduction in the number of diagnoses of clinically insignificant cancers that are unlikely to cause harm (4,10), with the potential to reduce overtreatment, treatment-related complications, and active surveillance rates (6); (c) improved detection

management. All these advantages can be achieved with fewer targeted biopsy cores per patient, potentially reducing biopsy-related morbidity (6,8,11). The purpose of this article is to focus on how multiparametric MRI results can positively impact the health of men suspected of having clinically significant prostate cancer.

Who Should Undergo MRI before Biopsy?

Patients chosen for MRI before biopsy include biopsy-naïve men with elevated serum prostate-specific antigen (PSA) levels, abnormal digital rectal examination findings, or both, and men who are deemed to have persistent elevated risk of harboring clinically significant cancers despite prior negative or nonexplanatory systematic transrectal US biopsy findings. Indications for MRI should be based on the recommendations for screening and early diagnosis of the National Comprehensive Cancer Network and the European Association of Urology (12,13). Accordingly, biopsy-naïve men with lower

“To deliver the intended pathway benefits, the **quality** of the entire diagnostic process must be ensured [...]

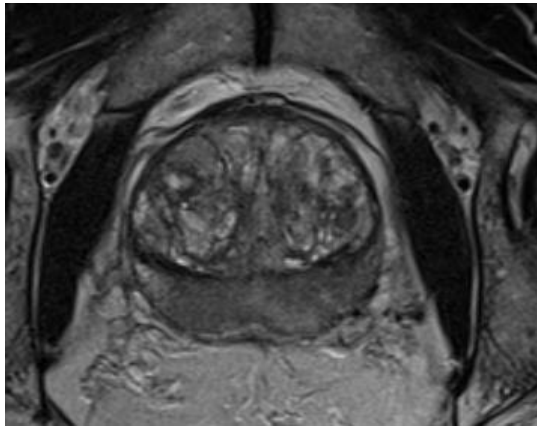
- #1 Many centers **struggle with image optimization** [...]
- #2 Reader expertise is also a major issue contributing to variability in reported studies and can potentially affect clinical care.”

#1: Image quality is a confounding factor for report quality in prostate MRI

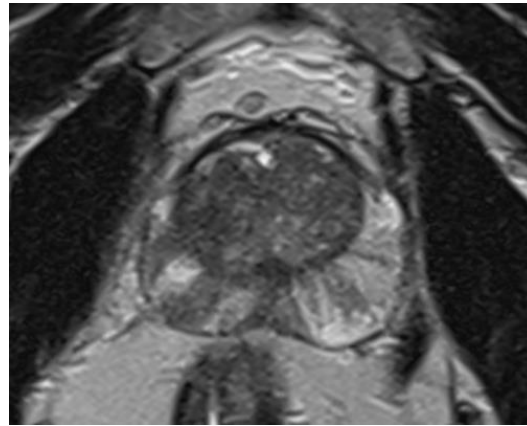


The handicraft of radiographers:
Tailoring and optimizing the exam for
the individual patient

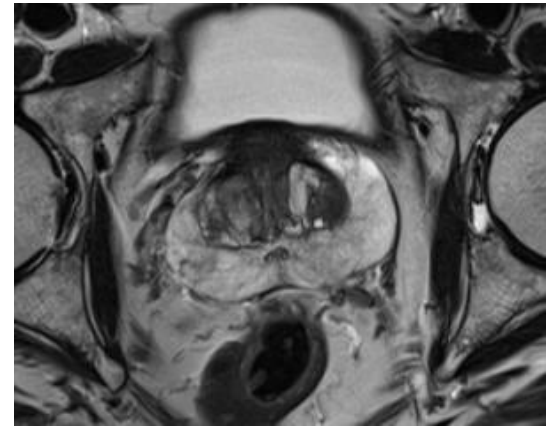
#1: High-quality imaging can be achieved across vendors, field-strengths and platforms



1.5T, 2002 MRI model



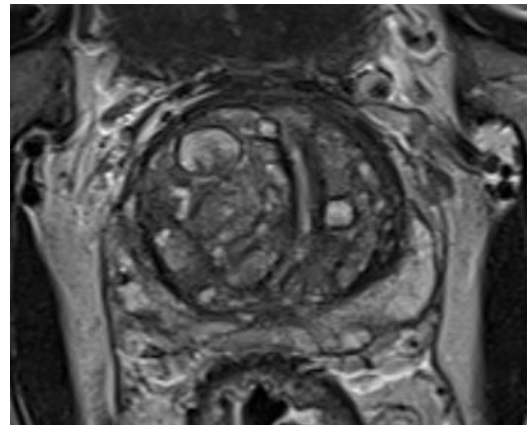
1.5T, 2012 MRI model



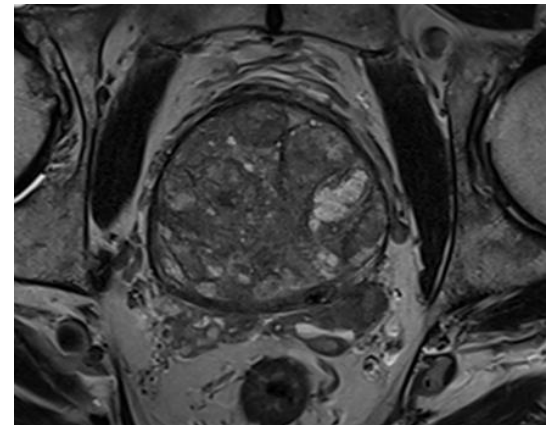
1.5T, 2018 MRI model



3T, 2006 MRI model

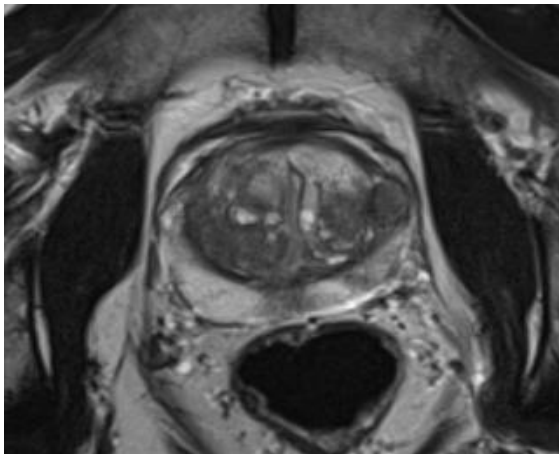


3T, 2012 MRI model

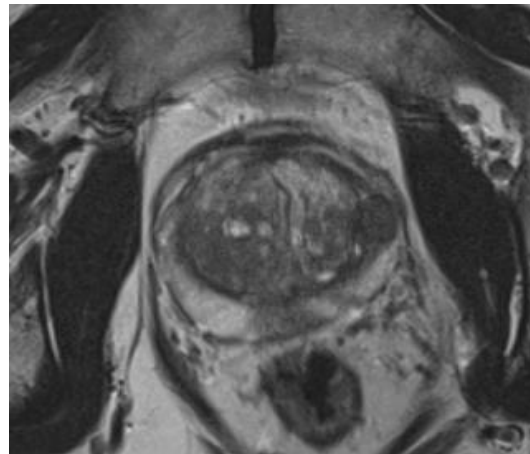


3T, 2017 MRI model

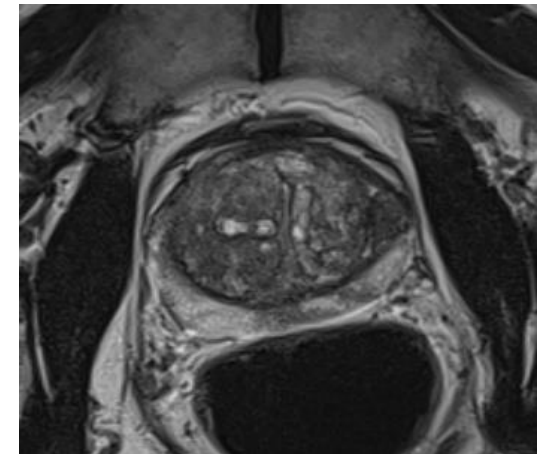
#1: AI assistance for the technologist to minimize errors in daily routine and performs mundane tasks



07/2014



10/2015

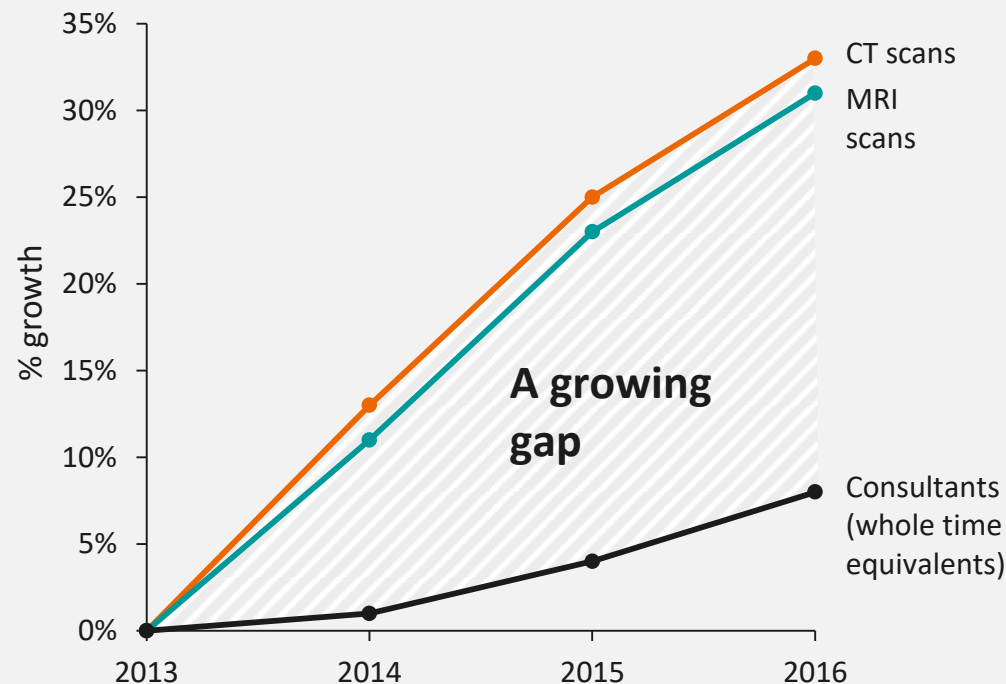


2/2017

Auto-focus	=	Auto detection, segmentation of the prostate
Auto-lighting	=	Optimization of imaging parameters with AI

Challenge #2

Reader expertise and increase of case numbers



Halving interpretation time
of radiologists leads to an increase in **interpretation error rate by 16.6%²**

Growth in the number of consultant radiologists and imaging examinations in England¹

¹ The Royal College of Radiologists (2017): UK workforce census 2016 report.

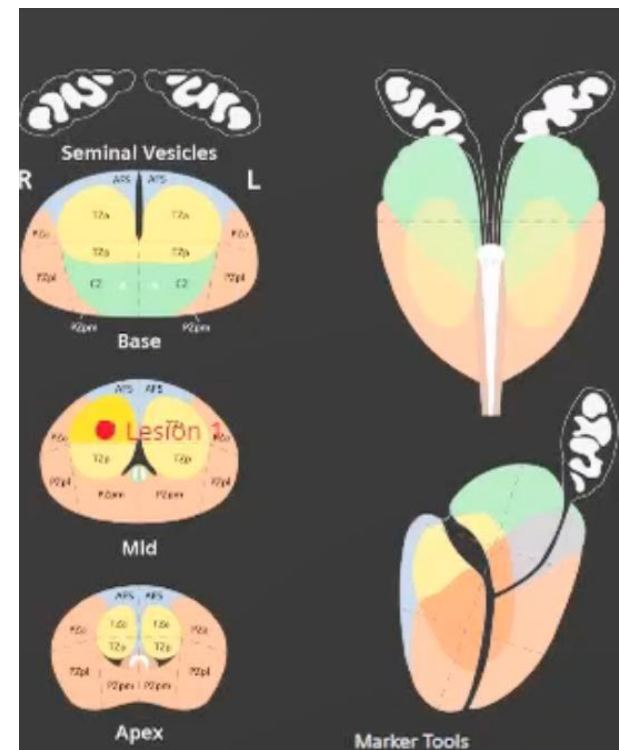
² Faster Reporting Speed and Interpretation Errors: Conjecture, Evidence, and Malpractice Implications, Journal of the American College of Radiology, Volume 12, Issue 9, September 2015, Pages 894-896

³ Cognitive and System Factors Contributing to Diagnostic Errors in Radiology American Journal of Roentgenology, 201, September 2013

#2: Radiologists with AI-assistance read faster, perform significantly better and more consistent*



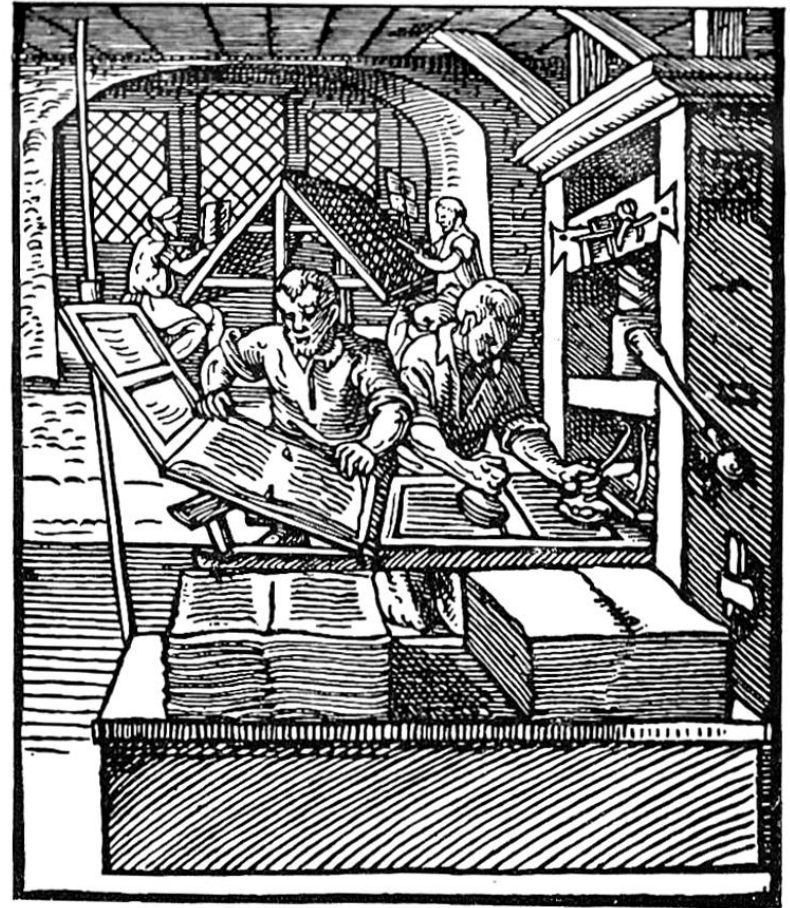
Automated detection & classification of lesions



Pre-populated report to save time and for seamless information transfer

* Results of a reader study with Siemens Healthineers AI Rad Companion Prostate MR.
The product is not for sale in the U.S. Its future availability cannot be guaranteed.

Scalability is key to bring benefits to men across Europe



If you want to go fast, go alone
If you want to go far, go together.

