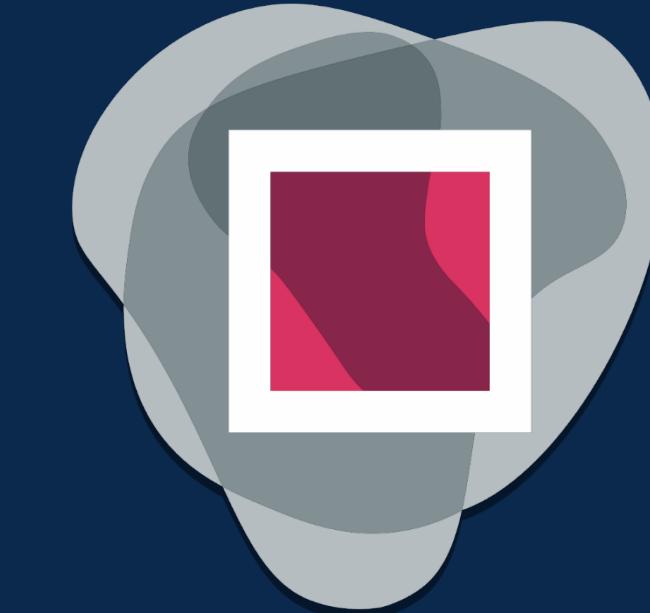




Politechnika  
Śląska



GRAYLIGHT  
MEDICAL IMAGING SOFTWARE

# CAN AI MAKE US SEE BEYOND THE VISIBLE: TOWARD CE MARKED DEEP LEARNING SOFTWARE FOR MEDICAL IMAGE ANALYSIS

Jakub Nalepa  
[jnalepa@ieee.org](mailto:jnalepa@ieee.org)



NARRATIVE REVIEW

Open Access

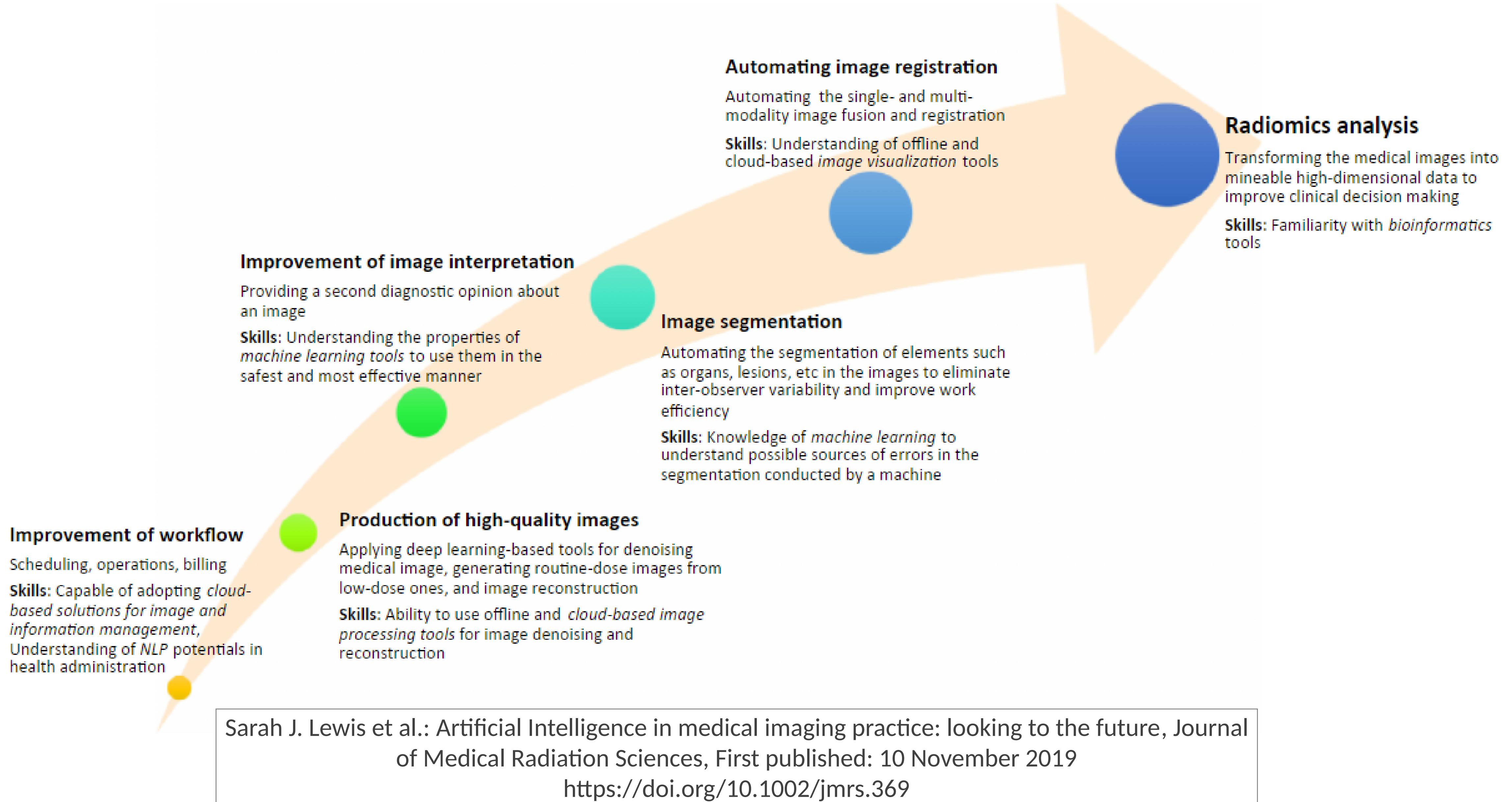


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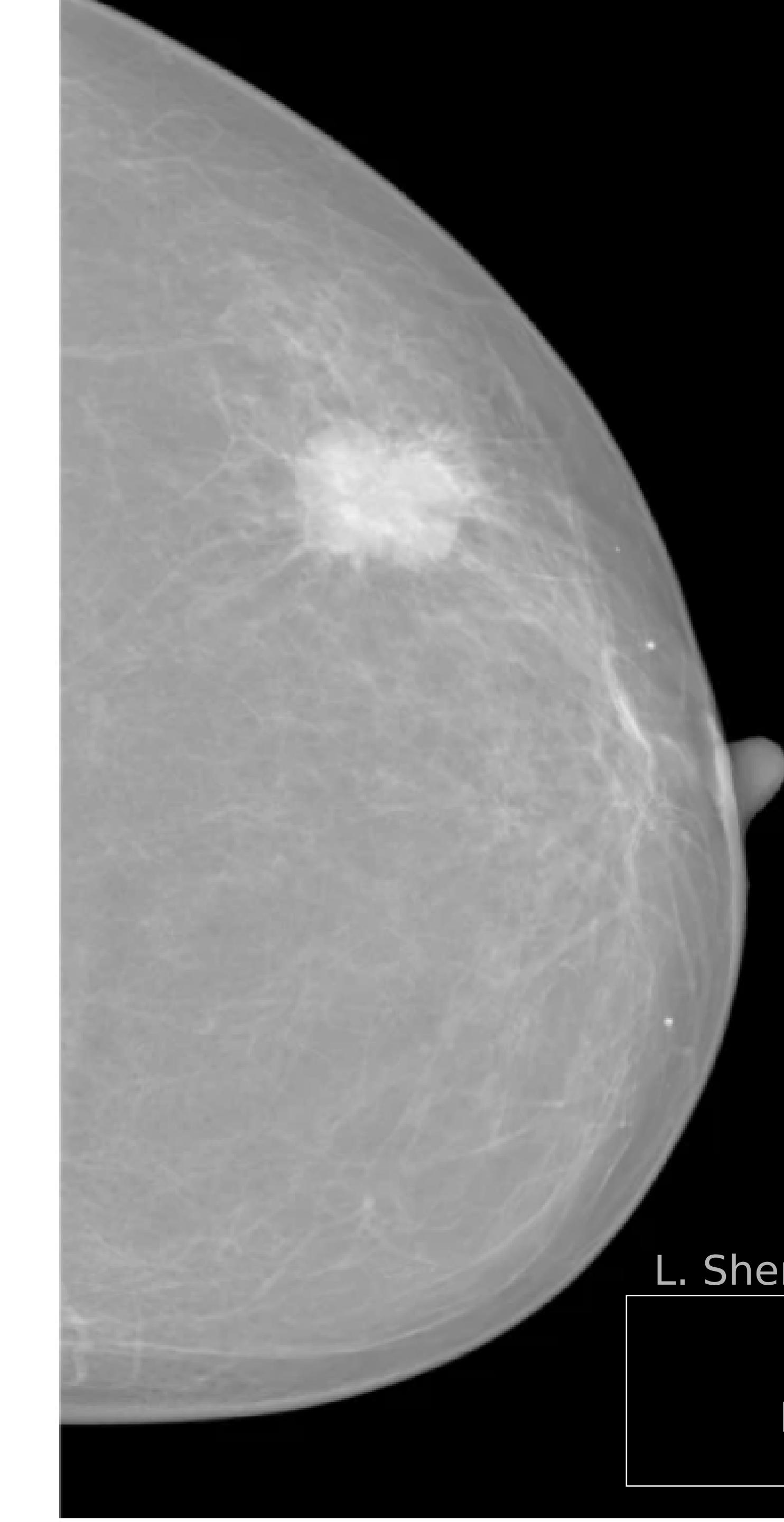
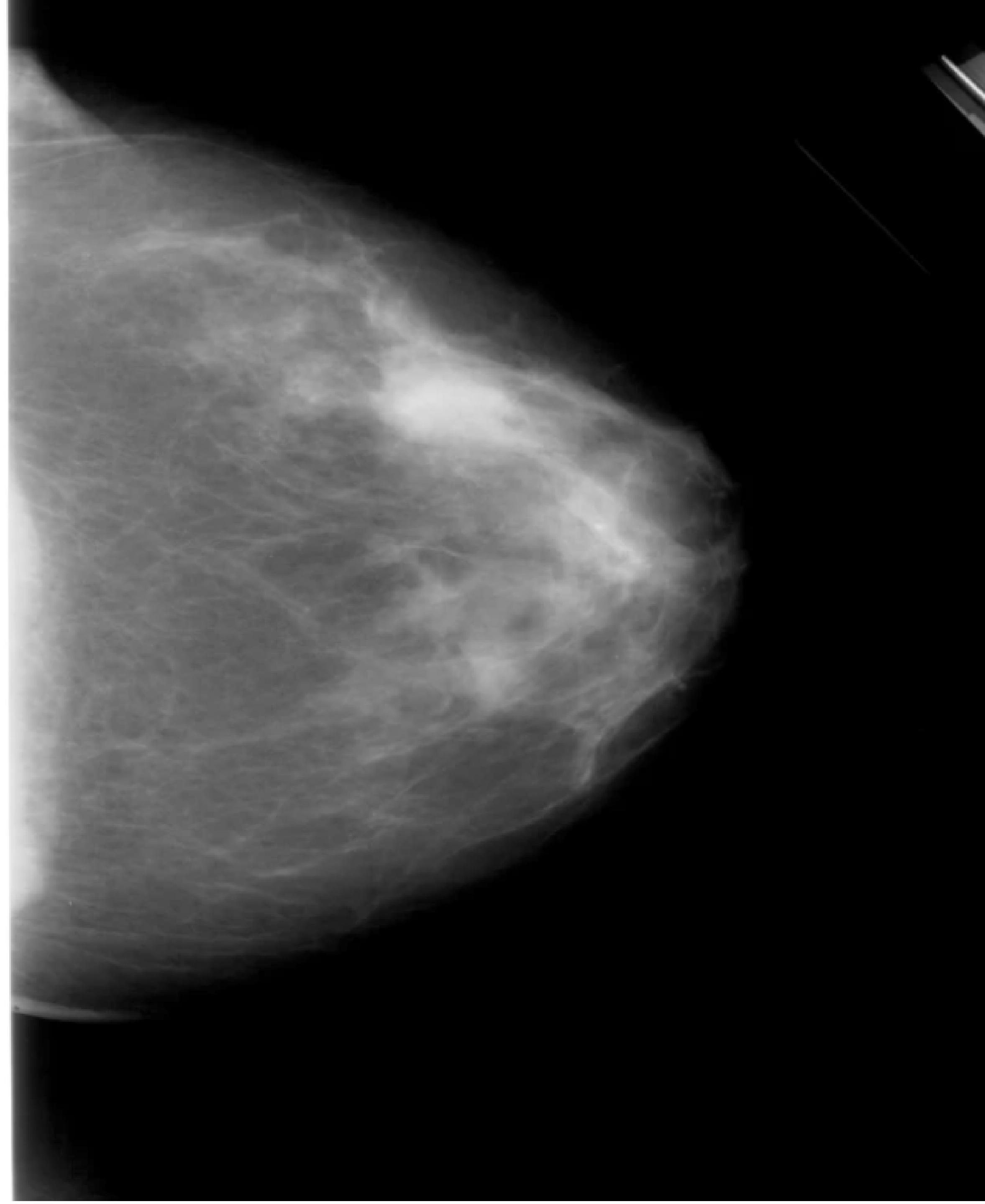
# Artificial intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine

2

Filippo Pesapane<sup>1†</sup>, Marina Codari<sup>2\*†</sup>  and Francesco Sardanelli<sup>2,3</sup>



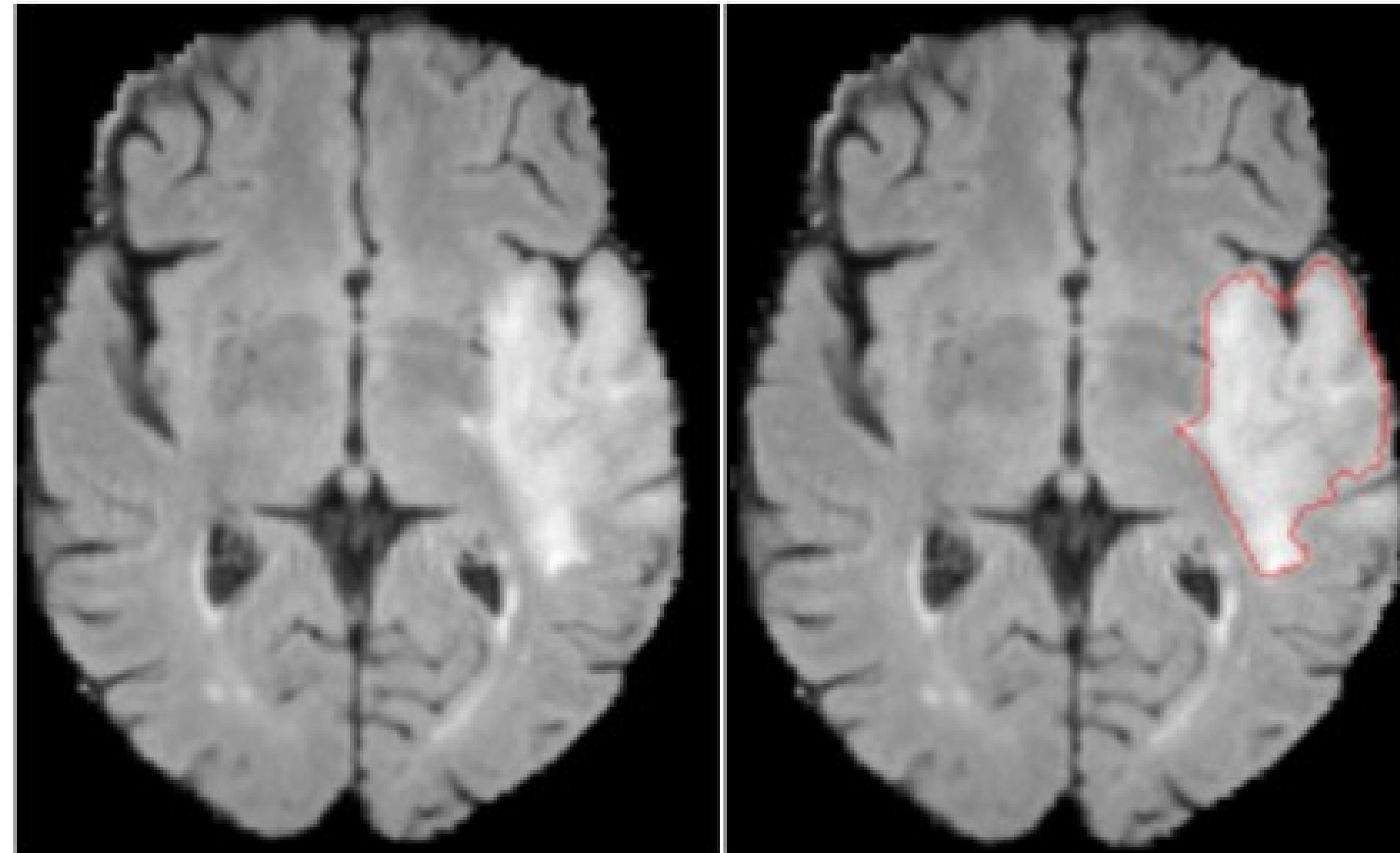
Sarah J. Lewis et al.: Artificial Intelligence in medical imaging practice: looking to the future, Journal of Medical Radiation Sciences, First published: 10 November 2019  
<https://doi.org/10.1002/jmrs.369>



L. Shen et al., Deep Learning to  
Improve Breast Cancer  
Detection on Screening  
Mammography, Scientific  
Reports volume 9, Article  
number: 12495 (2019)

## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (BRAIN MRI)

5



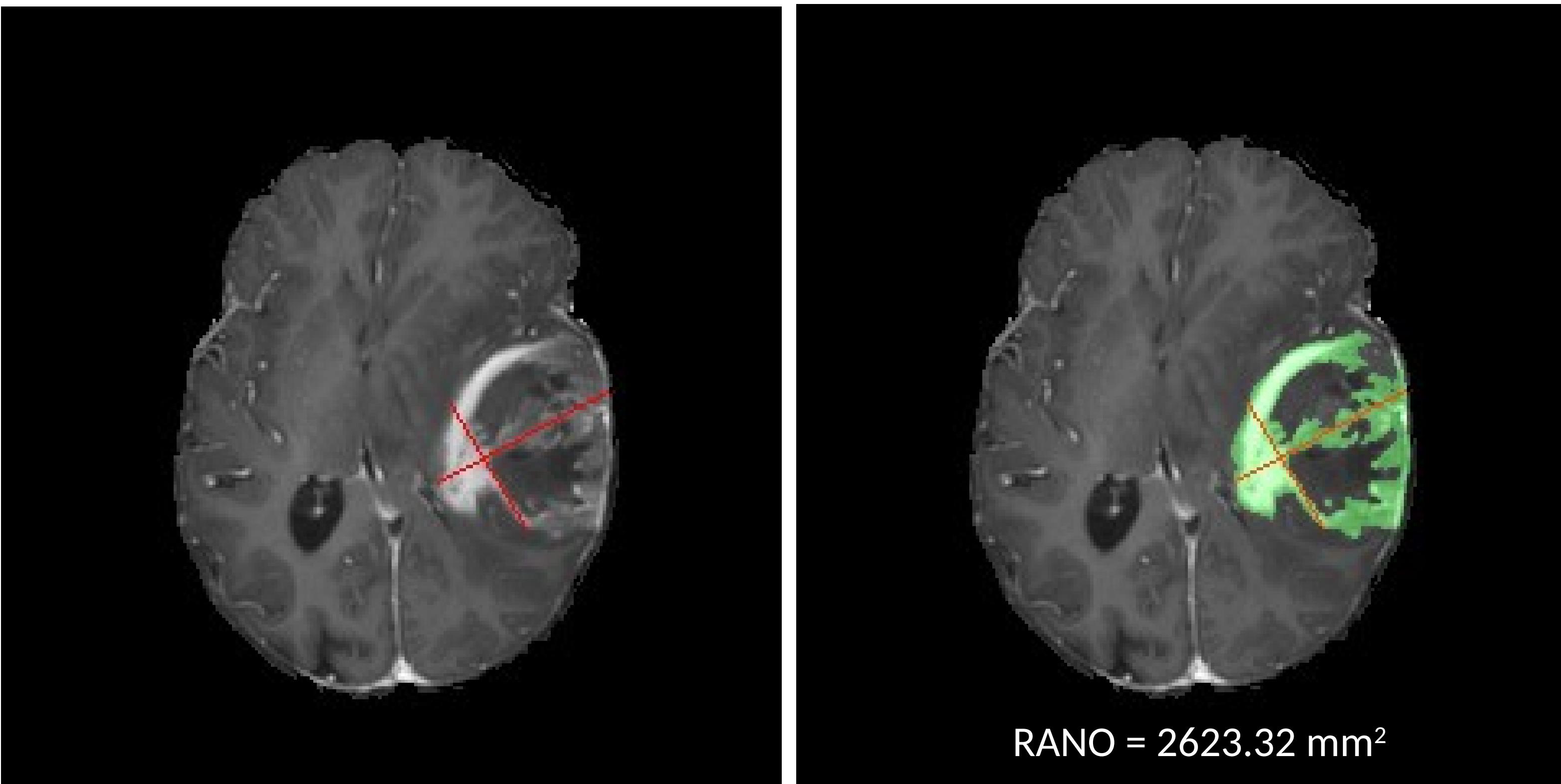
J. Nalepa et al.: Fully-automated deep learning-powered system for DCE-MRI analysis of brain tumors. Artificial Intelligence in Medicine: 102: 101769 (2020)

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## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (BRAIN MRI)

6



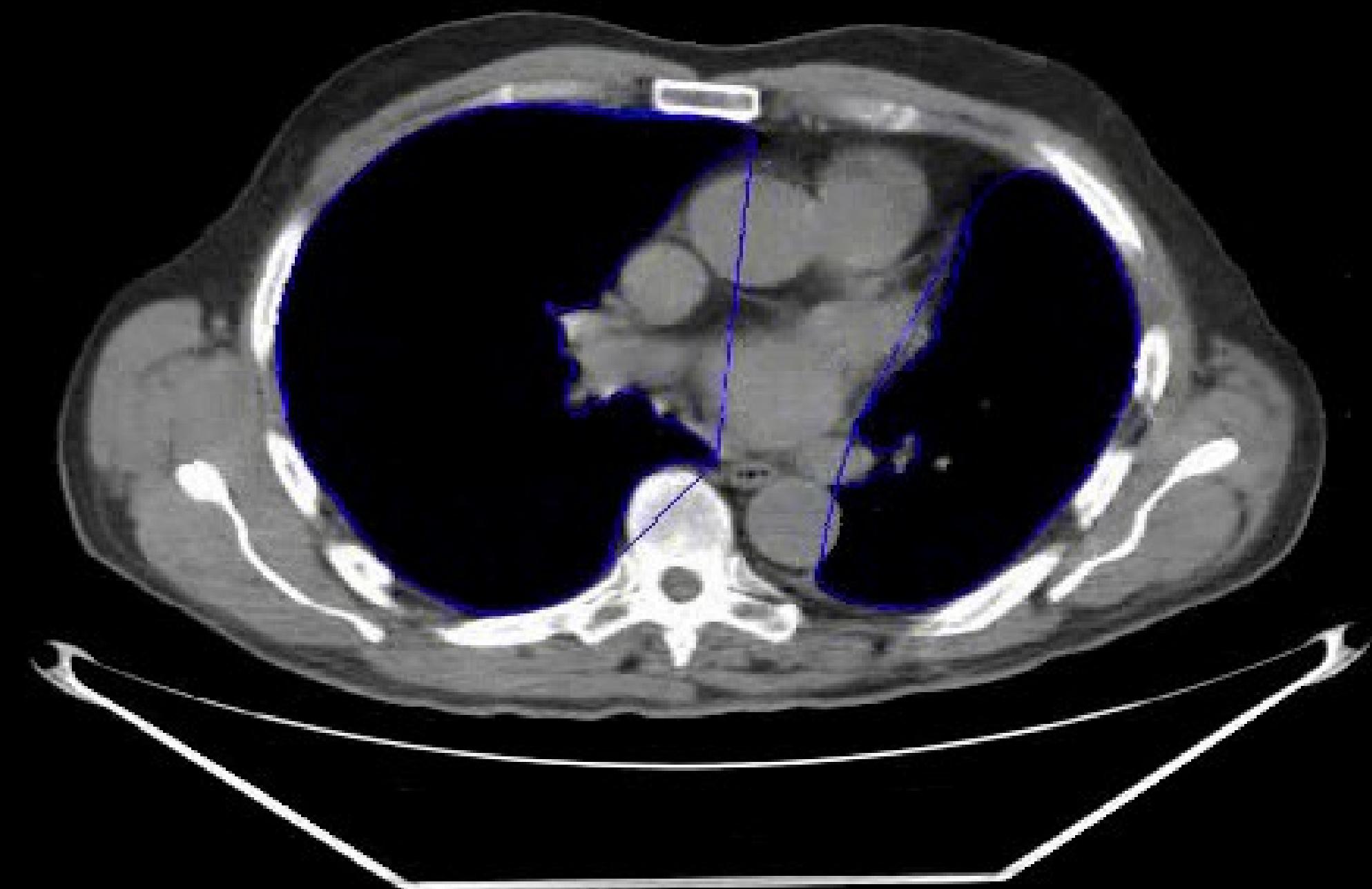
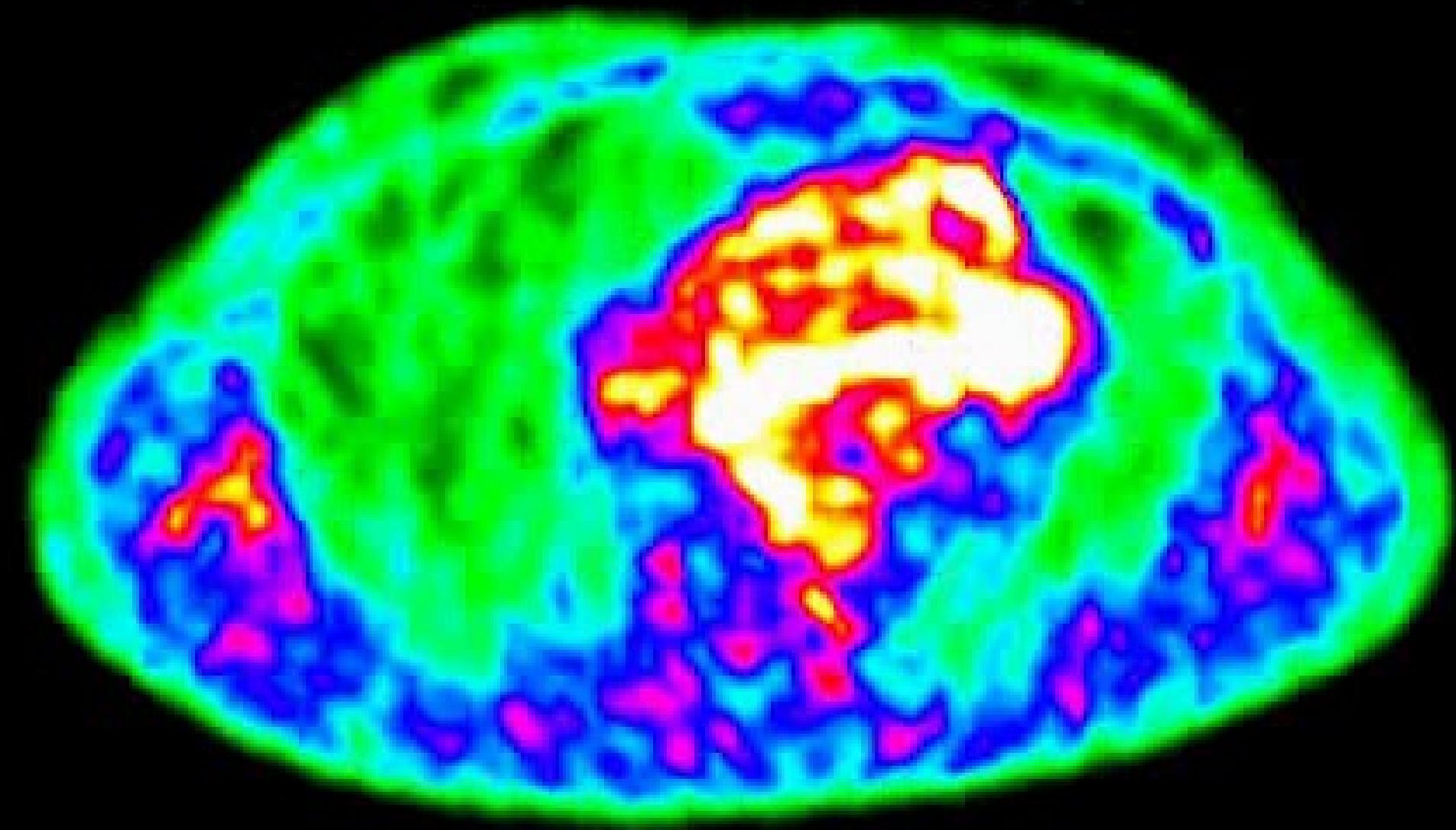
K. Chang et al.: Automatic assessment of glioma burden: a deep learning algorithm for fully automated volumetric and bidimensional measurement: Neuro-Oncology, Volume 21, Issue 11, November 2019, Pages 1412–1422, <https://doi.org/10.1093/neuonc/noz106>

## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (LUNG PET/CT)



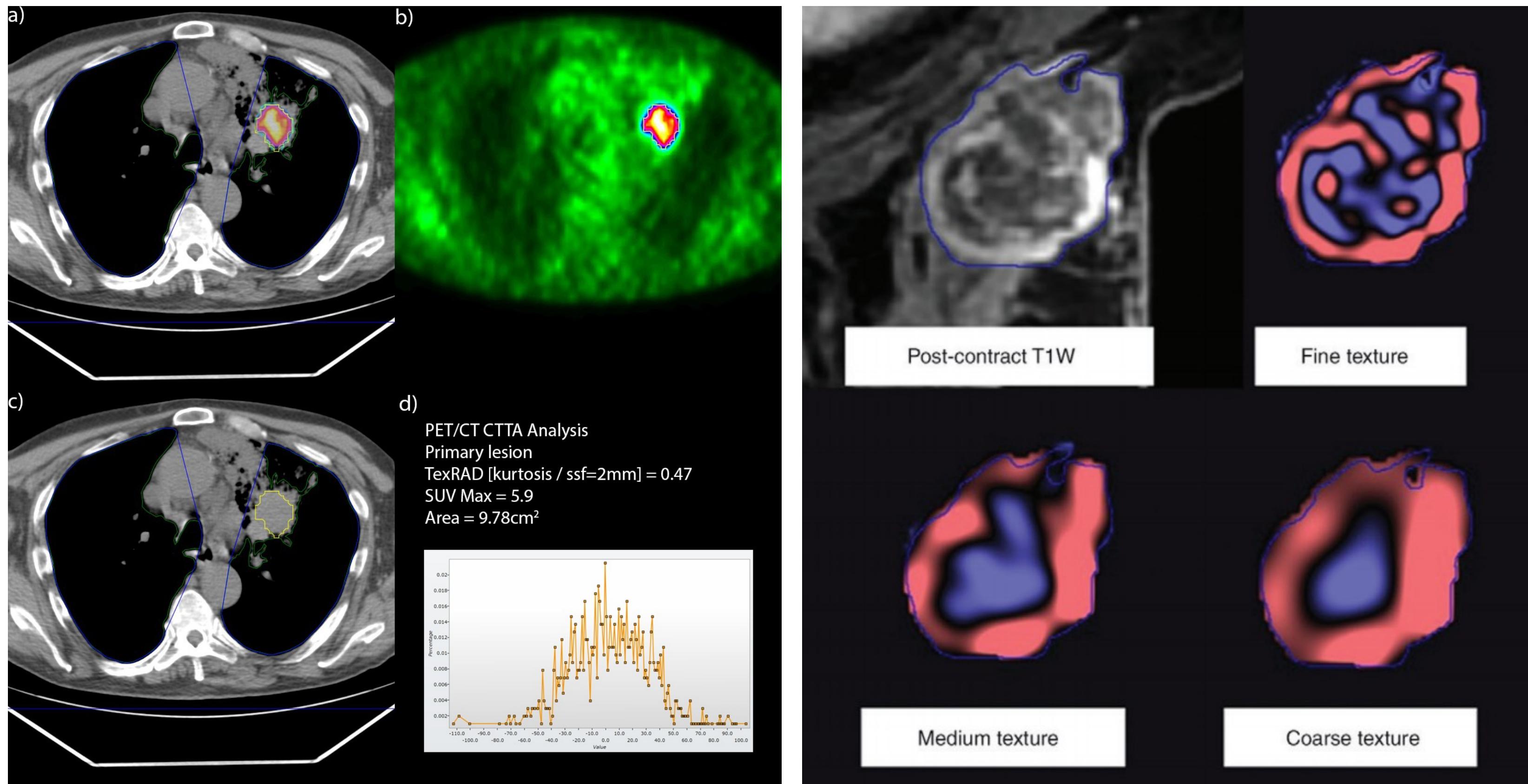
K. Pawelczyk, M. Kawulok, J. Nalepa, M. P. Hayball, S. J. McQuaid, V. Prakash, B. Ganeshan: Towards Detecting High-Uptake Lesions from Lung CT Scans Using Deep Learning. ICIAP (2) 2017: 310-320

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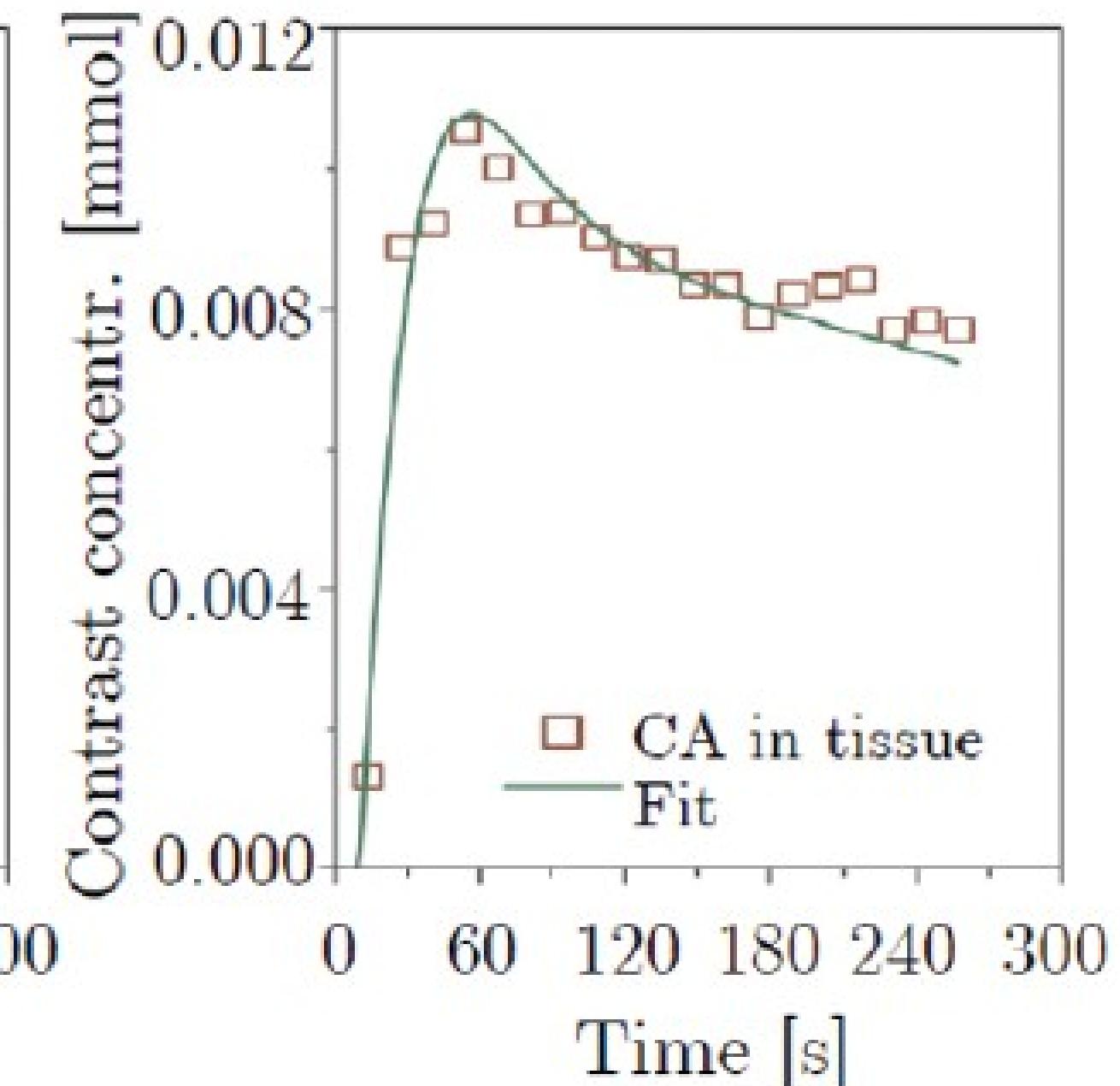
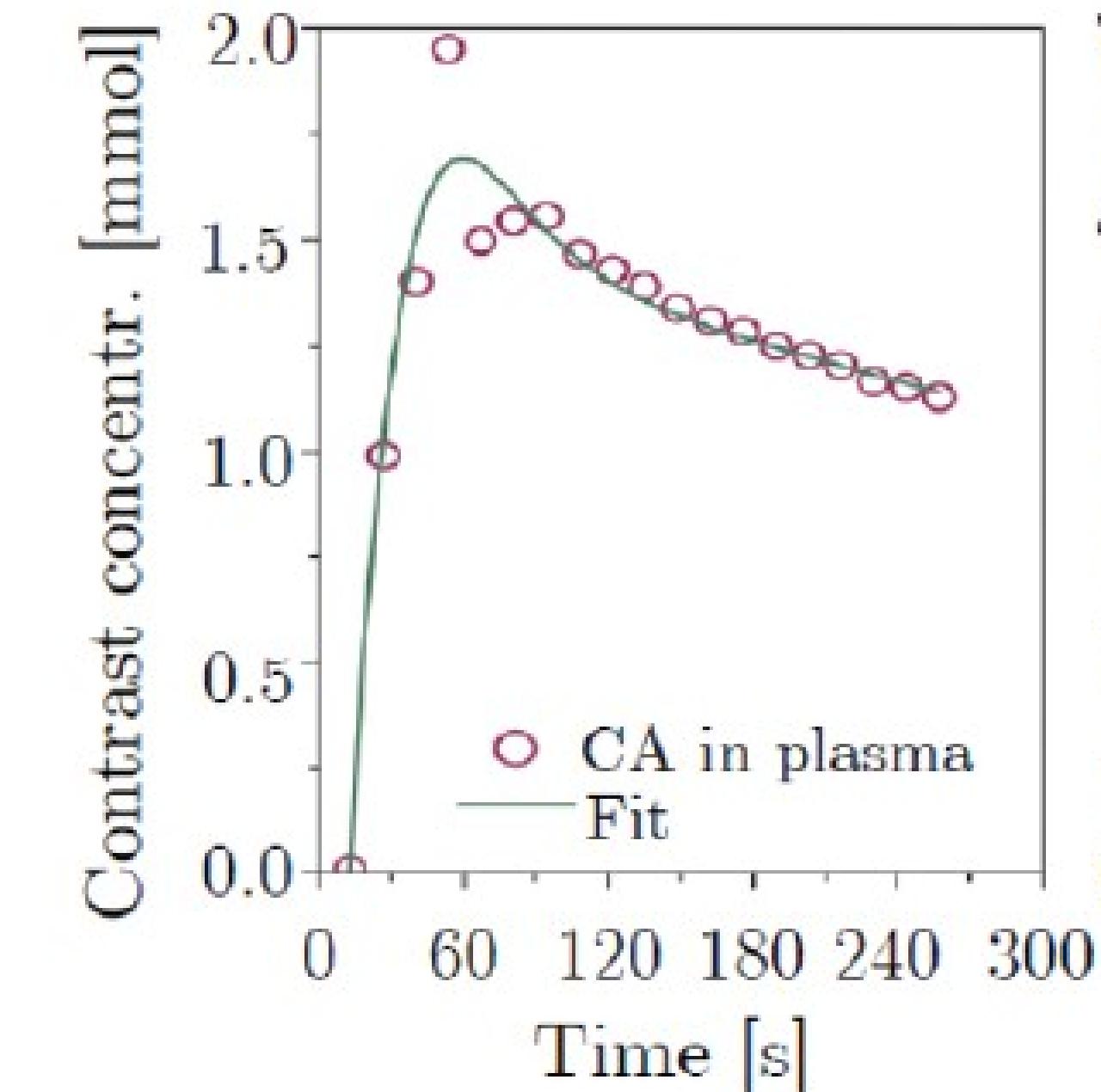
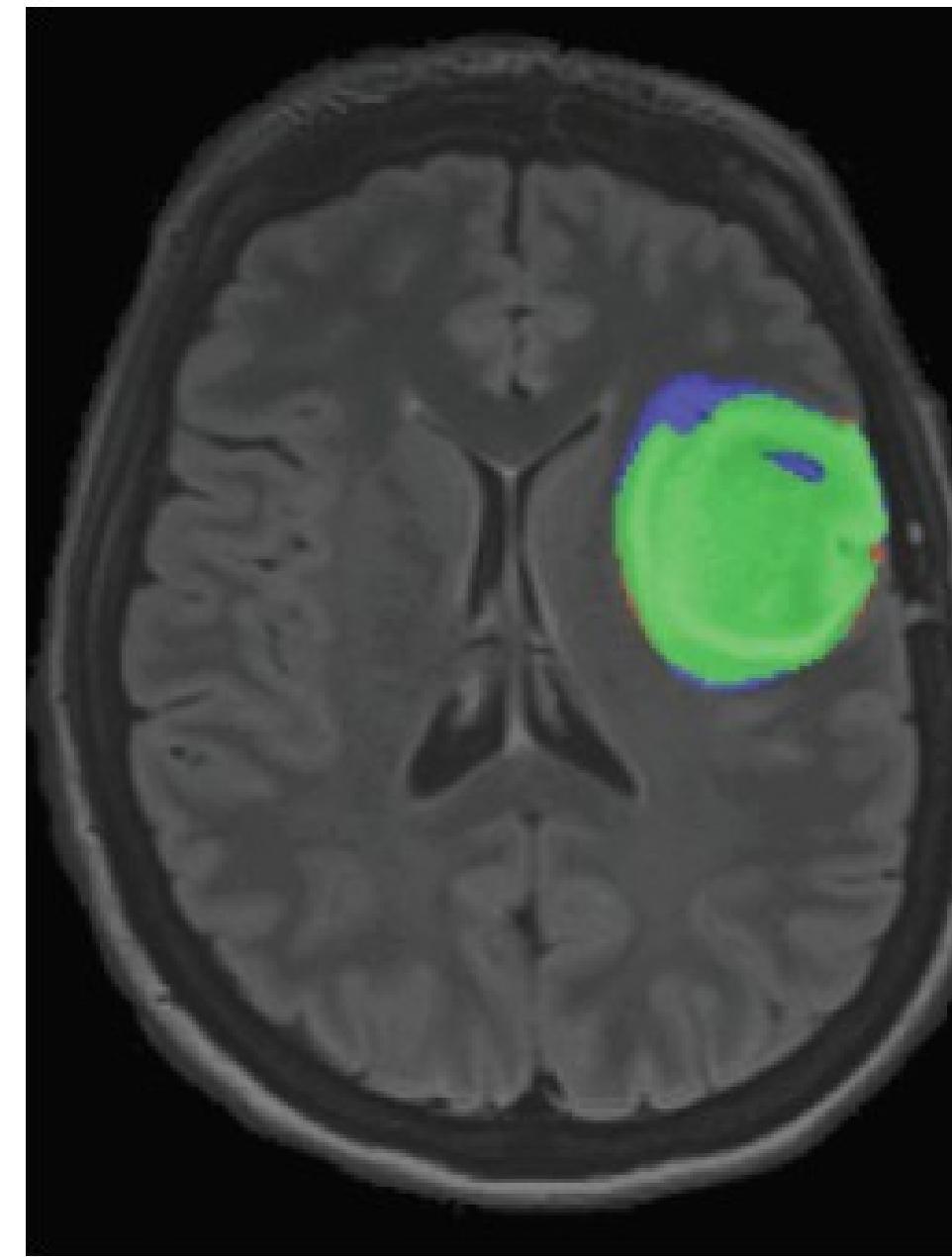
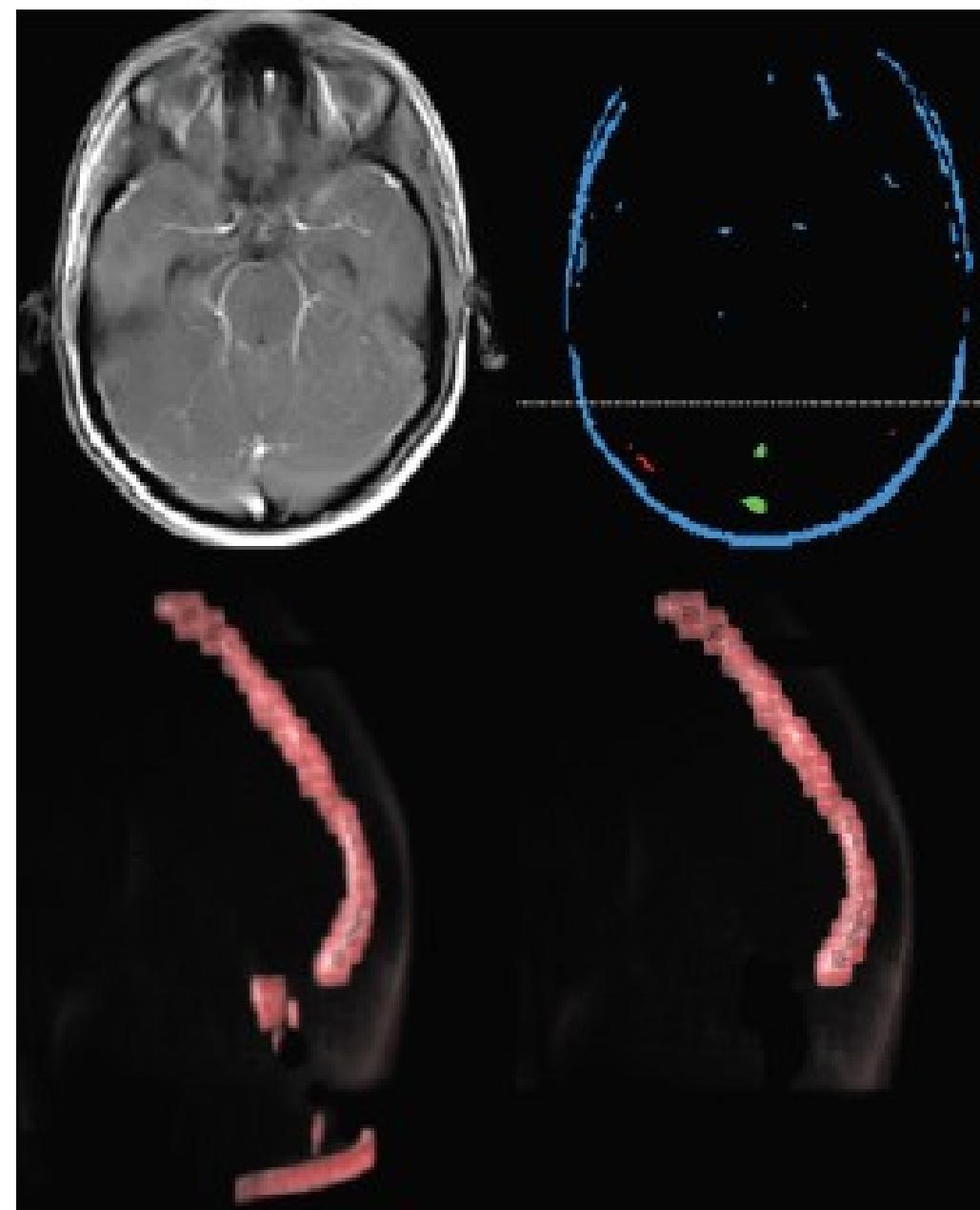
## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (LUNG PET/CT)

9



J. Nalepa et al: PET/CT in Lung Cancer: An Automated Imaging Tool for Decision Support, RSNA 2016. Left image:  
a) CT, b) PET, c) lung and lesion segmentation, and d) visualized textural features. Right image: textural features in  
breast imaging  
(Chamming et al., RSNA 2017).

## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (BRAIN DCE-MRI)

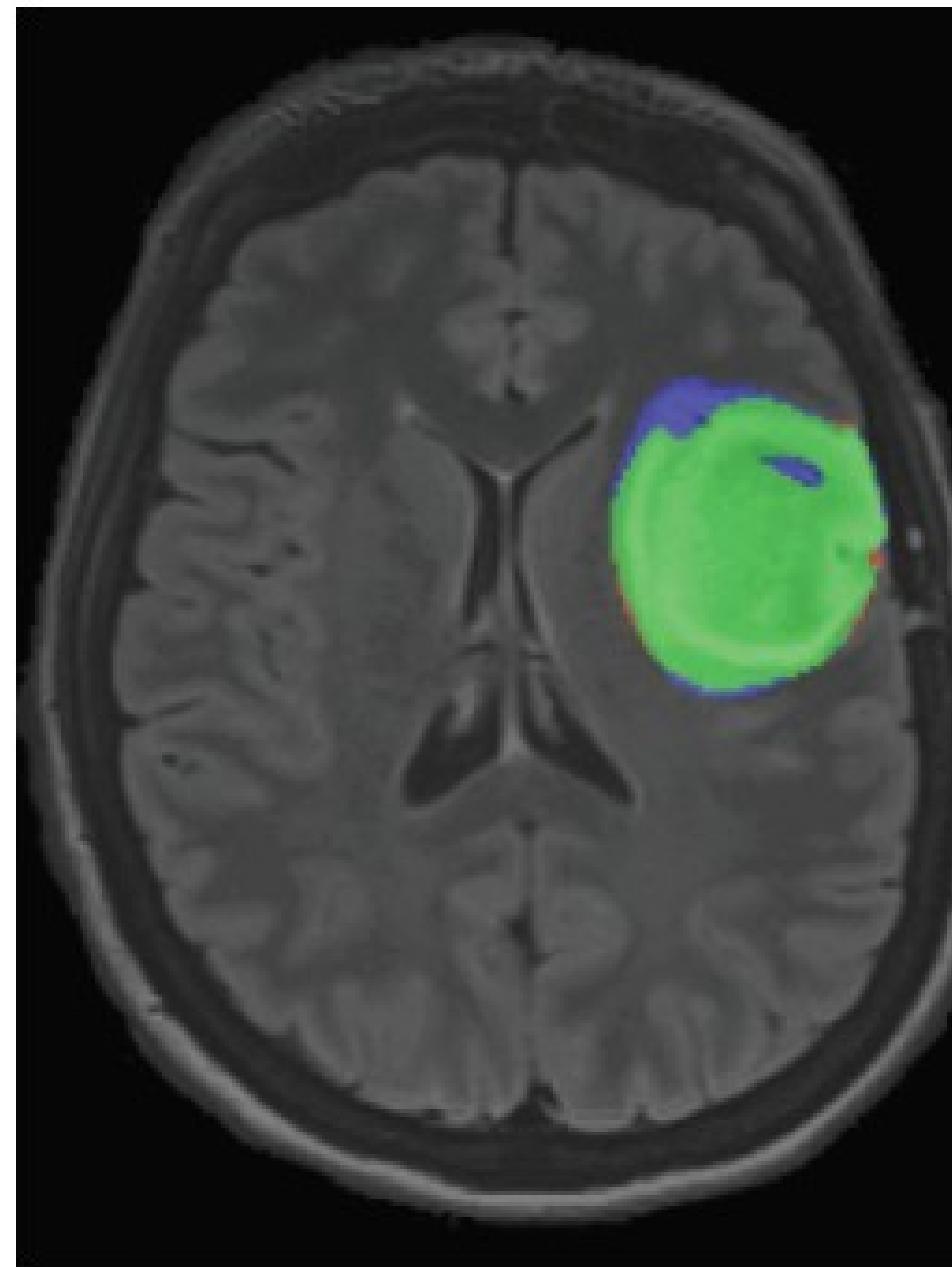
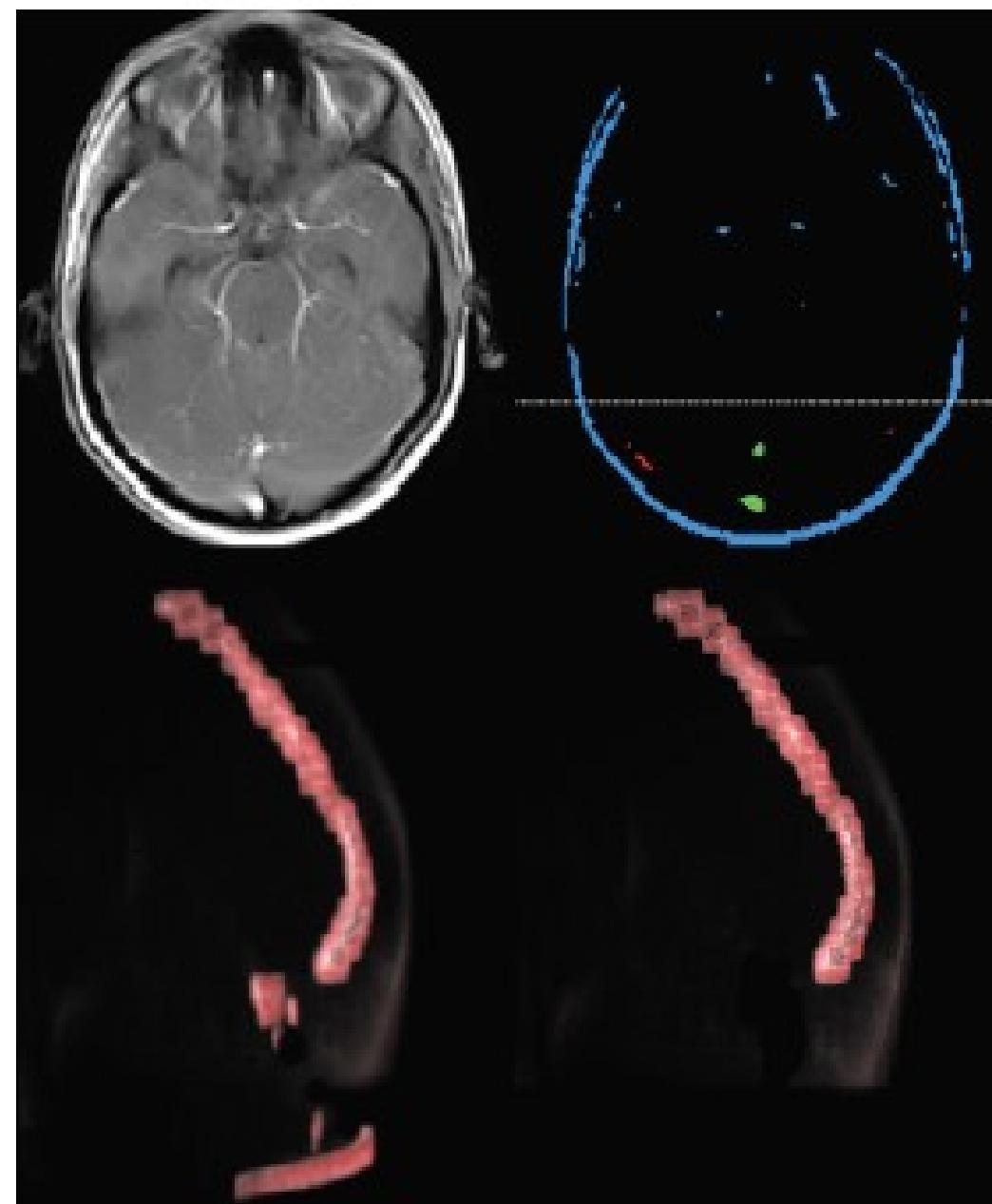


J. Nalepa et al.: Fully-automated deep learning-powered system for DCE-MRI analysis of brain tumors.  
Artificial Intelligence in Medicine: 102: 101769 (2020)

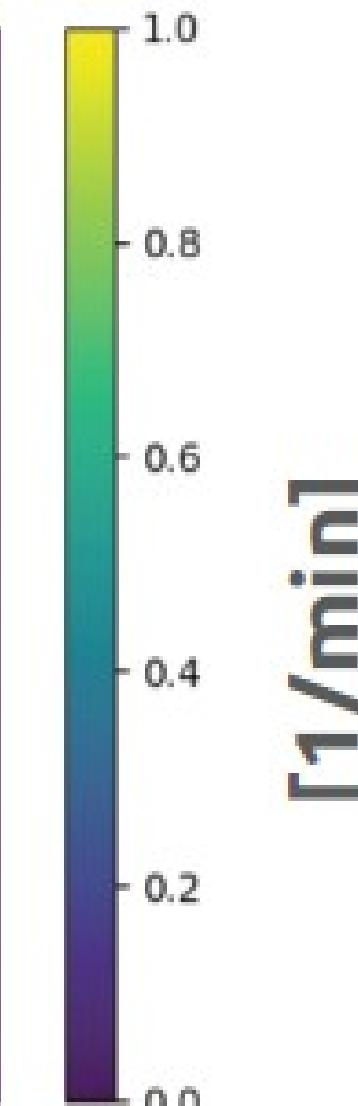
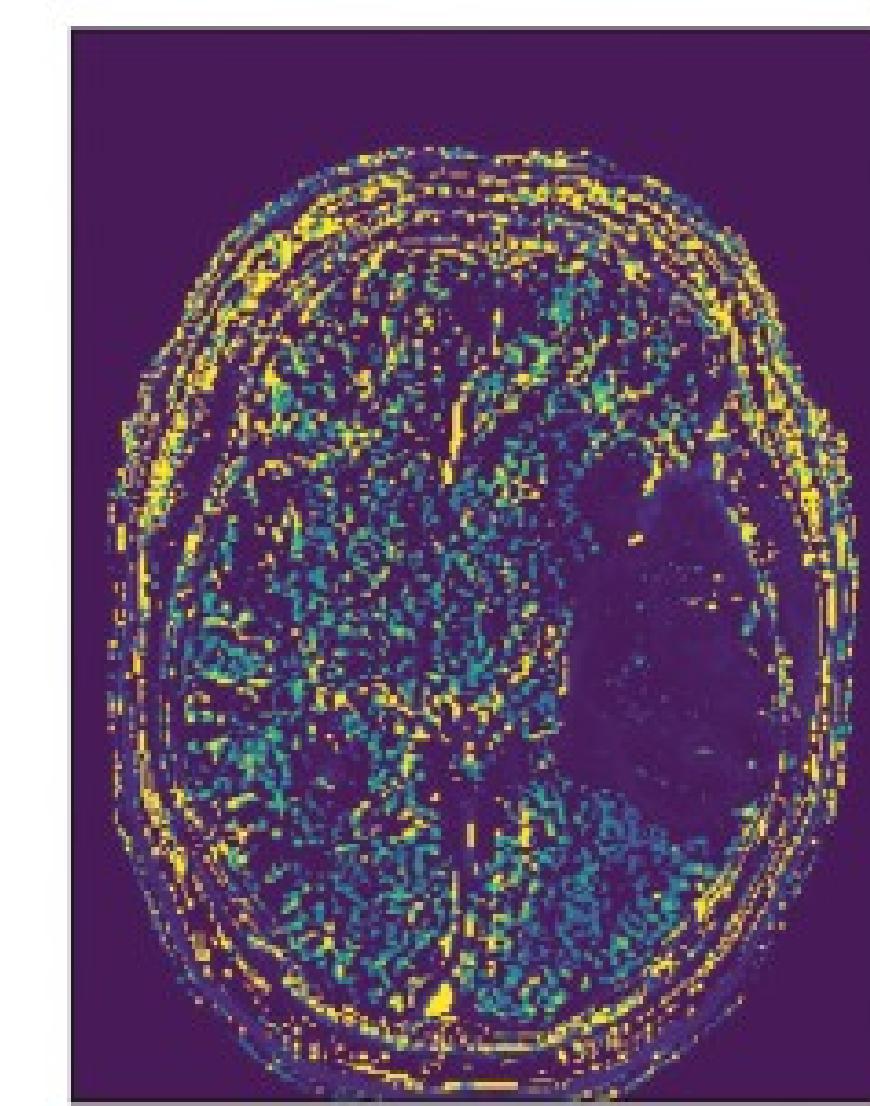
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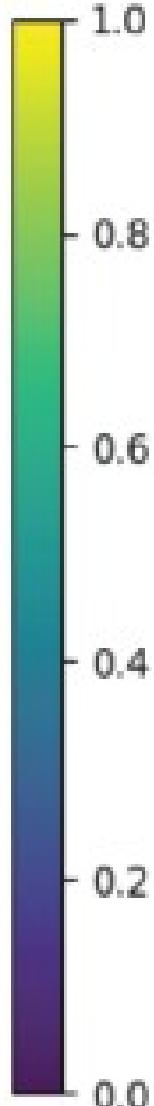
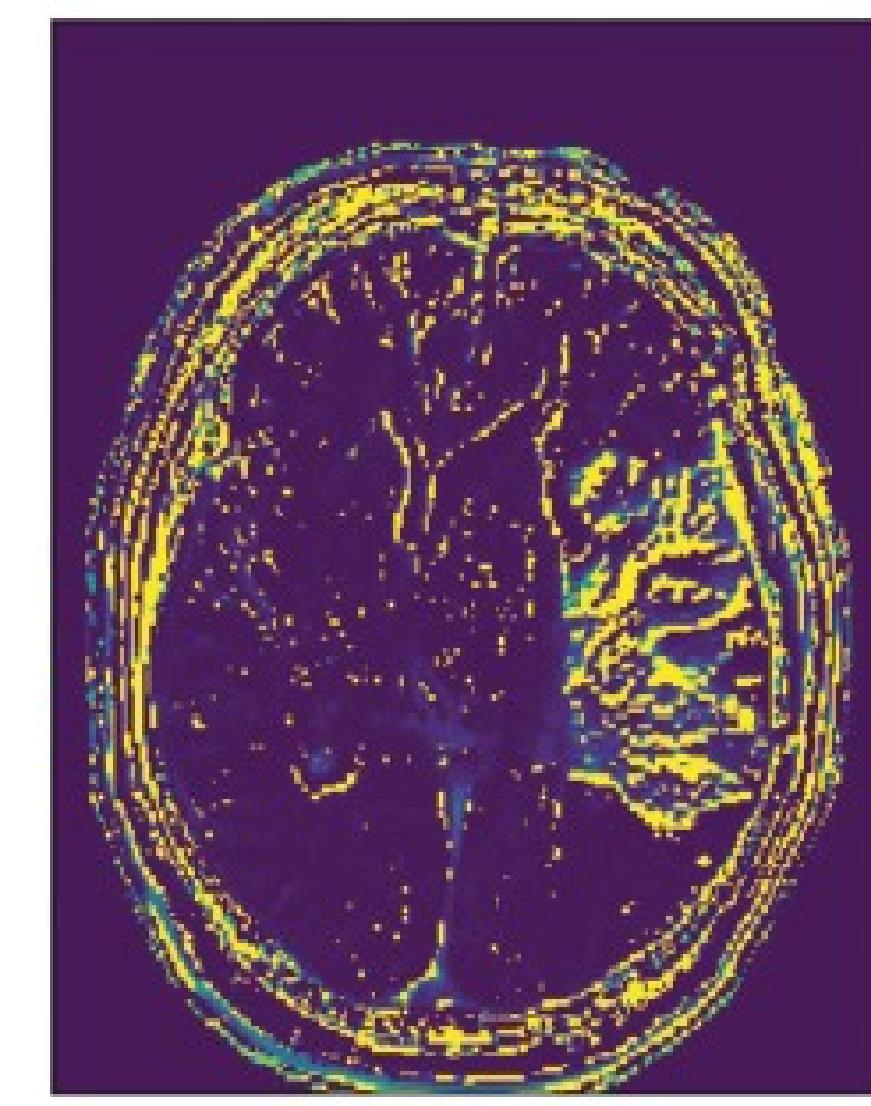
# CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (BRAIN DCE-MRI)



$K_{trans}$



$V_e$



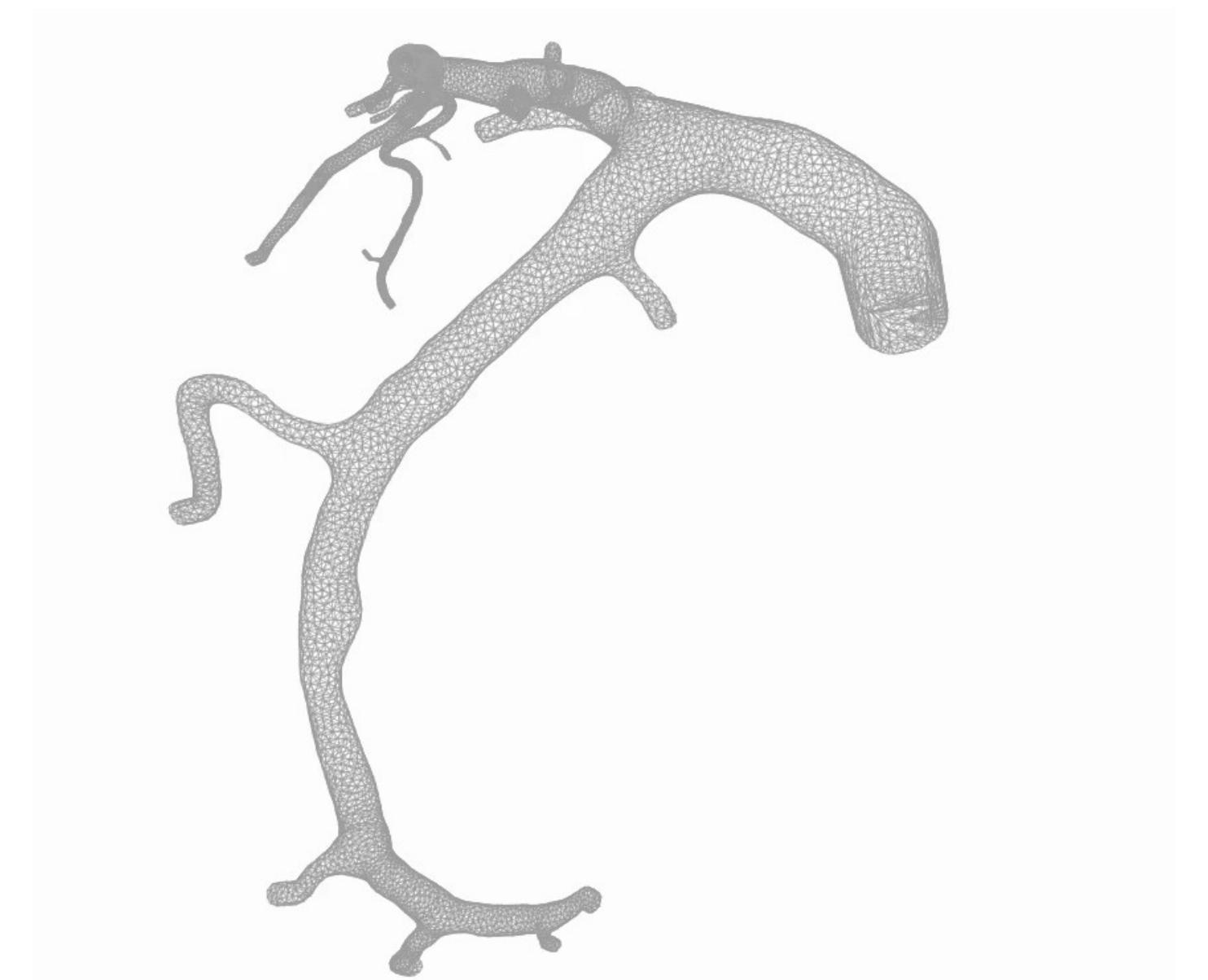
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Artificial Intelligence in Medicine: 102: 101769 (2020)

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## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (CORONARY CT ANGIOGRAPHY)

12

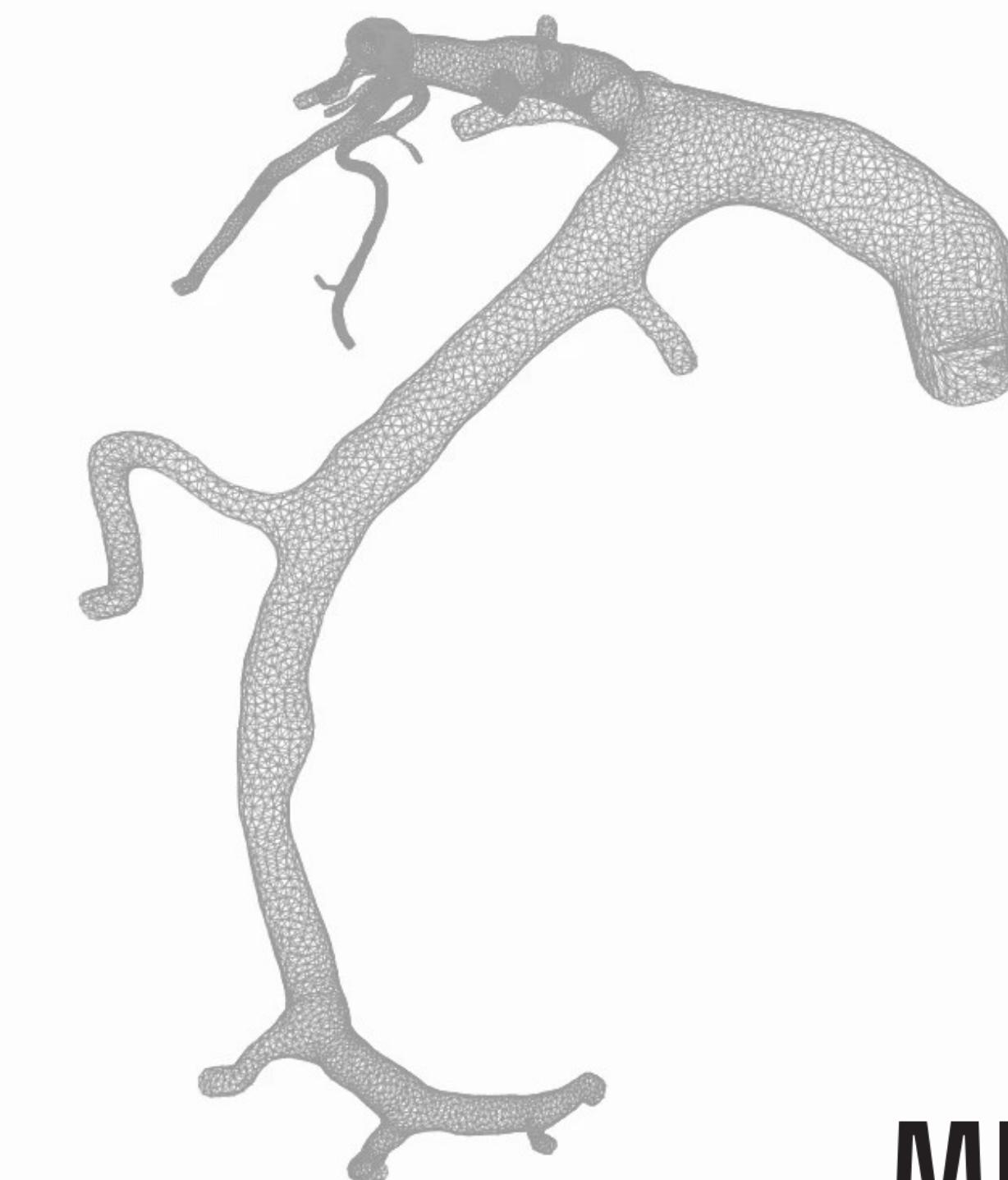
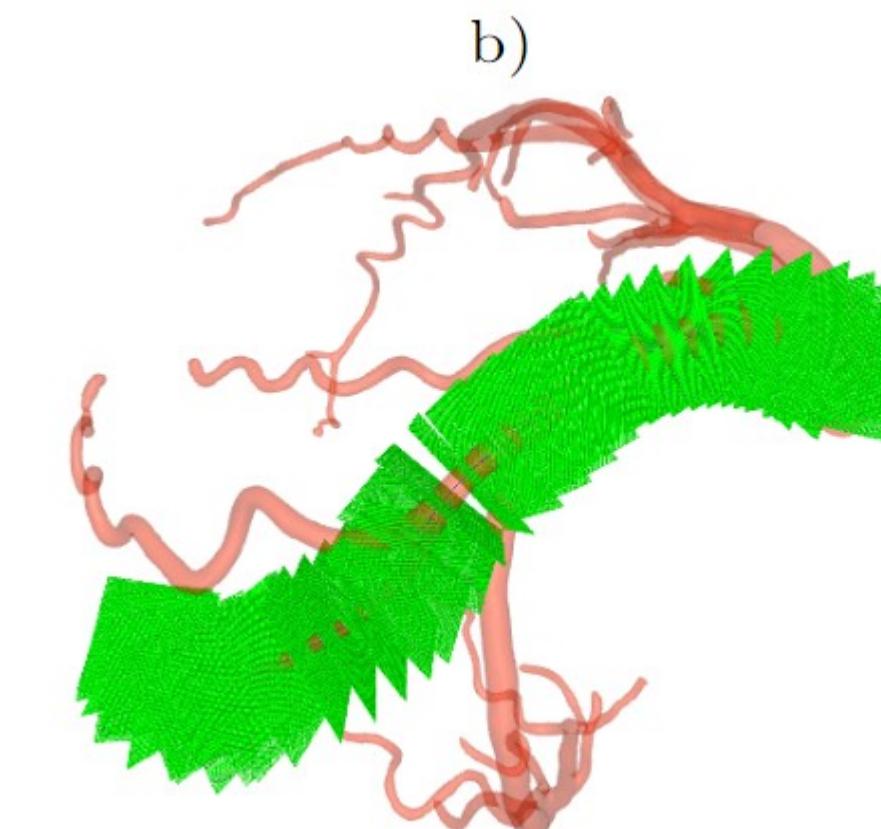
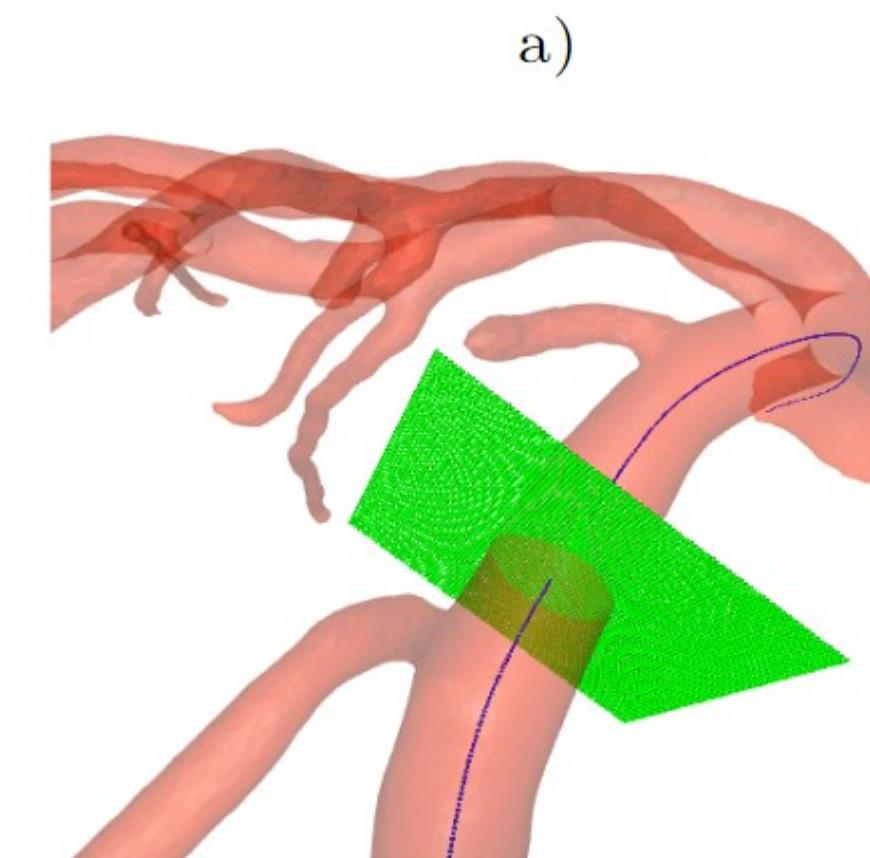


**MICCAI2022**  
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F. Malawski et int J. Nalepa.: Deep Learning Meets Computational Fluid Dynamics to Assess CAD in CCTA. AMAI@MICCAI 2022 (in press).

## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (CORONARY CT ANGIOGRAPHY)

Straightened representation of a vessel, a) a single 2D plane, together with a subset of b) all 2D planes.

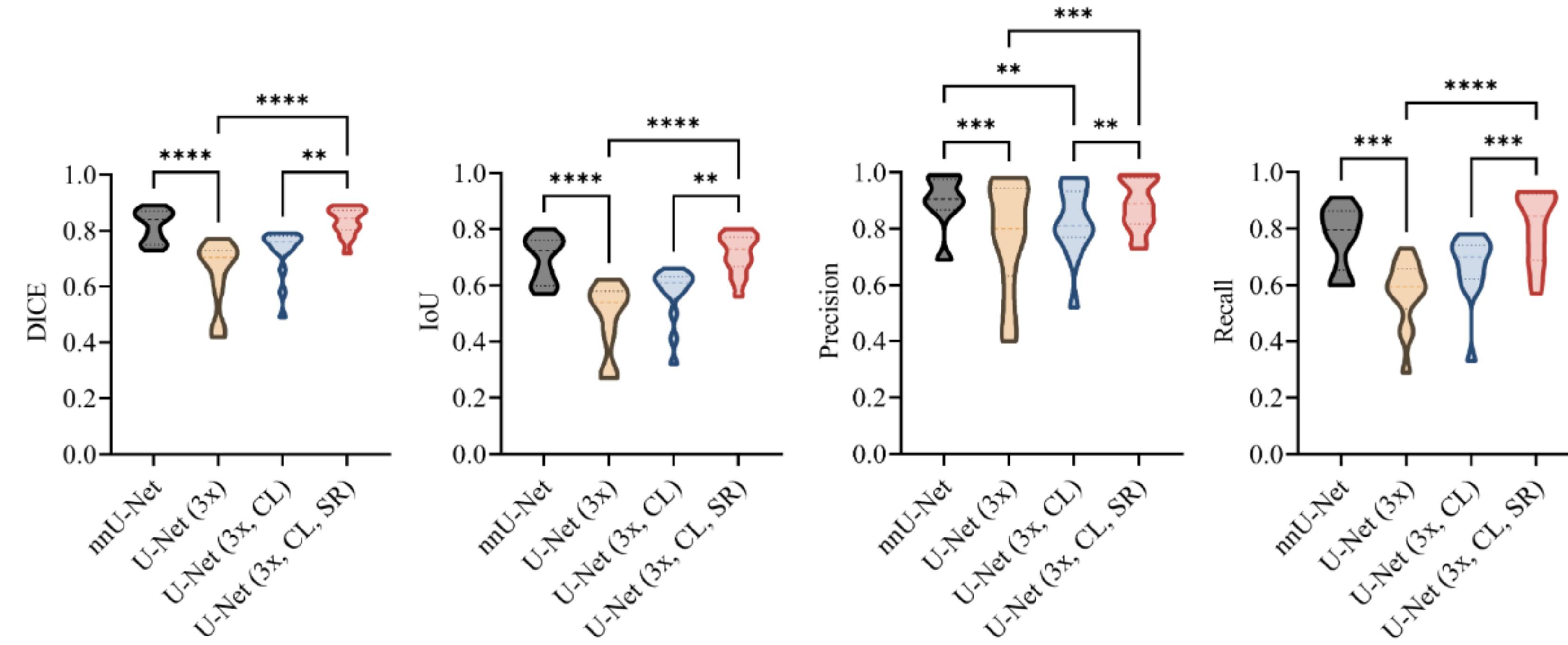


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# CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (CORONARY CT ANGIOGRAPHY)

14



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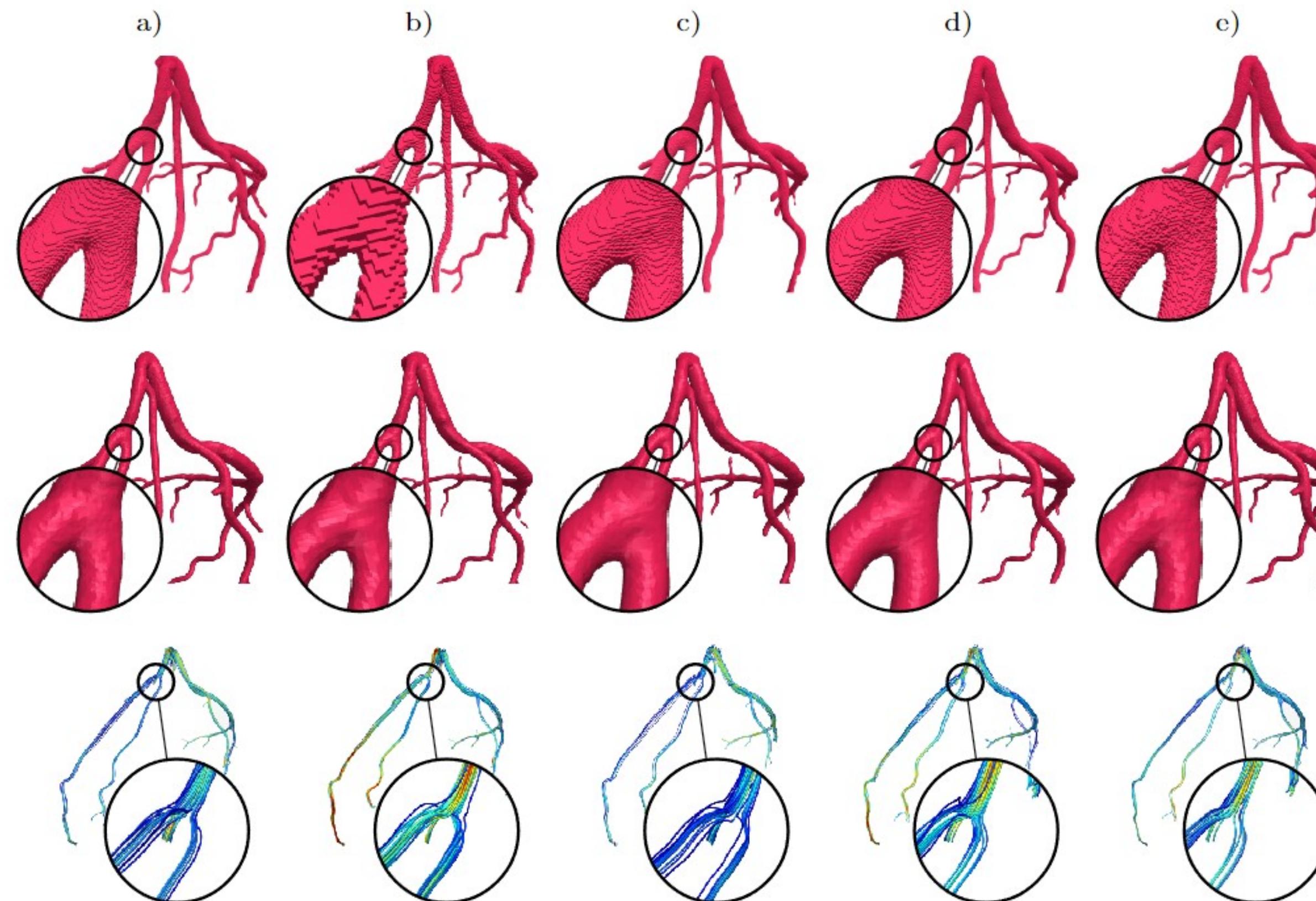
F. Malawski et int J. Nalepa.: Deep Learning Meets Computational Fluid Dynamics to Assess CAD in CCTA. AMAI@MICCAI 2022 (in press).

## CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (CORONARY CT ANGIOGRAPHY)

1!

Example

- a) ground truth,
  - b) nnU-Net (DICE: 0.86),
  - c) U-Net (3x) (DICE: 0.62),
  - d) U-Net (3x, CL) (DICE: 0.76),
  - e) U-Net (3x, CL, SR) (DICE: 0.89)
- segmentations.

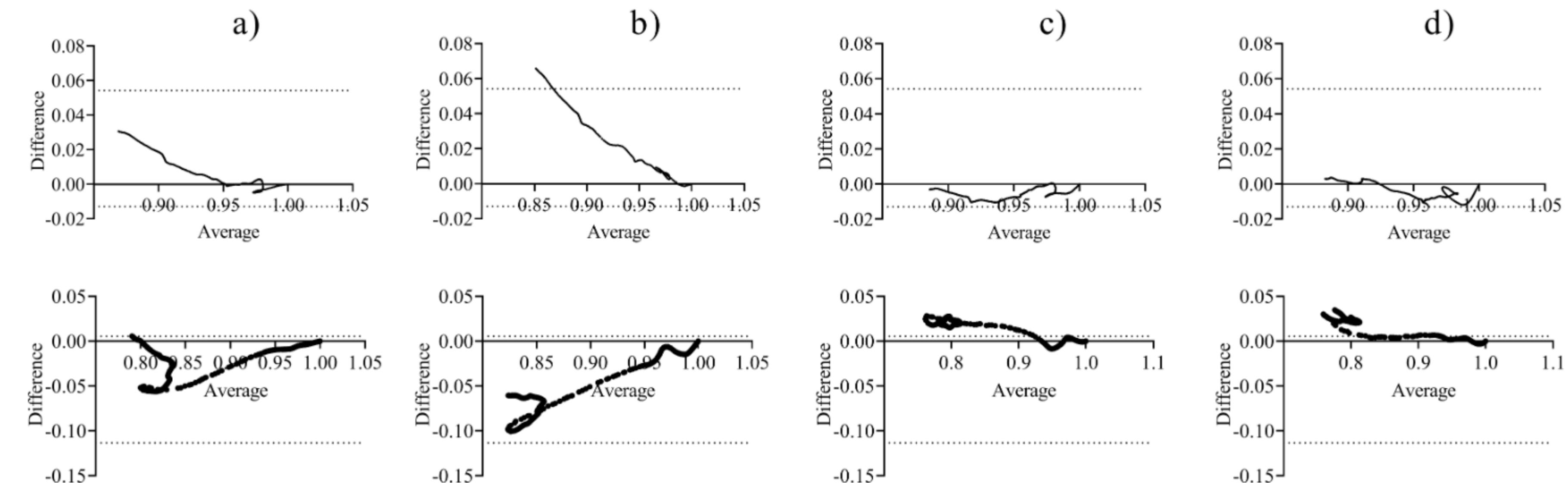


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*Singapore*

F. Malawski et int J. Nalepa.: Deep Learning Meets Computational Fluid Dynamics to Assess CAD in CCTA. AMAI@MICCAI 2022 (in press).

# CAN AI MAKE US SEE BEYOND THE VISIBLE: EXAMPLES (CORONARY CT ANGIOGRAPHY)

The disagreement for Patient A (top) and Patient B (bottom) between the blood flow parameters obtained for the ground truth and automated segmentation by  
a) nnU-Net,  
b) U-Net (3x),  
c) U-Net (3x, CL), and  
d) U-Net (3x, CL, SR).



**MICCAI2022**  
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F. Malawski et int J. Nalepa.: Deep Learning Meets Computational Fluid Dynamics to Assess CAD in CCTA. AMAI@MICCAI 2022 (in press).

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Article | Published: 01 January 2020

# International evaluation of an AI system for breast cancer screening

17  
Scott Mayer McKinney , Marcin Sieniek, [...] Shravya Shetty *Nature* 577, 89–94(2020) | Cite this article

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Article | Published: 01 January 2020

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Matters arising

# Transparency and reproducibility in artificial intelligence

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<https://doi.org/10.1038/s41586-020-2766-y>

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Received: 1 February 2020

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Accepted: 10 August 2020

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Published online: 14 October 2020

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 Check for updates

Benjamin Haibe-Kains<sup>1,2,3,4,5</sup> , George Alexandru Adam<sup>3,5</sup>, Ahmed Hosny<sup>6,7</sup>, Farnoosh Khodakarami<sup>1,2</sup>, Massive Analysis Quality Control (MAQC) Society Board of Directors\*, Levi Waldron<sup>8</sup>, Bo Wang<sup>2,3,5,9,10</sup>, Chris McIntosh<sup>2,5,9</sup>, Anna Goldenberg<sup>3,5,11,12</sup>, Anshul Kundaje<sup>13,14</sup>, Casey S. Greene<sup>15,16</sup>, Tamara Broderick<sup>17</sup>, Michael M. Hoffman<sup>1,2,3,5</sup>, Jeffrey T. Leek<sup>18</sup>, Keegan Korthauer<sup>19,20</sup>, Wolfgang Huber<sup>21</sup>, Alvis Brazma<sup>22</sup>, Joelle Pineau<sup>23,24</sup>, Robert Tibshirani<sup>25,26</sup>, Trevor Hastie<sup>25,26</sup>, John P. A. Ioannidis<sup>25,26,27,28,29</sup>, John Quackenbush<sup>30,31,32</sup> & Hugo J. W. L. Aerts<sup>6,7,33,34</sup>

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ARISING FROM S. M. McKinney et al. *Nature* <https://doi.org/10.1038/s41586-019-1799-6> (2020)

# Leakage and the Reproducibility Crisis in ML-based Science

20

We argue that there is a reproducibility crisis in ML-based science. We compile evidence of this crisis across fields, identify data leakage as a pervasive cause of reproducibility failures, conduct our own reproducibility investigations using in-depth code-review, and propose a solution.



PRINCETON  
UNIVERSITY

Draft paper

July 28 online workshop

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[List of failures](#)

[Taxonomy](#)

[Model info sheets](#)

[Case study](#)

[Terminology](#)

[Citation](#)

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# Leakage and the Reproducibility Crisis in ML-based Science

## 14/20 papers on the list found issues in medicine-related papers

We argue that there is a reproducibility crisis in ML-based science. We compile evidence of this crisis across fields, identify data leakage as a pervasive cause of reproducibility failures, conduct our own reproducibility investigations using in-depth code-review, and propose a solution.

Draft paper

July 28 online workshop

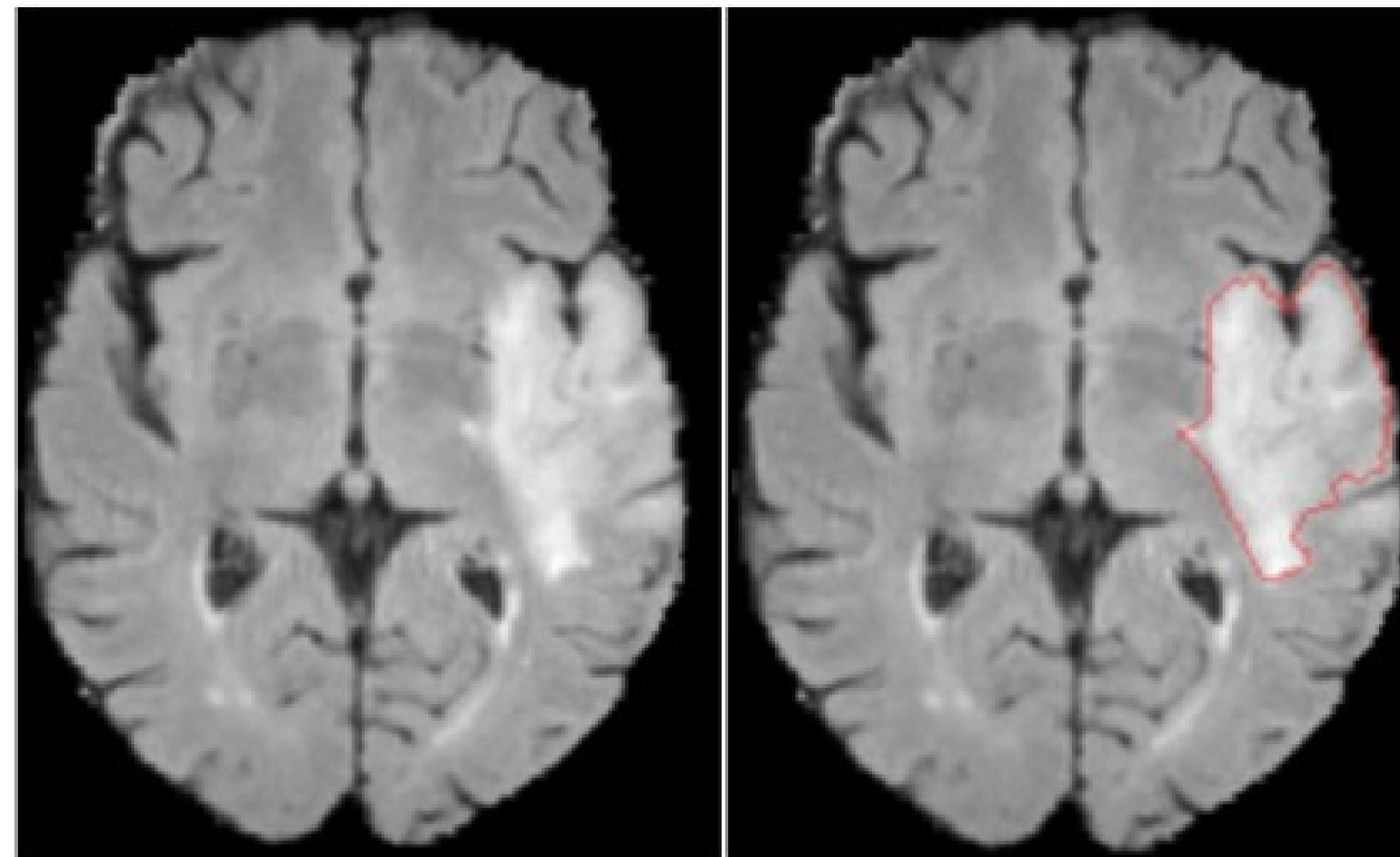
**More than 250 affected  
(training/test leaks, sampling bias,  
incorrect feature selection)!**

# TOWARDS CE-MARKED DEEP LEARNING SOFTWARE FOR BRAIN TUMOR ANALYSIS

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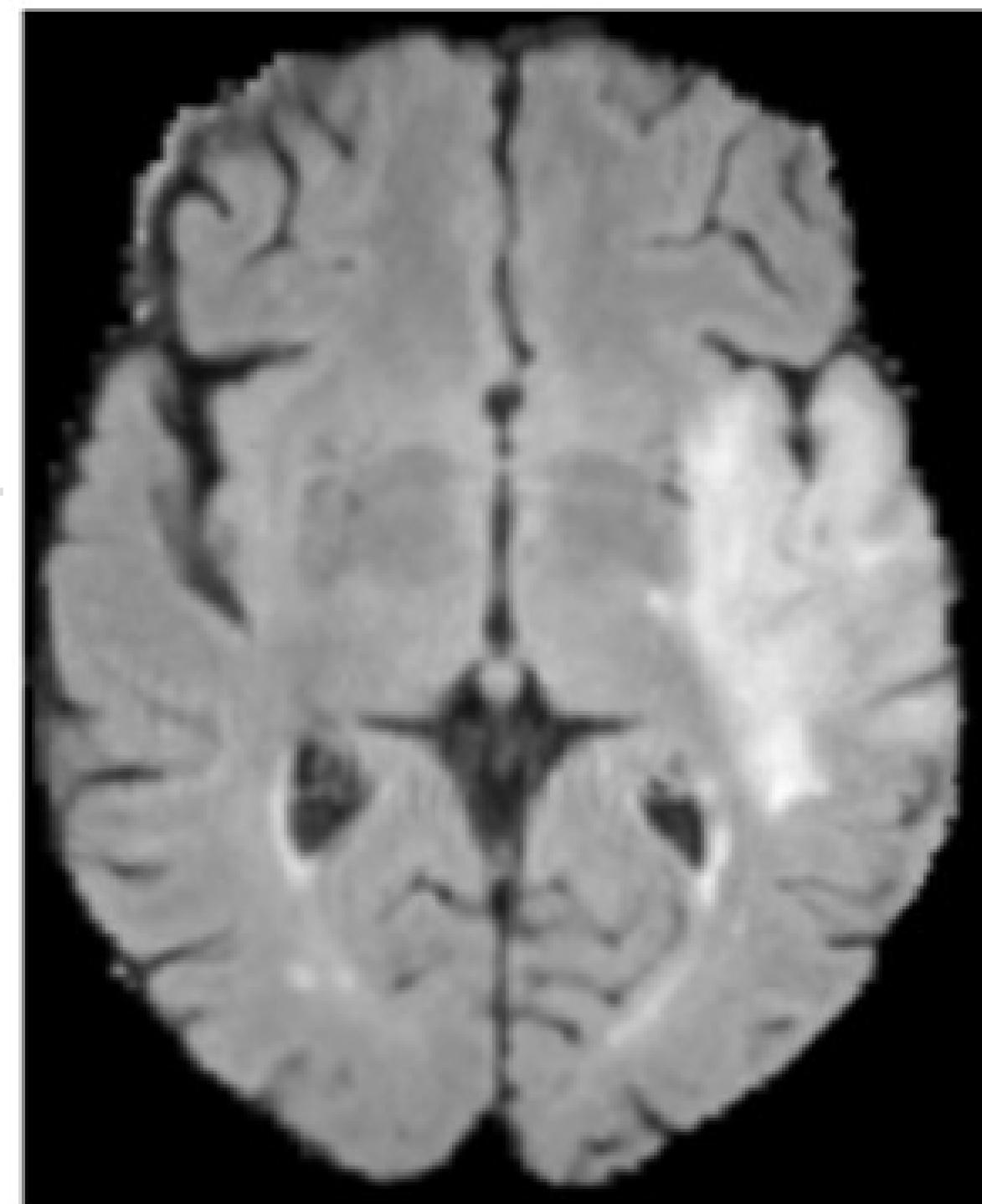
# Deep learning in medical products

23

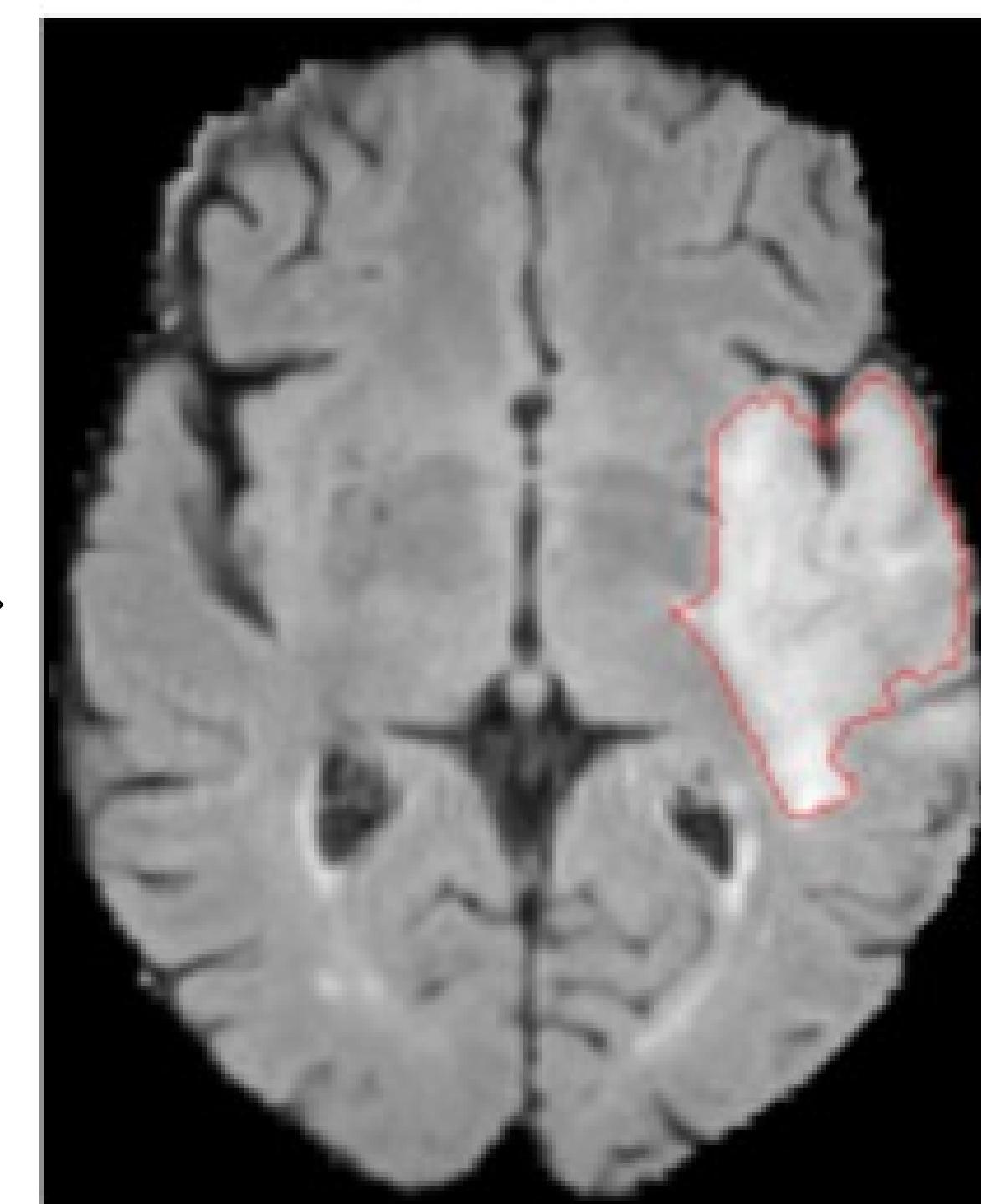


J. Nalepa et al.: Fully-automated deep learning-powered system for DCE-MRI analysis of brain tumors. Artificial Intelligence in Medicine: 102: 101769 (2020)

# Deep learning in medical products



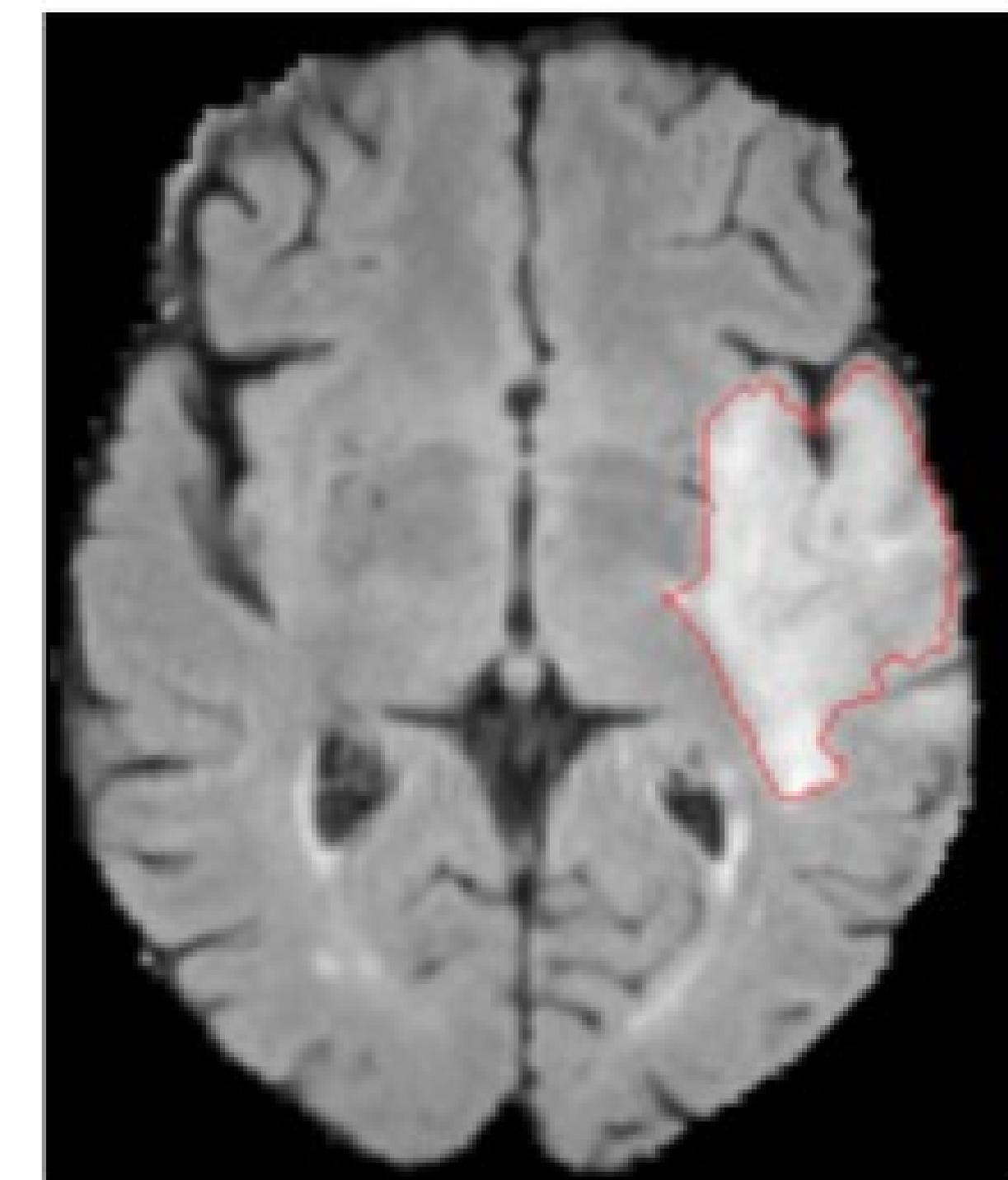
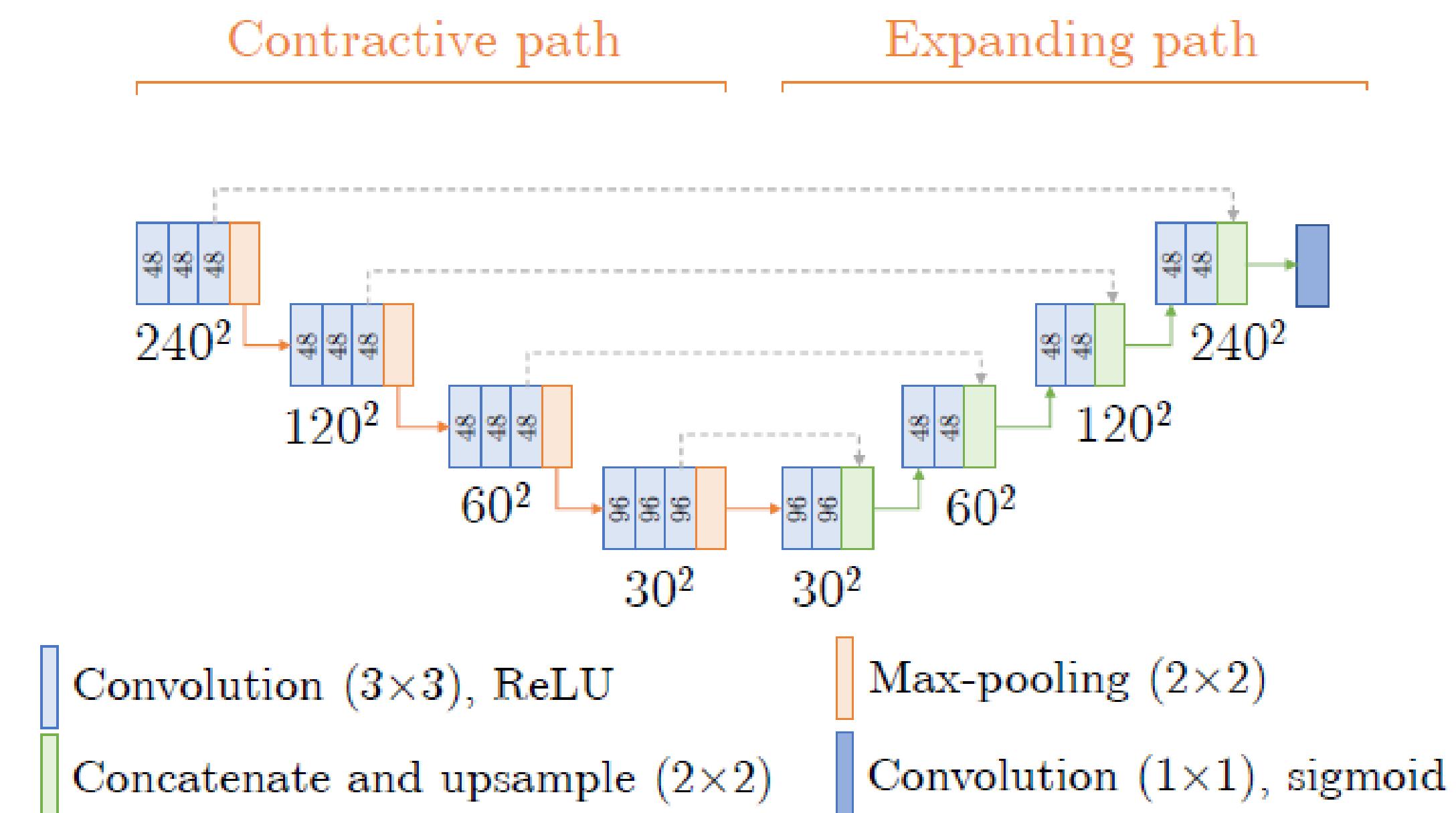
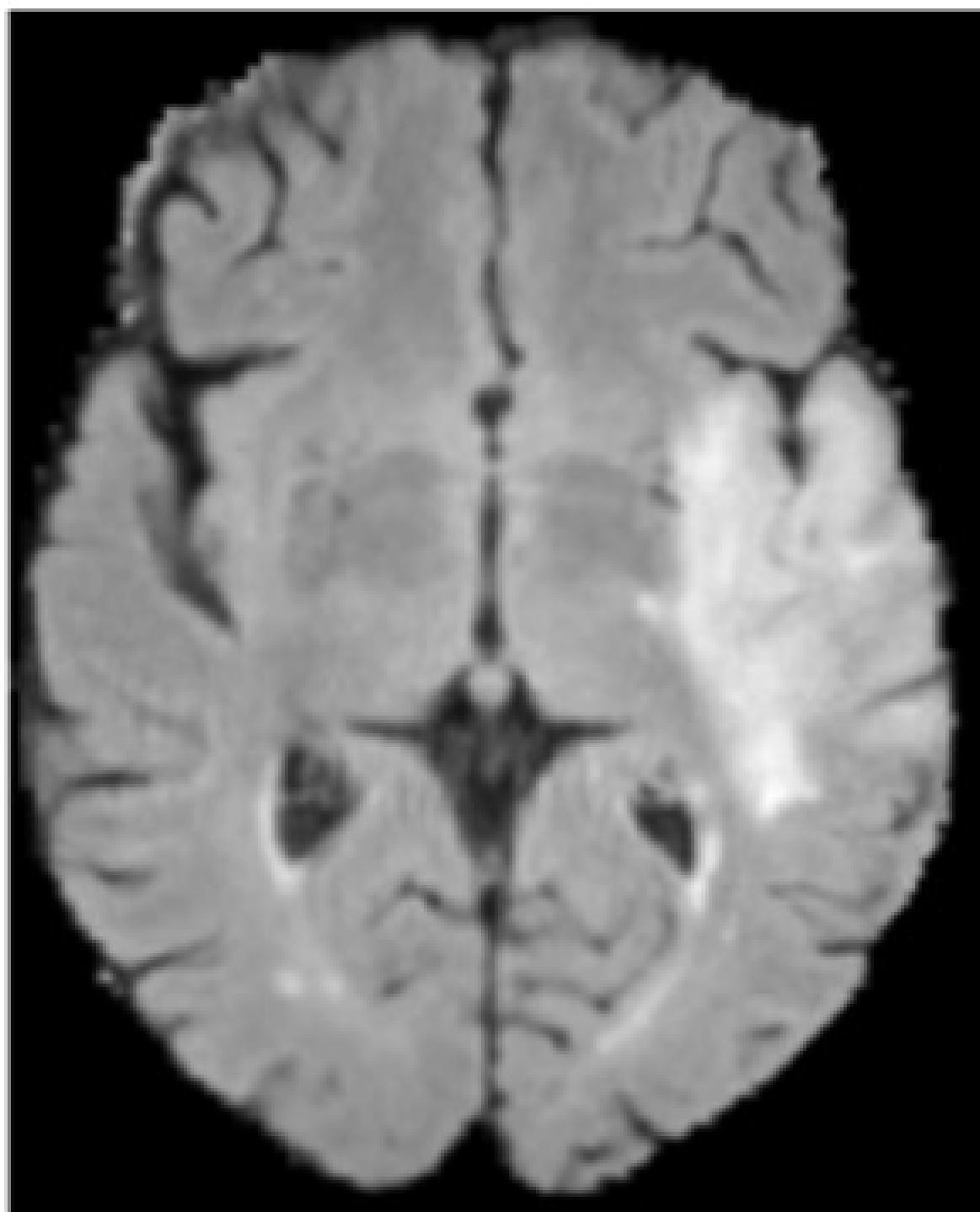
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Future Processing  
HEALTHCARE

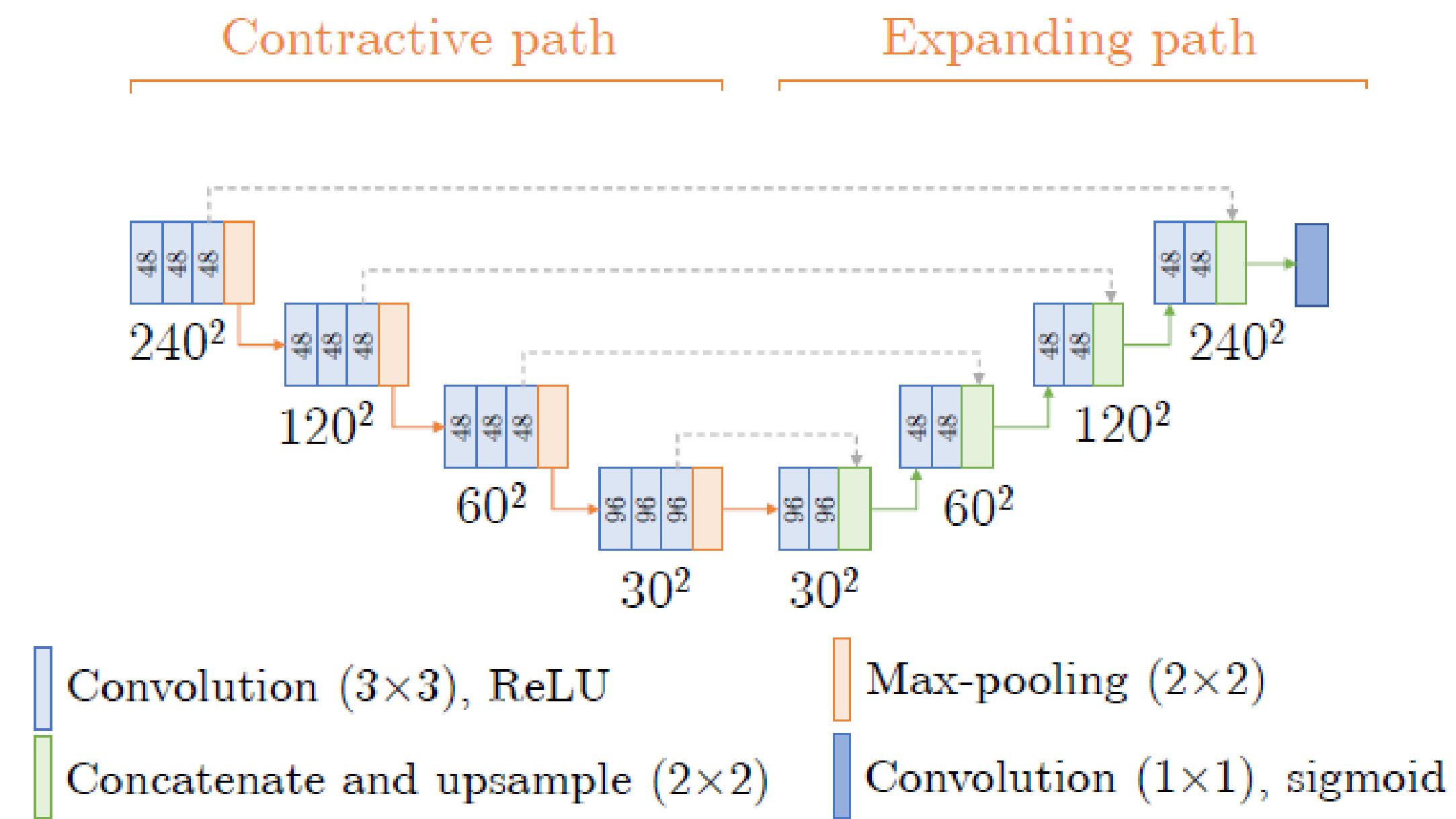
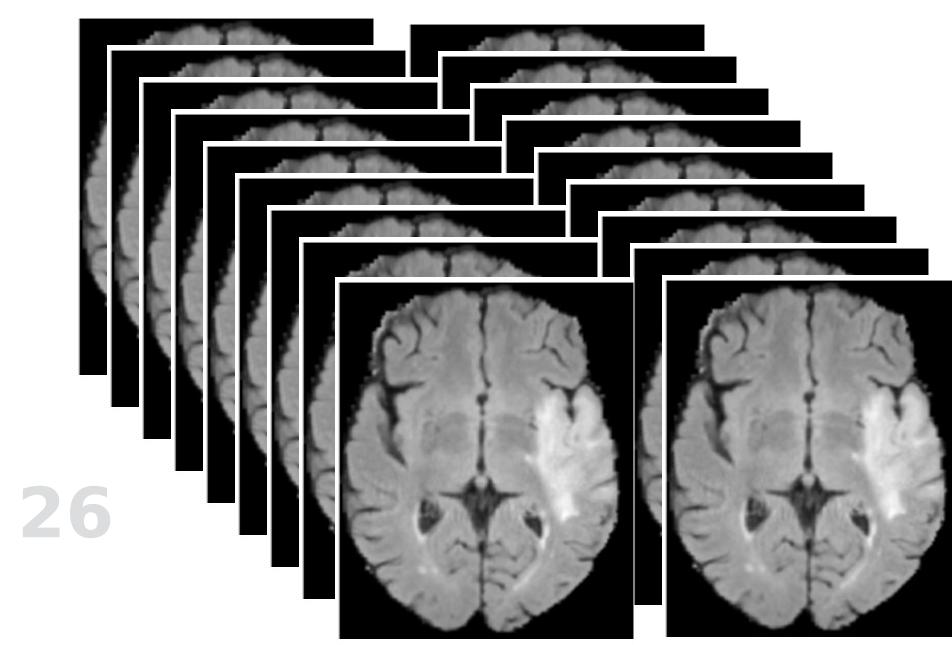
**Intended use:** This system automatically delineates and calculates the volumetric characteristics of the largest brain lesion (low- and high-grade gliomas) from T2-FLAIR.

# Deep learning in medical products



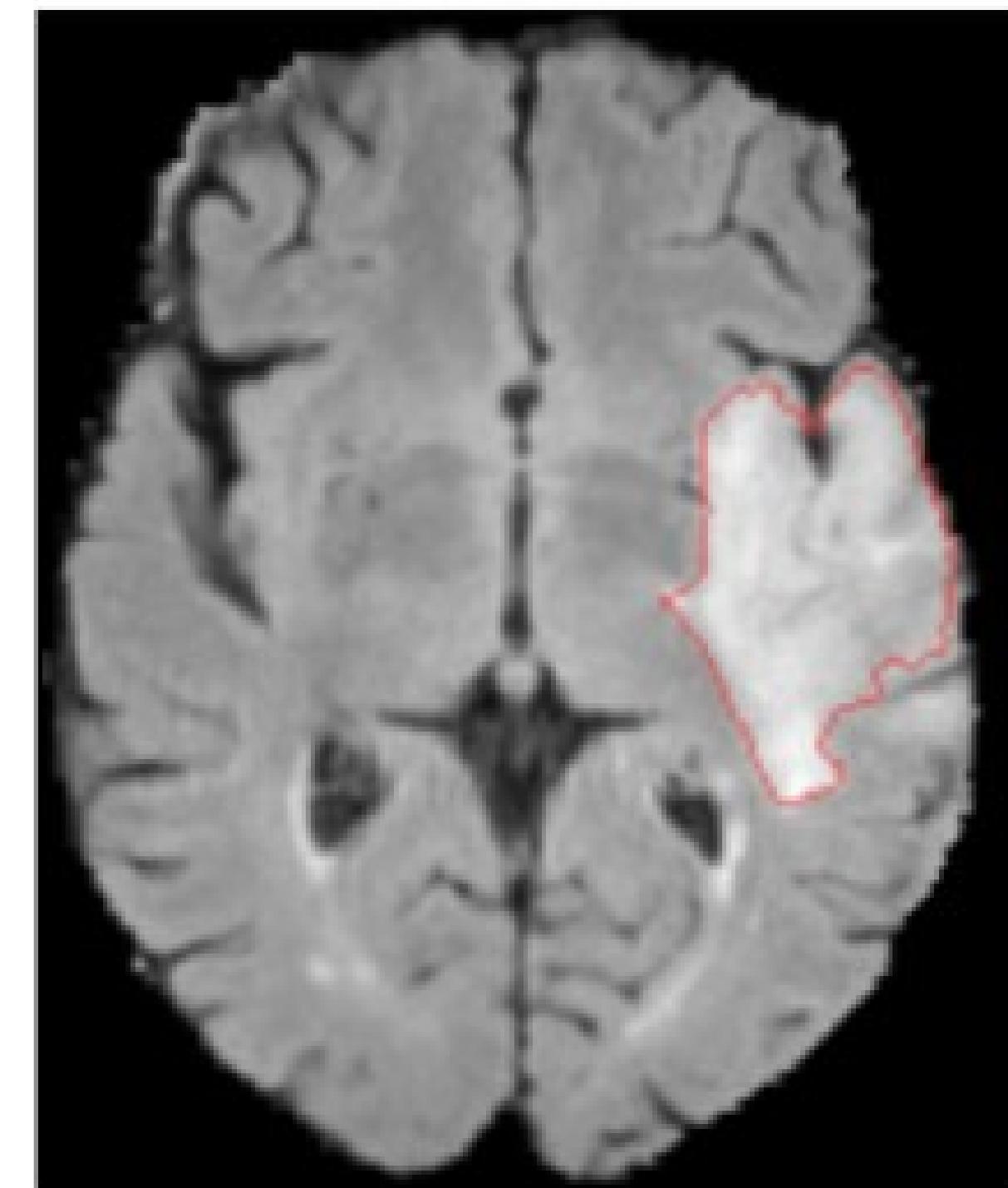
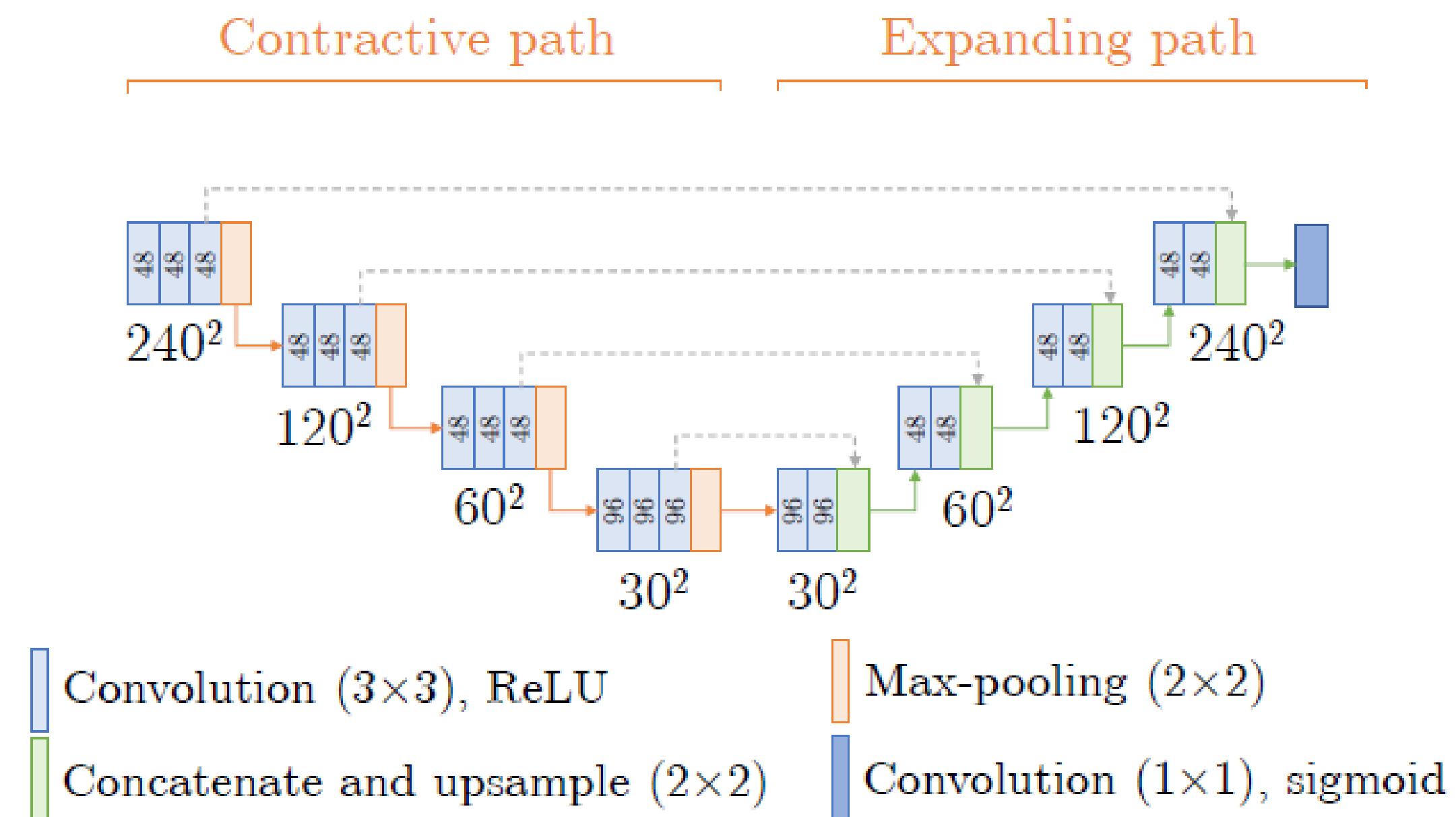
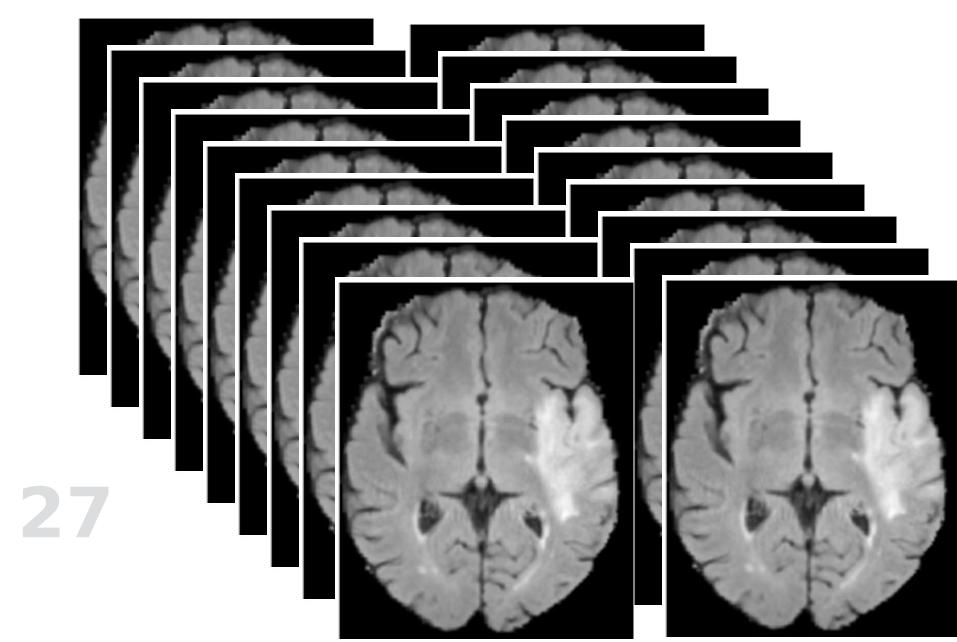
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# Deep learning in medical products



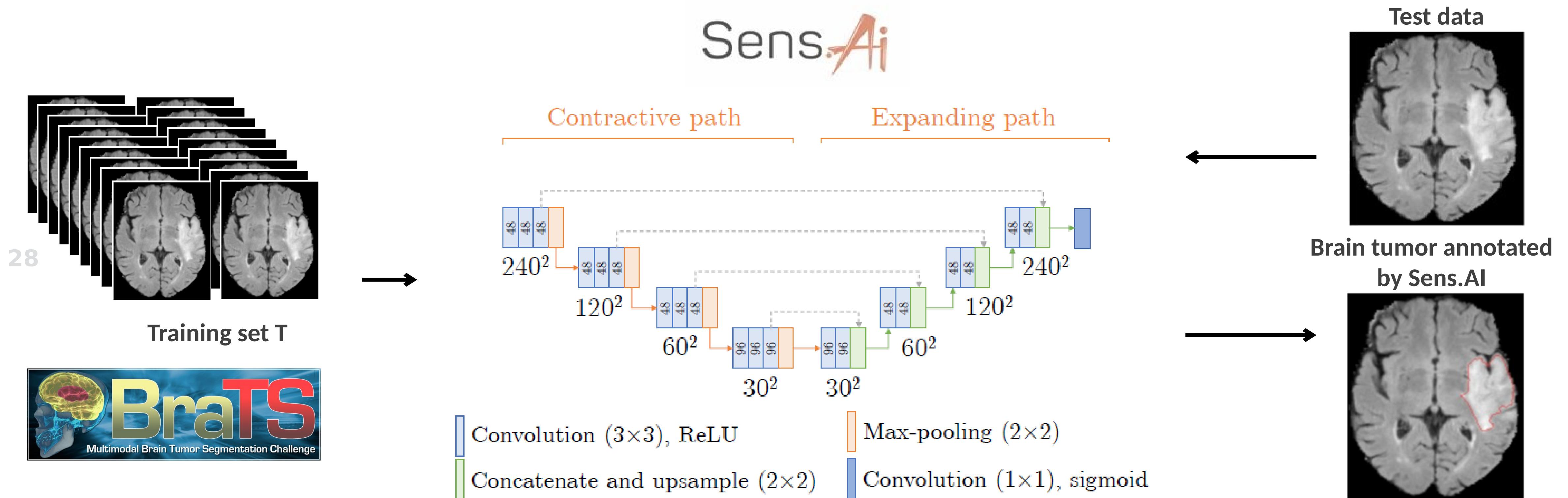
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# Deep learning in medical products

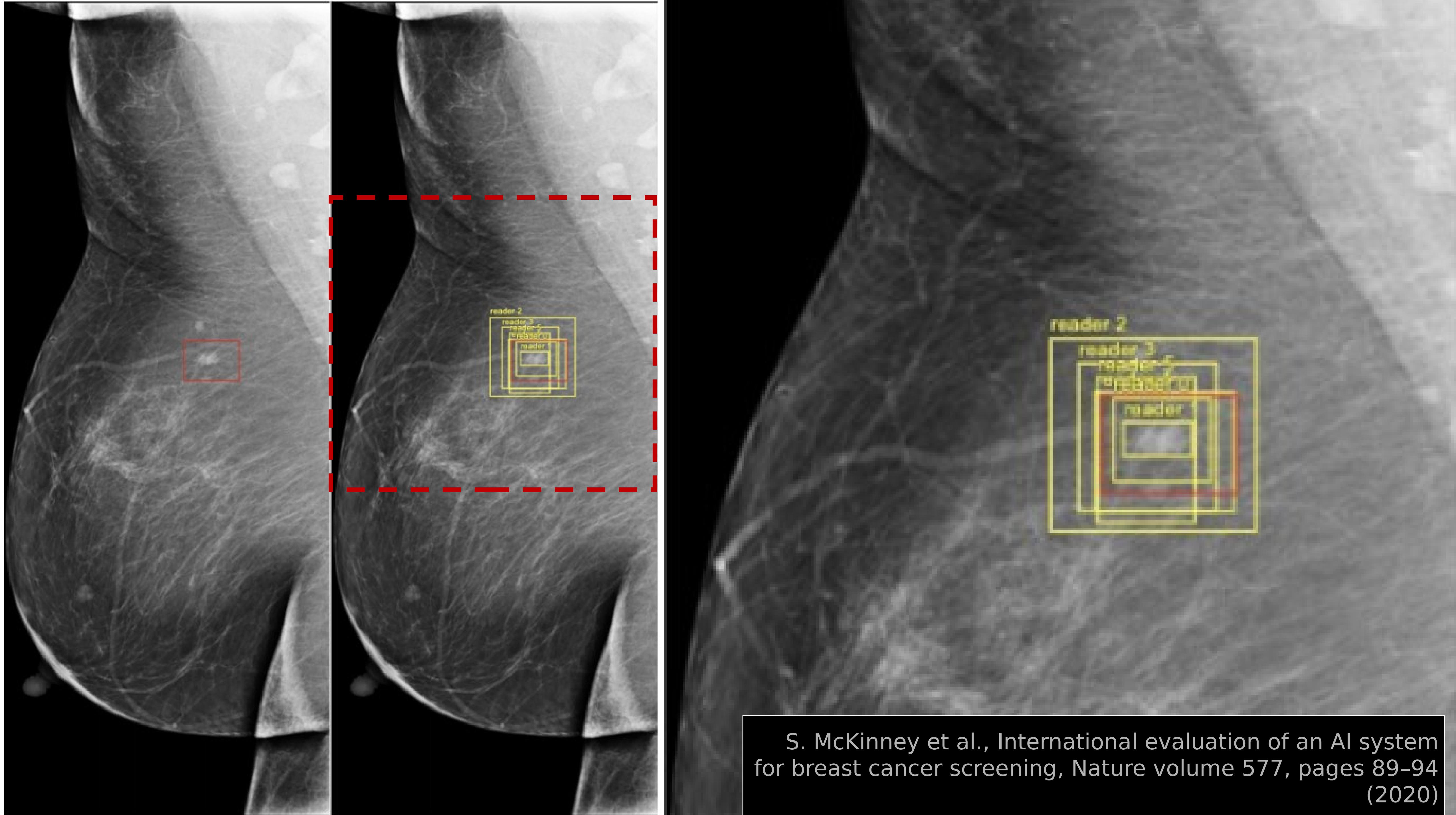


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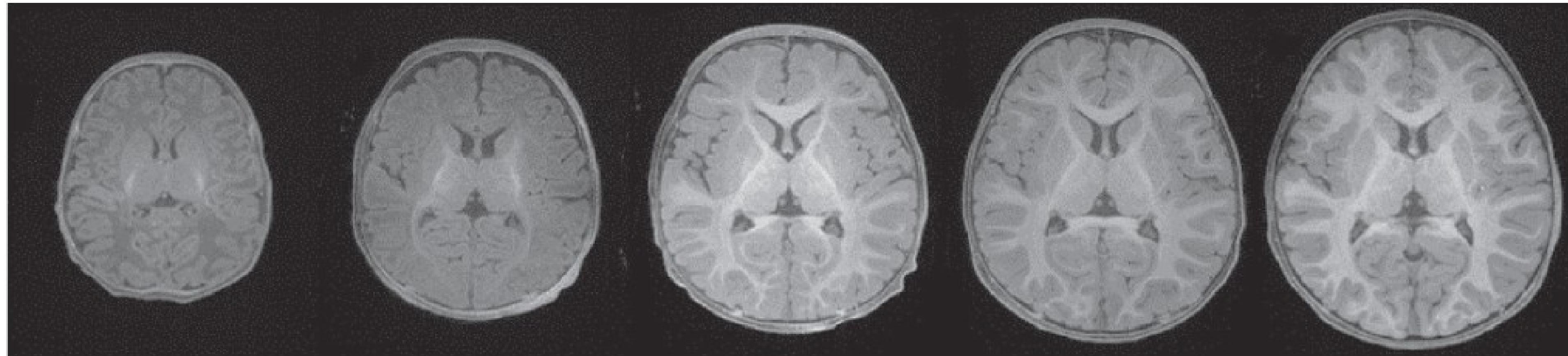
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S. McKinney et al., International evaluation of an AI system for breast cancer screening, Nature volume 577, pages 89–94 (2020)



30



0-month

3-month

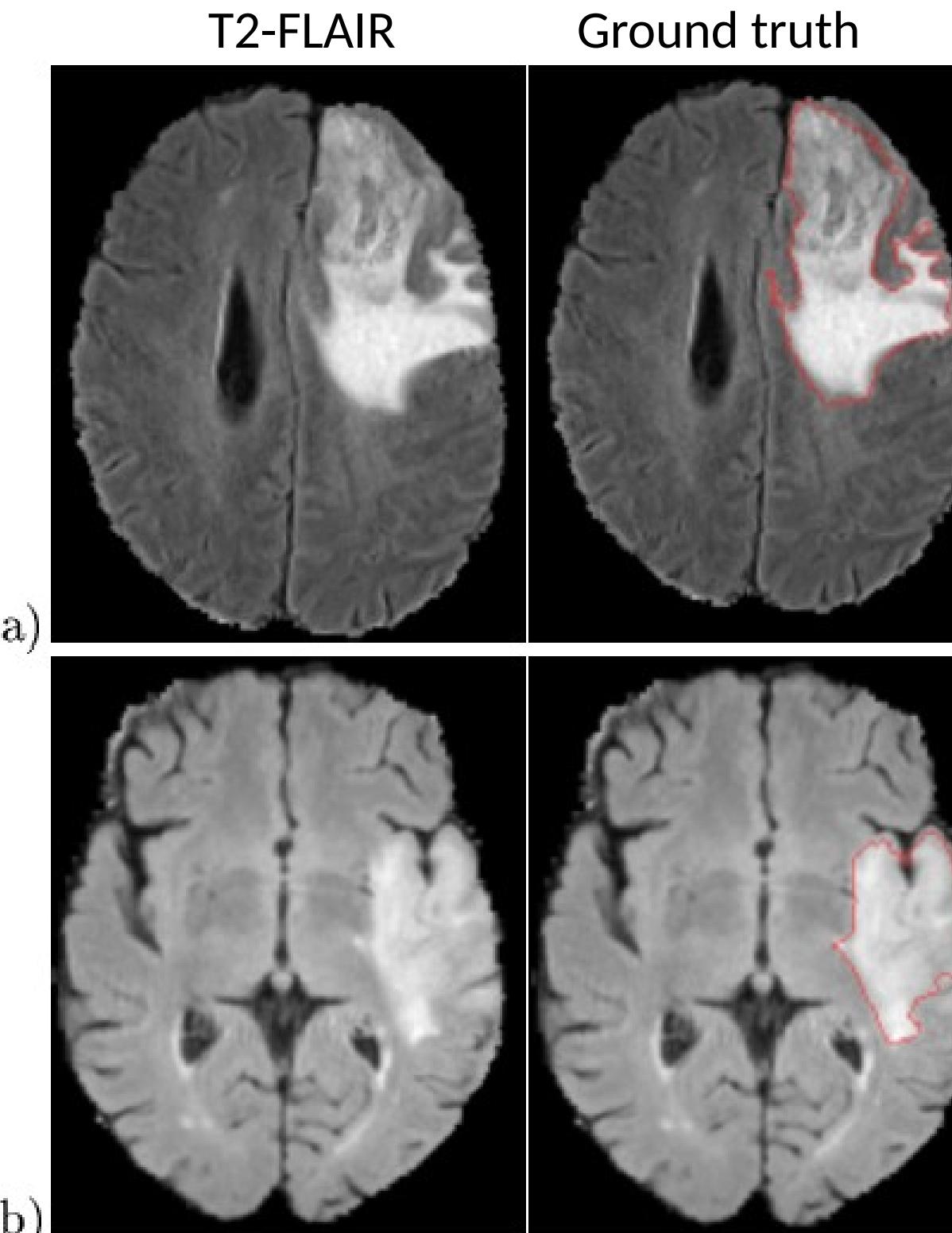
6-month

12-month

24-month

Mostapha and Styner, Role of deep learning in infant brain MRI analysis, Magnetic Resonance Imaging Volume 64, December 2019, Pages 171-189, 2019.

## Is our T of sufficient quality?



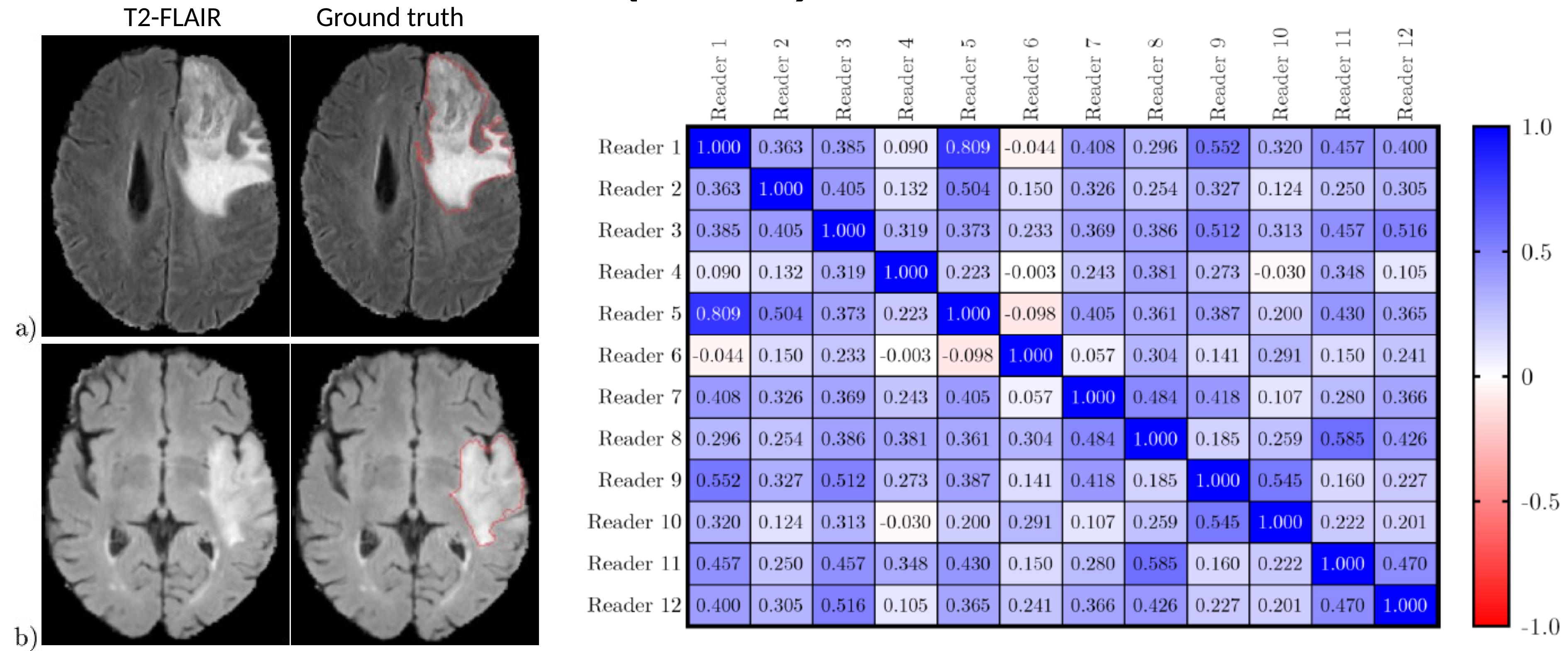
Score	Description	Outcome
1	<b>Very low quality</b> segmentation	No, I would not use it to support diagnosis
2	<b>Low quality</b> segmentation	No, I would not use it to support diagnosis
3	<b>Acceptable</b> segmentation	Yes, I would use it to support diagnosis
4	<b>Very high-quality</b> segmentation	Yes, I would use it to support diagnosis

Example ground-truth (GT) segmentations for patients a-b in BraTS 2017 (left image), alongside the Mean Opinion Score scale

# CHALLENGING SENSAI: TOWARDS CE MARKED DEEP LEARNING SOFTWARE

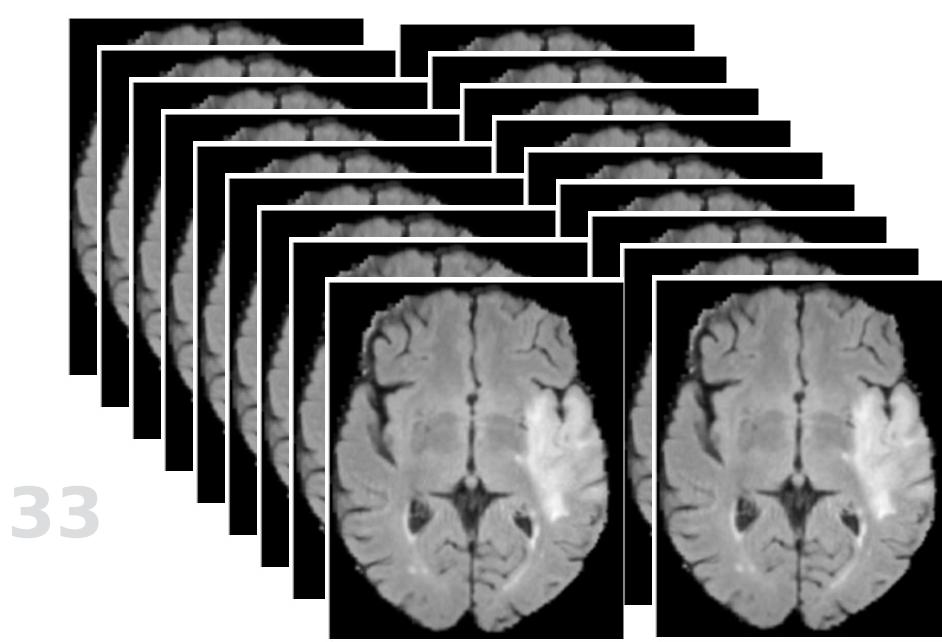
# Is our T of sufficient quality?

32

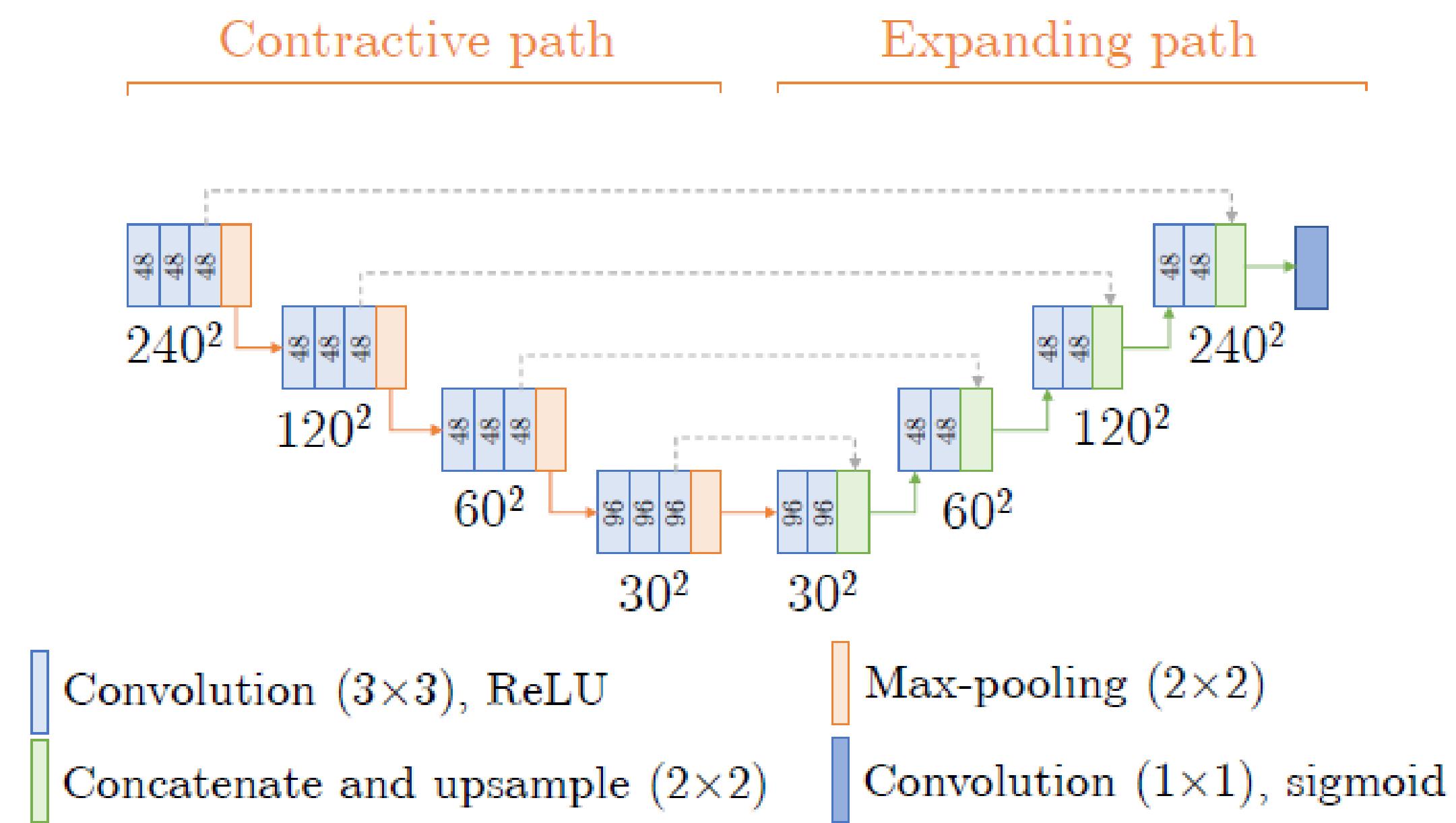


Example ground truth (GT) for patients a-b in BraTS - **165 HGG i 63 LGG** (left image) together with the inter-rater agreement

# Deep learning in medical products



~1250 MRIs for brain extraction (four data sources, various modalities, reviewed by 3 readers with 11, 7 and 5 YOE)  
228 MRIs for BT segmentation (165 HGG and 63 LGG)

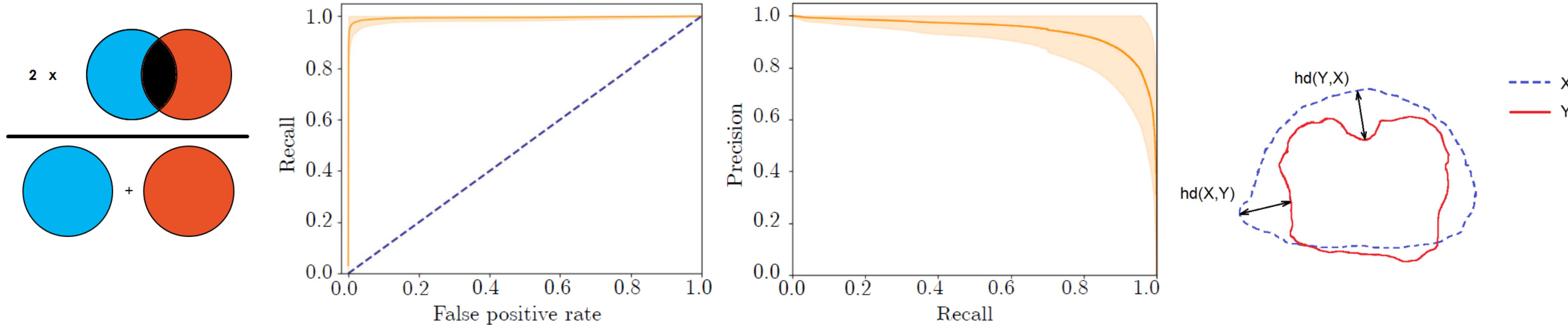


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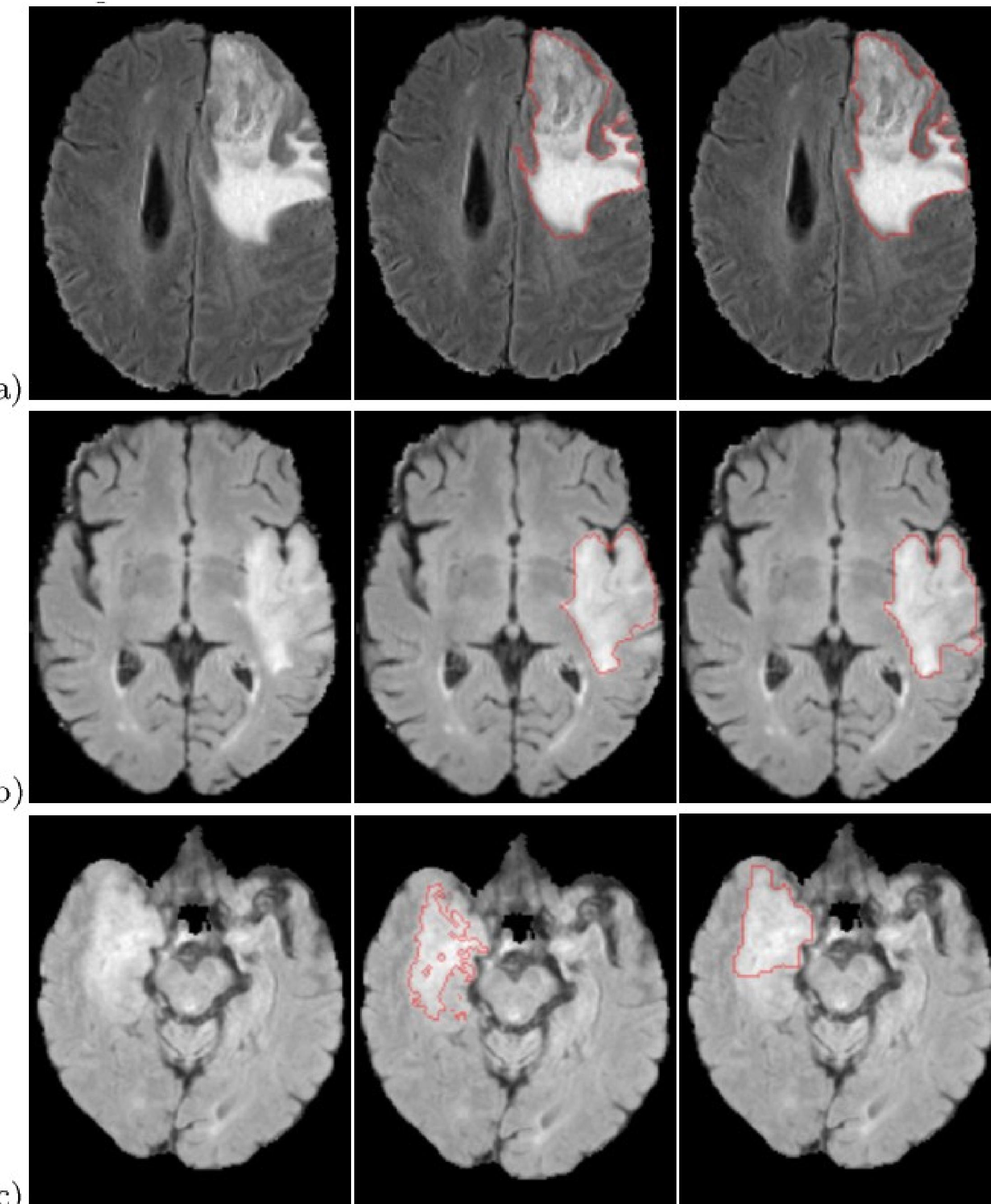
# Is the algorithm „ready”?

	DICE	GT Volume [mm <sup>3</sup> ]	Volume [mm <sup>3</sup> ]	Volume error [%]	AUC (ROC)	AUC (P – R)	HD	HD (95)
Min.	0.609	32051	29223	0.508	0.945	0.643	6.164	1.000
Mean	0.882	112120	105891	13.339	0.994	0.896	23.884	8.807
Max.	0.968	232098	212323	58.094	1.000	0.979	71.127	41.713
Std. dev.	0.095	59859	53784	15.794	0.014	0.095	20.217	11.769

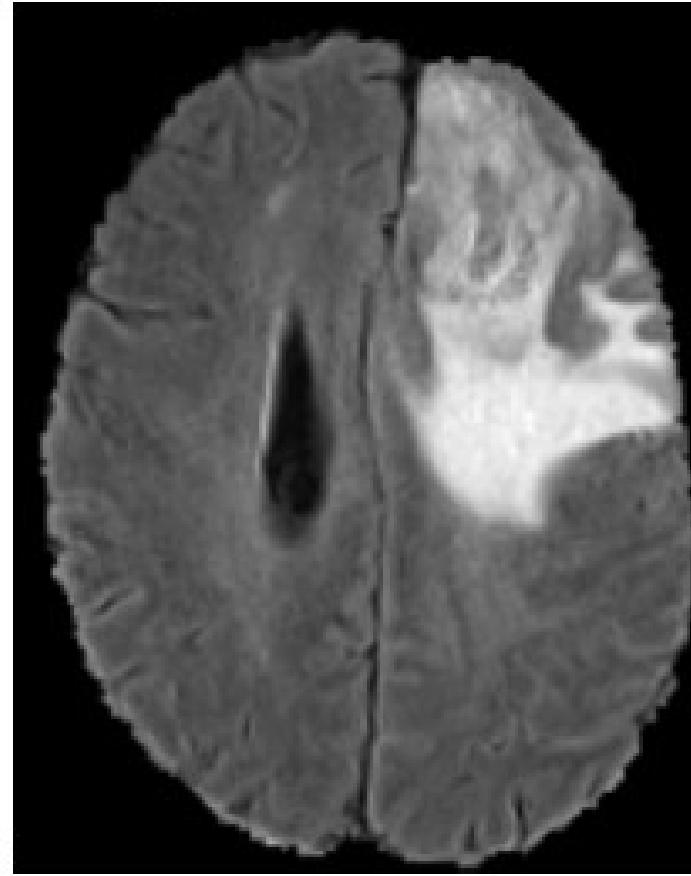
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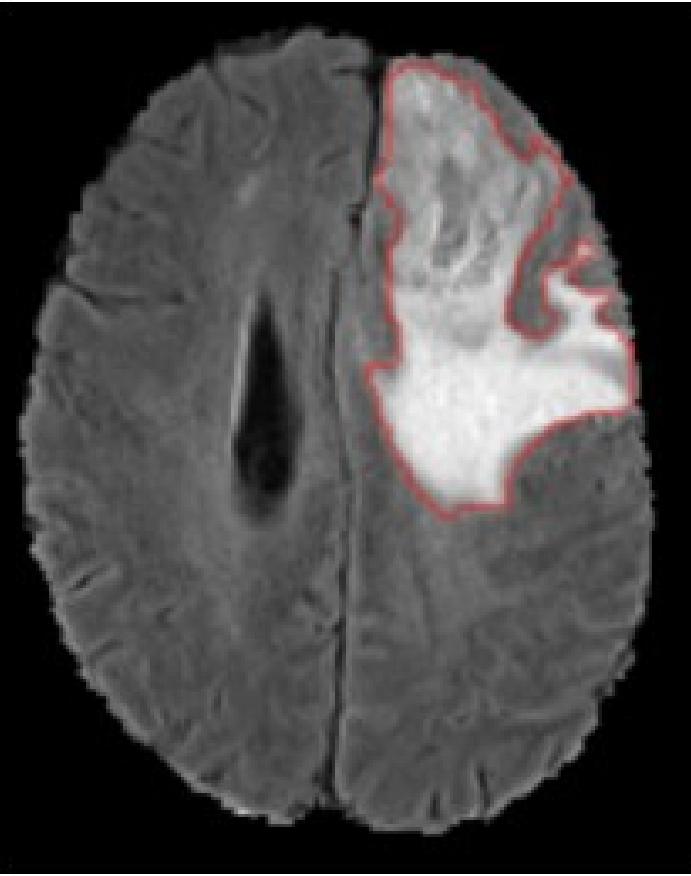
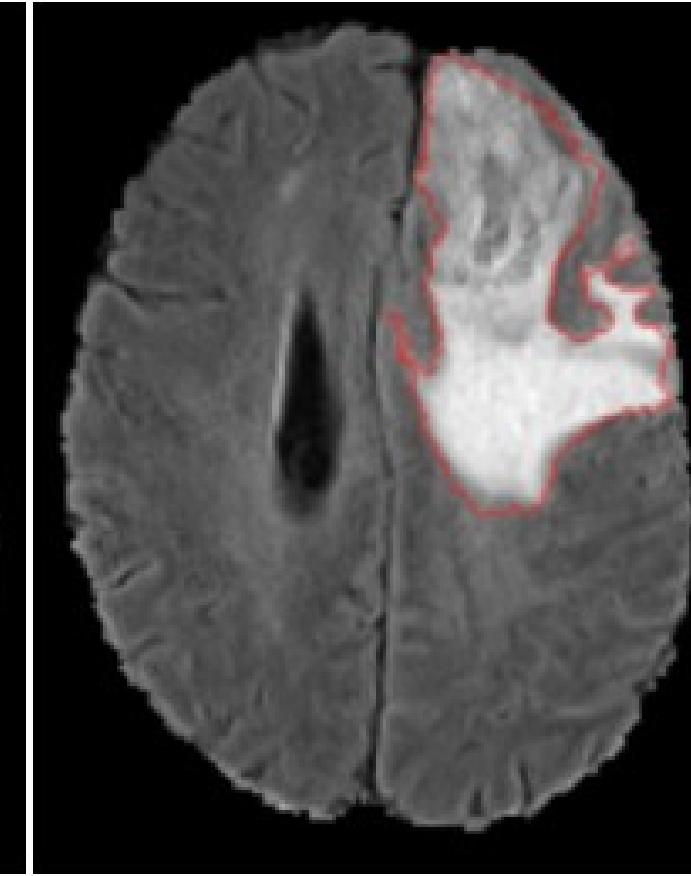
35



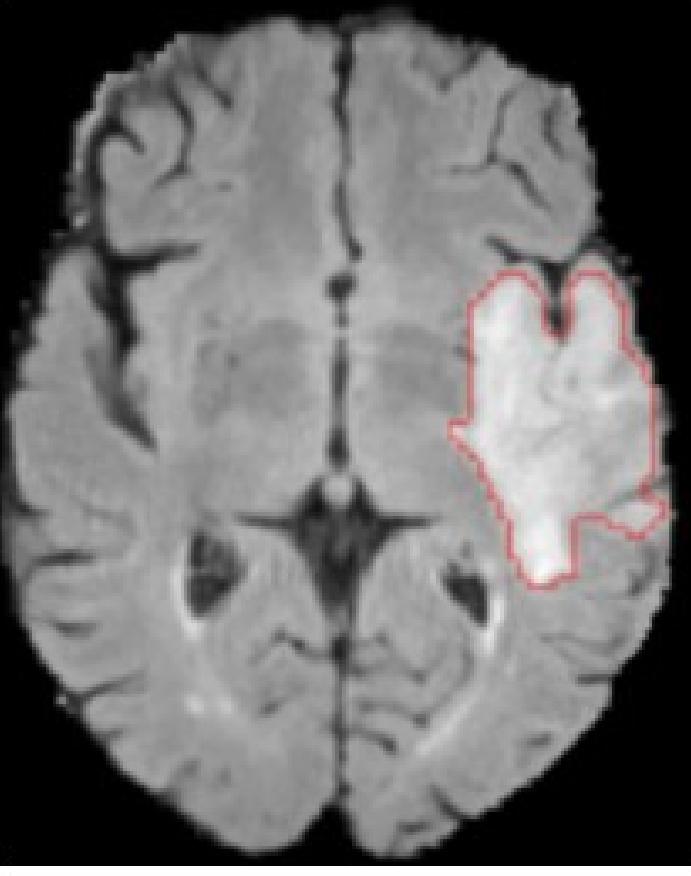
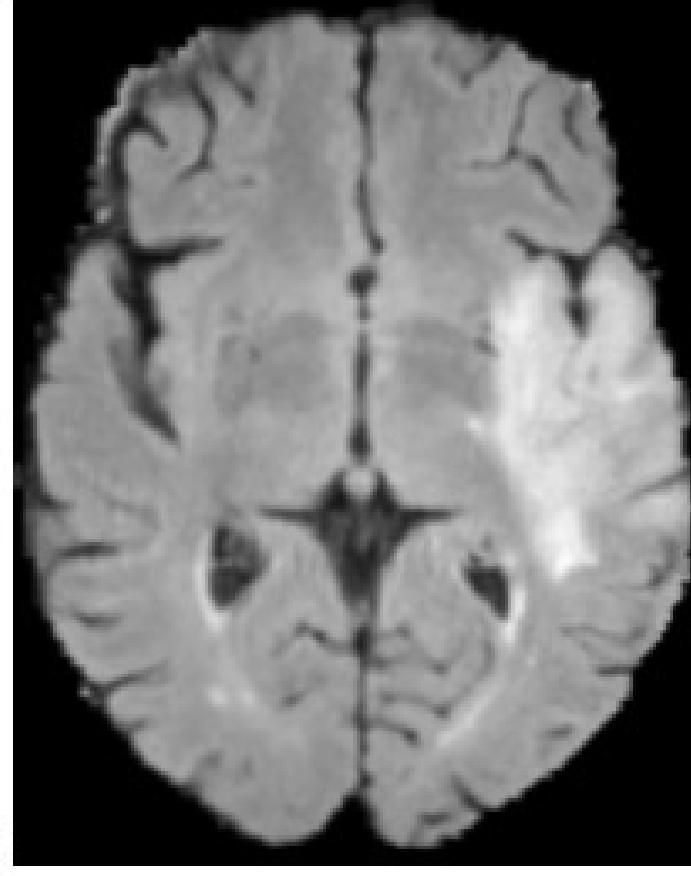
Original T2-FLAIR



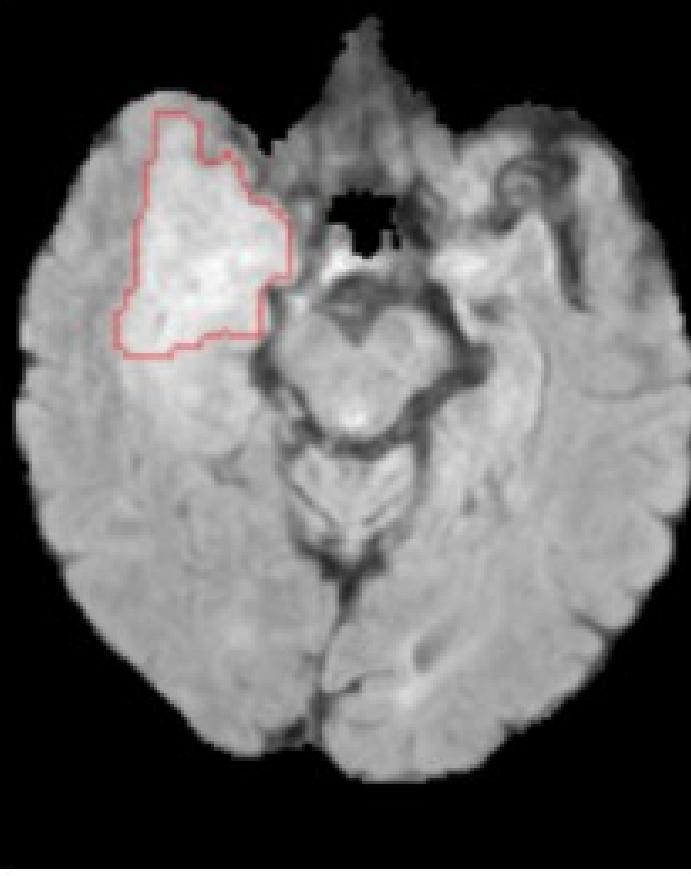
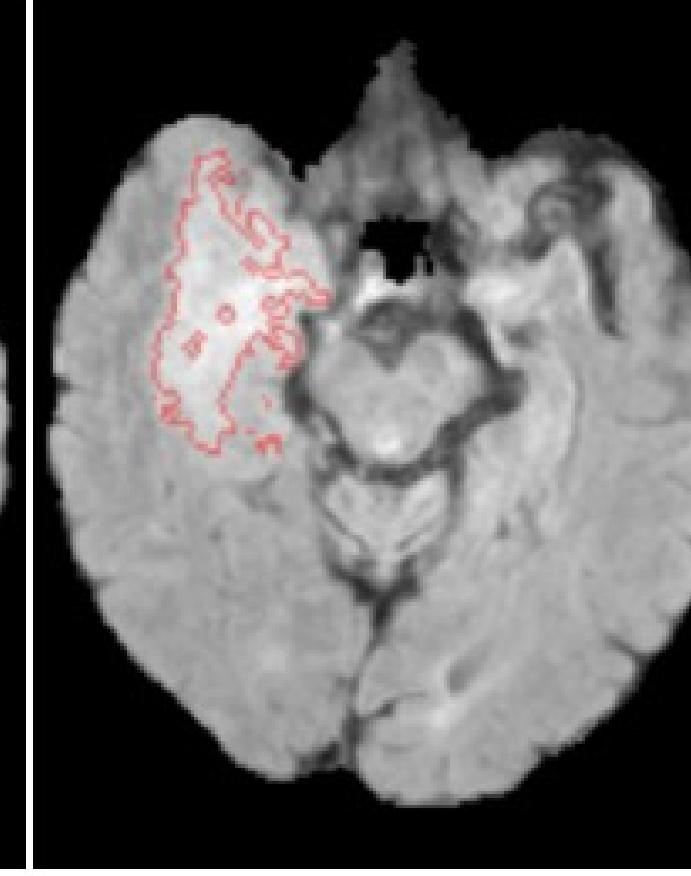
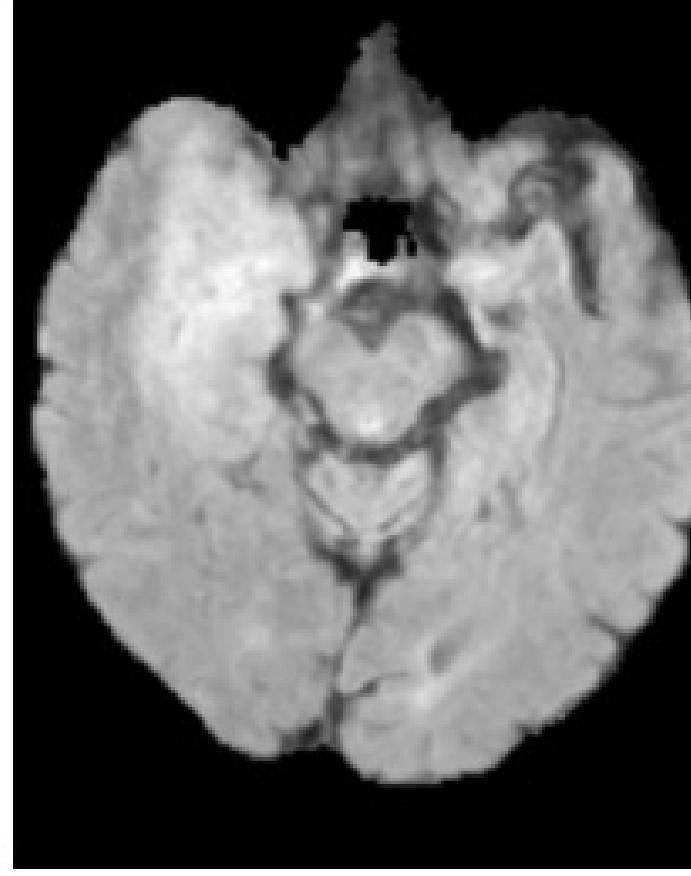
Ground truth



a)



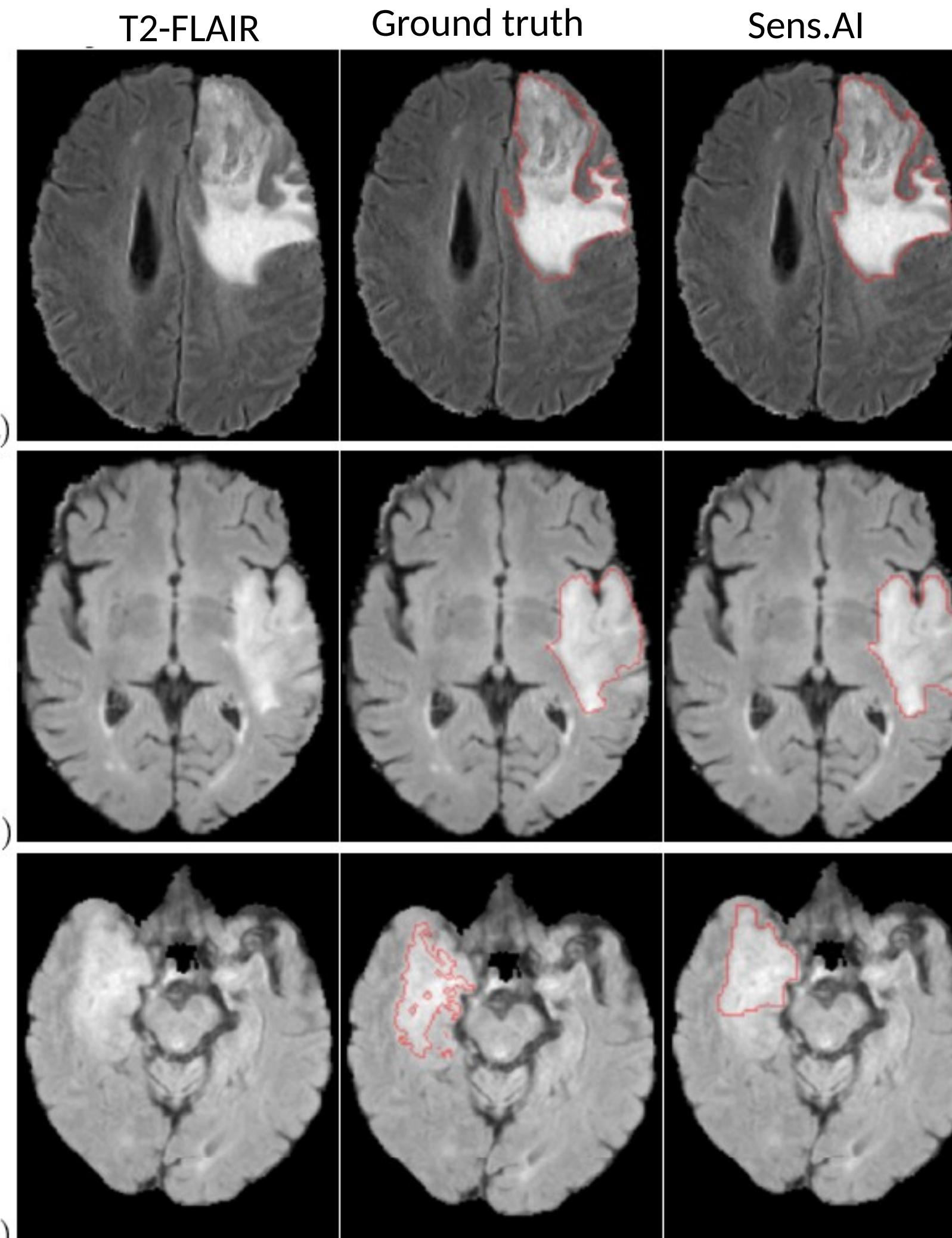
b)



c)

## CHALLENGING SENS.AI: TOWARDS CE MARKED DEEP LEARNING SOFTWARE

# Is the algorithm „ready”?



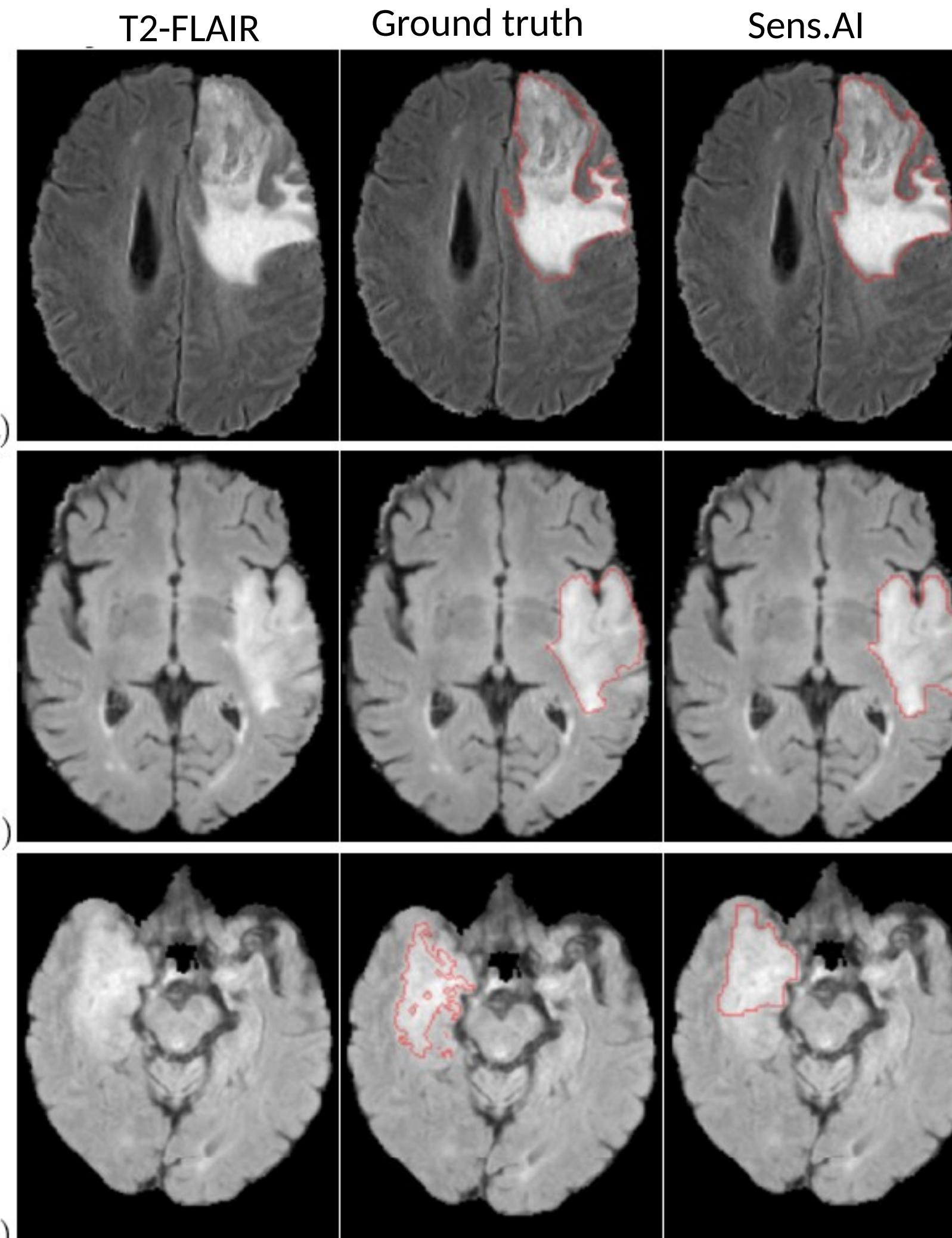
# Is the algorithm „ready”?

38

ID	Institution	YOE	BraTS (GT)	BraTS (Sens.AI)	CD
Reader 1	Institution A	3	3.000	2.697	2.300
Reader 2	Institution A	3	3.273	2.909	2.720
Reader 3	Institution A	3	2.152	1.909	1.660
Reader 4	Institution A	4	2.848	2.758	2.740
Reader 5	Institution A	4	3.273	2.939	2.620
Reader 6	Institution A	4	3.697	3.333	2.600
Reader 7	Institution A	5	2.242	2.455	1.940
Reader 8	Institution B	5	3.333	3.152	2.300
Reader 9	Institution B	7	2.909	2.758	2.040
Reader 10	Institution B	9	3.182	2.788	2.000
Reader 11	Institution B	11	2.848	2.636	2.080
Reader 12	Institution B	11	3.424	3.273	2.540
<b>Average score</b>			3.015	2.801	2.330
<b>Weighted average score</b>			3.050	2.842	2.318
Score	Description		Outcome		
1	<b>Very low quality</b> segmentation		No, I would not use it to support diagnosis		
2	<b>Low quality</b> segmentation		No, I would not use it to support diagnosis		
3	<b>Acceptable</b> segmentation		Yes, I would use it to support diagnosis		
4	<b>Very high-quality</b> segmentation		Yes, I would use it to support diagnosis		

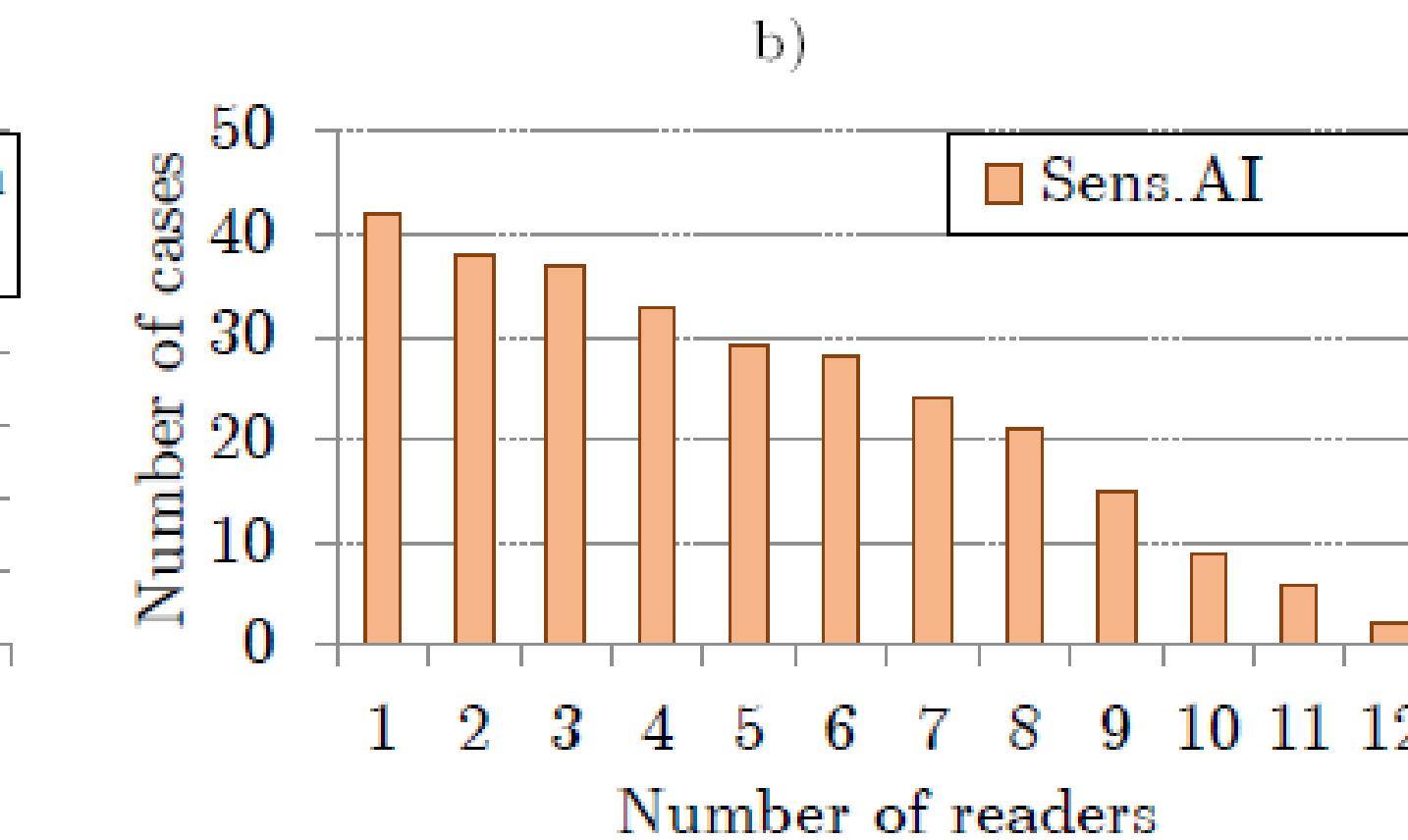
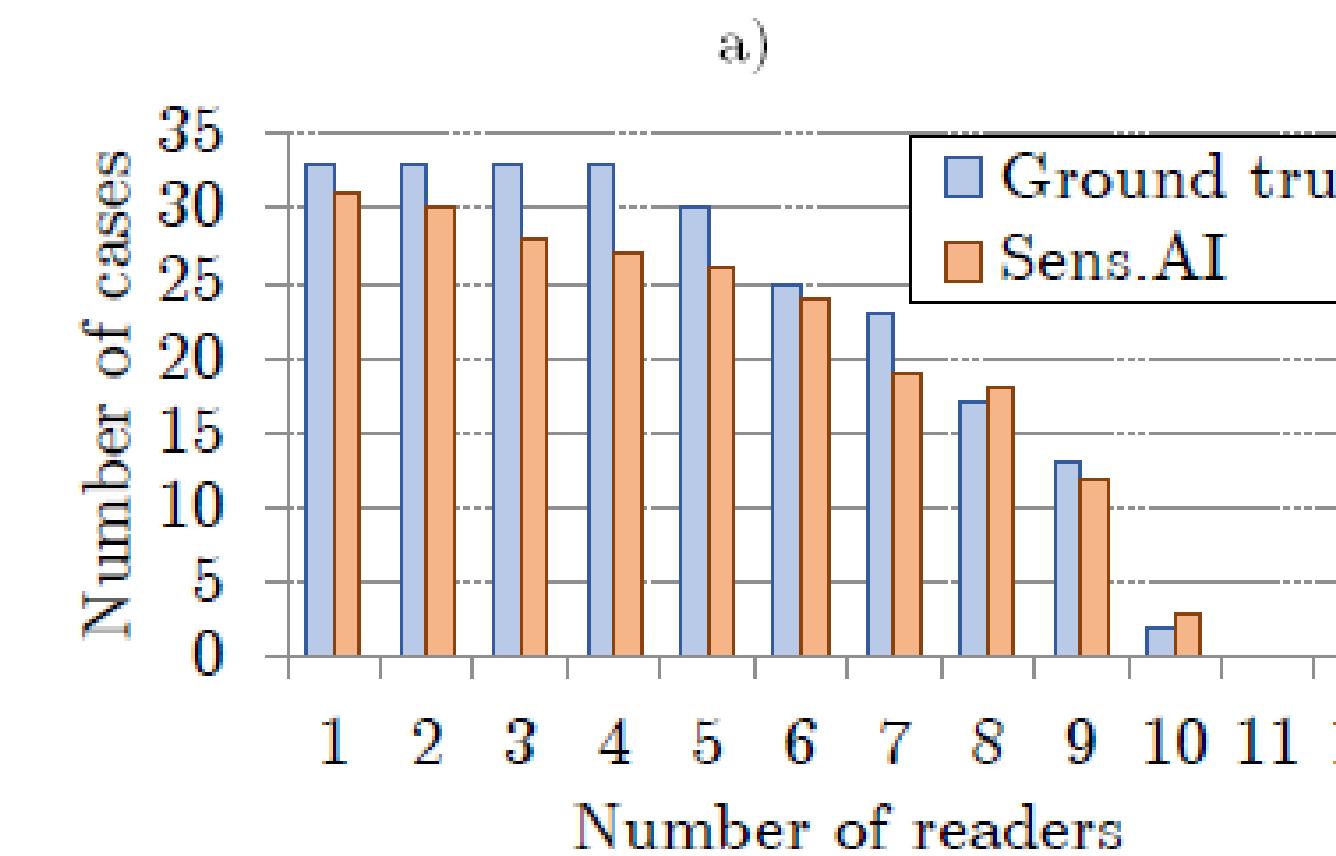
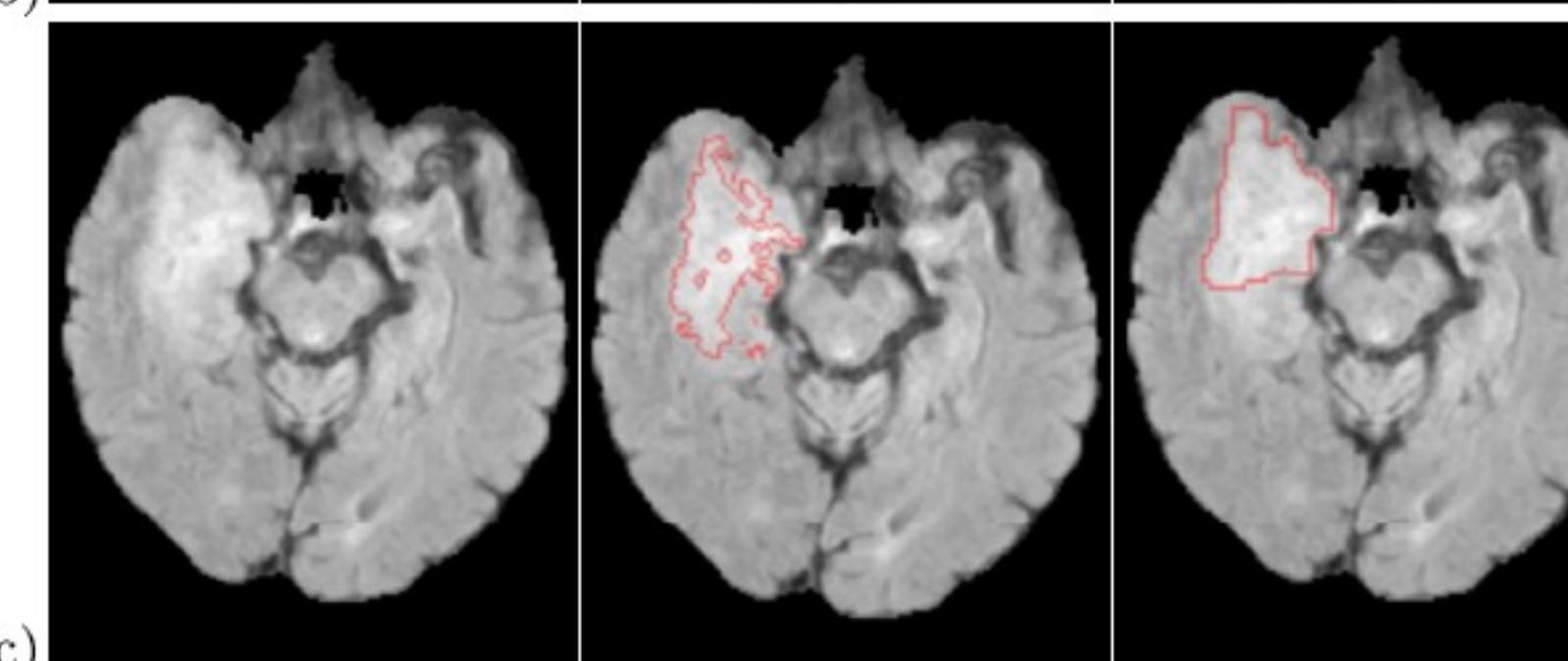
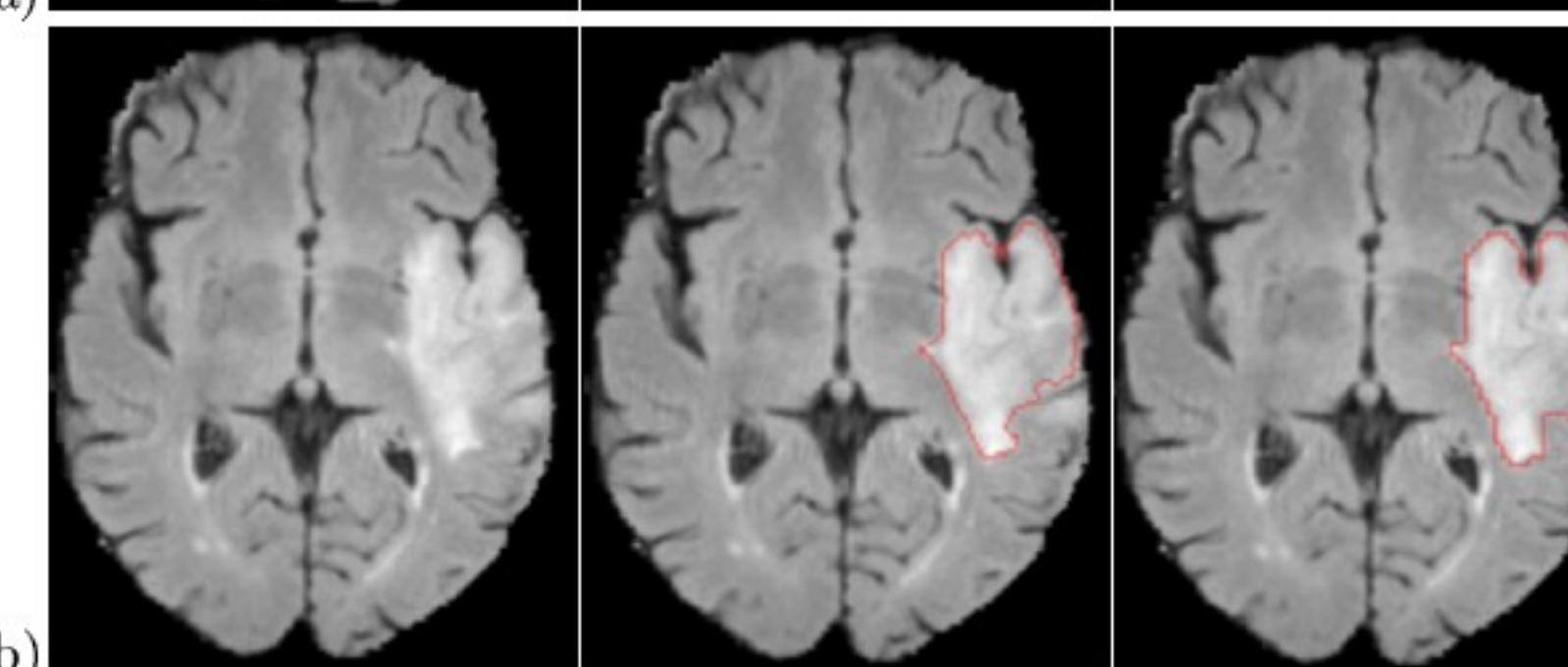
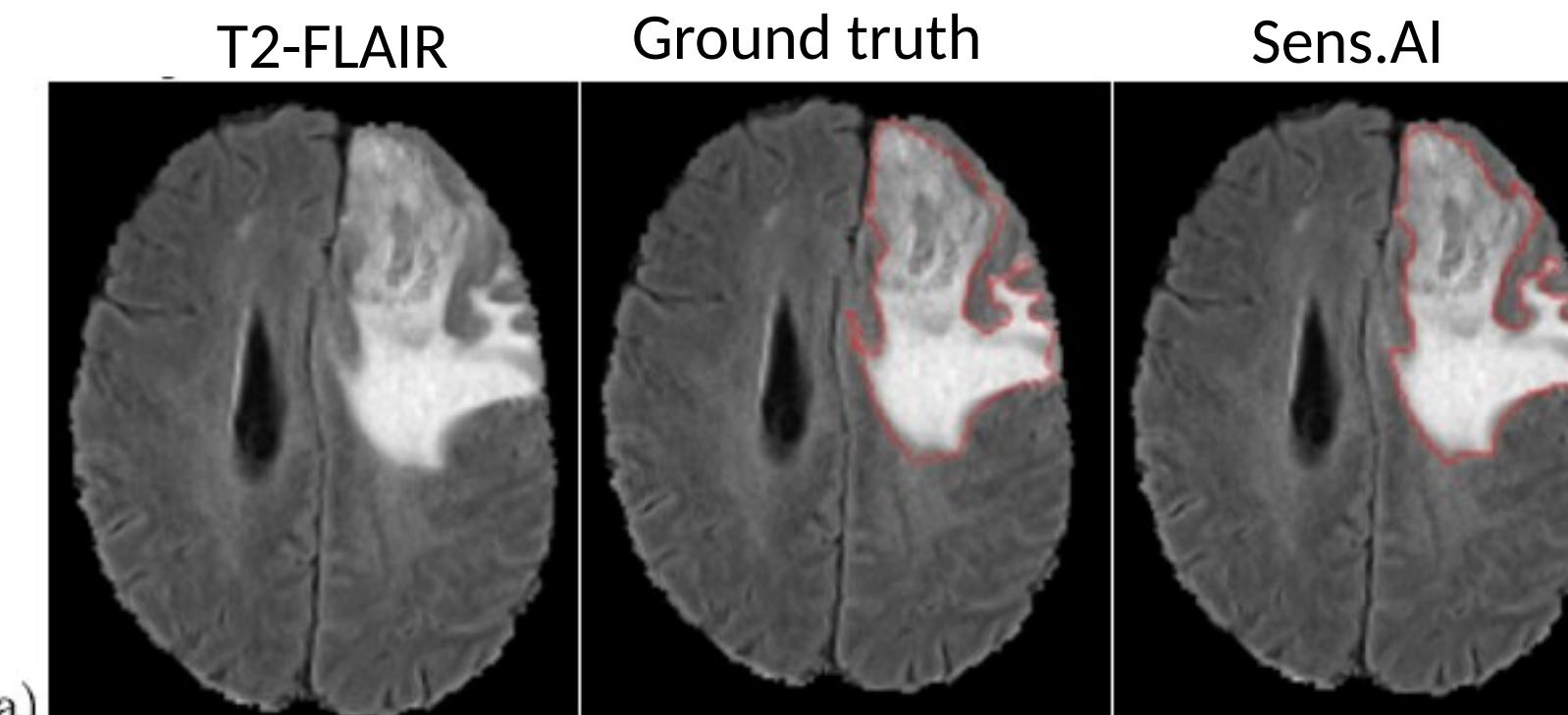
## CHALLENGING SENS.AI: TOWARDS CE MARKED DEEP LEARNING SOFTWARE

# Is the algorithm „ready”?

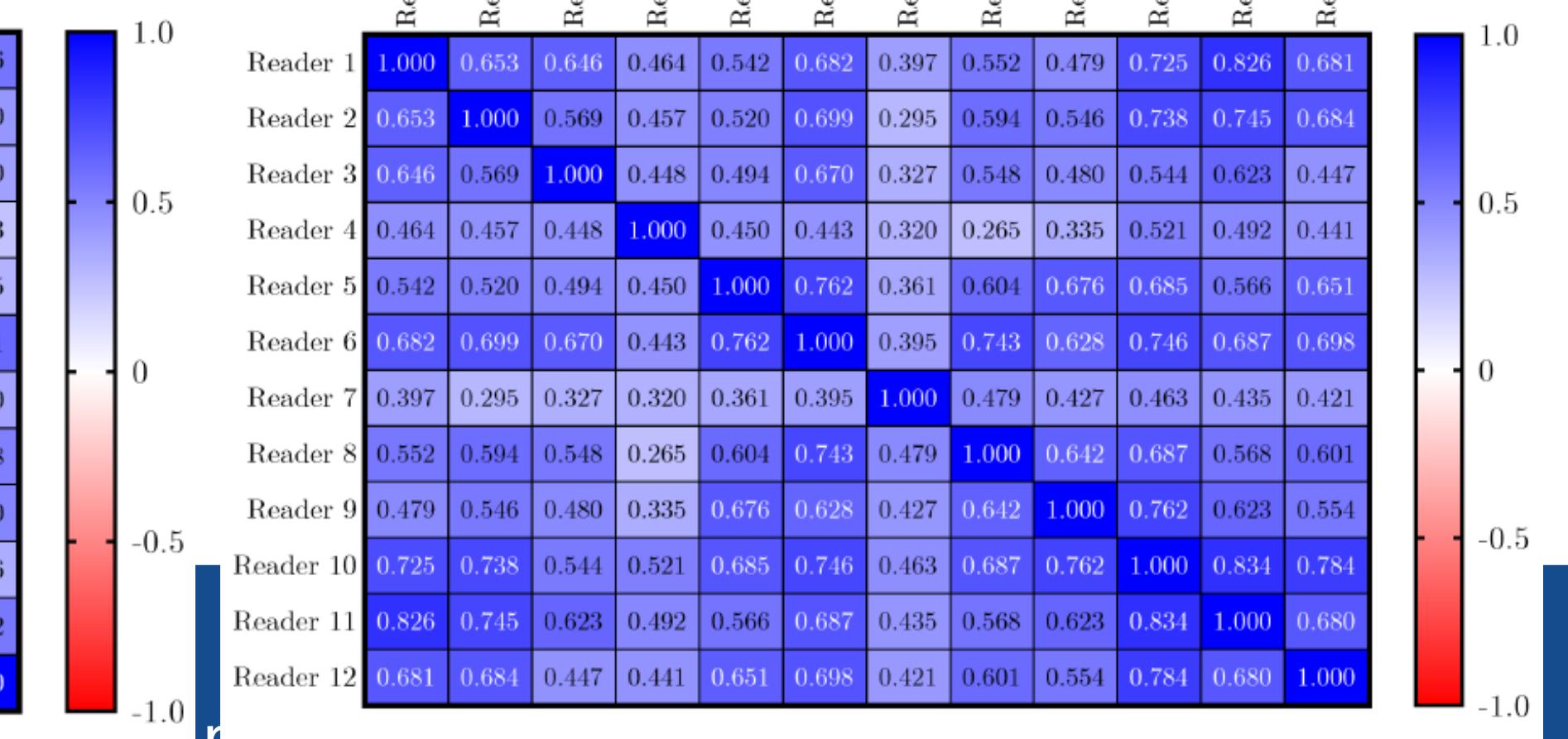


# CHALLENGING SENS.AI: TOWARDS CE MARKED DEEP LEARNING SOFTWARE

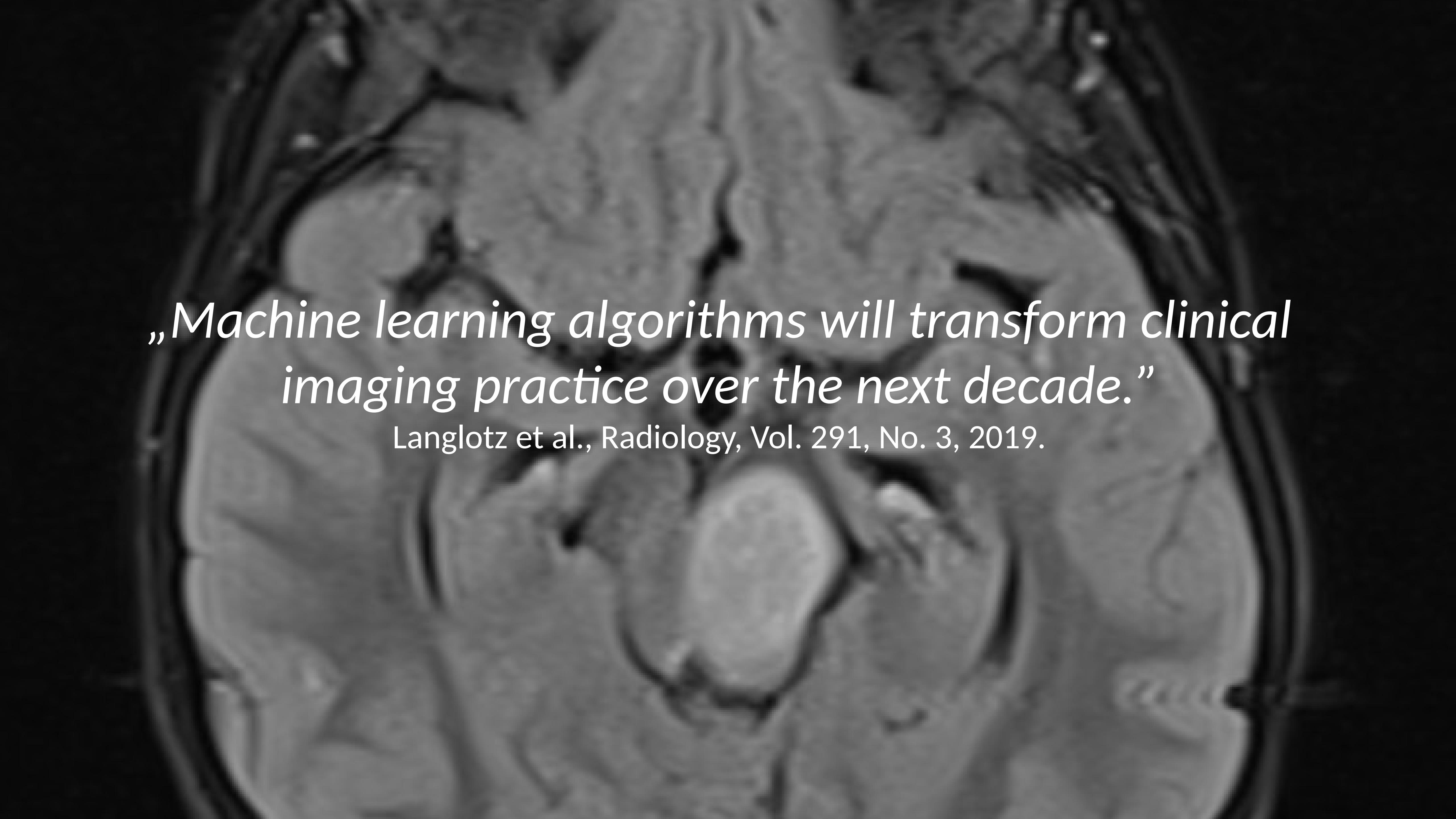
## Is the algorithm „ready”?



	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5	Reader 6	Reader 7	Reader 8	Reader 9	Reader 10	Reader 11	Reader 12
Reader 1	1.000	0.706	0.452	0.735	0.588	0.594	0.158	0.738	0.540	0.593	0.578	0.566
Reader 2	0.706	1.000	0.418	0.510	0.648	0.393	0.207	0.680	0.403	0.321	0.447	0.430
Reader 3	0.452	0.418	1.000	0.506	0.426	0.370	0.292	0.514	0.593	0.546	0.315	0.390
Reader 4	0.735	0.510	0.506	1.000	0.633	0.564	0.379	0.591	0.500	0.581	0.569	0.253
Reader 5	0.588	0.648	0.426	0.633	1.000	0.611	0.430	0.584	0.622	0.514	0.450	0.315
Reader 6	0.594	0.393	0.370	0.564	0.611	1.000	0.506	0.524	0.690	0.611	0.547	0.611
Reader 7	0.158	0.207	0.292	0.379	0.430	0.506	1.000	0.344	0.474	0.167	0.638	0.380
Reader 8	0.738	0.680	0.514	0.591	0.584	0.524	0.344	1.000	0.552	0.406	0.511	0.518
Reader 9	0.540	0.403	0.593	0.500	0.622	0.690	0.474	0.552	1.000	0.614	0.529	0.500
Reader 10	0.593	0.321	0.546	0.581	0.514	0.611	0.167	0.406	0.614	1.000	0.396	0.336
Reader 11	0.578	0.447	0.315	0.569	0.450	0.547	0.638	0.511	0.529	0.396	1.000	0.552
Reader 12	0.566	0.430	0.390	0.253	0.315	0.611	0.380	0.518	0.500	0.336	0.552	1.000



MOS from the a) training set from BraTS and unseen clinical data (CT – 25 HGG i 25 LGG).

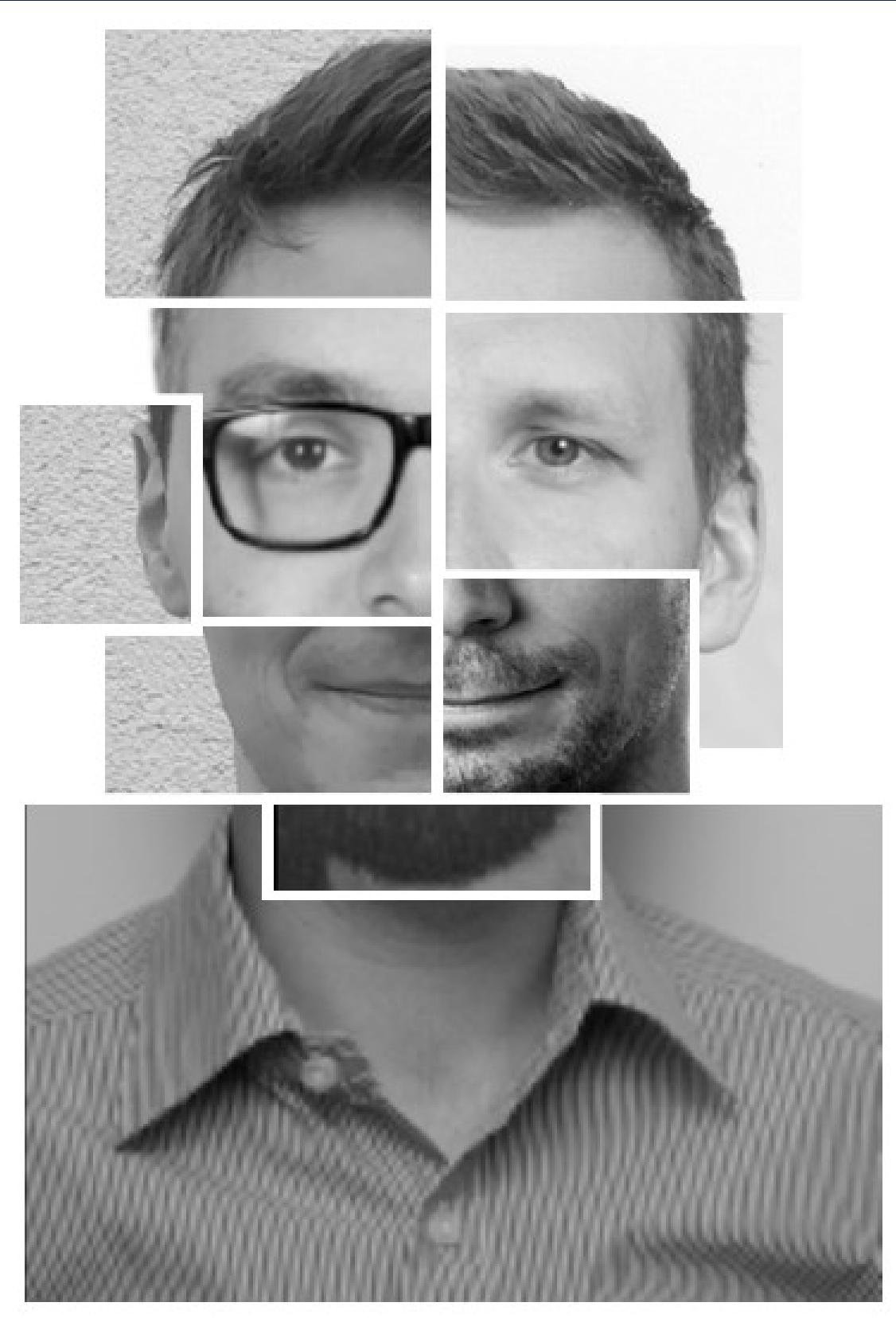


*„Machine learning algorithms will transform clinical imaging practice over the next decade.”*

Langlotz et al., Radiology, Vol. 291, No. 3, 2019.

# CAN AI MAKE US SEE BEYOND THE VISIBLE: TOWARD CE MARKED DEEP LEARNING SOFTWARE FOR MEDICAL IMAGE ANALYSIS

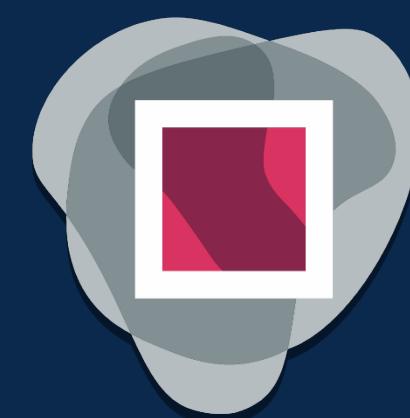
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Politechnika  
Śląska



**GRAYLIGHT**  
MEDICAL IMAGING SOFTWARE