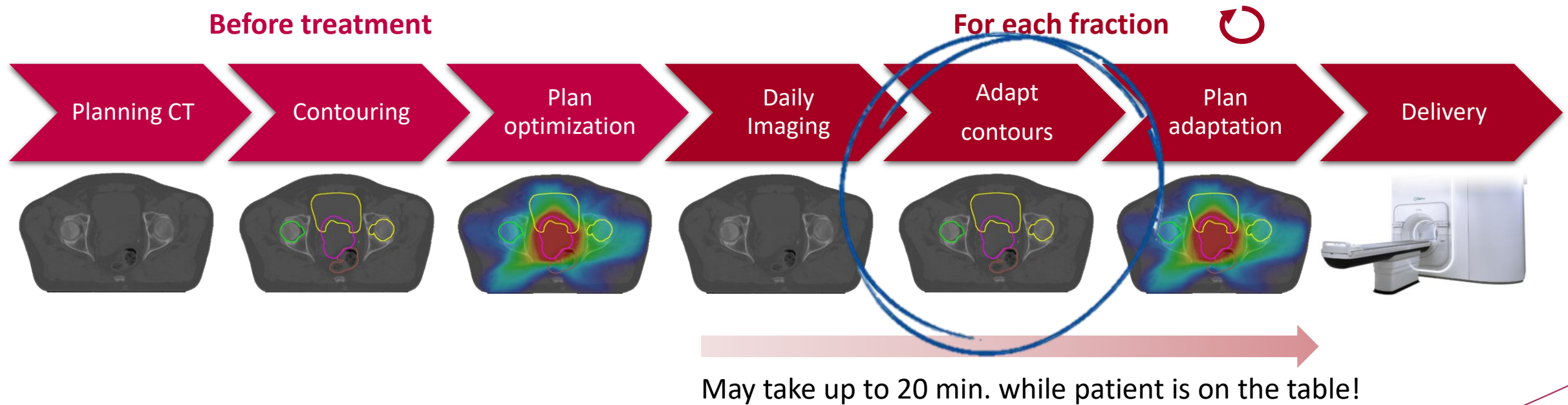


# Help! Mijn deep learning model werkt goed!

Tomas Janssen, Anton Mans, Rita Simões, Nicole Ferreira Silvério

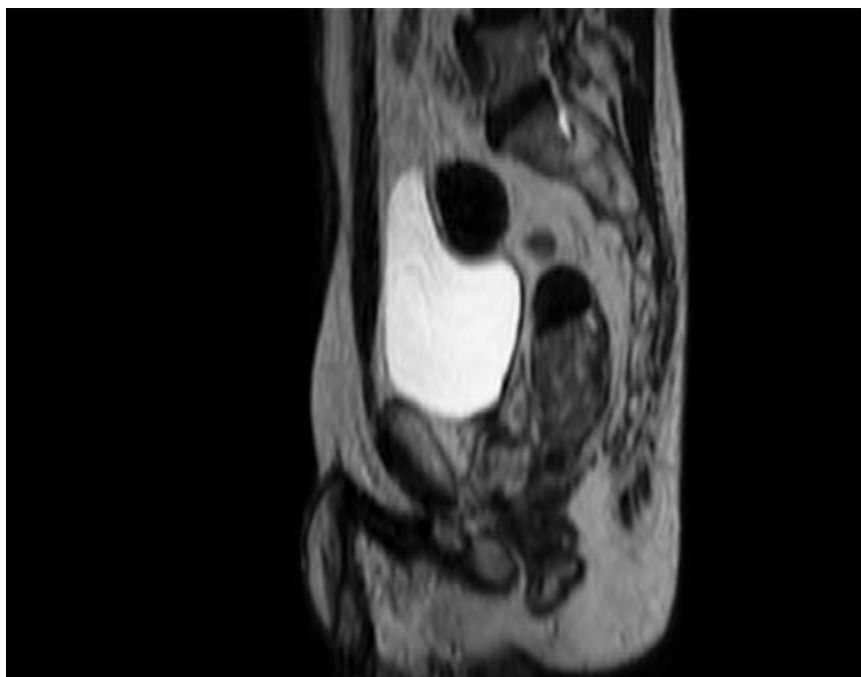
# Online ART voor rectum



MRL: Marge reductie: 15/10 mm  $\rightarrow$  7/5 mm  $\rightarrow$  30% reductie hoog dosis volume

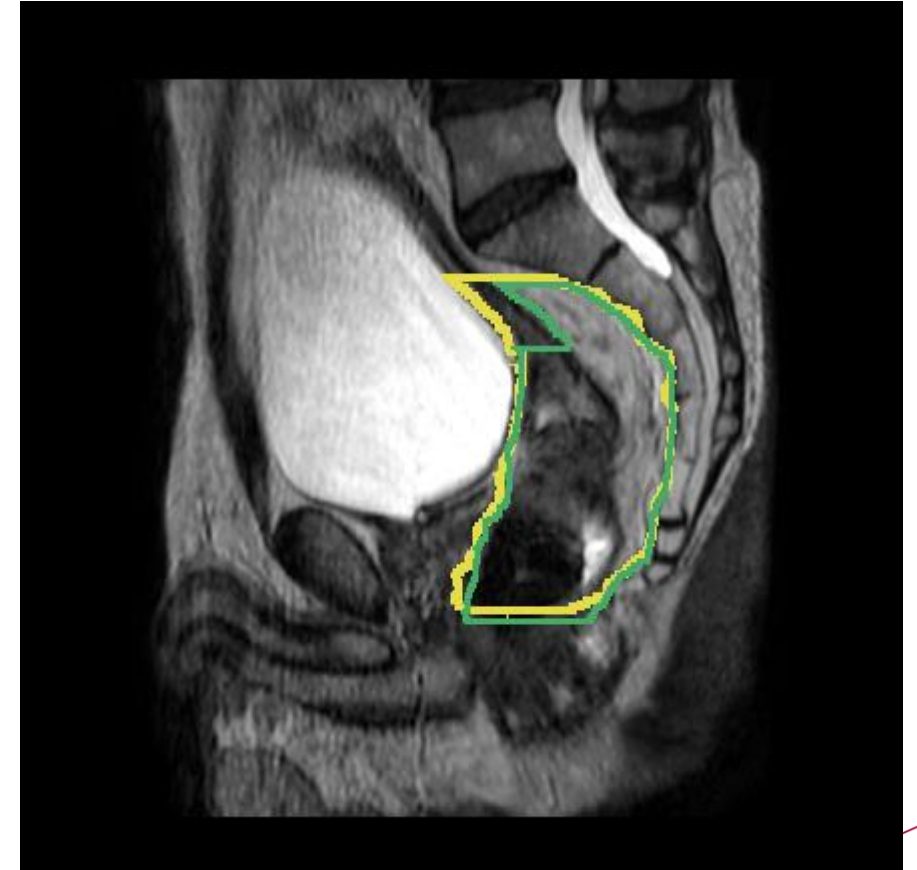
# Deep Learning (DL) autocontouring

## Segmentatie model



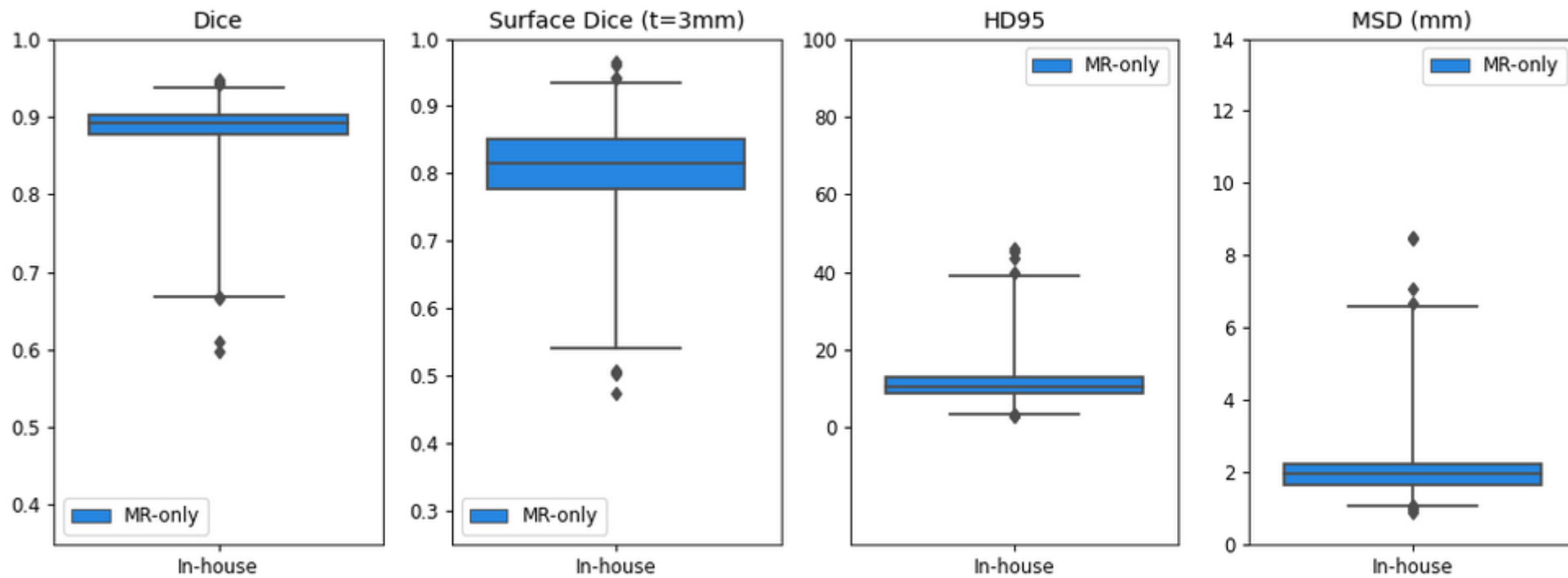
# Deep Learning (DL)

- nnUnet
- 30 patienten
- 5 fracties \* pre/post/during T2w scans
- → 483 scans
- Mesorectum offline ingetekend door experts om *golden standard* intekeningen te krijgen



# Deep Learning (DL)

## Resultaten



# What next?

Methods			DSC	ASD	HD	
#lab	Methods	Backbones	Epochs	Jaccard	Dice	Accuracy
basel	CDNN [31]	-	-	0.765	0.849	0.934
basel	DDN [15]	ResNet-18	600	0.765	0.866	0.939
basel	FrCN [1]	VGG16	200	0.771	0.871	0.940
basel	DCL-PSI [3]	ResNet-101	150	0.777	0.857	0.941
basel	SLSDeep [19]	ResNet-50	100	0.782	<b>0.878</b>	0.936
basel	Unet++ [33]	ResNet-34	30	0.775	0.858	0.938
	<i>TransFuse-S</i>	R34+DeiT-S	30	<b>0.795</b>	0.872	<b>0.944</b>
MTCL(c)			<b>0.7245</b>	<b>0.7570</b>	<b>1.1718</b>	<b>7.2111</b>

# of... is het goed genoeg voor klinische introductie?

1. Wanneer is het goed genoeg?
2. Klinische introductie; hoe testen en valideren?

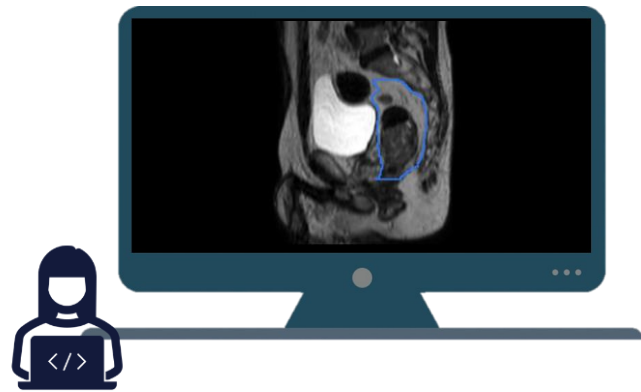
# Wanneer is het goed genoeg?

1. Kwantitatieve beoordeling + vergelijking met IOV
2. Expert observations en correcties → meten winst en opnieuw kwantitatief beoordelen
3. Evaluatie klinische impact: impact op target coverage (post treatment scan)



# 1. Kwantitatieve vergelijking met IOV

DICE



0.89 ↓



0.91

## 2. Expert observations and corrections



7m34s

3m08s

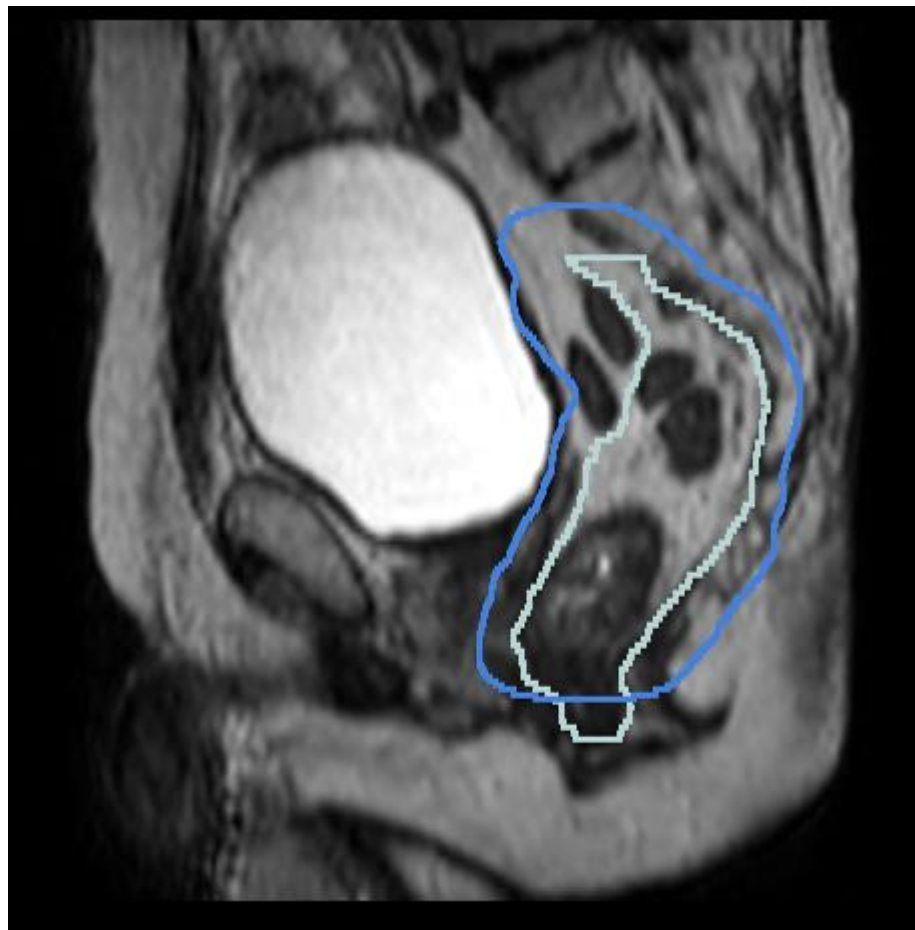


prediction

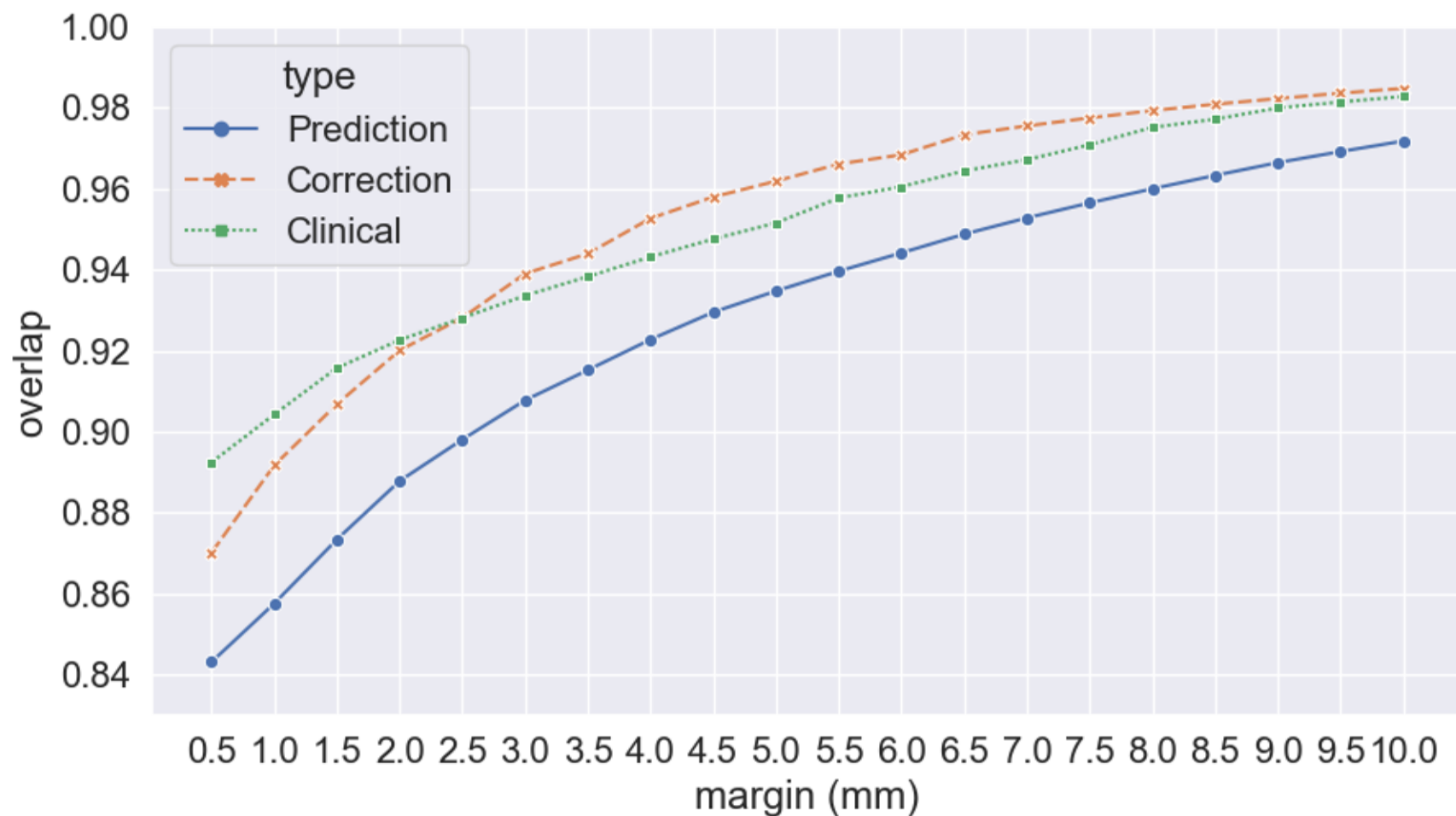
correction



### 3. Post treatment target coverage



### 3. Post treatment target coverage

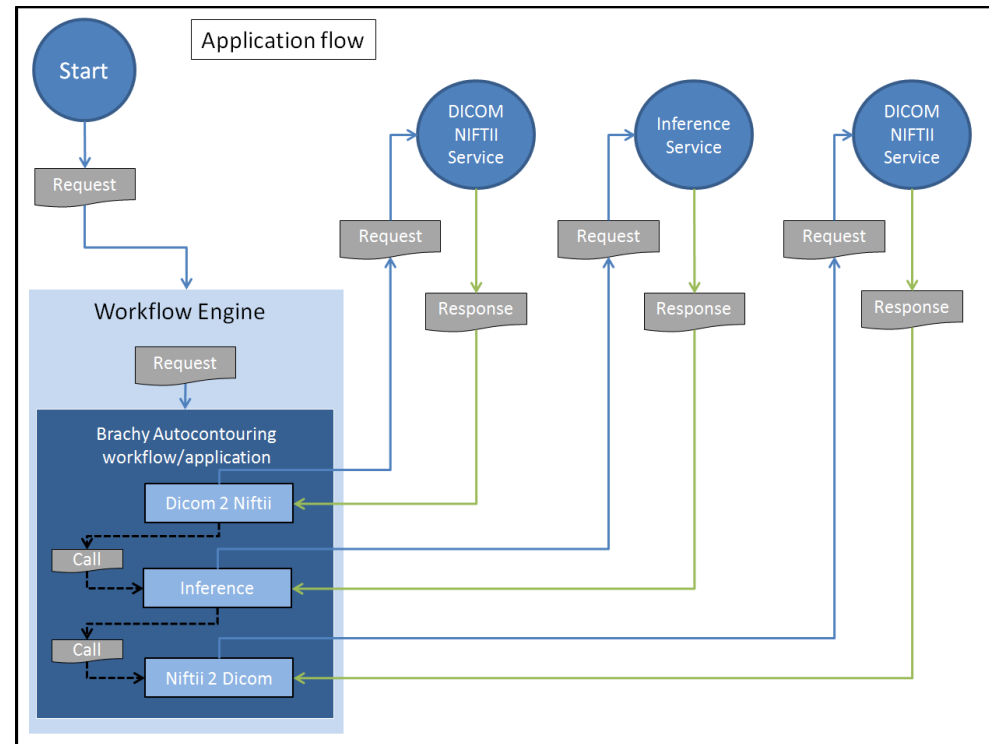
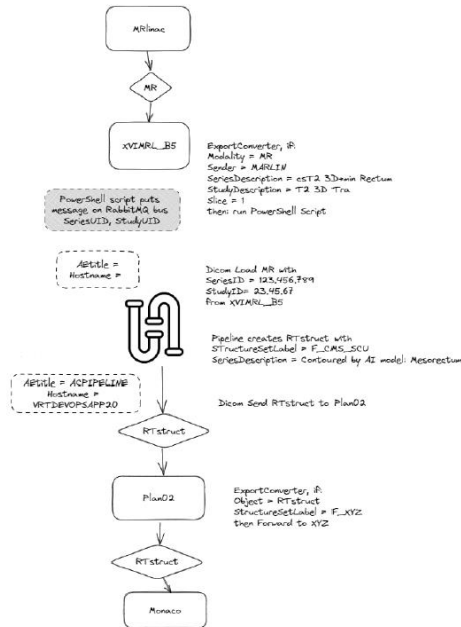




# Klinische introductie: hoe aan te pakken?

## DevOps (*Development + Operations*) team

- Multidisciplinary: clinical programmers, sys-admin, clinical scientists, medical physicist
- Stakeholders: o.a. gebruikers, research
- Agile/scrum methodology



# Klinische vrijgave: MDR → IMDD

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# Klinische vrijgave: IMDD – MDR classification



TOPIC	YES / NO
1. Is the product 'software' according to the definition in guidance MDCG-2019-11? <i>"Software" is defined as a set of instructions that processes input data and creates output data.</i>	YES
2. Is the software an 'MDR Annex XVI device', an 'Accessory' for a medical device according to Art. 2(2) of the MDR or IVDR or 'software driving or influencing the use of a (hardware) medical device'?	NO
3. Is the software performing an action on data different from storage, archival, communication or simple search? <i>If the software does perform an action on data, or performs an action beyond storage, archival, communication, simple search, lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) then it may be a medical device software.</i>	YES
4. Is the action for the benefit of individual patients? <i>Examples of software which are not considered as being for the benefit of individual patients are those which are intended only to aggregate population data, provide generic diagnostic or treatment pathways (not directed to individual patients), scientific literature, medical atlases, models and templates as well as software intended only for epidemiological studies or registers.</i>	YES
5. Is the software a Medical Device Software (MDSW) according to the definition in guidance MDCG-2019-11? <i>Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the MDR or IVDR, regardless of whether the software is independent or driving or influencing the use of a device</i>	YES
Given the above, is the software covered by the MDR?  1. Yes, 2. Yes → Covered by MDR 1. Yes, 2. No, 3,4,5. Yes → Covered by MDR  All other cases: not covered by the MDR.	YES

FUNCTIONALITY	BRIEF DESCRIPTION	CLASS
AI based autocontouring of the mesorectum from MR data	Although the results of the software are reviewed by trained users, the contours are used in radiotherapy treatment planning. This can be regarded as "is used to take decisions with diagnosis or therapeutic purposes" and therefore class IIa	IIa  (approved Fysica Overleg 05-12-2023)

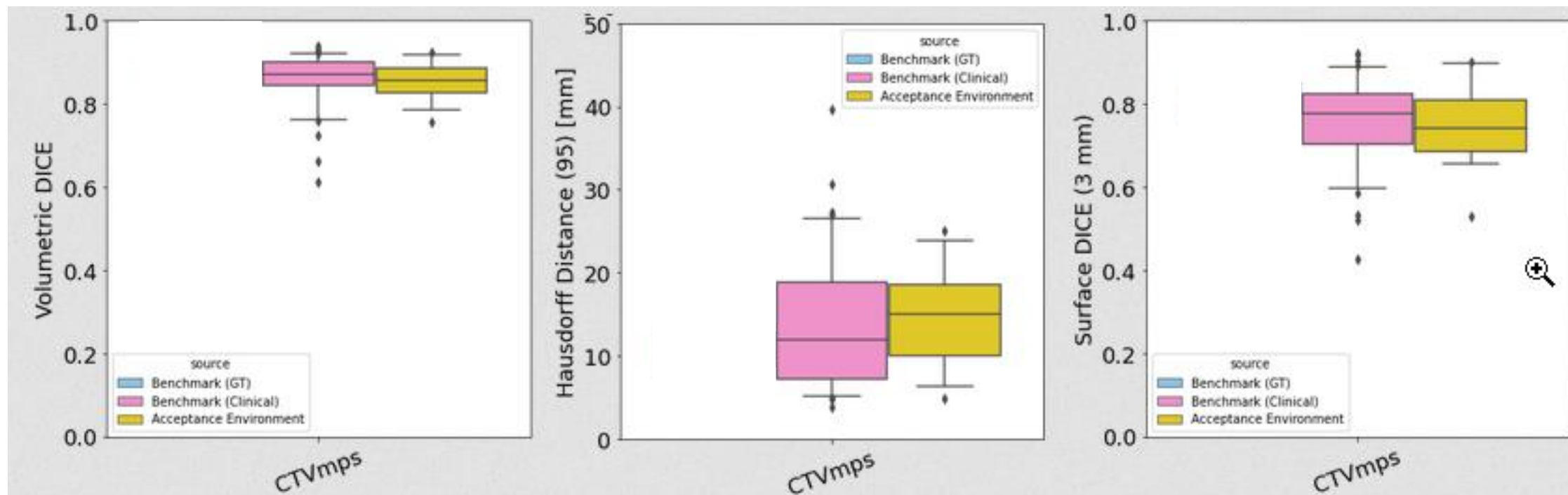


# Klinische vrijgave: IMDD – model fact sheet

- Summary
- Mechanism
  - Target population
  - Output
  - Input data source
  - Input data type
  - Training data
  - Model type
- Validation and performance
  - Dice etc.
- Uses and directions
  - Benefits
  - Target population and intended use case
  - Safety
  - ...
- Warnings
  - Risks
  - Inappropriate settings
  - Clinical rationale
  - Inappropriate decision support
  - Generalizability
  - Descontinue use if...

# Klinische introductie : validatie test A

**Description:** Compare the distributions of clinical pipeline on new clinical data with the distributions during model development.



# Klinische introductie : validatie tests

Test: run 5 identical cases in clinical and development pipeline

Result:

difference in output ranged from 9 – 24 voxels on a total of ~ 13 million

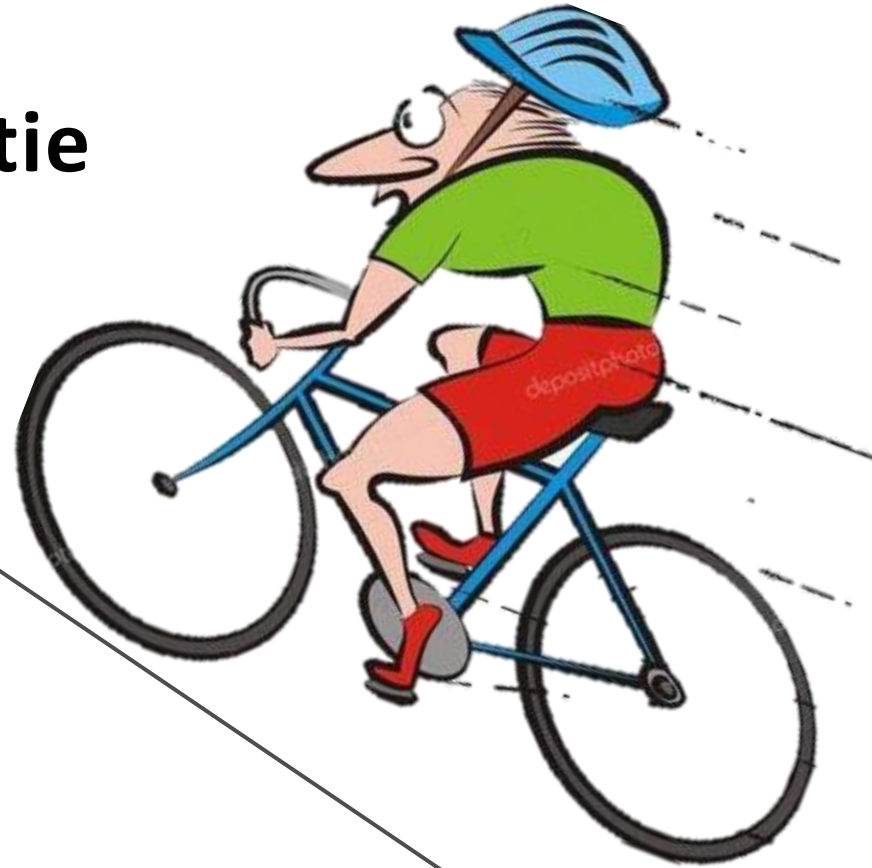
Test: Push 120 cases to the node and monitor performance

Result:

- Average run time 51 sec
- All runs successful

**Klinische introductie**

**Online Monaco**



**Huidige workflow**

**MR-scan**

**Klinische introductie**

**Online Monaco**

**Structuren op  
scan zetten**

**Offline Monaco**

**DL workflow**

**Matchen**

**MR-scan**



# Klinische introductie: 1 februari 2024

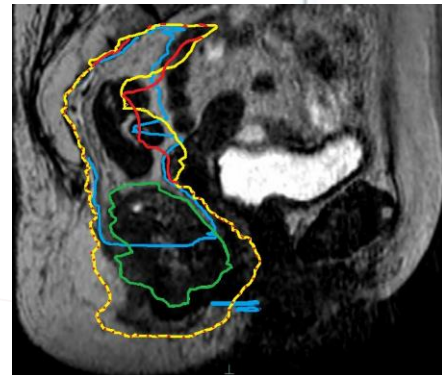
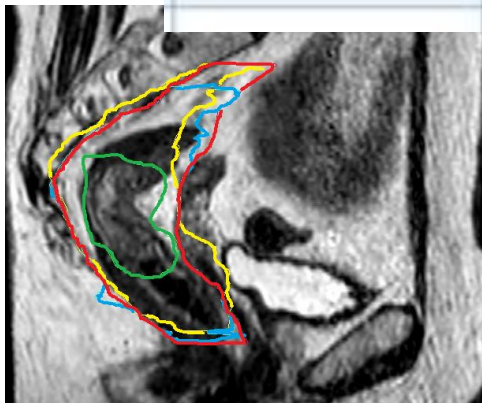
## Vragen

Ti

Hoe

Hoe goed

	C	D	E	F	G
	Datum	Gebruikte contour	Score van de autocontour	Tijd nodig voor correcties	
	31-01-2024	Autocontour	1 - kleine aanpassingen, weinig impact	06:44	F
	01-02-2024	Autocontour	1 - kleine aanpassingen, weinig impact	04:50	
1	14-02-2024	Rigid registration	3 - contour onbruikbaar, weggooien	05:30	g voor correcties
2	13-03-2024	Rigid registration	2 - mix van grote en kleine aanpassingen		
3					
4	14-03-2024	Autocontour	1 - kleine aanpassingen, weinig impact	06:30	
5	15-03-2024	Autocontour	1 - kleine aanpassingen, weinig impact	?	
6	28-03-2024	Rigid registration	2 - mix van grote en kleine aanpassingen		
7					
8					



**Groen** = GTV  
**Geel** = Origineel  
**Blauw** = Autocontour  
**Rood** = Aangepast door laborant voor plan

# Samenvatting : vragen voor klinische introductie AI?

- Wanneer is het goed genoeg?
- Wat levert het op?
- Team voor introductie?
- Architectuur?
- MDR?
- Validatie tests?
- Workflow?
- Monitoring na klinische vrijgave?

# Dank

- Rita Simoes
- Nicole Ferreira Silverio
- Anton Mans
- Lisa Wiersema
- Sanne Conijn
- Corrie Marijnen
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