



# Machine learning in medical software done right

How to do machine learning and continuous integration of medical software

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3shape 

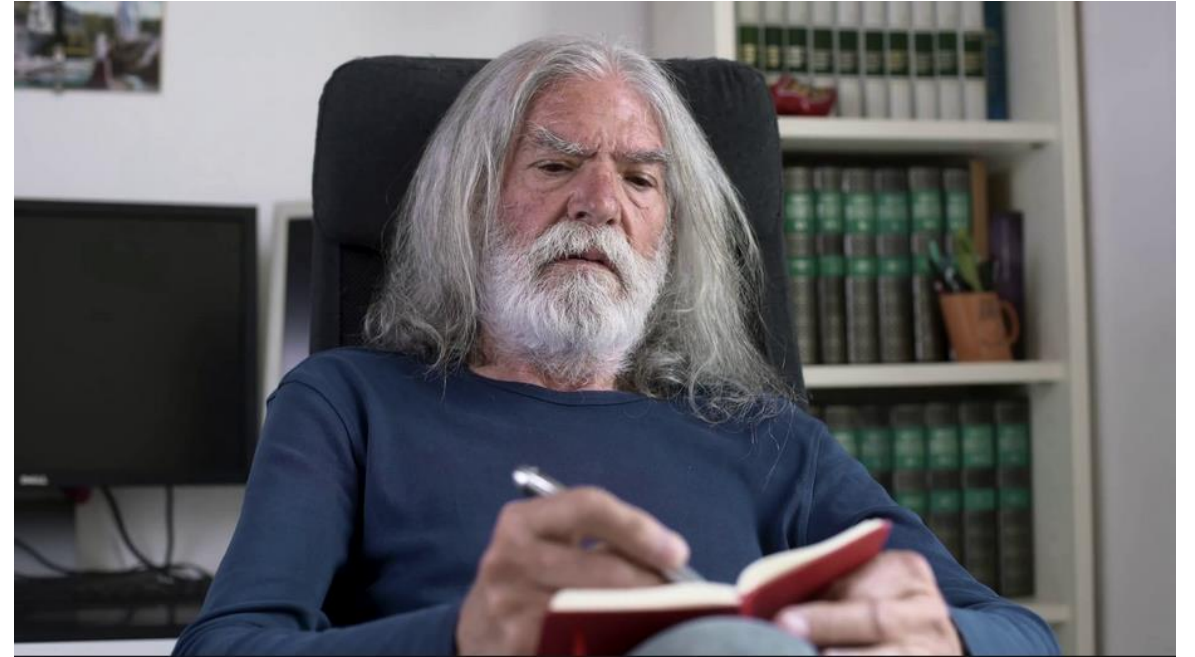


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# Agenda

- About me, 3Shape and the data that we are working with
- Motivation, how to enjoy making medical software
- Machine learning and medical software, what's the big deal
- What to do about it
- Medical software and Agile
- Our pipeline and results



"Old man writes the agenda" Stock photo

# About the speaker and 3Shape

## Whoami:

- Team lead of 8 experts in machine learning and algorithm development
- 5+ years experience in making medical software (Oticon R&D, 3Shape R&D)
- Ph.D. in math, signal processing, mathematical modelling of auditory perception
- Working with orthodontic software in 3Shape

## Whoarewe:

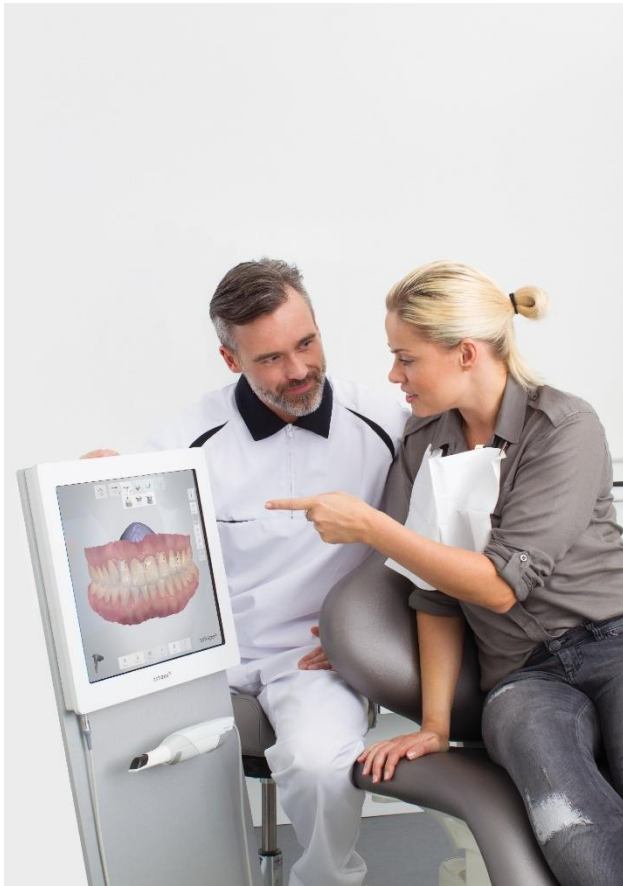
- 3Shape A/S, Danish medical device company
- 1500+ employees, HQ in Copenhagen (500+ employees, 30% in R&D)
- Visible light and x-ray scanners for teeth
- Software for workflows in dentistry
- Small scanner section for hearing aids and high-end earphones



3shape 

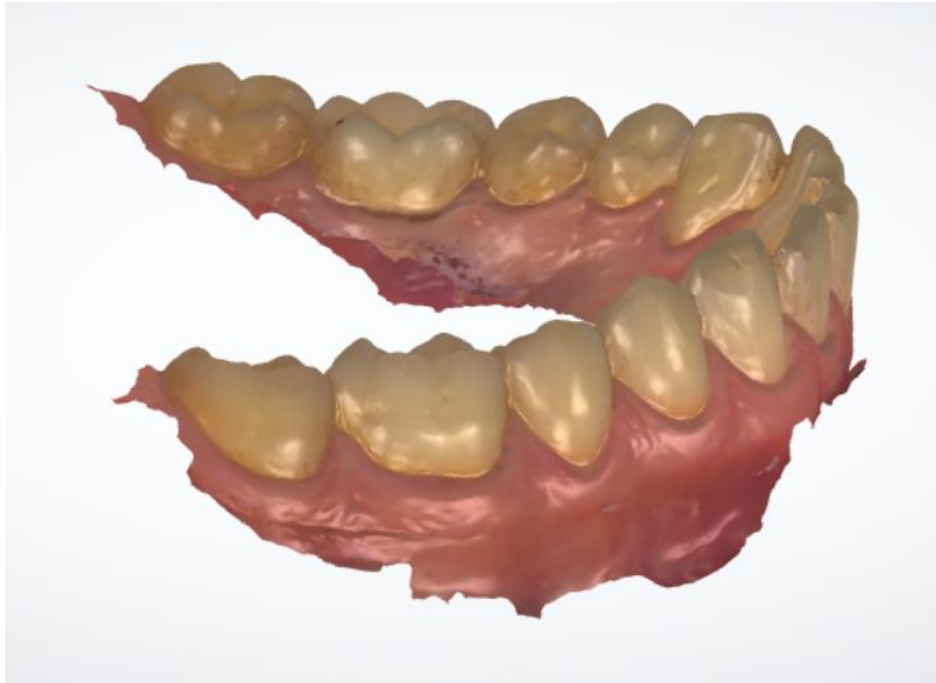
# Data

Main data source: Output from the Trios Interoral Scanner - 2D surface scans in 3D space

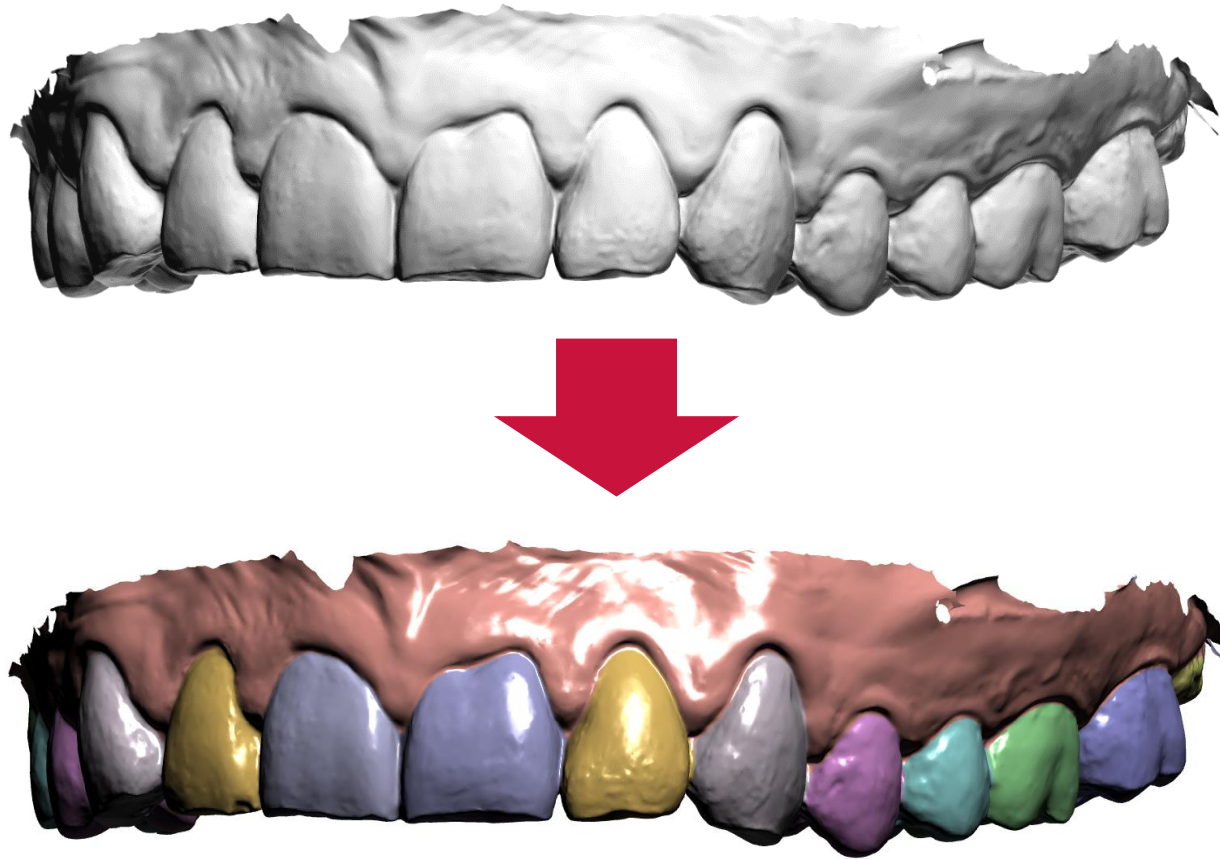


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An example machine learning application: Segment a jaw scan into gingiva (gum) and individual teeth



# The challenge of developing medical software

When developing medical software, you get to play with FDA and EU

Why? Because it matters what you do! You can cure people of diseases and physical problems or improve their quality of life



Matters!



Doesn't matter



Medical Device Regulation



# Do Not Fear the FDA and EU

Normal reaction: FDA and EU just adds bureaucracy

Remember, we have the same goals!

1. Effective software, it should work
2. Safe software, it should not harm people
3. Fast delivery, people shouldn't wait years for new treatments and technological advances

Make these goals your own, then you are compliant by default!

(and your devs do not need to understand the guy to the right)

## Quality Nightmares

by MasterControl

"The FDA has issued a 483 for an MDR with a weak FMEA. When tracing the DHF, it seems the 510(k) did not reference the whole DMR. We have opened a CAPA to review all the NPD SOPs in our QMS to make sure this doesn't happen again."



How you know when you've been assimilated by the Quality Department.

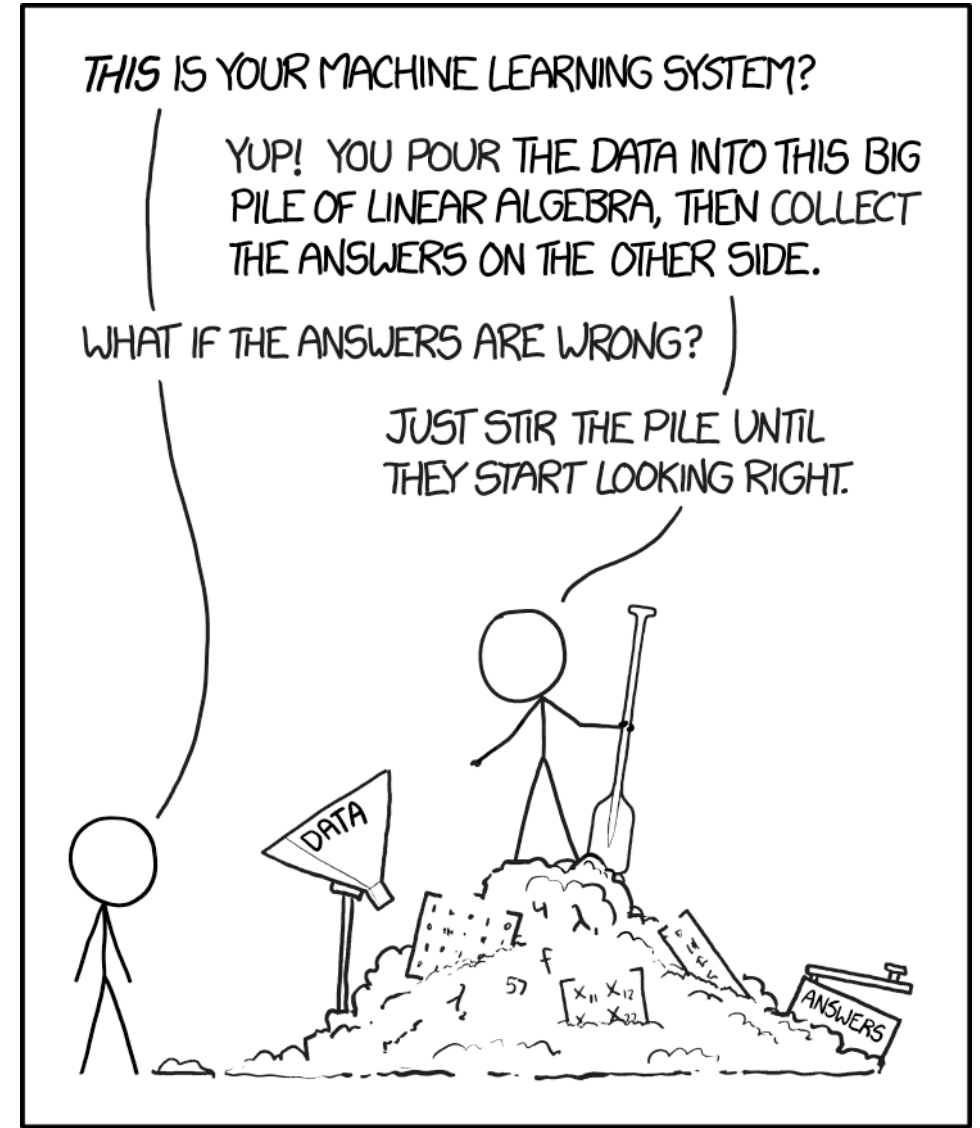
# So, what's the big deal

Machine learning poses a new challenge for medical regulation:

- It's essentially a black box. Even more so with deep learning. Trust = 0
- Traditional verification is done through inspection and analysis, logic reasoning

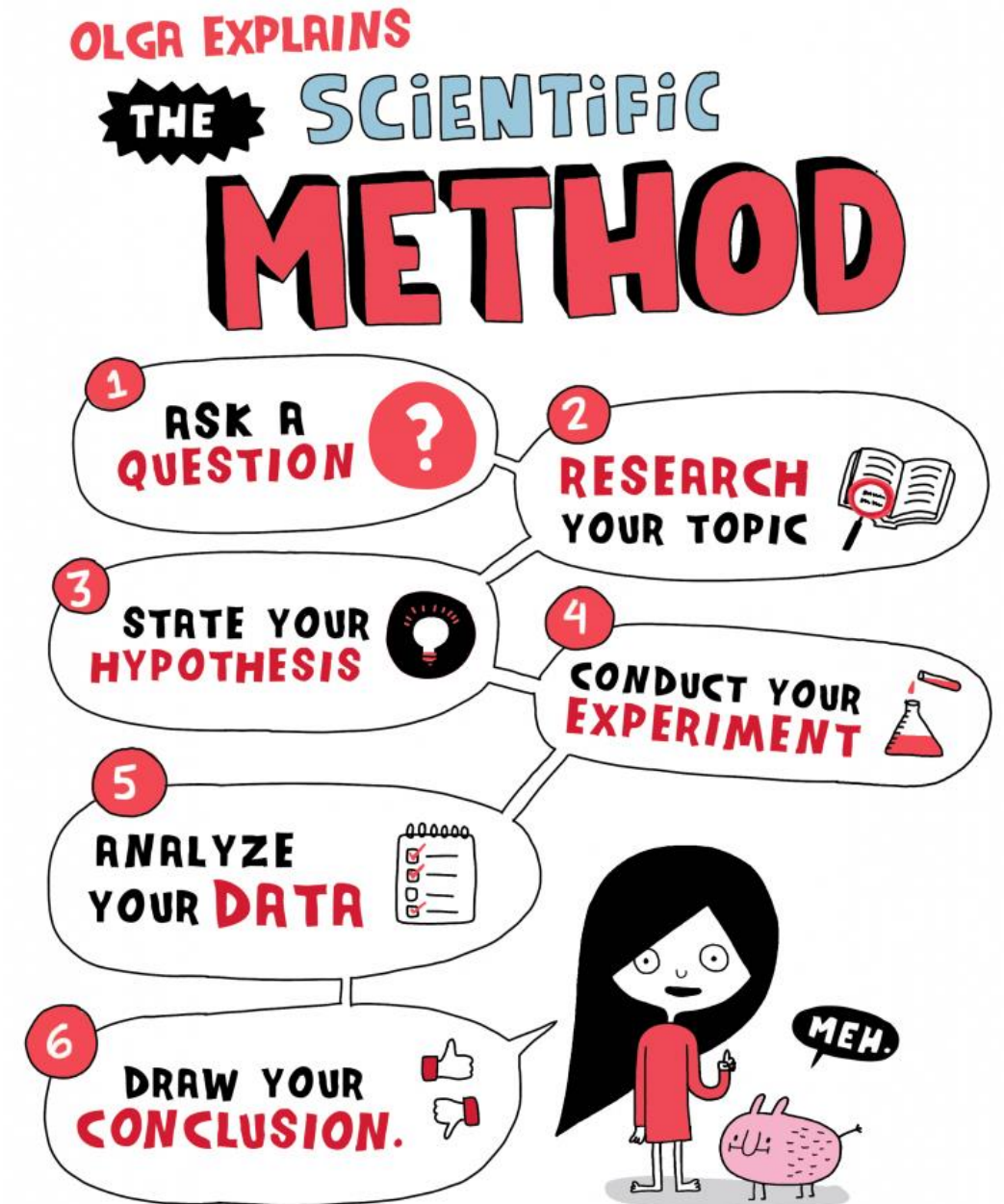
What can we do about this:

1. Use the scientific method
2. Restrict your input to the black box
3. Restrain the output from the black box



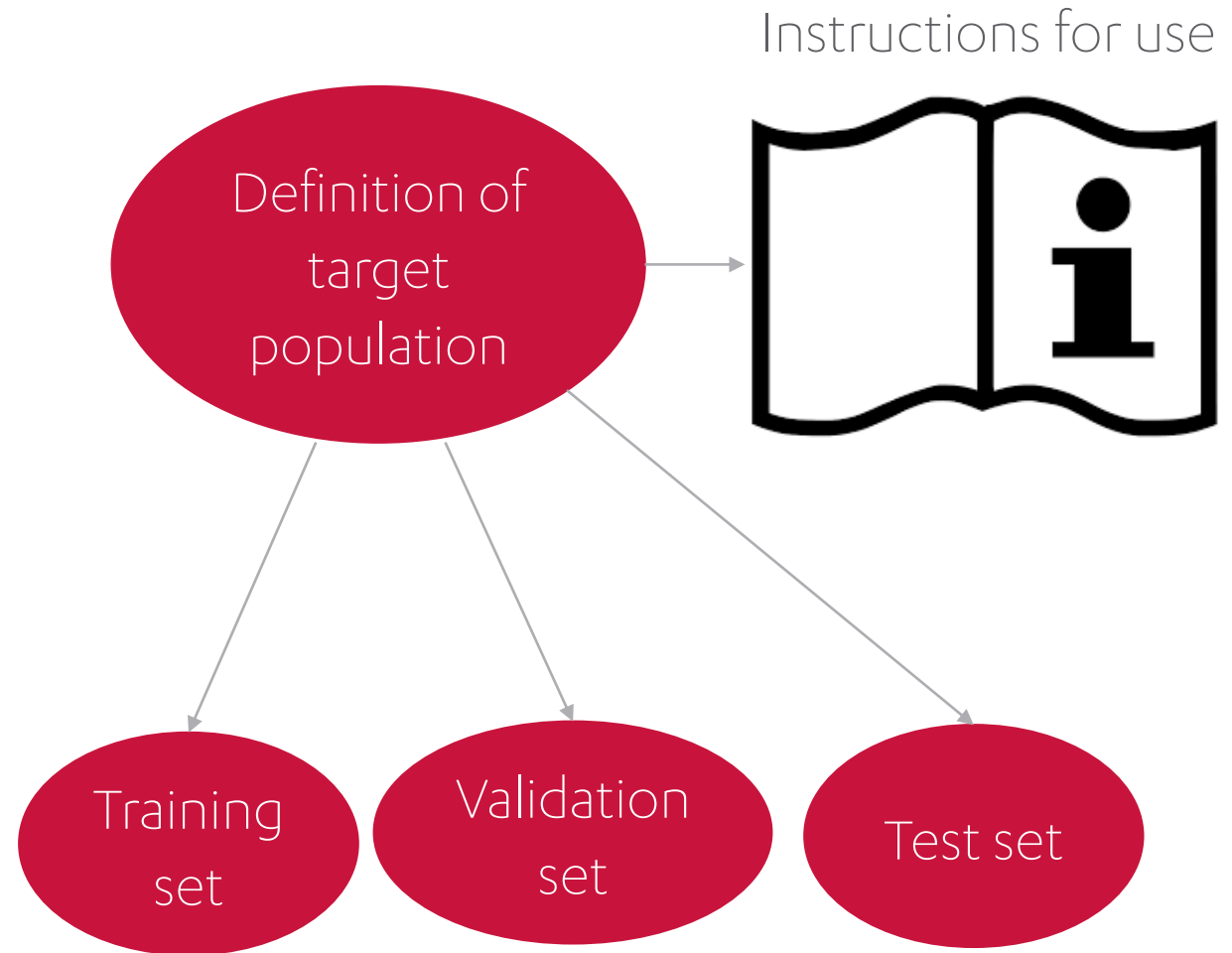
# The scientific method

- Actually practise what you learned in school and university
- If you fool yourself, you might fool the company and the medical authorities, but you will not fool the world-wide deployment
- Fixing the bug beforehand is much cheaper than dealing with the fallout of an incident in EU / US



# Restrict the input

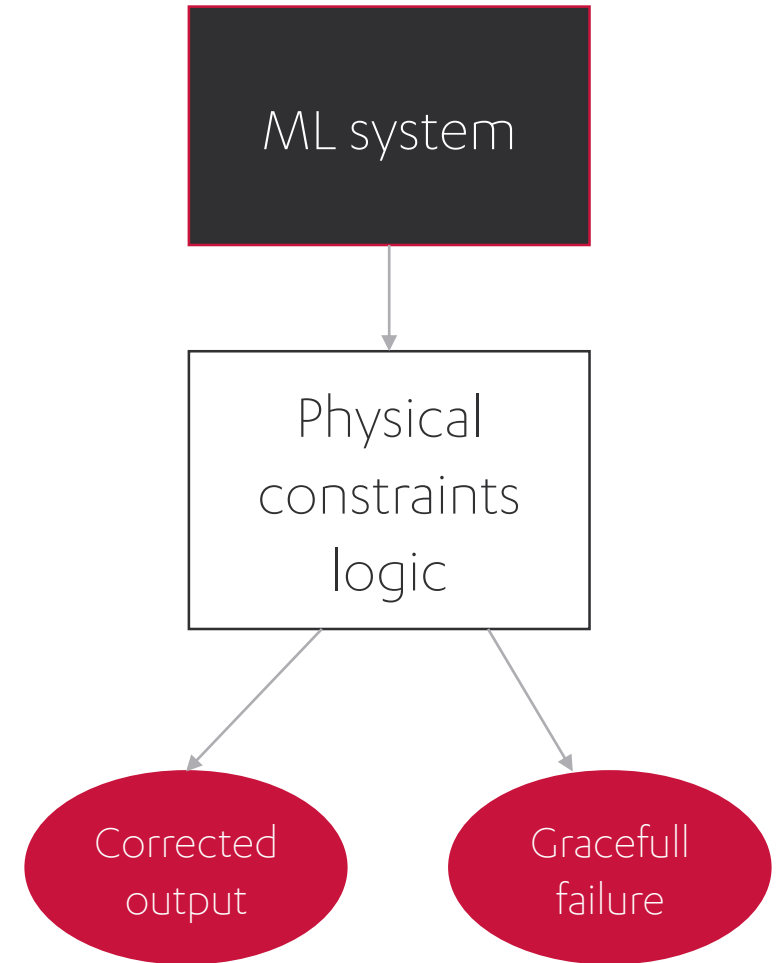
- Define a “target population” to remove any elephants in the room
- Describe it in the IFU: “Instructions For Use”
- Choose your datasets from this population
- Look out for the residual risks:
  - Your test set does not follow the same distribution as the actual usage of your system
  - The IFU is not followed



# Restrain the output

You know your domain, put in logic to control edge cases

- If you know something is physically impossible, detect it and act on it, i.e. a tooth is too large:
  - Re-evaluate the output or
  - Fail gracefully.
- About failing gracefully
  - The AI system is always an assistant to the doctor or technician, so it is a viable option
  - A graceful failure just means a delay in treatment time, an uncontrolled failure may lead to patient harm





# An example problem: Weird edge case patch

Increate performance  
or increase trust?



# Study human performance

You will never get 100% performance. Deal with it:

- Determine what performance level is safe, what level is effective?
- Measure the performance of humans on the same task



# Make it fun for the developers

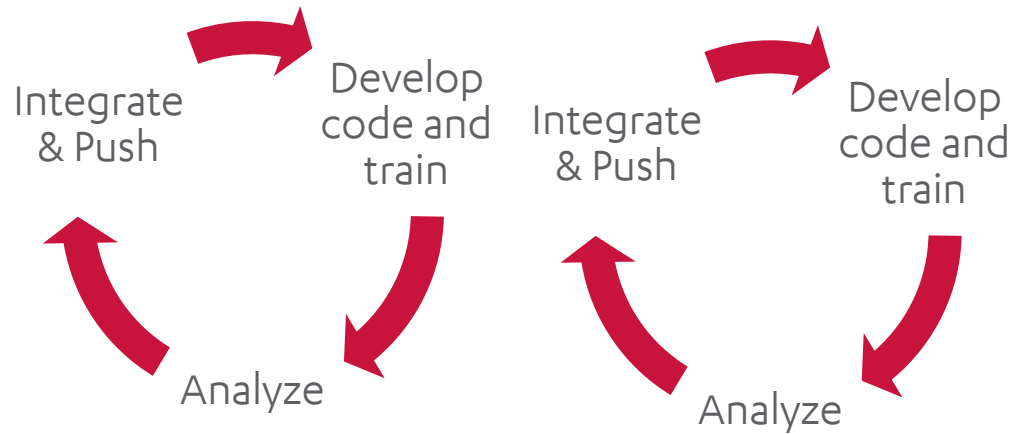
How to get developers to write documentation?

- Code it in Python using Jupyter notebooks
- Create the notebooks as part of the development process to document performance and experiments
- Use a modern documentation system like Atlassian Confluence for documentation of experiments, architecture overview etc.



# Do it the Agile way, also the documentation

- The usual way (wrong)



Trust increases only in documentation phase

Reverse engineer your own code and document it

- The right way



Trust is always high

Finalize doc.

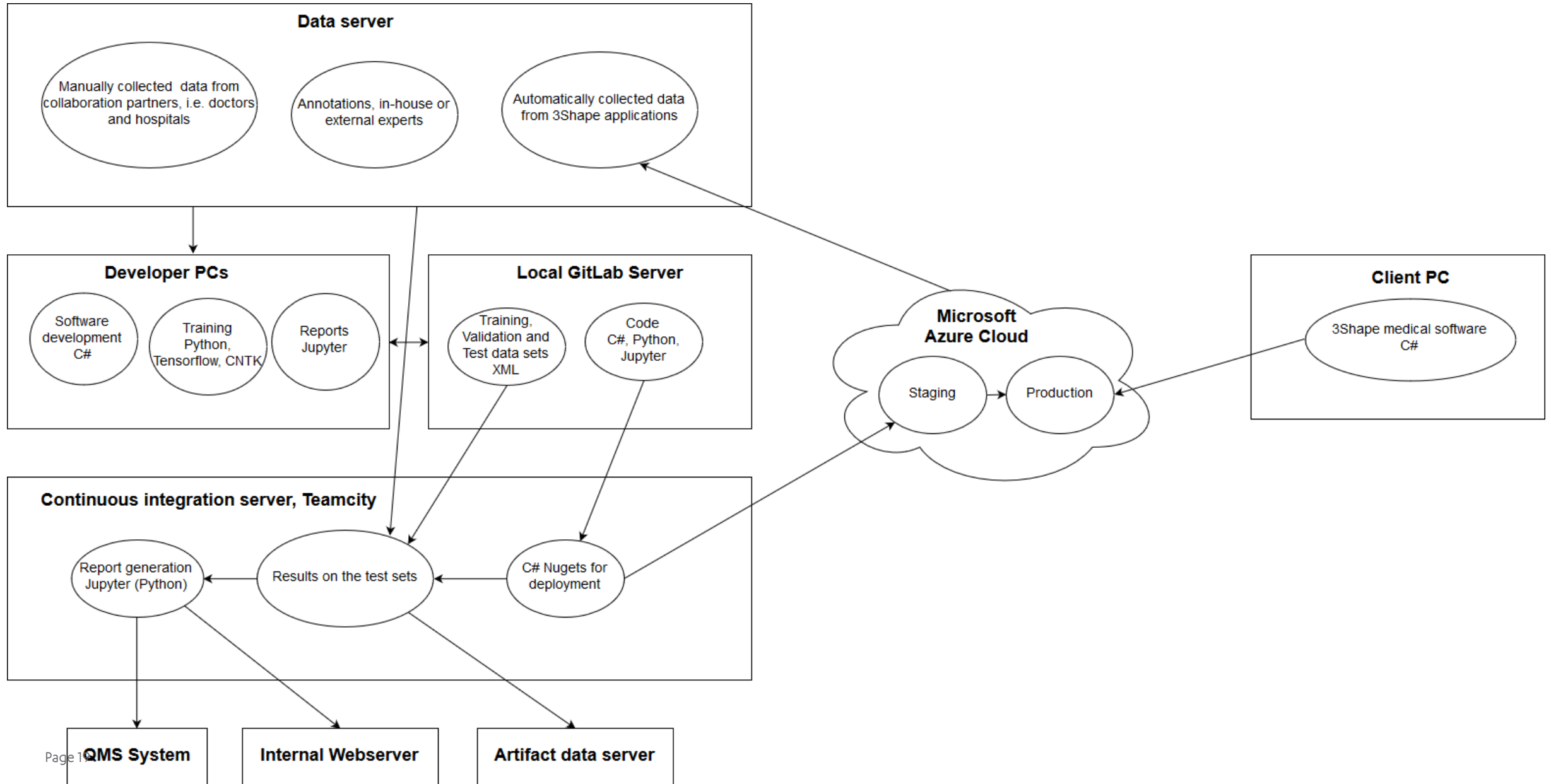
# Differences when working with machine learning and medical software



Medical device	Snapchat
Restricted input	Unrestricted input
Trust over Accuracy over Speed	Speed over Accuracy over Trust
#failgracefully	#failfast
Clinical trials	Live A/B testing, Chaos engineering
Permantly improve quality of life	Just for fun



# Our pipeline



# Results

- When training is done
  - Documentation is generated nightly
  - Reports are inspected and signed
  - Project manager gives "go" for release
  - Nugets are uploaded to the cloud, deployed software on client PCs automatically starts using the cloud system
- Result: Total release process (for a small update): 1-2 days

Thank you very much for  
attending this talk

Please drop by our booth

Questions?





*Please*

**Remember to  
rate this session**

*Thank you!*

