

Validation Plan

Intended Use case:

The intended use case of the model is to classify Alzheimer patient scans for the neurodegenerative condition by quantifying hippocampal volume.

Validation:

FDA lists planning, verification, testing, traceability, configuration management, and many other aspects to validate software. The validation process is described using the following flowchart in the FDA process validation document:

<http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf>

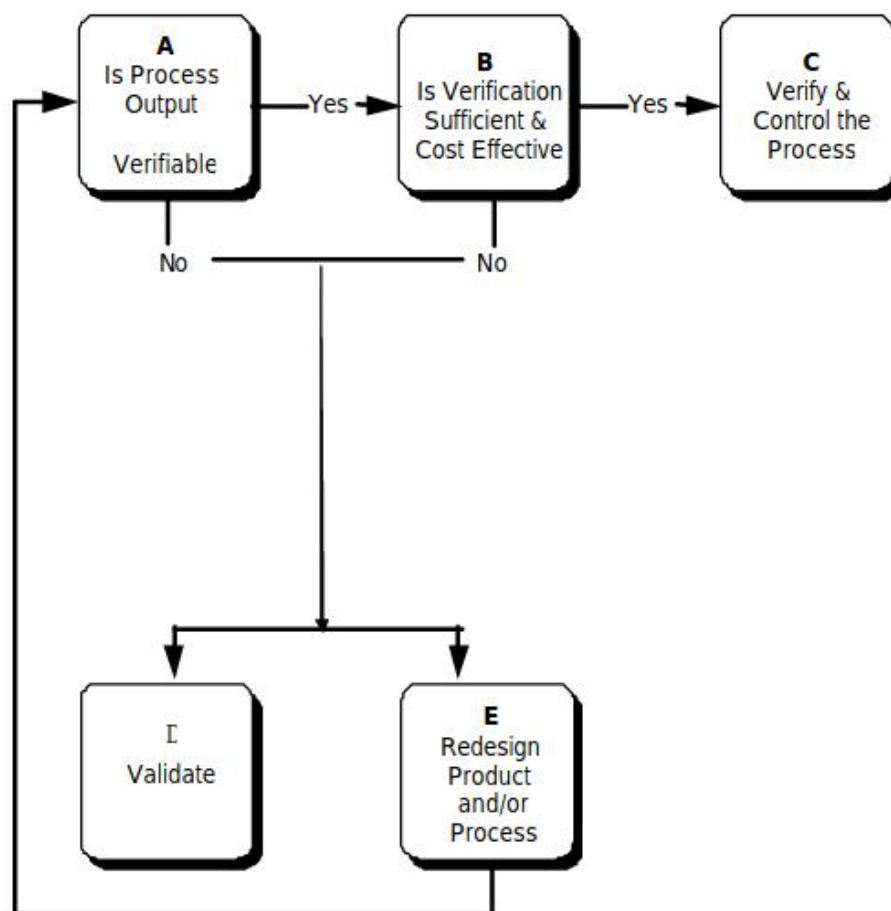


Figure 1: Process validation decision tree

This would include data from the following categories:

(a) personal information: age, gender, previous neurological disease history, occupation to check for causal factors like stress.

(b) demographic/geographic information.

(c) imaging details: types of radiography recommended/used, view positions, body part scanned

(d) Other: we could further include prevalence of disease of interest to understand the condition in more localised and global contexts, and comorbidities in the population.

Obtaining ground truths

The impact of segmentation annotation quality is as discussed here:

<https://arxiv.org/pdf/1901.00001.pdf>

There are multiple methods to obtain ground truths such as:

(a) Manual data annotation is definitely a tedious task but crowdsourcing using platforms such as AMT can be considered where the annotators will be medical professionals. 20 annotators will have to look at approximately 13 images each.

<https://medium.com/thelaunchpad/spinning-up-an-annotation-team-c74c6765531b> highlights best practises and other details. This however requires

(i) ensuring privacy of patients and (ii) implementation of quality-control mechanisms

(b) Automated tools exist for auto-annotations like:

Scale(<https://scale.com/image/segmentation>),

playment(<https://playment.io/semantic-segmentation-tool/>)

(c) Annotated methods can include other ML methods as discussed here:

<http://vision.soic.indiana.edu/papers/segmentation2019iros.pdf>

Other methods are highlighted here:

<https://software.intel.com/content/www/us/en/develop/articles/hands-on-ai-part-9-data-annotation-techniques.html>

SECTION 7 - Conclusion:

Medical imaging AI is a very rapidly growing space, and the potential of the field is staggering. Information flow between data scientists and clinicians is key to unlocking the potential of medical AI and helping clinicians reduce the amount of mundane work, become more precise, efficient, and less stressed. The potential of such technology to work alongside medical staff to help better treatment as well as reduced burden on healthcare highlights the need for such automated systems.