

# FDA Validation Plan of HIPPOAI

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## **Intended use**

The intended use of the algorithm is to predict anterior and posterior hippocampus volumes of the brain

## **How training data was collected**

The training data was collected from T2 MRI scans of the brain, with cropped volumes of the region of the brain where Hippocampus resides.

## **How training data was labelled**

The data was manually labelled by radiologists

## **How the training performance of the algorithm was measured**

The training performance of the model was primarily measured using the Dice score and also using the Jaccard Index

## **How real world performance going to be estimated**

To estimate real world performance, we will create a validation dataset of images each labelled by radiologists as the gold standard.

## **The algorithm performance in real world**

The model will perform well on clearly labelled data, for complete volumes of the hippocampus region of the brain. It will not perform well on data from other types of imaging modalities, and images of the brain not cropped around the hippocampus.