VALIDATION PLAN

Alzheimer's disease is a progressive disorder that causes brain cells to waste away (degenerate) and die. Alzheimer's disease is the most common cause of dementia — a continuous decline in thinking, behavioral and social skills that disrupts a person's ability to function independently.

Benefits of validation:

- Thorough understanding of a process
- Improves product quality and reliability
- FDA Perspective: Large portions of field actions and inspection deficiencies could have been prevented if processes were properly validated.

We can follow a decision tree to decide on whether a process needs to be validated. The process under consideration in this model is the simplest possible - many processes may be large and/or a complex set of sub-processes.

Where the results of a process cannot be fully verified by subsequent inspection and test, and that process influences critical attributes of a product or process, then the process should be validated with a high degree of assurance and approved according to established procedures.

The validation versus verification decision can also be based on organizational policy. It may be an approach of the organization to validate change where not strictly necessary in order to facilitate improved process understanding, or to facilitate reductions in future levels of in-process testing. For example, the results of a process may be fully verifiable via subsequent testing, however, organizational policy may be to move away from in-process and final testing towards high stability, low variability processes, with minimized levels of inspection and testing. In this approach, there will be a continuous push for higher levels of validation as a means of reducing future operating costs and variability reduction.

Accuracy assessment workflow:

Ground truth can be collected in the field; however, this is time consuming and expensive. Ground truth data can also be derived from interpreting high-resolution imagery, existing classified imagery, or GIS data layers.The most common way to assess the accuracy of a classified map is to create a set of random points from the ground truth data and compare that to the classified data in a confusion matrix. Although this is a two-step process, you may need to compare the results of different classification methods or training sites, or you may not have ground truth data and are relying on the same imagery that you used to create the classification.

To accommodate these other workflows, this process uses three geoprocessing tools: Create Accuracy Assessment Points, Update Accuracy Assessment Points, and Compute Confusion Matrix. The most common workflow is when you have classified imagery and you want to compare it to ground truth data. The first set of steps creates a set of random points.

Conclusion:

The dust is now beginning to settle on the idea of AI in imaging—an idea that once took the industry by storm. The questions being asked by radiologists have now changed from "will it replace me?" to "how can it help me?"—and rightly so. AI continues to make significant progress in the field of diagnostic imaging, as can be gauged using the recently concluded Radiological Society of North America's (RSNA) Annual Meeting in Chicago as a barometer.

AI in imaging is not just here to stay—it's already helping build new equations in the industry. The next frontier will be improving upon the lives of patients and helping radiologists do this in a more efficient way—from image analysis, workflow applications, and later with intelligent medical imaging machines.

Reference:

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