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Title: Evaluating Computational Pathology at the US FDA and Related Research

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Abstract: The FDA has been evaluating and regulating computer algorithms that process medical images for many years in radiology. While there are some algorithms that have been cleared or approved in digital pathology, the pace of submissions is expected to increase as the first whole slide imaging (WSI) system was permitted to be marketed in the US. In this talk, I will outline the basic algorithm types (computer-aided detection, CADe; computer-aided diagnosis, CADx; automated detection or diagnosis; semi- and fully-automated measurement or quantitation). I will also discuss how these algorithms fit into the US FDA regulatory framework. The pathways and methods used for evaluating algorithms in radiology guide us in developing the pathways and methods in pathology. I will provide a case study of one computer-aided detection (CADe) algorithm and outline its evolution over two decades. This evolution generalized the indications for use to new imaging systems (film to digital to 3D; one imaging system to many others), new performance claims, and new operating characteristics. I will also outline some regulatory and research programs and projects happening at the FDA related to computational pathology.

Slides

Gallas2018_EuroCongressPath-v6.pdf (2 MB, uploaded by Brandon D. Gallas 5 years 7 months ago)

Related info

This presentation includes the early thoughts about collecting images and annotations for the evaluation of algorithms. Please check out the subsequent project and proposal at this link.