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A business case for quantitative digital pathology

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Pathologists all over the developed world are increasingly challenged both by the growing diagnostic volume and the complexity of cases to be read. These challenges are further amplified by shrinking budgets and the competitive pressures from new diagnostic modalities such as gene expression assays and next-generation sequencing. The widely published lack of data quality in terms of reproducibility, sensitivity and specificity of manual readings has probably contributed to generating a growing demand for new diagnostic modalities and probably also contributed to the growing pressure on budgets. Image analysis has the potential to impact significantly on data quality. In order to have such an impact, a number of essential technical solution components are required for mitigating several error sources on the journey from biopsy to diagnostic, prognostic or predictive tissue data. Solution requirements include: Correct and verifiable identification of invasive tumor cells, excluding stromal and pre-invasive cells, handling of tumor heterogeneity and identification of hot-spots, standardized quantification of sub-cellular biomarkers and gene probe assays in tumor cells and assessment of staining quality, which at least is possible for immunohistochemical markers. In studies, evidence is found suggesting that these four solution components have a profound impact on data quality. These studies further indicate that the combination of immunohistochemistry with image analysis controls are capable of yielding data of a quality and clinical utility which is at least comparable to alternative and competing methods but at a significantly lower cost. The underlying technical solution components and clinical study results are presented.

Biography

Michael Grunkin is the CEO of Visiopharm A/S, Denmark. He has obtained his PhD in Image Analysis and Spatial Statistics from the Technical University of Denmark in 1993. His Post-doctoral work at Massachusetts Institute of Technology and Harvard Medical School was focused on the application of image analysis for medical devices. From 1996, he was the technical Founder of two Danish medical device companies based on image analysis as the platform technology. In 2001, he has Co-Founded Visiopharm A/S, which is a quantitative digital pathology company with focus on cancer research, diagnostics and the general standardization of tissue data.

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