**Quantitative imaging (QI), radiomics and precision medicine: Regulation and assessment approaches of QI tools**

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The U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) is responsible for the safety and effectiveness of medical devices marketed in the U.S. An important part of CDRH’s purview is regulating medical imaging technologies including quantitative imaging (QI) and radiomic tools for use in precision medicine. Precision medicine is often thought of in terms of identifying patients with similar genetic factors but identifying patients with similar image–based findings especially when the similarities are quantifiable is another important approach for tailoring treatment. Recent advances in QI and radiomics — an emerging field where image data is converted to a mineable feature space using quantitative extraction techniques — may be able to capture distinct phenotypic differences of tumors and patients and will likely have a role in realizing true precision medicine.

There is a strong need for reliable quantitative imaging tools to both improve the diagnosis of disease and the monitoring of patients undergoing treatment. The successful adoption of quantitative imaging and radiomic tools into clinical practice, and their evaluation in the context of FDA regulatory process, is dependent on understanding and limiting the uncertainty in the quantitative measurements. In this presentation, we will: 1) provide an overview of the FDA medical device regulatory framework as it relates to radiological medical imaging devices and QI/radiomic analysis tools and 2) discuss our ongoing FDA research efforts in QI tool assessment where we are developing phantoms and an assessment paradigm for validating specific QI/radiomic tool and biomarker claims. Our research has focused on lesion measurement tools for high and low contrast lesions as well as tools for quantifying coronary artery plaque.