

## FDA/CDRH perspectives on imaging biomarkers: Technical performance and analytical validation

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The Center for Devices and Radiological Health has responsibility for radiological device pre-market reviews and participates in biomarker qualification review teams for imaging biomarkers through the Medical Device Development Tools program (CDRH) and the Biomarker Qualification Program (CDER). CDRH's perspective on the evidentiary approach to quantitative imaging devices and imaging biomarkers will be presented. A regulatory perspective on the interaction between claims and analytical validation expectations will be explored for radiological imaging devices. Combinations of technical performance assessments including combinations of physical phantoms, digital reference objects and *in vivo* imaging may be used to approach analytical validation of imaging devices. Differing evidentiary expectations will be presented with examples. Research within CDRH continues to refine and expand the available methods for assessing the performance of quantitative imaging biomarkers.

### Biography

Daniel Krainak obtained his PhD in Biomedical Engineering from Northwestern University and completed a Post-doctoral fellowship at CDRH investigating diffusion tensor imaging. He has been a reviewer in the division of Radiological Health since 2012 with an emphasis on magnetic resonance imaging technologies. He participated in the review of radiological devices, imaging biomarkers, and radiological imaging in therapeutic product clinical trials.

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Robert Ochs is the Director of the Division of Radiological Health within the U.S. Food and Drug Administration, Center for Devices and Radiological Health. He received his Ph.D. in Biomedical Physics from the University of California, Los Angeles. The Division of Radiological Health at FDA is responsible for pre-market review compliance, and post-market surveillance for radiological medical devices (e.g., CT, MRI, mammography, ultrasound, radiation oncology devices and radiological image analysis software) as well as the regulation of medical and non-medical radiation emitting electronic products (e.g., lasers, microwaves).

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