IMAGING BIOMARKERS IN CLINICAL TRIALS: WHERE IMAGING SCIENCE MEETS REGULATORS

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ABSTRACT

Medical imaging has developed a key role in drug development. Quantitative imaging can provide biomarkers that can help with key aspects of drug development, including assessing target engagement, selecting drug doses, producing evidence of efficacy, and monitoring safety. While it remains the case that drugs will only be approved by regulators if they provide clinical benefit in how people feel, function or survive, imaging biomarkers can be used to aid in internal decision making and provide evidence of disease modification. Increasingly the remit of imaging biomarkers is expanding to selecting patients and stratifying patient populations. This is likely to have an impact on healthcare – as if drugs are approved based on studies that use imaging to include or exclude subjects, or to identify those that get the best benefit, then regulators may require that these same imaging methods are on the label of the drugs when they enter the clinic. This could transform the way imaging is used in healthcare, leading to widespread use of quantitative imaging for the first time, providing new challenges and opportunities for imaging researchers and companies.

Index Terms— Medical imaging, clinical trials, quantitative analysis, biomarkers, validation