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Importance of Quantitative Imaging Biomarkers in Clinical Trials

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INTRODUCTION

Quantitative Imaging Biomarkers (QIBs) are objective features obtained from *in vivo* imaging measured on ratio or interval scales as indicators of normal biological processes, pathogenic processes, or responses to therapeutic interventions. His QIB advantage over qualitative imaging biomarkers is that it is more suitable for patient follow-up and clinical trials. Examples of commonly used QIBs are the RECIST criteria that measure changes in tumour size to assess response to treatment in cancer patients, neck scans used for prenatal screening, or multiple sclerosis. There is an assessment of the patient's lesion burden and brain atrophy. Clinical trials are known to be one of the most valuable data sources in evidence-based medicine. For a drug, device, or procedure to be approved for routine use in the United States, it must be rigorously tested in clinical trials and demonstrate sufficient efficacy. Unfortunately, clinical trials are also very expensive and time-consuming. Endpoints such as morbidity and mortality are used as measures to compare groups within clinical trials.

DESCRIPTION

Mortality, the most basic endpoint used in clinical trials, requires years and even decades of follow-up for proper assessment. Morbidity may be quicker to measure than mortality, but it can also be a very difficult endpoint to measure clinically because it is often highly subjective. They are increasingly used in clinical trials to detect subtle changes in physiology and pathology before they are detected clinically. Biomarkers serve as surrogate endpoints. The use of surrogate endpoints has been shown to significantly reduce clinical trial time and resources. Surrogate endpoints allow researchers to assess markers rather than patients, allowing participants to act as their own controls and often facilitating blinding. In addition to surrogate endpoints, imaging biomarkers can be used as predictive classifiers to help select suitable candidates for specific treatments. Predictive classifiers are widely used in molecular imaging to ensure enzymatic response to treatment. The FDA Modernization Act of 1997 was introduced to improve the medical device regulatory process. Section 112 of the Act expressly authorizes drugs to treat serious medical conditions for accelerated approval as long as they are shown to be efficacious on surrogate endpoints reasonably indicative of clinical benefit. Other provisions require FDA to ensure the efficacy of surrogate endpoints through post-marketing surveillance of products and to establish programs to facilitate the development and use of surrogate endpoints for serious diseases. Although the law does not specifically address the use of alternative endpoints for medical devices, Section 205 requires the use of "less burdensome means" in their approval. Although the language is much more general than pharmaceutical regulations, it is widely accepted that surrogate endpoints are often thought of as 'low burden drugs'.

Understanding the clinical significance of a particular biomarker can be a difficult process. To fully configure the surrogate endpoint, here are her two authentication steps: Qualification and verification in order for a biomarker to be certified, it has to go through a somewhat formal certification process. An application must be submitted to her IPRG to adapt an imaging biomarker for a specific use. A biomarker accreditation review team recruited from nonclinical and clinical review departments evaluates the biomarker-related context and available data. They also evaluate the methods and results of qualification research strategies and ultimately make approval or rejection decisions.

CONCLUSION

Once qualified, biomarkers can only be used as surrogate endpoints to a limited extent. They can be used in Phase I and II

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clinical trials, but only in Phase III trials due to initial futility analysis. Verification has her two steps: Probable verification and known verification. A “probable validation” requires broad agreement in the medical or scientific community about its efficacy. “Known Validation” requires a scientific framework or body of evidence that appears to elucidate the efficacy of the marker. For full validation, biomarkers must show that differences between treatments and controls are similar to differences in clinical outcomes between treatments and controls. Simply showing that biomarker responders live longer than biomarker non-responders is not sufficient.

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CONFLICT OF INTEREST

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