Special Issue

Mathematical and Statistical Assessment of Biomarkers and Surrogate Endpoints in Clinical Trials

Message from the Guest Editors

Appropriate outcome measures are critical for the validity and efficiency of clinical trials. Clinical endpoints that directly measure how a patient feels, functions, or survives are the regulatory requirements to evaluate trial efficacy and safety. However, clinical endpoints may take time to observe and require large trials to reach conclusions. Biomarkers that include physical signs of disease, laboratory measures and radiological tests or intermediate clinical endpoints have a potential to be surrogate endpoints that are used as substitutes for clinical endpoints or are used to help early decisions, such as stopping trials for futility. Mathematical and statistical methods are critical for the appropriate uses of biomarkers and intermediate clinical endpoints in trials. The focus of this Special Issue is mainly on new mathematical and statistical methods to assess whether biomarkers can be surrogate endpoints and when they should be used in clinical trials, medical practice, product development, and public health policy.

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The journal *Mathematics* publishes high-quality, refereed papers that treat both pure and applied mathematics. The journal highlights articles devoted to the mathematical treatment of questions arising in physics, chemistry, biology, statistics, finance, computer science, engineering and sociology, particularly those that stress analytical/algebraic aspects and novel problems and their solutions. One of the missions of the journal is to serve mathematicians and scientists through the prompt publication of significant advances in any branch of science and technology, and to provide a forum for the discussion of new scientific developments.

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