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An Overview on Drug Discovery and Development Process in Biomarkers

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INTRODUCTION

Disease biomarkers are important in medicine and have begun to play a larger role in drug discovery and development. The challenge for biomarkers is to enable more accurate and timely drug safety and efficacy measurements. For the foreseeable future, their role in drug development will expand. Greater understanding of disease progression and therapeutic intervention is required for biomarkers to play their proper role. Furthermore, there is a need for a better understanding of the requirements for biomarker selection and validation, biomarker assay method validation and application, and clinical endpoint validation and application. Biomarkers must be considered while the therapeutic target is still being identified and the concept is being developed.Biomarkers must be integrated into a continuous cycle that transfers what is learned from the discovery and development of one set of biomarkers to the next set of biomarkers [1]. Because of the multifaceted nature of biomarker selection, validation, and application, optimal biomarker development and application will necessitate a team approach, employing techniques such as pharmacoepidemiology, pharmacogenetics, pharmacogenomics, and functional proteomics; bioanalytical method development and validation; disease process and therapeutic intervention assessments; and pharmacokinetic/pharmacodynamic modelling and simulation to improve and refine drug development. The least effective component of the processes will limit the potential for biomarkers in medicine and drug development.

DESCRIPTION

The team approach reduces the possibility that the least effective component will be fatal to the rest of the process. As the scientific/regulatory foundations for biomarkers in medicine and drug development are established, successes and applications must be effectively communicated with all stakeholders, including not only internal and external drug developers and regulators, but also the medical community, to ensure that biomarkers are fully integrated into drug discovery and development as well as medical practice [2]. For efficient and effective rational drug development, four elements are critical: mechanism-based biomarker selection and correlation to clinical endpoints; quantification of drug and/or metabolites in biological fluids under good laboratory practises; GLP-like biomarker method validation and measurements; and mechanism-based PK/PD modelling and validation. Even if they do not become surrogate endpoints, biomarkers can provide significant predictive value in early drug development if they reflect the mechanism of action for the intervention. In this process, PK/PD modelling and simulation can be extremely useful. Biomarker discovery and identification are aided by genomic and proteomic data that distinguishes between healthy and disease states.Multiple genes regulate complex diseases through a plethora of gene products found in biometabolic pathways and cell/organ signal transduction [3]. Pilot exploratory studies should be carried out to identify pivotal biomarkers that can be used to predict disease progression and the effect of drug intervention. The majority of biomarkers are endogenous macromolecules that can be measured in biological fluids. Many exist in heterogeneous forms with varying activity and immunoreactivity, posing bioanalysis challenges. For quantitative methods, reliable and selective assays could be validated in a GLP-like environment. While the need for consistent reference standards and quality control monitoring during sample analysis is similar to that of drug molecules, many biomarkers have unique sample collection requirements that necessitate well-coordinated team management.Bioanalytical methods should be validated to meet study objectives at various stages of drug development, and they should be capable of quantifying biochemical responses specific to disease progression and drug intervention [4]. The design of a protocol to generate enough data for PK/PD modelling would be more complex than that of PK. Mechanism knowledge from discovery and preclinical studies is useful for

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designing clinical study designs in cascade, sequential, crossover, or replicate mode.

CONCLUSION

The appropriate combination of biomarker identification and selection, drug and biomarker bioanalytical method development and validation, and mechanism-based PK/PD models for fitting data and predicting future clinical endpoints/outcomes provides powerful insights and guidance for effective and efficient rational drug development, toward safe and efficacious medicine for individual patients.According to the findings, salivary and serum TSA levels can distinguish between chronic periodontitis patients and healthy people. As a result, it can be used as a supplement to diagnose, monitor response to therapy, determine current periodontal disease status, and evaluate treatment outcomes.

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CONFLICT OF INTEREST

Authors declare no conflict of interest.

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