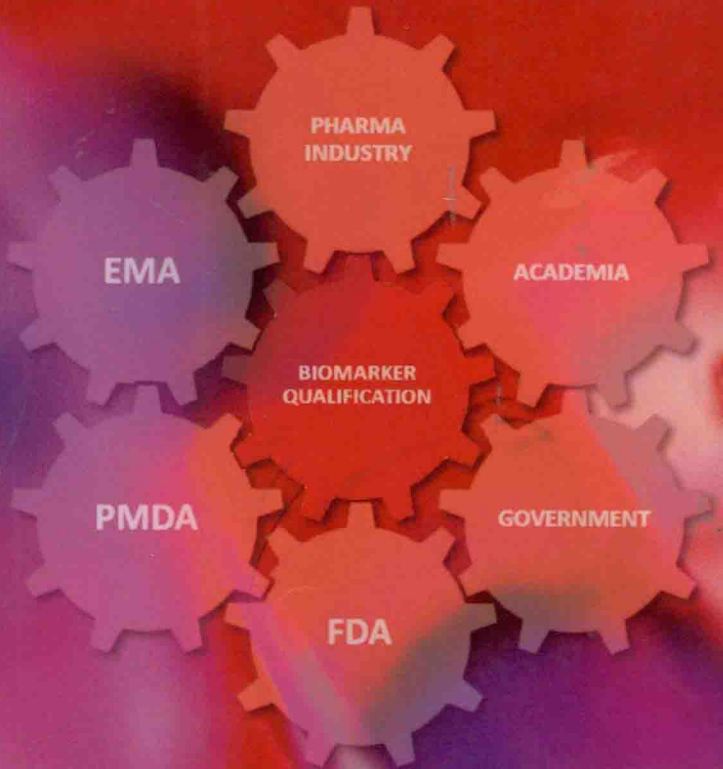
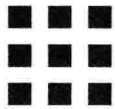
Federico Goodsaid
William B. Mattes

The Path from Biomarker Discovery to Regulatory Qualification





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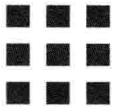

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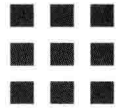

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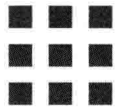


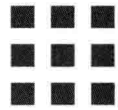
Preface

Successful work on drug development and regulatory review is often associated with strictly normative thinking. Drug development paths and regulatory policy can reach a level of acquiescence where the science which should drive these is only marginally integrated in them. The result of this process is drug development which yields less useful and less new drugs and regulatory review which mirrors and exacerbates the weaknesses of drug development.

The use of biomarkers in drug development at all levels is a powerful link to the science responsible for the identification, development and testing for transformative therapies. Whether in the assessment of drug safety or drug efficacy, in early or late development, in patient selection and characterization, and within a broad range of analytical platforms, biomarkers provide the information with which industry and regulators can determine whether a drug is safe and efficacious. While conventional definitions seek increasingly tenuous classifications for biomarkers, their shared value continues to be in what these biomarkers tell us about a drug and about what a drug can or cannot do in patients which should benefit from it. Results from biomarker measurements are not necessarily normative, and their inclusion in evolving concepts about why and when a drug is safe and efficacious continuously reminds us that we will only succeed with new therapies if we fully understand this information and the science behind it.

The collection of papers in this book includes contributions from scientists in academic institutions, pharmaceutical companies and regulatory agencies who have worked and continue to work on the best way to develop and use biomarkers from both the perspective of the critical path for drug development as well as from the perspective of the integration of these biomarkers in regulatory review. We hope that this snapshot of work carried out over the past decade will encourage further discussion about novel biomarkers and about how – and when – to make the best use of these powerful tools.

Federico Goodsaid and William B. Mattes



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