



# Genomic Biomarkers for Pharmaceutical Development: Chapter 4. Molecular Heterogeneity, Biomarker Discovery, and Targeted Therapy in Asthma (Japan Annual ... Computers and Telecommunications)

By Joseph R. Arron, Jeffrey M. Harris

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Asthma is a heterogeneous disorder on molecular, cellular, physiological, and clinical levels, but there is a lack of consensus on how discrete subtypes of asthma should be defined. Gene expression profiling of bronchial samples from asthma patients and healthy controls has enabled the definition of molecular subtypes of asthma which correspond to distinct pathophysiological features. Genomic data from bronchial samples has been used to identify non-invasive biomarkers such as serum periostin, fractional exhaled nitric oxide (FeNO), and blood eosinophil counts which correspond to these molecular subtypes. These biomarkers have been used in recent proof-of-concept clinical trials of investigational biologic therapies directed at the type 2 cytokines interleukin (IL) 5 and 13 to stratify patients according to the activity of the targeted pathways, enabling the enrichment of subsets of patients most likely to show clinical benefit from those interventions. However, translating these biomarkers into companion diagnostic tests subject to regulatory approval will be a complex process, and intriguing initial findings must be verified prospectively in pivotal clinical trials.

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