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Drug Combinations: New Rules, New Opportunities

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Abstracts

Single symptom. Single illness. Single drug.

For years, drug therapy has been built on that basic equation. Yet as genomic biology sheds light on the astonishing intricacy of disease pathology, it is clear that drugs that combine several compounds must be developed in response.

According to Biovista president Dr Aris Persidis, the possibility of such combination drugs “opens up this wonderful world of re-exploration of shelved, ineffective compounds in the pipelines of pharma companies that can be investigated for additive effects.”

This “wonderful world”, however, has its hurdles. While recent US Food and Drug Administration (FDA) guidance offers much-welcomed room for establishing codevelopment strategies, it also opens the door to wider questions regarding pharmacovigilance requirements, additional trials and more complex risk-benefit calculations. What’s more, the FDA strictly limits the scope—for now—of scenarios for codeveloped drugs, indicating approval will not be easy.

In our latest report, Drug Combinations: New Rules, New Opportunities, FirstWord unravels some of these issues by drawing on the insight of 18 experts working in cutting-edge biological research and regulatory affairs. The tightly-written report outlines the guidance offered by the FDA, and explains how it can be deployed to develop effective new treatments. The report also addresses the remaining barriers to development and provides insight into co-development trials as well as discussing commercial factors such as anti-trust, intellectual property and working across different corporate cultures.

Scope

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The report includes:

A concise overview of where codevelopment currently sits and what lies ahead

Insight into the FDA guidance and how it can be applied

Key features:

Explanation of the FDA’s regulatory approach

Examination of legal challenges presented by working collaboratively across companies

Four cases studies of companies actively codeveloping or have the potential to do so

Overview of non-regulatory issues, such as antitrust, financials, intellectual property and corporate culture

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NON-REGULATORY HURDLES

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