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Nota di bibliografia	Includes bibliographical references.
Nota di contenuto	PART ONE: Setting the Scene -- Introduction -- The Context and the Problem in Focus -- Secondary Analysis of Clinical Trial Data - A Primer -- PART TWO: Analysis de lege lata,- Legal Sources of Control over and Access to Clinical Trial Data under the EU Applicable Framework -- Implications of IPD Disclosure for Statutory Innovation Incentives PART THREE: Analysis de lege ferenda -- Defining the Intervention Logic of Access-To-Data Measures - A Problem Analysis -- Access to Clinical Trial Data as a Case on R&D Externalities - A Theoretical Framework -- IPD as a Research Resource - Exclusively Controlled or Readily Accessible? -- Evaluating Legislative Options -- Final Conclusions and the Outlook.

Sommario/riassunto

This book draws a unique perspective on the regulation of access to clinical trial data as a case on research and knowledge externalities. Notwithstanding numerous potential benefits for medical research and public health, many jurisdictions have struggled to ensure access to clinical trial data, even at the level of the trial results. Pro-access policy initiatives have been strongly opposed by research-based drug companies arguing that mandatory data disclosure impedes their innovation incentives. Conventionally, access to test data has been approached from the perspective of transparency and research ethics. The book offers a complementary view and considers access to individual patient-level trial data for exploratory analysis as a matter of research and innovation policy. Such approach appears to be especially relevant in the data-driven economy where digital data constitutes a valuable economic resource. The study seeks to define how the rules of access to clinical trial data should be designed to reconcile the policy objectives of leveraging the research potential of data through secondary analysis, on the one hand, and protecting economic incentives of research-based drug companies, on the other hand. Overall, it is argued that the mainstream innovation-based justification for exclusive control over the outcomes of research and development can hardly rationalise trial sponsors' control over primary data from trials. Instead, access to such data and its robust analysis should be prioritised.
