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ISBN	3-11-028328-X 3-11-038159-1
Descrizione fisica	1 online resource (210 p.)
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Nota di bibliografia	Includes bibliographical references (pages [191]-196) and index.
Nota di contenuto	Study modes -- Protection masks and procedures -- Coding methods for de-identified samples/data -- Relationships among the protection masks -- Data types -- Anonymization -- Validation : a brief introduction -- Request management -- Legal requirements & regulations -- Informed consent -- Selected data protection & medical sites -- Impact of external services on data protection -- Practical approach to clinical trials with supplementary genetic parts.
Sommario/riassunto	Establishing ethical and privacy protection aspects in scientific research, especially in medical research, has a long history. Medical data are usually more sensible than other personal data and require therefore an even higher degree of protection than other personal data. In recent research projects genetic evaluations become more and more important and trigger thereby new and continuing activities in the context of data protection. Genetic data as a subset of medical data are the most sensible category of personal data and require therefore the highest degree of data protection.The book provides a systematic and

itemized approach to data protection in clinical research including the handling of genetic material, genetic samples as well as derived genetic data and the subsequent secure storage of them. The set up of different kinds of clinical trials having in addition a genetic part, the concept of a genetic informed consent as well as collection schemes of samples are described in detail. Technical requirements and aspects of data protection including pseudonymization and anonymization procedures taking into account ethics committees requirements as well as the underlying legal framework are also presented.Without any exception, all principles and methods presented are best practices, repeatedly applied in different clinical environments and by no means theoretical considerations.