1. Record Nr. UNINA9910725023903321

Autore	Friske Franziska B.
Titolo	Rechtliche Zulassigkeit von Placebokontrollgruppen in Arzneimittelstudien : Unter besonderer Berucksichtigung der Blankoeinwilligung und der Zulassigkeit weiterer Kontrollvarianten / / Franziska B. Friske
Pubbl/distr/stampa	Gottingen : , : Universitatsverlag Gottingen, , 2017
Descrizione fisica	1 online resource (315 pages)
Disciplina	615.7040724
Soggetti	Drug testing
Lingua di pubblicazione	Tedesco
Formato	Materiale a stampa
Livello bibliografico	Monografia
Sommario/riassunto	Clinical trials of medicinal products on human subjects are a balancing act between the protection of the study participant and the preservation of his dignity on the one hand and the constant striving for medical progress on the other hand. This applies likewise to the control group as an essential part of every clinical testing of pharmaceuticals without which no drug will receive marketing authorisation in Germany by the competent authorities. Nevertheless, significant gaps in the German legislation concerning this matter still remain as the German legislator has yet to implement any specific rules with regard to the handling and management of the control group in clinical trials. In view of this unsettled legal situation, the author critically analyses the core of the problem areas in this field's current research practice and creates solutions reflecting the interests of the study participant as well as the practical needs of medical research. Only legal clarity regarding the control group can provide for the safety that is crucial in this field of tension between ethics, medicine and the law.