Available online on 15 Sep, 2025 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Research Article **Open Access**

Remarkable facts when concluding contracts for the conduct of clinical trials for medical devices in Germany

Raees Ahmed*, Paula Hasselmann, Christoph Gerst

Legal Department, Universitätsmedizin Göttingen, Germany

Abstract

1. Introduction: The objective of clinical trials for medical devices is primarily the investigation and evaluation of their performance and safety. Of particular importance in this context is the contractual design of clinical trials for medical devices in the relationship between the sponsor and the trial center. The legal basis for this is the German Medical Device Implementation Act (Medizinprodukterecht-Durchführungsgesetz (MPDG)), which came into force on May 26, 2020, and is intended to concretize the EU regulations on medical device law at national level. Due to the principal of private autonomy, there are various options to draw contracts for the implementation of clinical trials for medical devices. However, certain points should be considered when drafting the contract and should become part of the contract. These include a heading and a preamble - they serve to clarify the contract and introduce its contents. Other important parts of the contract are the subject matter, contractual obligations, subject recruitment, audit and inspection, monitoring, provisions for premature test termination, test components, remuneration, contract duration and termination options, confidentiality, partial invalidity, and applicable law. They define the complex legal relationship between the clinic, the investigator and the sponsor, as parties to the contract.

2. Materials & methods: A specific data base was used for law www.beck-online.de and digital journal archives (https://ezb.ur.de;www.digizeitschriften.de) at Universitätsmedizin Göttingen. All assumptions are based on the authors own day-to-day experience as a lawyer or legal advisor at legal department of Universitätsmedizin Göttingen.

3. Discussion & Conclusion: For the legal certainty of all parties, the contractual components should definitely become part of the content of contracts for the performance of clinical trials for medical devices. It should be noted, however, that individual cases and their contractual requirements should be considered.

Keywords: Contract; Clinical Trial; Medical Device; German Medical Devices Act (MPDG)

Article Info: Received 13 Aug 2025; Review Completed 12 Sep 2025; Accepted 15 Sep 2025

Cite this article as:
Ahmed R, Hasselmann P, Gerst C. Remarkable facts when concluding contracts for the conduct of clinical trials for medical devices in Germany. Int. J. Drug Reg. Affairs [Internet]. 2025 Sep 15 [cited 2025 Sep 15]; 13(3):116-121. Available from:
http://ijdra.com/index.php/journal/article/view/803

DOI: 10.22270/ijdra.v13i3.803
*Corresponding author. E-mail address: Raees.Ahmed@med.uni-goettingen.de (R. Ahmed)

1. Introduction

Contracts for the conduct of clinical trials on medical devices are intended to provide a clinical evaluation of the medical device. (1) Accordingly, it should be ensured that the medical device achieves its intended effect under average circumstances and that the benefit outweighs the risk associated with the medical device (medical device safety). (1, 2) Another purpose of the conduct of a clinical trial is to check conformity with the provisions of the law on medicinal devices and the law on fair trading for subsequent marketing. (1, 2) A necessity for such legal transactions is the cooperation of the industry and medical institutions or physicians as representatives by the sponsor, (3) who are the respective contracting parties.

The legal framework for these contracts is above all the new Medical Devices Act (Medizinprodukterecht-Durchführungsgesetz (MPDG), which serves the national concretisation and implementation of the new EU regulations on medical device law despite their direct applicability in the Member States. It came into force on 26.05.2020 and replaced the current Medical Devices Act (MPG). (4)

There are various options for drafting contracts for the conduct of clinical trials on medical devices given the freedom of contract granted by the German Civil Code as a result of the principle of private autonomy. (5) However, specific points are essential and must or should always be part of the content of the contract.

The following explains in more detail what these points are and how they should be differentiated in more detail in the contract.

2. Materials & methods

For this research article, the authors used a specific data base for law www.beck-online.de and digital journal archives (https://ezb.ur.de;www.digizeitschriften.de) at Universitätsmedizin Göttingen. Additionally, all assumptions are based on the authors own day-to-day experience as a lawyer or legal advisor at legal department of Universitätsmedizin Göttingen.

3. Contract design

A contract for the performance of clinical trials on medical devices should introduce with a caption and a preamble. Topics such as the subject matter of the contract, respective obligations, subject recruitment, audit and inspection, monitoring, procedures for early termination, inspection results, remuneration, contract duration and termination options, secrecy and confidentiality as well as partial invalidity and applicable law should form part of the contract. Eventually, it must be considered that the concrete, individual clinical trials can vary greatly from one another and cause other contractual needs, which means that an individual standard of the concrete clinical trial should be applied to the contract design, especially in abnormal cases.

3.1 Caption

Due to clarity, the introductory element should initially be a rubric in which the contracting parties are identified by name with their respective functions and the persons authorised to represent them. The conclusion of a three-sided contract between the parties "clinical investigation site, the investigator and the sponsor" is recommended. The investigator is a physician responsible at the clinical investigation site within the meaning of § 30 II of the MPDG, although it is possible, using the sponsor's order within the meaning of § 30 I of the MPDG, to appoint an investigator, a principal investigator and a leading principal investigator for the clinical trial.

3.2 Preamble

The preamble serves to introduce the content of the contract. More detailed information is provided on the sponsor's field of activity and its research focus as well as the relevant product area are named. Furthermore, the medical device in question should be designated and the goal of the clinical trial disclosed, whereby it should be made clear that both the sponsor and the project partner (clinical Investigation site) pursue the same aim.

3.3 Subject of the contract

This part of the contract should also include the objective of the clinical trial and the medical device, but with concrete, detailed indications. In addition, the title of the clinical trial should be stated and the intended use of the results explained. Moreover, the explicit date of the start and end of the clinical trial should be specified to ensure planning security.

Furthermore, the sponsor has drawn up a clinical investigation plan which forms the framework of how the clinical trial is to be conducted. This should also be mentioned in this part and a reference should be made to the Annex where it is illustrated. This clinical investigation plan is also relevant for the review of the application to the ethics committee according to § 35 I of the MPDG and for the procedure with the federal authority according to § 38 I of the MPDG.

In addition, a reference to further required annexes, the subject information and the consent form, are to be inserted. It should be made clear that the Annex is part of the contract and can therefore also indirectly formulate obligations and rights. (6)

Ultimately, it would still have to become apparent, that the sponsor is the client and that the project partners (medical institutions) have been commissioned to carry out the clinical trials for medical devices.

3.4 Obligations

It is essential to establish the various obligations of the respective contracting parties. Although the contracting parties – whether written down or not – must, in any case, comply with the legal provisions governing the clinical trial, a corresponding clause should be inserted. It serves to hedge the risk if not all responsibilities are mentioned enumerative in the contract. (7) The more precise differentiation of the obligations can then be subdivided for manageability.

a) Obligations of the clinical Investigation site

The clinical investigation site should commit to provide the necessary personnel and material repertoire for the conduct of the clinical trial and conduct it by the defined clinical investigation plan. Since the investigator is usually dependent on the cooperation of the clinical investigation site to fulfil its obligations, (8) the clinical investigation site should be obliged to enable the investigator to fulfil the contract, including participation in any investigator meetings.

b) Obligations of the investigator

For the investigator, a comprehensive catalogue of obligations within the meaning of §§ 62, 63 of the MPDG should be written down. On the one hand, he must perform all the actions required for approval by the competent federal authority and for a successful application to the ethics committee, cf. §§ 32ff. and §§ 38f. of the MPDG. To avoid criminal liability under § 93 I No. 2 of the MPDG, the investigator should not begin the clinical trial under § 47 II of the MPDG until the approval of the ethics committee and the authorisation of the federal authority have been obtained.

Furthermore, the investigator is the contact person & referrer for the clinical trial, whereby the subject health should always be superior to the contractual purpose pursued.

The investigator shall be bound by the intended purpose of the medical device as specified by the sponsor when performing. He is responsible for ensuring that the medical device is used following the purpose of the contract and that unused stock is returned to the sponsor.

The investigator has a prior obligation to ensure that the subjects are lawfully informed and have consented, but the information itself must be provided by a medical

practitioner and not necessarily by the investigator itself. (9) Consent should always have been obtained in writing and must have been given in front of a witness. (10)

The data collected in a clinical trial must be handled with confidentiality given their relevance to the health of the subjects. (11) Accordingly, § 62 II of the MPDG stipulates an obligation to absolute confidentiality and a prohibition on the disclosure of data to unauthorised third parties, which should also be stated in the contract given its importance.

In addition, the investigator or the principal investigator has a reporting obligation according to § 63 of the MPDG, according to which sustained negative occurrences must be reported immediately to the sponsor, but also emerging product deficiencies of some importance.

c) Obligations of the sponsor

The sponsor is responsible for the initiation, organisation and conduct of the clinical trial and provides the necessary financial resources for the clinical trial. (12) The sponsor is responsible for providing information about the clinical investigation plan, the medical device in question and, above all, the risks associated with the clinical trial.

At first, he must obtain a favourable assessment from the ethics committee, with the legal nature of an administrative act, (13) as well as approval from the federal authority, cf. §§ 33 I, 38 I of the MPDG. In addition, it should be contractually ensured that the sponsor covers the insurance within the meaning of § 26.

As a consequence of the investigator's obligation to report adverse, serious events, the sponsor has an even more comprehensive obligation to notify and to report to the federal authority under § 64 of the MPDG.

Besides that, the sponsor is also obliged to disclose the federal authority and the ethics committee by § 54 of the MPDG in the event of changes to the procedure in the clinical trial contrary to the previously submitted documents. In the case of such serious changes that could have a substantial impact on the safety, health or rights of the trial subjects, the sponsor must submit a renewed application to the ethics committee for its opinion by §§ 55ff. of the MPDG. This prevents the ethics committee's favourable assessment from being bypassed. However, according to the new MPDG, a renewed approval of the federal authority is unnecessary – in contrast to the old MPG, where according to § 22c II No.1 of the MPG a renewed approval of the federal authority was always required. (14)

Finally, the contract should also include the sponsor's obligation to organise investigator meetings in accordance with the principle of compliance and to conduct them at his own expense. (15)

d) Retention obligations

In contrast to the MPG, the MPDG provides in § 5 for retention obligations with regard to regulatory documents. (16) Accordingly, it is incumbent on the manufacturer and its authorised representatives to keep the documents standardised in paragraph 1– even in the event of termination of the business activity, for example, due to insolvency. More specific details may be provided by a statutory order of the Federal Ministry of Health under paragraph 3. The period of the respective retention obligations follows from paragraph 1 in conjunction with the provisions of the annexes to the EU regulations referred to therein.

3.5 Subjects recruitment

It makes sense to specify the period of subject recruitment with a corresponding clause, whereby the project partners, i.e., the clinical investigation site as well as the investigator, are obligated to include the subjects in the clinical trial according to the given clinical circumstances and to the best of their abilities.

Given the most personal legal interest of physical integrity protected by fundamental rights according to Article 2 II of the constitution, it should also be stipulated in writing that the well-being of the patient is significant in all phases of the clinical trial and must be the sole decisive factor.

In the case of a multicentre trial, it is appropriate to allow the sponsor to terminate the clinical trial if a total number of subjects is achieved that falls short of the number of subjects calculated by the project partners.

3.6 Audit and inspection

Audit and inspection are terms not defined by the MPDG. Audit refers to the process of evaluating and assessing the clinical trial. (17) In contrast, inspection in the context of a clinical trial means the physical control measures relating to the clinical investigation site. (18)

Given the need to ensure that the sponsor has the means to carry out audits, it is the responsibility of the clinical investigation site and the investigator, which should also be made clear in the contract.

In addition, the exact scope of the auditing desired by the contracting parties should be noted. For example, provisions such as the regular monitoring of compliance with the clinical investigation plan or the consideration of data protection limits with regard to the handling of subjects' data can be included.

It is the responsibility of the sponsor to ensure that the persons assigned to the inspections and audits are subject to confidentiality and comply with the data protection requirements.

After completion of the audit or inspection, the clinical investigation site and the investigator receive a report on the results. Any deficiencies identified must be corrected by the project partners within a specific temporary framework negotiated with the sponsor and communicated to the sponsor. The purpose of including such a clause is to ensure the functioning of the quality assurance system (19) intended by the audits and inspection.

3.7 Monitoring

Monitoring is the control that the clinical trial actually complies with the clinical investigation plan and the legal requirements, but also that any relevant guidelines are adhered to. (20) The sponsor is authorised to carry out monitoring and may delegate this task to third parties. The clinical investigation site and the investigator must each

ensure that the requirements are given, e.g., to provide the necessary documents, such as medical records, to carry out the monitoring.

3.8 Early termination reasons

In the event that the investigator leaves the clinical trial, for example due to health reasons, but also in the event of premature termination of the clinical trial, the question arises as to how the clinical trial is to be handled in the future. To avoid the risk of failure to achieve success due to premature termination of the clinical trial, it makes sense to contractually regulate these risks.

a) Retirement of the investigator

The early departure of the investigator, for example by leaving the clinical investigation site, does not affect the agreements between the clinical investigation site and the sponsor.

The clinical investigation site has an immediate obligation to inform the sponsor of this early termination. Furthermore, it must endeavour to acquire a new investigator who complies with the legal requirements and who has the qualifications and experience to enable trouble-free supervision of the clinical trial as soon as possible. Finally, the sponsor must also conclude an identical contract with this investigator and notify the federal authority and the ethics committee of the change of the investigator and the departure of the investigator.

However, if no other suitable investigator is available, the clinical trial shall be stopped immediately. Otherwise, if the clinical trial is continued without a suitable investigator, punishment of this offence is possible according to § 93 I No.4 in conjunction with § 47 I No.3 of the MPDG. But the constellation in which, in the case of premature termination, the continuation of the clinical trial is sought due to health protection aspects of the subjects is an exception. In this case, a continuation would still be permissible.

The clinical trial can be continued without further ado if several investigators were involved from the beginning and only one investigator withdraws prematurely.

b) Termination of the clinical trial

The clinical investigation plan not only explains the specific conduct of the clinical trial, but also specifies criteria for the termination of a clinical trial for individual subjects, the clinical investigation site or, for example, the clinical trial as a whole. The investigator is then obliged to notify the sponsor or the clinical investigation site. However, if the sponsor already becomes aware of such indications, he is obliged to inform the clinical investigation site and the investigator immediately.

Ultimately, the consequence is the immediate closure of the clinical trial. The sponsor must notify the competent authorities of the discontinuation within 15 days (cf. § 64 II p.1 of the MPDG), unless the discontinuation is for safety reasons, in which case a 24h period for notification applies (cf. § 64 II p.2 of the MPDG). Lastly, the sponsor is obliged to submit the final report to the higher federal authority one year after completion of the clinical trial.

3.9 Inspection results

To avoid subsequent problems with the question of ownership and rights of use, especially regarding the inspection results, these should be determined by consensus. The inspection results and thus also all associated rights of use are the property of the sponsor from the time they are obtained in the course of the clinical trial. However, should the need arise, the investigators shall separately assign rights to the inspection results to the sponsor within the meaning of §§ 398ff. of German Civil Code. Obviously, the subject files do not become the property of the sponsor, which should be clearly mentioned in the contract.

Inventions created within the scope of the subject matter of the contract shall be transferred by the clinical investigation site with the respective rights to the sponsor. All associated documents, such as invention disclosures, research results, etc. (with the exception of patient files) shall also become the property of the sponsor. Accordingly, the sponsor is entitled to file an invention disclosure and must notify the clinical investigation site of this or the failure to do so within a period determined by the parties – which can be approximately 2 months. (21) In the event of non-registration, the sponsor is then obliged to reassign the inventions or the rights to the inventions at the request of the clinical investigation site.

Additionally, it should also be regulated how to proceed in the case of inventions that arise within the scope of the clinical trial without being the subject matter of the contract. It makes sense to refer to the above regulations and to apply them in such a case.

3.10 Remuneration

The diversity of remuneration models also offers numerous possibilities for structuring remuneration. Mainly "mixed models" are used, which combine several elements, such as total number of participating subjects and a payment after submitted final report to maintain capacity and willingness to be efficient. (22)

The sponsor finances the conduct of the clinical trial. In order to have planning security and to be able to plan the inspection in relation to the financial resources available, the specific amount, plus sales tax if applicable, that the sponsor undertakes to pay should be written down.

The overhead costs in particular should be considered here. For clinical trials, recourse is made to the facilities of the clinical investigation sites and to the use of the infrastructure, so that the university administrations demand their share of the grants in the sense of overhead costs. (23) For example, a clause could be inserted to the effect that the amount of money provided by the sponsor already includes the deduction amount for the additional administrative expenses and all other additional costs of the clinical investigation site.

Besides, it should be clear that with the amount of money provided by the sponsor, all services & expenses of the clinical investigation site and the investigator under the contract have been fulfilled. This ensures that the sponsor only must pay the amount he has made available and that no further non-considered cost items approach him.

Finally, the due date should always be specified. This can be done, for example, by contractually stipulating that individual instalments of the total remuneration are based on the present contract, i.e. the first instalment is paid at the start of the clinical trial specifically named in the contract and the last instalment must be paid before the specifically named completion date of the clinical trial.

3.11 Contract period and termination

Upon proper signature of the contracting parties, the contract becomes mandatory. It only loses its mandatory effect upon completion of the clinical trial or in the event of its premature termination.

Both the sponsor and the clinical investigation site should have the option of immediate, extraordinary termination for good cause. It makes sense to list the most important and possible reasons. For example, an important reason for termination for the sponsor could be that the investigator decides to discontinue the development of the medical device in question or if the proper data collection and data evaluation is endangered in the case of violations of the relevant legal requirements for the conduct or the clinical investigation plan. On the other hand, the fact that there are reasonable grounds for believing that the clinical trial is no longer acceptable from an ethical and/or medical point of view could be a valid cause for the clinical investigation site to terminate the contract.

In addition, both parties should have the option of immediate termination in the event of the premature departure of the investigator and if no other suitable investigator is available in the foreseeable future.

Furthermore, formal requirements for termination, such as the written form, should be contractually specified.

It should be clarified that a termination under this clause does not affect the confidentiality obligations and the obligations that arose until the termination of the contract.

3.12 Secrecy and confidentiality

When conducting clinical trials, scientific, insightful added value is always to be expected. To ensure that their economic return is preserved for the contracting parties, especially the sponsor, and that the results do not become known to unauthorised third parties and especially not to competitors in the market economy, it is desirable to include a confidentiality clause. (24) It should be considered that the possible options can vary greatly depending on the concrete individual clinical trial.

First of all, the contracting parties should each undertake to treat all information obtained in the context of the conduct of the clinical trial as confidential. In doing so, the clinical investigation site and the investigator must provide the sponsor with all findings obtained and, in each case, keep them confidential, not publish them and deny third parties access to them.

To clarify which information is to be kept secret, it is advisable to insert an enumerative exception clause from the principle of secrecy. Thus, the contracting parties know that all information in the context of the clinical trial that is not mentioned in this clause is subject to confidentiality. For example, the obligation of confidentiality may not apply to information that has been identified by the parties independently of the context of this contractual agreement or to information that was already known at the time of disclosure.

Furthermore, to maintain confidentiality beyond the termination of the contract, parties should undertake to hand over, upon request, all documents containing confidential information after the termination of the contract, unless stipulated by law.

To protect the confidentiality interests of the sponsor, (25) in particular, the contracting parties should undertake that all persons involved in the conduct of the clinical trial who are confronted with information to be handled confidentially are also contractually obliged to maintain confidentiality in the sense described here.

In addition, the project partners should agree that only the sponsor is authorised to use the findings in any way, including publication. However, publication rights may also be granted to the clinical investigation site and the investigator provided they have previously agreed in writing with the sponsor and there is no risk that property rights applications cannot be completed as a result. The inclusion of a priority of property rights applications takes account of the fact that university contract partners are required to publish research results. (26)

3.13 Miscellaneous (applicable law, partial invalidity, written form)

The applicable law in the event of a conflict can cause problems, especially for international contracting parties. Nevertheless, a legal order or, as a compromise, silence should be contractually agreed upon. A corresponding determination of the place of jurisdiction should also be made.

Whether legal individual agreements can be implemented in practice as agreed is not always guaranteed. It can also happen that, despite legal assistance, ineffective clauses become part of the contract in the course of drafting the contract.

In the event of such partial ineffectiveness, a contractual individual agreement may be made instead of applying the law of the general terms and conditions. For example, in such a way that ineffective or unenforceable provision are to be replaced by other provisions that correspond to the intended result of the contract so that the parties would also have concluded the contract with this clause instead of the ineffective one. If no such regulation exists, the validity of the contract should not be affected. Unless these clauses are of such relevance to the contract that there is a reason to believe that the parties would not have concluded the contract without this ineffective or unenforceable provision.

In consideration of the fact that there may be subsidiary agreements in addition to the contract, it is advisable to insert a clause that considers the contract, including its annexes, to be conclusive and that preserves the clarity of the obligations and rights for the contracting parties.

It is also recommended to insert a clause stating that in the event of amendments or additions to the contract, these will only be effective if they are made in writing.

4. Discussion & Conclusion

Consequently, it can be concluded that in a contract for the performance of a clinical trial of medical devices, all the areas mentioned should be contractually covered for the legal security of all parties. This essay can serve as a guideline. Of course, it is always necessary to consider the concrete individual case and to stipulate the corresponding contractual requirements.

Acknowledgments

The author would like to thank Ms. Ronja Haußknecht for reviewing and editing work for the article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Reference

1. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 253.
2. Dewitz C. Ethik-Kommissionen zur Wahrung der Sicherheit von Teilnehmern an klinischen Prüfungen von Medizinprodukten und Leistungsbewertungsprüfungen von In-vitro-Diagnostika – Teil 1, MPR. 2014: (4), p. 109-120.
3. Diener P. Handbuch Compliance im Gesundheitswesen, 3rd ed. München: C.H.Beck; 2010. Kap. 6. B. Leistungsbeziehungen, Rn. 16.
4. Rehmann WA. Das neue Medizinprodukte-Durchführungsgesetz (MPDG). pharmid. 2020: (8), p. 1014-1018 (1014).
5. Musielak J. Vertragsfreiheit und ihre Grenzen. JuS. 2017: (10), p. 949-954.
6. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 255.
7. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 278, Rn 11.
8. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 279, Rn 12.
9. Wachenhausen H. § 40 Allgemeine Voraussetzungen der klinischen Prüfung, Rn 49. in: Kügel JW, Müller RG, Hofmann HP, editor. Kommentar Arzneimittelgesetz. München: C.H.Beck; 2016.
10. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 280, Rn 25.
11. Weichert T. Art. 4 Nr. 15 Gesundheitsdaten. In: Kühling J, Buchner B, editor. Kommentar Datenschutz-Grundverordnung/BDSG. 2nd ed. München: C.H.Beck; 2018, Kapitel I, DS-GVO Art. 4 Nr. 15, Rn. 4.
12. Bischoff C, Wiencke J. Datenschutzrechtliche Voraussetzungen klinischer Prüfungen - Das Verhältnis von AMG und DS-GVO. ZD. 2019: (8), 8-13.
13. Häberle P, in: Erbs G, Kohlhaas M, Häberle P., MPG § 22 Rn. 1
14. Irmer F, Henßler T. Die Auswirkungen der 4. MPG-Novelle auf die klinische Prüfung von Medizinprodukten. MPR. 2009: (3), p. 73-79.
15. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 283, Rn. 45.
16. Rehmann WA. Das neue Medizinprodukte-Durchführungsgesetz (MPDG). pharmid. 2020: (8), p. 1014-1018.
17. Hegendörfer G. Der aktuelle Stand der Reform des EU-Medizinprodukterechts. MPR. 2013: (6), p. 181-188.
18. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 283, Rn. 47.
19. BGH legt dem EuGH im Zusammenhang mit einer möglichen Haftung des TÜV Rheinland im PIP-Skandal Fragen zur Auslegung der Medizinprodukte-Richtlinie vor. VuR. 2015: (7), p. 268.
20. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 283, Rn. 49.
21. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 261, Rn. 13.6.
22. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 284, Rn. 56.
23. Sträter B, Klement L. Overhead-Kosten in der Drittmittelforschung – Zur Rechtfertigung nach dem Hochschulrecht und dem Beihilferecht der EU. PharmR. 2015: (7), p. 329-333.
24. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 284, Rn. 60.
25. Sander A, Krüger C, Runge M. Vertrag zur Durchführung von klinischen Prüfungen bei Medizinprodukten. In: Bromm B, Stief M, editor. Vertragshandbuch Pharma & Life Sciences. München: C.H.Beck; 2005. 2. Kap. IV, p. 285, Rn. 61.
26. Schulze-Fieltiz H. 2. Kapitel Hochschulaufgaben, Rn.243. In: Geis ME, editor. Hochschulrecht Bayern. 2nd ed. Heidelberg: C.F. Müller; 2017.